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Ad Hoc Group on Food Safety

COMPENDIUM OF NATIONAL FOOD SAFETY SYSTEMS AND ACTIVITIES

Individual country reports were prepared by the Member countries.
This background document is available in English only. It is the intention of the OECD Secretariat to provide a French translation in due course.

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FOREWORD

As part of the OECD response to the request of G8 Heads of State and Government "to undertake a study of the implications of biotechnology and other aspects of food safety", the OECD Council established the Ad Hoc Group on Food Safety. This Group, composed of senior officials and experts from capitals with food safety policy responsibilities, was asked to report on what is being done at the national and international level to address current and emerging food safety issues. Specifically, the Terms of Reference for the Ad Hoc Group were:

- To supervise the compilation of a compendium of current and planned international food safety systems and activities, as outlined in Annex 3 of *OECD Work on Biotechnology and Other Aspects of Food Safety* [C(99)148(REV4)].

- To undertake the compilation of a compendium of current and planned national food safety systems and activities, based on reports from Member countries in which reference may be made to precautionary approaches and principles.

- To provide a report to Council on the results of its work, including the compendia of international and national food safety systems and activities, the ongoing work across the Organisation and related work underway in capitals or otherwise available to members, as part of the response to the G8 request, in order to contribute to international and national efforts in the area of food safety.

Under the chairmanship of Dr. Ewald Wermuth, Special Advisor to The Netherlands Minister for Agriculture, Nature Management and Fisheries on Biotechnological and Safety Issues, the Ad Hoc Group on Food Safety prepared and approved the final report for transmission to the OECD Council. This report includes the following elements:

- Overview of Food Safety Systems and Activities: Executive Summary
  [SG/ADHOC/FS(2000)6/FINAL]

- Overview of National Food Safety Systems and Activities
  [SG/ADHOC/FS(2000)5/FINAL]

- Overview of International Organisations with Food Safety Activities
  (Part I of Overview and Compendium of International Organisations with Food Safety Activities)
  [SG/ADHOC/FS(2000)4/FINAL]

- Compendium of National Food Safety Systems and Activities
  [SG/ADHOC/FS(2000)5/ANN/FINAL]

- Compendium of International Organisations with Food Safety Activities
  (Part II of Overview and Compendium of International Organisations with Food Safety Activities)
  [SG/ADHOC/FS(2000)4/FINAL]

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**Please note that the original version of this text was submitted in French. The English translation is under the responsibility of the OECD Secretariat.*

AUSTRALIA

I. Synthesis

Australia operates a science-based food regulatory system that is effective at ensuring a safe food supply for consumers. The current regulatory controls have proven to be responsive to emerging food safety threats and to new developments in the rapidly changing food industry, but are subject to continuous improvement by virtue of established legislative and other review processes.

As a major food exporting country Australia has, additionally, developed specific systems to ensure that foods comply with requirements of importing countries where these might differ from standards applying domestically. The Food Standards Code details the basic requirements that food must meet in order to be eligible to be placed on the market in Australia. This Code applies in both Australia and New Zealand, through agreement of the national governments to a joint food standards elaboration process.

An array of Commonwealth and State/Territory Government Acts provide the necessary framework to deliver a consistent approach across jurisdictions, while ensuring food safety and other consumer protection outcomes for the food supply.

The operation and effectiveness of the food regulatory environment in Australia was the subject of a recent major review (the Blair Report) which advanced a number of recommendations concerning improvements in administrative and enforcement procedures, the avoidance of overlapping verification activities, improvements to verification of food safety outcomes; and to delivery of efficiencies to the sector. The Blair Report further identified the key role that industry plays in contributing to the achievement of food safety outcomes and the joint benefits of a co-regulatory approach by government and industry throughout the food production chain in this regard. The recommendations of the Blair Review are presently the subject of detailed consideration by governments and are likely to lead to some changes in existing co-ordination arrangements for food standards and for inspection programs.

Australia's food standards largely reflect international norms, especially those elaborated by the Codex Alimentarius Commission, but may vary in some aspects due to unique production, climatic and other factors which allow alternative, but appropriate, approaches to be utilised. In developing food standards, Australia complies with its international commitments under the World Trade Organisation (WTO) agreements, specifically the Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures and the Agreement on technical Barriers to Trade.

Processes within Australia ensure that legislation is enacted and administered in a transparent way, providing opportunity for consumers, industry and other interested parties to have an effective input into processes. In this regard, Australia's regulatory framework applies an evidence and risk-based approach to standard setting and is well placed to deal with emerging issues such as the safety assessment of foods which are derived through the use of modern bio-technology.

These transparent processes have served to ensure a high level of consumer confidence in the domestic food safety system and provide a framework for this to carry forward to the future.

This paper incorporates an Annex providing comment on the application of cautionary approaches used by Australia in food safety assessment and in food standards setting, which highlights that established risk assessment procedures adequately accommodate this aspect and in a way which is fully consistent with WTO requirements relating to sanitary measures.

II. Overview of Food Safety Systems

Under the Australian Constitution, the responsibility for regulating the safety of food produced for consumption within Australia is vested in the States and Territories. Food intended for export may, in addition, be subject to federal legislation made pursuant to the commerce and foreign affairs powers of the Constitution.

Australia therefore, has a complex and varied food regulatory system, covering several agencies and types of legislation spread across three levels of government. The Blair review of food regulation (1998) found approximately 150 Acts and associated regulations related to food or agrifood businesses in Australia. These laws are developed, administered and/or enforced by several Commonwealth agencies, over 40 State and Territory agencies, and over 700 local governments.

The responsibilities of Commonwealth agencies in relation to food include setting national food standards (through the *Food Standards Code*); import and export controls (through *the Imported Food Control Act* and the *Export Control Act*); regulating therapeutic goods and genetically modified organisms; and consumer protection (through the *Trade Practices Act*).

The legislation for foods for export from Australia is framed so as to ensure that foods comply with relevant national standards and certain requirements set down by importing country legislation. The aim is to ensure the export of safe and appropriately described and labelled foods.

The Commonwealth legislation relating to imported foods is intended to ensure that foods imported into Australia meet requirements that are equivalent to those specified in the food standards code and therefore do not cause food safety concerns or mislead or deceive consumers.

State and Territory government functions include policy responsibility for and/or enforcement of food hygiene regulations and food standards; management of chemical residues; and development and enforcement of Fair Trading Acts.

State and Territory health departments may delegate the power to enforce the *Food Standards Code* and food hygiene regulations to local governments. As a general Rule State and Territory agriculture and fisheries departments do not delegate their regulatory responsibilities for food safety matters, although account may be taken of third party audit findings.

Food Standards Setting Process

National food standards are developed by the Australia New Zealand Food Authority (ANZFA) (under an arrangement with States and Territories dating back to 1991). These standards are adopted by the States and Territories by reference and without amendment after being agreed by a majority of members of the Australia New Zealand Food Standards Council (ANZFSC), comprising Commonwealth, State, Territory and New Zealand health ministers.

The 1991 agreement provides for limited departures from national food standards by State, Territory and New Zealand governments because of exceptional environmental conditions not presenting any public health or safety risk, or in emergency situations affecting public health and safety.

The legislated objectives for the development or variation of food regulatory measures, including food standards, are (in order of priority): the protection of public health and safety; the provision of adequate information relating to food to enable consumers to make informed choices; and the prevention of misleading or deceptive conduct.

In developing food standards, the legislation requires ANZFA to have regard to: the need for standards to be based on risk analysis using the best available scientific evidence; the promotion of consistency between domestic and international food standards; the desirability of an efficient and internationally competitive food industry; and the promotion of fair-trading in food.

ANZFA has undertaken a review of the whole *Food Standards Code* over the past five years. The main thrust of the Review has been to simplify existing food regulation, remove any unjustified prescription, and give industry greater freedom to be innovative in their business operations while maintaining the protection of public health and safety.

The new joint Code will focus on regulations that are both risk and evidence based and takes into account international regulatory benchmarks. Prescriptive commodity standards for specific foods or food components will only be retained in the joint Code where their removal may be detrimental to public health or lead to consumer deception. At the same time, the joint Code will strengthen the requirements that are applied generally to all foods.

For further information please refer to Annex II (attached to this report).

Overall Approach to Domestic Food Standards

ANZFA uses a cautionary approach in relation to individual foods and food ingredients that do not have an established history of safe human use. The philosophy applied to these foods within the food regulatory system is that, due to potential health concerns about their use, they should be prohibited unless expressly permitted. A similar cautionary approach is taken with environmental contaminants.

Risk Assessment and Scientific Data (a fuller description of this issue is at Annex 1***)***

The processes of risk assessment employed by ANZFA in the elaboration of domestic food standards are broadly consistent with those of other national food regulatory agencies and with principles established both by the Codex Alimentarius Commission (Codex) and the International Programme on Chemical Safety in co-operation with the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

At the core of the risk assessment is an evaluation of all available relevant scientific data concerning the safety of the substance under question. The evaluation includes consideration of the scope of the data as well as the veracity of its sources. Uncertainty in the conclusions drawn from the available data or its relevance to the human population is addressed where necessary by the application of safety factors to take account of variations between humans and experimental animals and within the human population. Generally the greater the level of uncertainty about the conclusions the greater the safety factors applied. This empirical framework has been shown to be robust and effective in maintaining public health and safety over a long period of high innovation and change in the food supply.

Risk Management

Approval of a new substance or an increase on the limit for an environmental chemical is only recommended if it has been determined through a comprehensive risk assessment that the likely hazards have been identified and that these can be managed. (Note: this risk assessment includes, as appropriate, a detailed examination of potential exposure using a comprehensive model built on national dietary surveys). If there is a lack of confidence that likely hazards have been identified and are manageable, approval for a new ingredient or an increased limit for an environmental chemical is not recommended.

In relation to the management of risk arising from other classes of food-borne hazards, such as those of a microbiological nature, a variety of approaches are utilised depending on factors such as the method of processing of the food and its intended use. In this regard, there is a strong trend to apply Hazard Analysis Critical Control Point (HACCP) principles to individual food processing and production operations, both pre- and post-harvest, in order to manage risks posed by food-borne hazards. This is often referred to as the (farm) 'gate to plate' approach of assuring food safety. In many instances food inspection programs have recognised the advantage offered by integrating HACCP with Quality Assurance systems in order to assist with the consistent achievement of risk management measures.

Openness and Transparency

The legal requirement of the Australian food standard setting process requires full disclosure and public consultation. The full assessment reports and conclusions are circulated for public comment. The detailed application is available on a public register for scrutiny. In general, the making of legislation by Commonwealth and State/Territory governments requires the impact of the legislation to be taken into account and a Regulatory Impact Statement provided. In addition, the decisions taken by officials in the administration of legislation are subject to a variety of appeal mechanisms. These processes help ensure that the interests of affected groups are taken into consideration and that provisions are appropriately administered.

Data Gathering / Validation

Access to timely, accurate information is essential to the determination of risk. Accordingly, provisions exist under legislation that require applicants who seek a variation to the Food Standards Code or other relevant standard relating to food safety, to supply relevant supporting data. In some cases data requirements are prescribed in detail (e.g. to obtain a Maximum Residue Level (MRL) for residues of an agricultural or veterinary chemical in food).

A variety of approaches are used to validate assumptions made in risk management decisions, including data obtained from the National Notifiable Diseases Surveillance System (NNDSS) covering a number of food-borne diseases. ANZFA undertakes The Australian Total Diet Survey, which monitors pesticide residues and contaminants in food following its preparation and estimates the level of dietary exposure in Australia. Domestically produced imported and exported foods alike are subject to specific testing and surveillance measures so as to give a broad picture of food safety outcomes. In this regard the National Residue Survey conducted by the Department of Agriculture, Fisheries and Forestry – Australia (AFFA) is a key program that provides a statistical measure of the level of compliance with established MRL's and Maximum Permitted Concentrations (MPC's) for a wide range of chemicals and contaminants.

III. Activities in Addressing Food Safety Issues

Response to the Food Regulation Review (Blair) Report

The Blair Review found that the system of food safety management in Australia is very effective in delivering safe food and, consequently, recommended that Governments concentrate their efforts on improving the efficiency of the current food regulatory system. The Review Report was completed in August 1998 and makes a number of recommendations, which include a more developed whole-of-chain approach to safe food production.

The Review Report recommended a model for an integrated, co-ordinated food regulatory system through a partnership between the three levels of government; improved co-ordination and interaction between government regulatory agencies, the food industry and consumers; and a preventative, risk-based, co-regulatory approach to food safety.

The Senior Officials Working Group (SOWG) was established by the Council of Australian Governments (COAG) in March 1999 to develop a whole-of-government response to the Food Regulation Review Report. In developing its response, the Working Group was asked to consider the views of Agriculture, Fisheries and Health Ministers.

SOWG reported to COAG Senior Officials on 8 November 1999 with a model for an improved food regulatory system and a draft inter-governmental agreement for its implementation. A COAG decision on the Working Group's response to the Food Regulation Review Report is expected in April/May 2000.

The National Safe Food Working Group (NSFWG) was established jointly by Agriculture, Fisheries and Health Ministers in 1996 to develop a nationally co-ordinated approach to food safety.

In mid 1999, the NSFWG established the Risk Analysis Team (RAT) and Communications Advisory Team (CAT) to progress mechanisms to facilitate safe food production in the primary industry sector. Both teams reported to the NSFWG in October/November 1999. The recommendations of the RAT and CAT reports were endorsed by Agriculture Ministers at their six monthly meeting in early March.

The RAT report recommends a process for assessing the adequacy of existing food safety arrangements and assisting sectors to develop and implement appropriate arrangements where they do not already exist. The CAT report recommends a communication strategy to disseminate this and other food safety information relevant to the primary industry sector.

The recommendations of these reports are expected to provide an important contribution to the implementation of the Government's response to the Food Regulation Review Report within the primary industry sector, particularly with respect to ensuring the production of safe food in that sector. The COAG decision on the proposed new food regulatory system will, therefore, have implications for the future activities of the NSFWG.

Regulation of Modern Biotechnology

The Australian Commonwealth, State and Territory governments are establishing a comprehensive system of regulation for genetically modified organisms (GMOs) that safeguards public health and the environment. The regulatory system will comprise the new Office of Gene Technology Regulator (OGTR) which will co-ordinate the work of existing regulators (ANZFA, the Therapeutic

Goods Administration, the National Registration Authority, the National Industrial Chemical Notification and Assessment Scheme, and the Australian Quarantine and Inspection Service (AQIS)). OGTR will operate in collaboration with State and Territory governments, to cover any gaps where no other regulator has responsibility (such as commercial release of some genetically modified crops).

The use of GMOs in food products is assessed and regulated by ANZFA under the direction of ANZFSC. ANZFA has developed *Standard A18- Food produced using Gene Technology*, which requires that all foods derived from a GMO are assessed as safe, prior to being allowed on the market place. Safety assessments for GM foods are open to public comment at various stages of inquiry and if any significant doubt exists about the safety of a food product, ANZFA will not recommend its approval.

Cautionary Approaches and Principles

In assessing food-related risks there is always a degree of scientific uncertainty in estimating the risks associated with a food or food ingredient. A general description of how Australian authorities use caution in setting food standards is outlined in Annex I.

Antibiotic Residues in Foods

The use of antibiotics in food-producing animals has recently been considered by a special Committee established by the Commonwealth government, the Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR). The report of this Committee was presented to Government Ministers on 1 September 1999 and its recommendations are currently under consideration.

Regulatory Enforcement and Compliance

The enforcement of food standards is the responsibility of the Australian State and Territory governments and each operate separate Food Acts, which include compliance and enforcement arrangements.

AQIS has responsibility for enforcement of the Export Control Act and Imported Food Control Act. A separate compliance activity is employed by AQIS to verify effective administration and enforcement by inspection programs established under these Acts.

The Blair Report on food regulation contains specific recommendations relating to the effectiveness and efficiency of enforcement of legislative provisions of relevance to all three tiers of government.

Addressing Socio-Economic Concerns

The socio-economic framework in which regulatory frameworks sit are set by the Commonwealth Government. Food standards must focus on the objectives set out in the ANZFA Act (refer section II). If, after a thorough examination of the evidence, it is considered that a regulatory measure is required, then a regulatory impact assessment is undertaken to determine the regulatory option that most effectively achieves the objective. These assessments consider wider issues such as the impact of regulation on food availability, cost and quality, consumer choice and other social costs.

Communication and Consultation

Australia's food standards setting system is based on the concepts of openness, accountability, consultation and transparency. Public submissions are sought on a number of occasions during the development of standards. Procedures are constantly being monitored in order to improve communication and consultation. A variety of mechanisms are employed by regulators to ensure effective interaction with consumer groups, industry organisations and other parties. These include formal Consultative Committees, issue specific Working Groups, newsletters and public announcements. Additionally, the Commonwealth government is committed to utilisation of the Internet for the conduct of its business and improving the public transparency of its operations.

ANNEX I

The Application of Cautionary Approaches in Food Safety Assessment and in Food Standards Setting

The Regulatory Approach

The current food regulatory system in Australia is based upon a community standard in relation to the safety of food that reflects a long history of safe consumption by humans. It is recognised that there are risks and benefits associated with the consumption of many conventional foods. However, it is also recognised that the community has the knowledge necessary to manage or negate these risks while accessing the benefits. For these reasons, conventional foods are generally considered to be safe so long as manufacturers and consumers exercise due care in their preparation and handling.

An explicitly cautionary approach is applied to foods and food ingredients that do not have an established history of safe human use and to environmental contaminants. These include:

- Substances added to food for technological purposes (i.e. food additives and processing aids).
- Foods with no prior history of safe human consumption (novel foods).
- Foods produced using novel processes (e.g. foods produced using gene technology and irradiated foods).
- Metal and non-metal contaminants that may occur in food through adventitious contamination.

The philosophy applied to these foods within the food regulatory system is that, due to potential health concerns about their use, they should, prior to marketing, be assessed as safe. The basis for permitting substances with no prior history of safe use is that is that:

- Pertinent scientific data indicate that the foods (or ingredients/additives used in foods) are as safe as their conventional counterparts when present in food.
- The consumer is, if necessary, either empowered through labelling to make informed choices about their presence or is protected from fraud and deception by controls placed on their use.

In the case of environmental contaminants, a substance that raises health concerns is only permitted in food to the extent that:

- The relevant and appropriate scientific data shows that the contaminant does not pose an unacceptable risk to public health and safety.
- It is at the lowest level that is reasonably achievable through Good Agricultural and Manufacturing Practices.

Risk Assessment and Scientific Data

The processes of risk assessment employed by Australia have been elaborated in the publication "The assessment and management of food borne risks" (ANZFA 1996). The concepts and procedures

described are broadly consistent with those of other national food regulatory agencies and with principles established both by

- The Codex Alimentarius Commission (Codex) under the Joint FAO/WHO Food Standards Programme.

- The International Programme on Chemical Safety in co-operation with the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

Australian staff has played an active role in the elaboration of these principles through participation in Codex committees and in JECFA.

These risk assessment approaches are explicitly required by WTO rules relating to sanitary measures, and the procedures followed by Australian authorities in elaborating food standards are designed to comply with these obligations. It is further noted that the Australian risk assessment procedures explicitly provide for uncertainty arising from such features as knowledge or data gaps to be taken into consideration in finalising an assessment. This use of precaution in deriving risk assessments under Australian procedures is entirely consistent with the conclusion of the 1999 Melbourne 'FAO Conference on International Food Trade Beyond 2000' which agreed that precaution has been and should remain an essential element of risk analysis in the formulation of national food safety standards. Further, the approach helps ensure that Australian food standards, as elaborated, do not constitute arbitrary or disguised barriers to trade.

Hazard Evaluation

At the core of the risk assessment is an evaluation of all available relevant scientific data concerning the safety of the substance under question. The objectives of this evaluation are the identification of:

- All hazards (potential adverse biological effects) associated with exposure of the chemical or material being proposed, irrespective of the level of exposure.

- The thresholds at which these effects occur or the conditions under which they no longer occur.

The minimum scientific data requirements necessary are specified by ANZFA in terms of the types of experiments to be carried out, the results to be reported, the quality assurance procedures required, as well as its quantity and scope.

Data Uncertainty

The evaluation includes consideration of the scope of the data as well as the veracity of its sources. Uncertainty in the conclusions drawn from the data available or its relevance to human population is addressed where necessary by the application of safety factors to take account of variations between humans and experimental animals and within the human population. Generally the greater the level of uncertainty about the conclusions the greater the safety factors applied.

Dietary Exposure Assessment

An assessment of the potential level of exposure through the diet is made based upon actual food consumption data from national dietary surveys. The system used enables extremely conservative

scenarios to be examined which take into account high level consumers and vulnerable populations (e.g. children and the elderly).

Risk Management

Approval of a new substance or an increase on the limit for an environmental chemical is only recommended if it has been determined that through a comprehensive risk assessment that:

a. The likely hazards have been identified.

b. That these can be managed.

If these conditions cannot be met, approval for a new ingredient or an increased limit for an environmental chemical is not recommended.

Strategies for managing food borne risks include:

- Limiting the use of additives and other ingredients to specific foods where a technological justification has been demonstrated.
- Establishing maximum levels for ingredients and/or contaminants.
- Providing information to the community about safe handling of the product (e.g. requiring storage and preparation instructions on labels).
- Providing information to at risk groups about safe eating practices.
- Requiring products to carry warning statements.

Conclusions

The safety of the Australian food supply is regulated through a risk based, evidence based approach that includes both cautious and conservative elements, and reflects international standards and commitments under the Codex and the WTO. These elements, which are incorporated into both the risk assessment and risk management stages, require the utilisation of rigorous scientific data and include procedures to address uncertainty in the conclusions drawn from scientific data. The processes are considered to be operating satisfactorily and significant changes to this methodology are not currently envisaged. For these reasons, any reference to the application of ‘precautionary principle’ in the context of the food regulatory system is unnecessary.

ANNEX 11

Australian Food Standards

Australia, as a federation, has had to establish a multi-layered, rigorous and robust national food safety regime, which now extends across the Tasman to include New Zealand. In December 1995, Australia and New Zealand signed a treaty establishing a joint system for developing food standards in Australia and New Zealand. This is the first example, under the Australia New Zealand Closer Economic Relations Trade Agreement, of two sovereign nations joining forces to create a common set of standards in the interests of enhancing both public health and trade.

This system is based on the existing Australian arrangements, formalised in the 1991 Commonwealth, State and Territory Agreement on the adoption of uniform food standards. Under the Australia New Zealand food standards system, New Zealand, like the Australian States and Territories, will adopt standards developed by the Authority by reference and without amendment. State, Territory, local government and New Zealand authorities are responsible for food surveillance and for enforcing food law and the Food Standards Code.

The National Food Authority Amendment Act 1995 establishes the Australia New Zealand Food Authority and its committees. It provides for publication of Authority notices in New Zealand and brings the Authority's objectives for developing food standards into line with the treaty as agreed between the two governments.

There are three key bodies involved in food standards making the Australia New Zealand Food Standards Council (ANZFSC), The Australia New Zealand Food Authority Advisory Committee (ANZFAAC) and the Australia New Zealand Food Authority (ANZFA).

The Australia New Zealand Food Standards Council

The Australia New Zealand Food Standards Council (ANZFSC) considers recommendations made to it by the ANZFA on draft food standards or draft variations of standards and generally oversees the implementation and operation of uniform standards. The ANZFSC may adopt, amend or reject the Authority's recommendations or return them for reconsideration.

It is made up of Australian Commonwealth, State and Territory health ministers and the New Zealand Minister of Health. It is chaired by the Australian Minister for Health and Aged Care.

The Australia New Zealand Food Authority Advisory Committee

The Australia New Zealand Food Authority Advisory Committee (ANZFAAC) advises on matters referred to it by the Authority or by the States or Territories or New Zealand. It helps progress ANZFSC issues and plays a critical role in advising A4inisters and the Authority on all matters taken up at ANZFSC meetings.

ANZFAAC is made up of the ANZFA Managing Director, members nominated by each State and Territory, New Zealand, and other specific government agencies from Australia and New Zealand.

The Australia New Zealand Food Authority

The Australia New Zealand Food Authority (ANZFA) is a partnership between the Commonwealth, State, Territory and New Zealand governments. ANZFA is an independent, expert body.

It is responsible for developing, varying and reviewing standards for food available in Australia and New Zealand and for a range of other functions including co-ordinating national food surveillance and recall systems, conducting research, assessing policies about imported food, harmonisation of food standards across Australia and New Zealand and developing codes of practice with industry.

The Authority has a Board with a part-time independent Chairperson, the Managing Director, plus six part-time Board Members (four from Australia and two from New Zealand), and one New Zealand special purpose government member to oversee transition to the joint code. Their expertise includes knowledge of the food industry, consumer affairs, food regulation and food science. Members are appointed by government and can hold office for up to five years.

When it develops food regulatory measures or amendments to food standards, ANZFA makes decisions by considering them against the objectives set out in the Act. These are (in descending priority order):

- The protection of public health and safety.
- The provision of adequate information relating to food to enable consumers to make informed choices.
- The prevention of misleading or deceptive conduct.

In developing food regulatory measures, the Authority must also have regard to.

- The need for standards to be based on risk analysis using the best available scientific evidence.
- The promotion of consistency between domestic and international food standards.
- The desirability of an efficient and internationally competitive food industry.
- The promotion of fair-trading in food.

The Authority works in partnership with Australian and New Zealand governments, the Australian States and Territories and other government agencies. ANZFA's government partners and community and industry stakeholders are fundamental to developing sound and lasting food policy and practical food regulations. The Authority's relationship with consumers, the food industry, food technologists and professionals, and other government agencies is the basis of its strength and success. The scientific disciplines are well represented in ANZFA staff. They include toxicologists, microbiologists, food technologists and nutritionists. The Authority also employs professionals to provide legal, communications, policy and administrative advice.

The Authority is concerned to ensure uniform interpretation, risk-based surveillance and enforcement of the Code by all levels of government in relation to locally produced and imported foods. To do this effectively it has access to a wide range of relevant and reliable data, including scientific information about the safety of various foods, food components and technologies; food composition; the presence of chemical residues and contaminants; the processes used in production and packaging; and the estimated consumption of various foods by individuals and groups.

The Authority, in consultation with government agencies, also co-ordinates the microbiological, contaminant and pesticide residue surveillance of food available in Australia. It also co-ordinates a food recall system.

Participation in Design of International Standards

Australia and New Zealand are members of the World Trade Organisation (WTO). The WTO recognises the Codex Alimentarius Commission as the international body responsible for standards and guidelines, which protect public health, ensure fair-trading in food and promote harmonisation.

ANZFA contributes to the debate at Codex meetings and takes account of Codex principles in the Food Standards Code. ANZFA ensures that the integrity of the Australian and New Zealand food standards are maintained and that Australia's food producers are not disadvantaged on the international market.

CANADA

I. Synthesis

Canada has developed a comprehensive food safety system that is rigorous enough to protect consumers today, yet responsive to meet the challenges of tomorrow. The system has the flexibility needed to keep pace with rapid changes in the nature of food, increased trade globalisation, and shifting public expectations.

Canada's food safety system adheres to three fundamental principles: the health of the population must remain paramount; policy decisions must be grounded on scientific evidence; and all sectors and jurisdictions must collaborate to protect consumers.

At present, the core of the food safety system is the federal *Food and Drugs Act*, which derives its powers from criminal law, and several other agricultural-, consumer- and trade-related statutes. However, Canada is proposing to modernise, strengthen and integrate the legislative authorities under a new *Canada Food Safety and Inspection Act*.

The federal Department of Health (Health Canada) sets standards and policies governing the safety and nutritional quality of all food sold in Canada, throughout the food continuum. Health Canada also carries out food-borne disease surveillance activities providing a system for early detection and warning and a basis for evaluating control strategies. The federal Canadian Food Inspection Agency is responsible for enforcing those policies and standards. Complementary provincial/territorial legislation governs food produced and sold within their jurisdictions. The success of the system depends on close working partnerships between federal, provincial/territorial authorities, industry and consumers. The various levels of governments collaborate with non-governmental organisations to ensure the integrity and comprehensiveness of the food-safety system. Through increased product and process inspection activities, industry works to achieve and assure food safety standards themselves. Nevertheless, government will retain a strong oversight and intervention role to ensure the safety of the food supply.

This co-operative structure has served Canadians well because it retains clear lines of authority and accountability at all times. Equally crucial to the smooth functioning of the system is that food-policy decisions are made within a context that is both transparent and rational. In particular, Canada has adopted an internationally accepted risk analysis process that provides a common, consistent, comprehensive and scientifically sound mechanism to identify, assess and manage potential risks to health. The process incorporates a precautionary approach, under which potential threats to the food supply are controlled.

On the grounds that informed consumer participation is essential to effective public policy in a pluralistic society, Canada's regulatory framework for food emphasises stakeholder consultation and communication. Thus, while consumer confidence in the domestic food safety system remains high, government also recognises that the new century brings new challenges. Chief among those is increasing public concern about new foods and technologies such as biotechnology. Canada is addressing such concerns by soliciting the advice of independent experts, enhancing public dialogue, and ensuring its regulatory processes make appropriate allowances for socio-economic considerations.

II. Overview of Food Safety Systems

Introduction

The Government of Canada has a fundamental, but not exclusive, role in health protection including food safety. Collaboration of all stakeholders in the food continuum (feed manufacturers, primary producers, food manufacturers/operators, government authorities, consumers) is essential to ensure a comprehensive and integrated approach to the availability of a safe and nutritious food supply. Government has the primary responsibility for identifying health risks associated with the food supply, assessing the severity and probability of harm or damage, and developing national strategies to manage the risks. Industry has the primary responsibility for the safety of its products and for providing appropriate information to permit consumers to make informed choices. Consumers have the right to be informed about the health risks and benefits associated with food and have the responsibility to use this information.

Food safety policy is based on risk analysis. In Canada, food regulatory decisions are established on a rigorous and objective assessment of all available information, including scientific research that is reproducible, the identification and fair weighting of scientific uncertainty and the review of recent advances in knowledge.

Regulatory Framework

Canada's food safety system operates in a multi-jurisdictional context involving federal, provincial/territorial and municipal authorities.

The main federal legislation covering food safety is the *Food and Drugs Act*. This *Act* prohibits the manufacture or sale of all dangerous or adulterated food products anywhere in Canada. The Act, which derives its authority from criminal law, is supplemented by regulations designed to ensure the safety and nutritional quality of foods. Other federal trade and commerce legislation may reference the *Act* and impose additional requirements. Examples include the *Canada Agricultural Products Act, Meat Inspection Act, Fish Inspection Act, Seeds Act, Fertiliser Act* and *Feeds Act*. Also contributing to the regulatory framework is the *Pest Control Products Act.*

The government is currently proposing to consolidate and modernise existing food and agricultural legislation into a new *Canadian Food Safety and Inspection Act* (see Developing National Food Safety Framework). Based on broad consultations, proposals to update the *Pest Control Products Act* have also been initiated.

Provinces and territories (P/Ts) enact legislation governing foods produced and sold within their own jurisdictions. These laws are complementary to federal statutes. There is also legislation to govern animal husbandry, agricultural practices and the licensing of meat and dairy establishments selling their product intra-provincially. The inspection programs of the P/Ts apply to food-processing and food service establishments, food retail, hospitals, nursing homes, community kitchens and food banks within each province. P/T legislation also authorises municipalities to enact bylaws affecting food inspection.

Because legislative power may not be delegated from one level of government to another, governments collaborate in areas of shared jurisdiction, such as food inspection, and establish partnerships to ensure effective and efficient program delivery.

Institutional Structure

At the federal level, the responsibility for food safety is shared by Health Canada (HC) and the Canadian Food Inspection Agency (CFIA). HC sets standards and policies on food safety and nutrition, while the CFIA enforces them.

Specifically, HC engages in research, risk assessment, pre-market review and evaluation of all issues related to food safety and nutrition, and regulation and registration of pest control products and veterinary drugs. HC also delivers food safety programs within federal jurisdiction, such as First Nations and Inuit communities and on common carriers (e.g. ferries, trains, and airlines).

Moreover, HC is responsible for surveillance of food-borne, water-borne and enteric human illnesses and provides comprehensive expertise and support for the epidemiological and microbiological investigations. These surveillance activities provide up-to-date information to various levels of government and special advisory committees to assist them in developing and improving surveillance and control policies and in planning targeted studies.

Since 1997, CFIA has been responsible for all federally mandated food inspection, compliance and quarantine services previously delivered by Agriculture and Agri-Food Canada, Health Canada, Industry Canada and Fisheries and Oceans Canada. CFIA designs, develops and manages inspection, enforcement, compliance and control programs and service standards. It also negotiates partnerships with other levels of government and non-government organisations (NGOs), as well as industry and trading partners, with respect to inspection and compliance programs; and supplies laboratory support for inspection, compliance and quarantine activities.

To ensure the federal system is one with checks and balances, HC has responsibility for assessing the effectiveness of the CFIA's food safety activities.

At the local level, provinces and territories are responsible for public health, including food-safety surveillance, investigations and compliance. Often, they are the first to be notified of potential food-borne illnesses, and thus play an integral role in the food safety system.

Operational Linkages

HC and the CFIA have established a Memorandum of Understanding (MOU) that outlines their respective roles and responsibilities and establishes principles and mechanisms for an effective working relationship. Formal working agreements have been developed on issues such as Food Safety Emergency Response, Food Research Programs, and the Regulatory Control of Veterinary Biologics, Veterinary Drugs. Another MOU is being developed on interactions on regulation and inspection related to pesticides.

A "Roles and Responsibilities Framework" details the HC/CFIA responsibilities for each program element of the federal food safety and inspection system. Additionally, a Food Safety and Nutrition Co-ordination Committee at the senior management level ensures effective co-ordination of federal activities. The CFIA and HC have also established MoUs with P/T counterparts on shared responsibilities such as inspection activities and food-borne illness investigations.

Partnerships and Support Systems

In the area of food safety, there are several fora to facilitate co-operation among governments, industry, academia, consumers and NGOs.

Through an *Integrated Inspection Systems* approach, the CFIA works with food manufacturers and importers to develop and maintain a Hazard Analysis Critical Control Point (HACCP) system. The CFIA also facilitates the development of safety programs along the entire food continuum through programs such as the *Canadian On-Farm Food Safety Program.*

The *Federal Provincial Territorial Committee on Food Safety Policy* develops, co-ordinates and provides leadership on food safety policies and standards, educational programs and the exchange of food safety information on issues of regional, national and international importance.

The *Federal Provincial Territorial Agri-Food Inspection Committee* provides a forum for resolving inter-provincial technical trade barriers, and advises on a nationally consistent approach to food inspection policies and programs.

The Federal Provincial Territorial Committee on Pest Management and Pesticides provides a forum for co-operation on regulation of pesticides.

The *Canadian Food Inspection System* (CFIS) is a federal-provincial-territorial initiative to facilitate national harmonisation, streamline the inspection process, and reduce regulatory pressures on industry (see Developing National Food Safety Framework). Harmonisation with international standards is an objective of all CFIS initiatives.

The *Food-borne Illness Outbreak Response Protocol* is a partnership among P/T governments, HC and the CFIA that details an integrated approach in response to national food-borne illness outbreaks, and regional outbreaks causing high levels of severe morbidity or mortality. The *Protocol* ensures that all responsible agencies are notified promptly and work collaboratively to mitigate and contain risks.

Research and Development is undertaken at a variety of federal, provincial and university facilities across Canada, and there are frequent interactions and co-operation, both formal and informal, between parties. One such example is the *Canadian Institute for Research in Food Safety* – collaboration between the federal government and the University of Guelph in Ontario.

The *Enteric Disease Surveillance Committee*, which is part of the National Health Surveillance Network, is a federal/provincial/territorial system for early detection and warnings of foodborne, waterborne and enteric disease.

The *Canadian Partnership for Consumer Food Safety Education*, consisting of representatives from HC, CFIA, P/T governments, private sector and civil society including consumer organisations, provides consumers with information for safe food handling. This is an effort to reduce the number of food-borne illnesses and deaths associated with microbial contamination.

Expert Advisory Committees are established to assist in program or policy decisions. These committees, which are obliged to declare conflicts of interest, provide independent sources of information, bring leading-edge knowledge, and provide a mechanism to communicate policies externally, and increase the transparency of the decision-making process. Governments retain the ultimate decision-making authority and accountability.

The Risk Analysis Process

In addition to food safety, HC is responsible for controlling a variety of health risks from therapeutic products, agricultural chemicals and other consumer products. For this purpose, HC has developed a Decision-Making Framework (DMF) that provides a common, consistent and comprehensive means of identifying, assessing and managing health risks.

The DMF articulates fundamental values and principles of decision-making. These include health maintenance and improvement, integrity of science, stakeholder involvement, transparency and openness, a broad risk perspective, the use of precaution, effective communication, and consideration of acceptable risk levels. The DMF will also accommodate emerging challenges.

Similarly, the CFIA has developed a Risk Analysis Framework to guide its enforcement, compliance and control processes. The two frameworks are compatible and consistent with the approaches taken at the international level by the Joint FAO/WHO Codex Alimentarius Commission (Codex).

Both frameworks comprise the three components of risk analysis - assessment, management and communication. Prior to beginning a risk analysis, clarification of the issue and its context is critical since it provides direction and focus for risk assessment and management. The six steps in risk assessment and management are: Identify the issue and its context ➔ assess the health risks/benefits ➔ identify and analyse options ➔ select a strategy ➔ implement the strategy ➔ monitor and evaluate the results. Risk communication is considered an integral part of all steps.

Risk Assessment

Consistent with international practices, the Canadian risk assessment process consists of four components: hazard identification, hazard characterisation, and exposure assessment and risk characterisation.

A risk assessment is a scientific and independent evaluation of the likelihood that a specific adverse health effect will occur. In carrying out these assessments, Canada considers toxicological and epidemiological studies, surveillance information, and data from food-borne illness outbreak investigations and compliance and monitoring data.

The assessment of known and potential health risks resulting from exposure to a specific agent also involves the assessment of known and potential health benefits and examination of risks relative to these benefits.

During the risk assessment, any uncertainties, assumptions or judgements must be identified to determine their potential impact on decision-making. Such uncertainties can have an effect on the estimated level of risk and on selection of the risk management strategy. In Canada, these uncertainties are addressed by exercising the concept of “precaution” through a variety of means such as the use of “worst case” scenarios. Risk assessment is a key part of the decision-making process, not only because it provides an estimate of the level of risk, but also because it can help to identify possible options for risk management.

Risk Management

Risk management is the process of making and implementing decisions designed to mitigate risks identified by the risk assessment process. Canada accomplishes this through the establishment and enforcement of legislative and regulatory requirements, as well as the application of non-regulatory options such as guidelines, advice and education, and promotion of voluntary compliance by industry.

A number of factors are considered when selecting an appropriate risk management response. These are legislative authority, international trade obligations, national policies, feasibility, and how quickly the risk must be addressed. The process considers socio-economic factors such as culture, consumer concerns and demographics. This does not diminish the role of science or the risk assessment process; health takes precedence over all other considerations.

To the extent possible, options are evaluated in consultation with interested parties, especially when the responsibility for managing the risk is shared or where various parties must participate in the implementation of the selected strategy.

Once an appropriate response is selected, the CFIA works with partners/stakeholders to implement it in an effective manner. The CFIA's food compliance program verifies that products meet Canadian standards of safety, quality, and identity, processing and labelling. CFIA issues emergency food recalls, and conducts inspections, monitoring and compliance activities along the food continuum. The Agency is supported by a national network of service laboratories. After the implementation, the CFIA monitors and evaluates the effectiveness of the strategy.

Risk Communication

The Government of Canada is responsible for informing and educating Canadians about risks to their health, including those influenced by personal lifestyle. It also recognises that the exchange of information is a key element in successfully mitigating health risks and that risk communication is a two way process.

In a consolidated effort to reduce food-borne illness in Canada, governments worked with industry associations and consumer, environmental and health groups to create a program called the "Canadian Partnership for Consumer Food Safety Education." The partnership informs Canadians about safe food-handling processes to reduce the risk of microbial contamination.

The Government of Canada believes consultation is an integral part of policy development, including the development of food safety policies and regulations. Mechanisms have been established to provide opportunities, not only for the exchange of information but, where possible, for participation in the decision-making process. Various forms of consultation and communication are employed on issues related to food safety, including direct mailing, multimedia and stakeholder meetings. Similar consultations are conducted with Canada's major trading partners to assess the international impacts of such policies and standards and to work towards international harmonisation. Canada notifies its trading partners of regulatory changes through the WTO notification system. Publication in the *Canada Gazette* remains the official government mechanism for notification of proposed regulatory change.

HC and the CFIA, as well as P/T governments, maintain Internet web sites that publish information on food safety policies, regulation, programs, activities, and consultations. Most of these web sites provide a means for visitors to communicate with the program area.

III. Activities Related to Food Safety

Developing National Food Safety Frameworks

The Government of Canada is reviewing how it does business to optimise operational efficiency and ensures stakeholder participation. A key initiative is the proposed development of a consolidated legislative framework to address emerging technologies and food safety issues. By integrating and modernising existing food and agricultural statutes, the proposed *Canada Food Safety and Inspection Act* would bring a higher level of consistency, flexibility and comprehensiveness.

In addition, Canada is working with industry to harmonise sector-specific model regulations and codes of practices under the *Canadian Food Inspection System* (see Partnerships and Support Systems). The regulations are outcome-based and voluntary, allowing each jurisdiction to incorporate them into their

legislative and inspection programs. The regulations are interpreted by companion codes that detail acceptable industry practices.

Rapid technological developments, globalisation and information management challenges have necessitated a multi-faceted decision-making process. This process distinguishes between the role of scientists and policy advisors. The science team assesses the risk and develops options that deal with the risk and incorporates any public health benefit. The policy advisors consider the science within the broad range of international and socio-economic factors and develops a strategy that is relevant to the Canadian context.

Regulation of Modern Biotechnology

The Government of Canada uses the same approach to ensure the safety of all foods, including those derived from biotechnology. The focus is always on the safety of end products, not merely their method of production.

Specifically, HC is responsible for the human health and safety assessment of new, often referred to as "novel", food products, including those that have been genetically modified and for the regulation of microbial pest control products produced through biotechnology. The CFIA is responsible for carrying out environmental safety assessments on all other agricultural products with novel traits, proposed for confined and unconfined release, as well as other regulatory requirements pertaining to animals and plants with novel traits.

In Canada, novel foods are subject to a mandatory pre-market notification to HC for a safety assessment. Once approved, the novel food enters the market in the same manner as traditional food products, and remains subject to the same post-market standards applicable to other foods.

All food products, including those with novel traits, are required to be labelled to alert consumers to safety concerns, such as allergenicity and compositional or nutritional changes. The Government of Canada recognises that labelling foods derived from biotechnology has become an important issue and is developing voluntary labelling standards in Cupertino with consumers and industry groups. Internationally, Canada contributes to discussions of this nature at Codex.

The Canadian approach to safety assessment of novel food, plants and feed is based on the concept of substantial equivalence and follows principles developed by an international committee of experts working through the Organisation for Economic Cupertino and Development (OECD). Canada continues to be active in international fora (WHO, FAO, OECD), sharing expertise in assessment practices and ensuring that Canada's strategies are based on the best science.

Canada recognised that advances in biotechnology would unfold at a rapid pace. In response, the *Canadian Biotechnology Strategy* was renewed in 1998, to ensure that the products of biotechnology continue to be derived in a safe and sustainable way. The Government of Canada also acknowledges that these rapid developments are prompting consumer interest. It has therefore established a Canadian Biotechnology Advisory Committee, an arm's-length group of experts reporting to Ministers. The committee provides a forum for public discussion and is considering the scientific, ethical, social, economic, regulatory, and environmental and health aspects of several issues, with a particular emphasis on foods derived from biotechnology.

The Ministers of Health, Agriculture and Environment established an Expert Advisory Panel on the Future of Food Biotechnology to examine future scientific developments of food biotechnology. This committee will also assess methodologies developed internationally to evaluate the safety of new foods and identify any new policies, guidelines and regulations that may be required.

Precautionary Approaches and Principles

The concept of "precaution" is an intrinsic part in HC and the CFIA's risk analysis process. Uncertainties in scientific data are carefully considered in assessing the level of risk to which the public may be exposed and in the selection of an appropriate risk management strategy.

Recently, there has been considerable discussion both domestically and internationally on the explicit recognition of the "precautionary principle" or a "precautionary approach" in food safety decision-making. In this regard, HC and the CFIA believe that appropriate precautionary risk management measures should be implemented where there is reasonable scientific evidence that a health risk exists, even if a cause and effect relationship has not been fully established. As this concept is applicable to issues besides food safety, the Government of Canada is continuing to review the concept of precaution to fully clarify its consistent application across all areas of government responsibility.

Regulatory Enforcement and Compliance

The goal of the CFIA's compliance and enforcement activities is to control risks to human health. However, the philosophy is evolving from reliance on direct government inspections to increased use of government audits of industry activities.

The audits are based on risk, supported by strong compliance and enforcement tools. Under the HACCP-based Integrated Inspection System (IIS), industry will have primary responsibility for the inspection of its products and processes. To maintain the integrity and credibility of the inspection system, the CFIA maintains strong government audit, compliance and enforcement capabilities. The degree of ongoing government oversight and intervention depends on each company's history of compliance and the risk associated with its product.

Because intergovernmental Cupertino is essential for food safety, the CFIA is working with the provinces and territories to determine how government agencies can better share in the effective control of risk. The improved Canadian food inspection system will continue to be based on scientific risk assessment and will enhance an integrated inspection approach, harmonisation of standards, service to consumers and efficient use of resources.

Socio-Economic Factors

In selecting a risk management strategy, HC and CFIA take into account a number of factors, in addition to science and its international obligations. For example, socio-economic factors such as population income, education and personal health practices are reflected in the decisions.

Canada reserves the sovereign right of nations to make decisions appropriate to their societal values. But Canada also recognises the need to participate in a global marketplace, including collaborating on efforts to harmonise the international treatment of food products.

Socio-economic factors have always been incorporated in HC and the CFIA's decision-making process. Canada recognises that there is a growing demand that decision-makers more explicitly communicate which factors are considered and how they are applied.

Communication and Consultation

There is a growing demand among Canadian consumers to be more informed and involved in public decisions. In the area of food safety, for instance, the Government of Canada is employing various forms of communication formats (see Risk Communication), including comprehensive web sites, education programs and public fora.

Government is also committed to assessing public attitudes and satisfaction with its policies. Popular consultation strategies include raising public awareness, soliciting feedback, field testing risk management options, pre-testing communications messages and gauging public reaction to pending policies.

IV. Conclusion

This report summarises the comprehensive and responsive food safety system, which effectively addresses present and emerging challenges. This system is also flexible enough to encompass Canada's geographic diversity and multicultural population while providing safe food.

CZECH REPUBLIC

I. Summary

Background

The present situation and in some respects also the prospects of the system of food safety in the Czech Republic is influenced, above all, by profound political changes and their impact on the development of Central Europe in the course of the 20th century. The second half of the 1990s saw the onset of activities aimed at the harmonisation of the legislation with the EU prior to the joining of the EU, and at obligations to the WTO. The year 1997, when the new Act "on food and tobacco products" and its implementing regulations was passed, can be taken as the turning point in the organisation of the food safety system. Many other Acts concerning the activities of agriculturists, producers and control organisations were also passed. The national system of food safety in the Czech Republic is being adapted to the risk analysis scheme, which consists of three integral parts: risk assessment, risk management and risk communication.

Risk Assessment

In the Czech Republic priority is given to pathogenic micro-organisms and fungi, the occurrence of persistent organochloric pollutants, natural toxins, including mycotoxins, some heavy metals and metalloids, as well as residues of veterinary drugs. In the past decade, investigations of the population exposure were improved using the so-called Total Diet Study. The characterisation of microbiological risks is based on comparisons of the results of microbiological examinations of foodstuffs with the number of registered acute alimentary diseases. In terms of the chemical agents, main attention is devoted to chronical exposure. Non-carcinogenic and carcinogenic effects are evaluated. There is virtually no experience with substantial equivalence testing of GM foodstuffs.

Risk Management

Four basic tools for decision making are used in risk management: analysis of the risk / benefit ratio, evaluation of the impact on the producer and consumer, estimation of the value of health hazards, and link to the environment. The organisation of the national control system is defined by the Act No.110 / 1997 of the Coll. "on food and tobacco products" and is supervised by the hygienic service bodies (Ministry of Health), State Veterinary Administration and Czech Agricultural and Food Inspection (Ministry of Agriculture). The legal framework ensuring food safety in the Czech Republic is relatively wide and is based on both tradition and harmonisation with EU regulations. There are many independent Acts and implementing regulations (Decrees). Attention is devoted to good manufacturing practice (GMP) and good hygienic practice (GHP). Food producers were imposed to launch a system of critical points (similar to HACCP). Some food producers in the Czech Republic obtained an ISO 9000 certificate. The intent of large producers is to work out long-term strategies of quality control of food production (TQM plans).

Risk Communication

Over time it has often been proved that when we underestimate the communication strategy, we cannot achieve the expected reduction of health risks. The communication strategy is aimed at the preparation of hygiene-focused experts, education of professionals who handle food, and education of the general public.

Functionality of the System

In the 1990s it was confirmed that the national system of food safety worked relatively well. Nevertheless, the existing system may not be adequate for new problems, which are associated with the globalisation of the food trade, introduction of new technologies, increased migration of the population and with the ongoing social and economic changes in the country. In this respect we expect a development that will converge with the development of the EU system.

II. Historical Framework of the System

The present situation and in some respects also the prospects of the system of food safety in the Czech Republic are influenced, above all, by profound political changes and their impact on the development of Central Europe in the course of the 20th century.

After the political changes in 1989 and namely after the liberalisation of economy in 1991, the economy of former Czechoslovakia underwent fundamental changes. The division of Czechoslovakia into the Czech Republic (CR) and Slovak Republic in 1993 had virtually no effect on the system of food safety, because this had already been in effect independently on a federal basis.

In the 1990s, it was confirmed that the national system of food safety worked relatively well. No serious failure of the system in terms of the known risks is known to have happened after 1989 (an exception is higher number of registered acute infectious alimentary diseases). However, it is becoming clear that the existing system may not be adequate for the new problems associated with the globalisation of the food trade, introduction of new technologies, increased migration of the population and with the ongoing social and economic changes in the country. The demands for more sophisticated technology, for education of the staff and for communication abilities are rapidly growing.

The description of the national system of food safety in the CR is based on risk analysis, which consists of three integral parts: **Risk Assessment, Risk Management and Risk Communication**.

1. Risk Assessment

1.1 Hazard Prioritisation

The present system of prioritisation in the area of hazard agents is based on a combined application of information from own scientific institutions and on international information. Czech experts are participating in number of the activities of the majority of international organisations involved in the identification and prioritisation of dangerous agents in food, including the WHO, FAO, ILSI, COST, Codex Alimentarius etc.

The Ministry of Health pursues decisions on prioritisation in the area of hazard agents in food in co-operation with the Ministry of Agriculture and Ministry for the Environment. Based on a general

agreement the priorities are set down by the ministry experts. In some cases a multi-component scoring system is used for priority decisions (e.g. for environmental pollutants).

The present priority for the CR are investigations of pathogenic micro-organisms, persistent organochloric pollutants, natural toxins, including mycotoxins, some heavy metals and metalloids, and also residues of veterinary drugs. In terms of potential risks, radioactive substances, modern pesticides, additives and physical agents are not considered to be priorities at the present time.

1.2 Hazard Characterisation

Determination of the so-called safe exposure dose is considered to be the result of hazard characterisation. No recent domestic studies are known that would define infectious doses of microbiological agents in food. Proposals for safe exposure doses of chemical agents (e.g. for ochratoxin A) are published only sporadically. It is a rule to use internationally recommended values (ADI, PTWI, RfD etc.) for quantitative risk assessment of chronical exposure to chemical substances, preferentially values recommended by the Codex Alimentarius, sometimes also values recommended by US EPA (RfD). Data recommended by individual domestic and foreign experts are used for orientation purposes only if the international safe exposure doses had not been defined and when good documentation for this value are given (e.g. the TDI value that was recommended in the Netherlands was used for assessing the sum of PCBs).

1.3 Intake Assessment on the National Level

Three methods for defining the availability and consumption of food are used in the system of food safety. The basic method for the general assessment of food availability is the method of food balance sheets, which is currently used in agriculture. The method of household budget surveys is more precise and is based on quantitative data on food availability on the household level. The Czech Statistical Office collects the data continuously from more than 2500 households. It is envisaged that a representative national survey of consumption on individual level will be carried out in the near future.

1.4 Exposure Assessment

Over the past decade the system of population exposure assessment has been considerably improved. Pre-market assessment of exposure to new chemical substances in food is based on mathematical models. The post-market exposure assessment system is very extensive and uses the so-called Total Diet Study. Every year the median or average oral exposure dose for about 50 chemical substances for an average individual in the population is assessed and, in parallel, the intake of the main nutrients and micro-nutrients (17 items in total). Calculations of the exposure doses are based on the data availability for about 200 most frequently consumed foodstuffs, representing more than 95% different foodstuffs available for the Czech population.

1.5 Risk Characterisation

Risk characterisation is based on the general recommended system, which is in accordance with the obligations accepted within the framework of the WTO agreements (SPS agreement). The system applies to both biological and chemical agents in food.

1.5.1 Characterisation of Microbiological Risks

The method is based on comparisons of the results of microbiological food examinations in registered cases of acute alimentary diseases. Most of the diseases are attributed to the fact that basic rules for food handling were broken, particularly during preparation of meals. In official statistics, foodstuffs as the vehicle have been confirmed in only 5% epidemics of alimentary outbreaks. The rest were confirmed only in epidemiological associations without the possibility of laboratory confirmation. There are many uncertainties in the characterisation of microbiological risks. To date, the international criteria cover only partially the entire assortment of foodstuffs and so in many cases the precautionary principle has been applied. In risk management the conservative setting of zero tolerances for the presence of a pathogenic micro-organism in a certain volume of food samples is applied.

1.5.2 Characterisation of Chemical Risks

In terms of chemical agents, main attention is devoted to chronical exposure. The non-carcinogenic and carcinogenic effects are assessed. The qualitative approach based on the assumption of threshold doses using safety factors is applied to characterise the non-carcinogenic risks. The found exposure dose is compared with the so-called safe exposure dose (ADI, RfD etc.). For characterisation of the carcinogenic risk, the quantitative approach is applied, based on non-threshold linearised multistage models assessing the dose-effect response. For substances where the oral slope factor (OSF) for the carcinogenic risk was determined, it is the probability of increased occurrence of tumorous diseases caused by the exposure dose. An agreement of a group of experts or one expert, who is an authority in the given area, is applied to settle the uncertainties. Also the precautionary principle is used for the decision making.

1.5.3 Substantial Equivalence Testing

Officially there is no evidence that GM food is being developed in the CR. Therefore there is no experience with corresponding testing method of such food items. Partial experiences were achieved from tests of products of conventional breeding methods (e.g. potatoes, rape, sugar beet, etc.).

1.6 The Use of Biomarkers in Man

Sometimes the biomarkers of the internal exposure dose or effect of substances from food are used to assess the exposure or effect. That is to say that sometimes it is more convenient to monitor the internal exposure dose (uptake) or effect than to analyse the food in order to estimate the exposure dose (e.g. of some mycotoxins). Since 1994, within the integrated monitoring programme guaranteed by the Ministry of Health, biomarkers of the exposure and effect of several tens of chemical substances have been studied. The results are compared regularly with results of food, air and water analyses.

2. Risk Management

2.1 Consumer Risk Perceptions

The consumer risk perception has changed positively during the transition period in the CR following 1989. Before 1989 the public lacked information on the actual food safety. After the political changes the quality of domestic foodstuffs was not believed by public to be good. In the first place it was the environmental pollution that led the public to the conclusion that many health problems had been

caused by unsafe food. The consumer's perception that he/she is responsible for his/her own health was on a very low level, but began to change in the 1990s. The consumers realised that they themselves were responsible for their own health and that the support of the government to them could be effective.

2.1.1 Ranking of the Risks

The public differs from the experts in their awareness of the severity of the risk. In recent years, campaigns of interest groups have brought to the fore concerns about the risk of consuming GM food. The perception of the importance of pathogenic micro-organisms presents in food is relatively the same among the public and the experts, thanks to an extensive instructive campaign aimed at the reduction of food-borne diseases. Also the understanding that it is important to change dietary habits has increased and has contributed to the considerable reduction of consumption of animal fat. Increased attention is being devoted to the public perception of risks by means of various health promoting projects.

2.1.2 Risk Debates and Trust of the Public

Virtually all the participating parties, including media, are regularly involved in debates about the risk. Their extent is considerably under the sway of the social, economic and political situation. The experts have accepted the concept of risk assessment as a policy, while some interest groups of producers and consumers sometimes purposefully confuse the real risks for the expected ("wanted") ones, without any evidence that such a claim is true. Even under such conditions the trust of the public in information provided by the government agencies is relatively high.

2.2 Decision-Making Aids

Four basic aids for decision-making are used by the responsible ministries in risk management associated with food safety: risk / benefit analysis, assessment of the impacts on producers and consumers, valuing human health risks, links to the environment.

2.3 Risk Evaluation, Reduction and Control

The process of risk evaluation, proposals for risk reduction and control are the main elements of in the system ensuring safe food management.

2.3.1 RiskEvaluation

Information produced in the framework of investigations of the legislation enforcement are used for risk evaluation. The monitoring system of the Ministry of Health is directed at the description of the risk caused by dietary exposure, both to chemical and microbiological agent. The system is independent on food inspection bodies but uses some data from monitoring programmes of inspection bodies of the State Veterinary Administration and Czech Agricultural and Food Inspection. Experts from three ministries (health, agriculture and environment) are involved in risk evaluation. The complete reading of the results of the monitoring system are accessible to the political bodies and to the public (a summary of annual reports on the Internet).

2.3.2 Risk Reduction

If it is necessary to reduce a serious risk, then normally the first thing is to specify all the options and variants. In the next stage a suitable strategy to implement the measures is explored. The advantages and disadvantages of the proposed measures are evaluated, often in co-operation with health, agricultural and environmental experts, sometimes also after preliminary consultations with the major food producers. In serious cases, indicators of the effectiveness of the measures are incorporated into the enforcement monitoring plans. For instance, after the recommended content of iodine in salt was defined, a programme to control this content and an epidemiological study to describe the extent of consumption in the population were launched. The main tools used to reduce the risk in the CR are, in particular: the improvement of technologies, definition of hygienic limits, labelling the foodstuffs, education of the producers and consumers. Prohibitions and bans are applied only exceptionally.

2.4 Food Control

The organisation of the national control system for food safety is defined by the Act No. 110/1997 of the Coll. "on food and tobacco products" and is supervised by the hygienic service bodies (Ministry of Health), State Veterinary Administration and Czech Agricultural and Food Inspection (Ministry of Agriculture). In accordance with this Act, these governmental bodies are in charge of the organisation and supervision in the sphere of activities of the Ministry of Defence, Ministry of Internal Affairs and Ministry of Justice. In mutual co-operation the supervision bodies elaborate the conception of governmental supervision and they integrate the procedures of food control. The main control bodies and their competence is as follows:

- *Hygienic service bodies of the health sector* which control the catering facilities, they control the epidemiologically risky groups of foodstuffs based on the list and rules of selection determined by the Ministry of Health's decree. During supervision they perform the obligations of the Act No.20/1966 of the Coll. "on the health care, in the wording of later regulations".

- *Bodies of the State Veterinary Administration* carry out control in the course of production, storage, transport, import and export of animal-based raw materials and food, sales of raw material and animal-based food in market halls and market places, and sales in shops where meat, milk, fish, poultry, eggs are handled and venison is sold, and duties based on the Act No.166/1999 of the Coll. "on veterinary care".

- *Czech Agricultural and Food Inspection* controls the production of food and its introduction to the market, provided supervision which is not carried out by the veterinary administration bodies, and observed the Act of the Czech National Council No.63/1986 of the Coll. "on the Czech Agricultural and Food Inspection in the wording of the Act No. 110/1997 of the Col.".

2.5 Food Safety Legislation

The legal framework ensuring food safety is relatively wide and is based both on tradition and harmonisation with EU regulations. There are many independent Acts and dozens implementing regulations which are guaranteed by the Ministry of Health (the Bill "on the public health protection" etc.), the Ministry of Agriculture (the Act "on food and tobacco products", the Act "on varieties, seeds and planting material", the Act "on feeds", the Act "on veterinary care", the Act "on Czech Agricultural and Food Inspection" etc.), the Ministry for the Environment (the Act "on chemical substances", the Act "on waste", the Bill "on GMO and products" which is under preparation etc.), the Ministry of Industry and Trade (the Act "on technical requirements for products", the Act "on consumer protection" etc.). The legislation includes many other related Acts and they're implementing regulations.

2.5.1 Competence of the Ministries Based on the Act "on food and tobacco products"

Based on the key Act "on food and tobacco products" it is the duty of the Ministry of Agriculture and Ministry of Health to issue regulations on food safe. The Ministry of Agriculture has issued regulations defining, in particular, the following:

- Method of food labelling in terms of their composition, or the method of labelling the batch.
- Method and extent of food equivalence testing, mode of transport and sampling of food by the producer, provided the samples are not intended for microbiological control.
- Food for which the producer or importer will issue a written declaration on equivalence, the extent and content of this declaration.
- Types of food divided into groups and sub-groups.
- Method of defining critical points in the technology of production.
- Permissible deviations from data on the amount of "e" marked products.
- Food used for special nutritional purposes and modes of use.
- Types of perishable food which must bear the "best before" date.
- Types of food where the minimal shelf life need not be indicated.
- Technical name-related requirements for individual types of food.
- For individual types of food, including frozen food listed in the implementing regulation, also the thermal regime and relative storage and refrigeration humidity, methods of market food storage and handling, special requirements for transport and the minimal technological requirements.

For the existing types of food the Ministry of Health determines the following:

- Requirements for health safety of the respective types of food, food raw materials and seasoning, especially the amount and types of food supplements, additives, aromatising, contaminating, toxicologically important and auxiliary substances, residues of pesticides and veterinary drugs and biologically active substances used in animal production (chemical requirements), their purity, identification and conditions of use in foodstuffs, foodstuffs or groups of foodstuffs in which these substances could be contained and labelling them on the packaging.
- Microbiological requirements for the respective types of food, food raw materials, auxiliary substances, additives and supplements, particularly the method of selection and number of samples, mode of control and evaluation.
- Conditions of irradiation of the respective types of food and the highest permissible irradiation doses to which the respective types of food may be exposed and the method of labelling.
- Method of calculation and presenting the nutritive value, giving data on the potential unfavourable health effect or stating that its consumption is unsuitable for a certain group of consumers.

- Hygienic requirements for retail sales and equipment of the shop based on the assortment of sold food.

- Requirements for table water.

- Rules for the selection of epidemiologically risky groups of foodstuffs.

The Ministry of Health is further authorised to certify the introduction on the market of food which:

- Contains types of food supplements, additives, aromatising, contaminating or toxicologically important substances, auxiliary substances, residues of pesticides and veterinary drugs and biologically active substances used in animal production (chemical requirements), to date not stated in the decree.

- Are not listed in the decree determining the chemical and microbiological requirements for food.

- Are used for special nutritional purposes.

Such foodstuffs may be put on the market only under given conditions. At the present time all novel foods (including GMOs) are included in this authorisation. The conditions may also include the method of labelling. The part concerning novel foods, including GMOs, is now the object of the amendment of the Act "on food and tobacco products".

2.5.2 Regulation Releasing of the Products of Modern Biotechnologies into the Environment

The basic legal provision in the area of modern biotechnologies will be the Act "on handling genetically modified organisms and products". The Bill has been harmonised with EU directives. The Act should be in effect as of 1 January 2001. The Ministry prepared the Bill for the Environment in co-operation with the Ministry of Health and Ministry of Agriculture, with scientists and representatives of NGOs.

2.5.3 Code of Practice, Good Hygienic Practice

Technical standards regulating food production (code of practice) are important in terms of their impact on the production of safe food as well. In the CR the character of these standards at the present time is not obligatory, but the producers apply them. There are hundreds of such standards issued by the Czech Institute for Normalisation, Measurements and Controls. Before some activities associated with the handling of most foodstuffs are launched, the person has to prove a knowledge of what is called the hygienic minimum. The operator must elaborate operation rules and the control authorities control their observance. Most of the problems are caused by small and medium-sized facilities.

2.5.4 Implementation of the HACCP System

A higher form of the care for safe food is the HACCP system. As of 1 January 2000, food producers in the CR were imposed the duty of launching the so-called system of critical points (interpreted as HACCP) by decree No. 147/1998 of the Coll. For these producers the Ministry of Agriculture prepared examples for the elaboration of the systems of critical control points for some commodities. The number of registered food producers in the CR is relatively high (ca 9000). The problem is how to launch the

system in small and medium-sized businesses. It is expected that the HACCP system will also be launched in large catering facilities according to prepared regulations.

2.5.5 VoluntaryAgreements, ISO 9000

The integrated system of care for safe food does not include only obligatory measures for the producers (GMP/GHP and HACCP), but also a higher, as yet voluntary, participation of enterprises producing, processing or selling food. Many food producers in the CR have obtained the ISO 9000 certificate for quality management. Large producers have proceeded even further in their efforts to achieve better quality and they are elaborating long-term TQM strategies.

2.6 Organisation of Food Safety Surveillance and Monitoring

Surveillance can be divided into routine compliance testing based on preliminary plans of sampling and target control activities. A specialised "monitoring programme" is usually added to the routine surveillance.

2.6.1 Organisation of Routine Compliance Testing

For routine compliance testing, which should correspond with the given regulations, the control organisations determine plans, which are the result of a compromise between financial sources and prioritisation of the surveillance. The plan is usually harmonised with EU recommendations, provided that they exist. Prioritisation of compliance testing takes into account the results of risk characterisation, technical possibilities of the control bodies, and some other requirements.

2.6.2 Assessment of Food Equivalence

Since 1998 the system of control of safe food in the CR has been made an integral part of the food equivalence assessment being in agreement with the requirements of decree No.220/1998 of the Coll. issued according to the Act No.110/1997 of the Coll. "on food and tobacco products" which demands that the producer of certain types of food should regularly control the selected parameters affecting the safety of food determined in the decree with regard to their risks.

2.6.3 Monitoring Programmes of the Control Bodies

In addition to routine compliance testing and targeted control activities also long-term monitoring programmes, whose aim is search function, are organised observing such parameters of food safety, which usually do not appear in plans of routine compliance testing.

2.7 International Consequences

In the management of health risks in the CR the importance of international influences is increasing. It is a traditional that the recommendations of the Codex Alimentarius are used most frequently. Also the induction of the CR into the WTO has largely influenced the system of food safety. In particular, the SPS Agreement using the risk analysis is reflected into the organisation and management of the system of food safety more and more. But it is not free of problems, which arise when using new approaches, for instance when defining the hygienic limits with using precautionary principle. However,

most important is the harmonisation of regulations with the EU. Complete harmonisation should be reached before the end of the year 2000.

2.8 Precautionary Principle

The precautionary principle is understood as an approach, which compensates the absence of scientific data and, if necessary, enables to make immediate legislative decisions. It should, however, always be accompanied by an increased pressure to carry out research, which would remove or explain the usually very conservative solution caused by applying the principle. Clear rules how to use the principles have not been established yet.

2.8.1 Application of the Principle when Preparing the Bill "On Handling the GMOs and Products"

The Bill was prepared by the Ministry for the Environment in co-operation with the Ministry of Health and Ministry of Agriculture and with scientists and representatives of ecological NGOs. The Bill includes only organisms capable of reproduction or transfer of hereditary characters and products, which contain these organisms capable of reproduction. It does not concern the GMOs products, which do not contain any viable organisms (this will be covered in the amendment of the Act "on food and tobacco products"). Basing on the precautionary principle the following conditions were determined before launching on the market:

- A two-step registration for introduction on the market will be applied in cases where this introduction is regulated by special legal regulations. First of all, the GMOs or product must be registered (after evaluation of the health risk) for introduction on the market according to the Act "on handling GMOs and products" and then according to other legal regulations, for instance the Act "on food and tobacco products", the Act "on varieties, seeds and planting material" or the Act "on feeds" introduced on the market with the consent of the Ministry of Health or Ministry of Agriculture.

- According to the Act everybody who introduces GMOs or products on the market is under obligation to keep the conditions given in the decision on registration for introduction on the market (e.g. instructions for the consumer, packaging) and the duty to label the GMOs and products clearly as "genetically modified organisms" or "this product contains a genetically modified organism".

2.9 Sustainable Development

The CR acknowledges the basic principles of sustainable development. Part of the professional and lay public considers some of the new technologies, including modern biotechnologies, as technologies endangering this development. They call for much stricter regulations. There have to be equipoise between the potential of these technologies and the new, much more sophisticated, system of control of potential risks, in comparison with conventional breeding technologies.

3. Risk Communication

An integral part of risk analysis is risk communication. History has proved many times that if we underestimate the communication strategy, we cannot achieve the expected reduction of health risks in practice. The communication strategy is aimed at the preparation of hygiene-focused experts, education of professionals handling food and education of the general public.

3.1 Information Sources

Topical information on the health protection is now widely distributed by the television and press. Media of various kinds have proved competent for educational information. Leaflets, brochures and videos produced by the National Health Programme are very useful tools. The popularity of the Internet is growing. Various educational programmes are very effectively helping to change consumer attitude. Professional information is distributed through consumer unions; some of them publish their own magazines, which are popular among the public, as a contrast to official information. We must not forget that the label on the food product is a very important source of information. The labelling of consumer food packaging in the CR is being harmonised with the EU.

3.2 Target Recipients

The information is aimed at many target groups. The communication system provided by the Ministry of Health is based on prioritisation of the health risks. The endangered groups are analysed in order to find an effective strategy for communication. The special target groups are, for instance, school children and the youth, mothers with children, the elderly, sick, but also the minority populations where the nutritive behaviour is very specific, such as the gypsy minority or vegetarians. A specialised educational programme guaranteed by the Ministry of Agriculture has been launched for agriculturists and food producers.

3.3 The Role of the Government

The government plays an irreplaceable role in the communication among the respective governmental institutions, food producers, non-governmental organisations, and the general public. Co-ordination activities among the control bodies are very important, because the competencies are divided among different branches. Many co-ordination groups, working groups and advisory bodies have been established. On the vertical level the efficiency of their work is relatively very good. Still, more can be done on the horizontal level.

The government plays its role particularly when preparing the new legislation, in operative risk communication and education of the public. The new legislation concerning food safety is now undergoing the obligatory internal and external review before the final version is submitted to the government and parliament for discussion and decision. This mechanism enables the broad technical and lay public to present their comments and opinions before the legislative standards are passed. The drafts are distributed to no less than 150 different organisations. Operative risk communication is carried out through the media. Drafts of some regulations and many of the educational programmes are accessible on the Internet.

3.4 The Role of the Media

The role of the media has considerably increased. Television is considered to be the most widely spread and fastest method of spreading information. The national television is now broadcasting two regular programmes aimed at health protection and promotion. Food safety is also on. The professional and educational standard of specialised TV programmes prepared under the supervision of experts is good. On the other hand, information spread by the major news agencies is sometimes out of focus and is technically inaccurate.

3.5 The Role of the Producers

In terms of the education of the public, the role of producers has grown very much in the 1990s. Governmental institutions alone are not capable of covering all the aspects of public education. In communication between the government and the producers, the government has addressed the producers with a new demand, i.e. that they become more initiative in the education of customers in terms of reducing potential health risks. Pressure is also exerted on commercials, but here not all the goals have been achieved.

References and Contact Address

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EUROPEAN COMMISSION

I. Synthesis

The European Union (EU) has developed its food safety legal system over several decades to harmonise standards between Member States (MS) in order to facilitate free trade, and to obtain and maintain a high level of health protection. This development has involved complex interactions between the EU Institutions and the MS, and has provided a strong framework of legislative and control measures, which provides the EC consumer today with a high degree of food safety.

Current legislation covers primary production (meat, fish and plant products), secondary production (foodstuffs, novel foods, food additives, flavourings, contaminants etc), animal feed and zoonoses. Standards for production are laid down and controls on implementation are required, both by the MS and by the Commission. These measures apply to imported products as well as to Community production. A Rapid Alert System facilitates circulation of information on serious food emergencies.

Risk assessments are provided by the Commission's scientific committees, which have recently been restructured. This system responds to the need for excellence, independence and transparency. Risk management is provided by the Commission, through proposals to the Council, and to the European Parliament where appropriate, and in consultation with stakeholders. Where there is a lack of scientific information, the precautionary principle has been accepted as a risk management strategy.

While the existing framework provides a very high level of food safety to consumers, the Commission is now looking forward to further improvements. A White Paper on food safety has been presented by the Commission on 12 January 2000. The strategy in this paper includes the setting up of a Food Authority with responsibility for certain key tasks e.g. scientific advice, information gathering, rapid alert systems and communication. The other main elements of the White Paper are the development of a fully integrated system for food safety legislation and controls covering all aspects of food production from "farm to table", improved consumer information and international issues. This paper will be discussed with MS over the coming months.

II. Overview of the EU Food Safety System

2.1 EU Institutions

The *European Parliament (EP)* is directly elected by the people of the Community. The Amsterdam Treaty has given it increased decision-making powers in relation to health and consumer protection.

The *Council of the European Union* is the Community's legislative body. For food safety issues, it exercises its legislative power in co-decision with the EP. It represents the Member States (MS) and their views and is designed to find common ground between them. It can act only on the basis of a proposal submitted by the Commission. The Council may confer implementing powers on the Commission.

The *European Commission* is the Union's executive body and the guardian of the Treaties. It represents the general interest of the European Union. It proposes Community legislation, monitors compliance with legislation and with the Treaties and administers common policies. The powers of the Commission for implementation of legislation are exercised in specialised Committees of Member State representatives. Four of these Committees deal specifically with food safety (Veterinary, Food, Animal Nutrition and Plant Health). The Commission can institute legal proceedings against MS or businesses that fail to comply with European law and, as a last resort, bring them before the European Court of Justice.

The *Court of Justice* is the judicial body of the Union. Its responsibility is to ensure that Community legislation is correctly interpreted and applied.

2.2 Objectives of EU Legislation

At the time the European Community was established, each MS had its own food safety legislation. This created many potential barriers to trade within the Community, as each MS wanted to be sure that its national standards were met by the others. This led to a gradual process of harmonisation of EC legislation, to facilitate free trade. This process was accelerated in the lead-up to the Single Market in 1992, in order to achieve the objective of movements without border controls between MS. The Single Market also stimulated a change of perspective, from simple harmonisation to the objective of a high health standard. The legal situation described in this document is the result of this process. It has created high standards of food safety for the European consumer.

2.3 Legal Instruments

2.3.1 Treaty Provisions

The EU food legislation can be based on various provisions of the EC Treaty: Article 95 in the case of measures for the completion of or the functioning of the Internal Market (taking as a basis a high level of consumer and health protection), Article 37 where agricultural aspects are preponderant, as well as Article 152 for measures in the veterinary and phyto-sanitary fields which have as their direct objective the protection of public health, Article 153 relating to consumer protection. Articles 152 and153 were introduced recently by the Amsterdam Treaty.

Depending on the legal basis, measures are adopted by the Council in co-decision with the European Parliament or after consultation of the European Parliament on a proposal by the Commission.

2.3.2 Primary Legislation

Primary legislation is adopted by the Council acting alone or in co-decision with the Parliament on a proposal by the Commission. The Parliament, acting jointly with the Council can make Regulations, issue Directives, take Decisions, make Recommendations and deliver Opinions.

Regulations have general application, are binding and directly applicable in all MS. Directives are binding as to the result to be achieved but leave to the MS' authorities the choice of form and methods. Sectoral and horizontal primary legislation in the food sector consists mainly of Directives. Decisions are binding upon those to whom they are addressed. Recommendations and Opinions have no binding force.

2.3.3 Implementing Legislation

Implementing legislation is generally adopted by the Commission under conferred powers. It can take the form of a Regulation, a Directive or a Decision.

2.4 Areas of Community Competence

2.4.1 Legislation

2.4.1.1 Animal Feed

The EU legislation on animal feed covers four main areas: materials used in animal nutrition, additives in feedingstuffs, undesirable substances in animal feed and official controls.

The legislation contains the general requirement that materials used in animal nutrition shall not represent a danger to animal/human health or the environment. This legislation lays down a list of materials the use of which is prohibited for public or animal health reasons. It lays down labelling rules and lists the feedingstuffs which may be used for specific nutritional purposes. Additives may only be used in feedingstuffs provided they have been authorised following a safety evaluation. A series of measures have been taken to reduce the number of antibiotics authorised as feed additives because of increasing concern that such use contributes to the appearance of resistant bacteria.

Maximum levels have been set for a series of undesirable substances, such as heavy metals, aflatoxins and dioxins.

Controls on feed (inspection, sampling, analysis) must be carried out by the MS, both on products originating from the EU and on imports. It is required to register or approve establishments producing certain additives (e.g. coccidiostats, vitamins, and trace elements), premixtures prepared from these additives and compound feedingstuffs containing them.

2.4.1.2 Food of Animal Origin

Sectoral Legislation

Community legislation on food of animal origin has been developed since 1964 in response to the needs of the internal market taking into account a high level of health and consumer protection. Nineteen sectoral Directives have harmonised the health rules for the production and placing on the market of products of animal origin intended for human consumption. The range covered includes fresh meat of the various edible species (domestic and wild), processed meat products, fish and fishery products, live bivalve molluscs, milk and milk-based products, egg-products and other products of animal origin such as honey, snails, frog-legs, gelatines, casings, reptile meat etc.

The rules lay down conditions for raw material, production conditions, hygiene requirements, defined standards (e.g. microbiological criteria), conditions for health marking, labelling, wrapping and packaging, storing and handling, and transport. Appropriate health marking and documentation demonstrating compliance and traceability of the product is also required. All establishments have to be identified and registered or approved (depending on the production process and the product) by the competent authority.

Additionally, rules are set to establish control procedures by the operator (own checks) and by the competent authority (official control). Administrative and penal measures may be taken in cases of infringements.

Horizontal Legislation

Several fields are covered by horizontal legislation:

a) Prevention of food borne diseases such as those caused by Salmonella sp., E. coli, Listeria, Campylobacter etc are of utmost concern. Rules have therefore been laid down for the collection of information on zoonoses, and the relevant measures to be taken in the MS and at Community level. Animal health legislation covers the prevention of certain other diseases such as tuberculosis and brucellosis, animal identification and tracing, movement controls etc, all of which contribute to public health.

b) Residues control in live animals and products.

c) Prohibition of the use in stock farming of certain substances having a hormonal or thyrostatic action and β-agonists.

d) Control of the quality of water used in food production.

e) Treatment of animal waste.

2.4.1.3 Foodstuffs Legislation

Hygiene of foodstuffs - the Directive on the hygiene of foodstuffs (93/43/EEC) covers the part of the food supply chain closest to the consumer, that is the retail and catering part, and the manufacturing of foodstuffs which are not primarily of animal origin.

In addition sectoral legislation covers the following areas:

Food labelling - The framework Directive on labelling (79/112/EEC) provides for harmonised rules to ensure the smooth functioning of the Single Market, whilst ensuring that the prime consideration for such rules is the need to inform and protect the consumer. It is based upon the principle of functional labelling, its objective being to ensure that the consumer gets all the essential, objective information as regards the composition of the product, the manufacturer, methods of storage and preparation, etc. Additional information may be given, provided that it is accurate and does not mislead the consumer.

Food additives - framework legislation lays down the principles for using food additives (there may be no health concern, there must be a technological need, the consumer shall not be mislead). Only approved food additives may be used in the European Union and only for the purposes approved (positive list approach). There are specific directives, which lay down provisions for use of sweeteners, colours, other food additives, and purity criteria.

Contaminants - framework legislation lays down Community procedures for contaminants in food. It provides for the establishment of lists of contaminants and maximum levels of occurrence in food, and methods for analysis and sampling, as well as marketing provisions. Specific legislation covers limits for the presence of nitrates in spinach and lettuce and sets limits and methods of analysis for the detection of aflatoxins. Limits on heavy metals (lead, cadmium, mercury) and other contaminants are under consideration.

Flavouring substances – legislation defines categories of flavourings, and lays down provisions for labelling. Purity criteria, analytical and sampling methods may be established. Lists of undesirable harmful compounds that may occur in flavourings or flavoured foods have been laid down, including maximum levels of presence and restrictions for use within certain categories of foodstuffs. Specific legislation covers chemically defined flavouring substances (around 2800 substances in total) which will be evaluated within the next five years; on basis of these evaluations an EU positive list of flavouring substances will be drawn up.

Food irradiation - the general and technical aspects for carrying out the process, labelling and authorisation of foods and food ingredients treated with ionising radiation have been laid down, A Community list of foodstuffs authorised for irradiation treatment has been established.

Food contact materials - the general criteria of safety and labelling for all types of Food Contact Materials have been laid down. Specific rules have been established for three materials: Ceramics, Cellulose Regenerated Films and Plastics.

Novel foods - legislation ensures that novel foods and novel food ingredients are subject to a single safety assessment throughout the European Community before they are placed on the market. The initial assessment is carried out by the competent authorities of the MS in which the product is to be placed on the market for the first time. Where an objection is raised by another MS or the Commission, an additional assessment is conducted by a Community scientific committee and a decision is taken under a Community procedure.

2.4.1.4 Phytosanitary Legislation

Safety evaluation of active substances for plant protection is harmonised at EU level. MS may only authorise a plant protection product containing a new active substance, if this substance has been included in the EU positive list. All active substances must be reviewed every 10 years. Active substances on the market before the legislation entered into force (i.e. in 1993) are subject to a review programme, which is currently on-going.

Maximum levels have been fixed by Directives for pesticide residues in and on certain products of plant origin, including fruit and vegetables, foodstuffs of animal origin and cereals. Supplementary legislation provides that formulae and processed food for infants and children must generally not contain detectable residues of pesticides. There is not yet full harmonisation of MRLs at Community level and where Community MRLs do not exist, MS may set national MRLs. The data requirements for the setting of Community MRLs are laid down in Guidance documents for MS. These requirements apply equally to Community and imported produce.

Annual co-ordinated monitoring programs for pesticide residues are conducted each year in the Community and Norway.

2.4.2 Rapid Alert System

Council Directive 92/59/EEC is the legal basis for the Rapid Alert System for Food. The system deals with all products which can be regarded as food, or which are intended to come into contact with food, and which are placed on the market within the EU. Alert notifications concerning products carrying a serious and immediate risk to the health and safety of the consumer are transmitted by the Commission to identified contact points in the MS. Information regarding products stopped at the external borders of the EU can also be transmitted through this system.

Participation of third countries is not formalised as they fall outside the scope of Directive 92/59/EEC. However, the Commission informs third countries if it is known that a foodstuff subject to an alert notification has been exported to that country and also when a product originating from their country has been the subject of a notification, so as to allow them to take corrective measures.

2.4.3 Control of Food Legislation

2.4.3.1 In the Member States

In addition to the specific controls and inspections laid down in sectoral and horizontal legislation, horizontal Directives lay down conditions for the veterinary control of products of animal origin intended for trade and of products imported from third countries. A Community fee has to be collected by MS to cover the costs occasioned by the inspections and controls. The level of fees to be collected is laid down.

2.4.3.2 At Commission Level

Member States must bring into force the laws, regulations and administrative provisions necessary to comply with EC Directives. A reference to the said directive should appear in the text transposed or at the moment of publication and the MS have to notify the Commission of this transposition and communicate the relevant texts of the main provisions of national law.

Implementation and uniform application of EC legislation in the MS is controlled by the Commission services (The Food and Veterinary Office based in Dublin, as part of General Directorate for Health and Consumer Protection). The control procedures have been laid down in Commission Decisions for the veterinary sector.

EC approach to controls is moving towards a system which will evaluate, using audit techniques, the manner in which competent authorities (at central, regional and local level) in both Member States and third countries implement and enforce Community legislation. This will emphasise that responsibility for the maintenance of acceptable standards rests on the shoulders of national authorities. Reports of these controls are made publicly available on the website of the General Directorate for Health and Consumer Protection. (http://europa.eu.int/comm/dg24/health/vi/reports/index_en.html).

Fraud is also addressed, in co-operation with the European Anti-Fraud Office.

2.5 Areas of Member States' Competence

Regulations are applicable in MS without further action, except for imposition of control measures. Directives must be transposed into national law. This can be by legislation or by administrative action. This allows MS to tailor the measure to fit with their legal structures. The national law will make provisions for the actual measures, for official controls on the implementation of the measures, and for sanctions for infringements.

In some emergency cases, the Commission has the possibility of taking measures on its own initiative.

In particular, controls are the responsibility of the MS, both for products produced inside the EU and imported products. These controls are in place at all levels – farm, slaughterhouse, processors and

distributors, as well as border inspection posts. The Commission is responsible for auditing the performance of the competent authorities, inside and outside the EU.

Since export requirements are set by the importing country, on the basis of bilateral contacts between non-EU countries and MS, it is largely the MS who are responsible for meeting export requirements (export in the EU context means to non-EU MS). However, the Commission has taken measures in recent cases (e.g. BSE and Dioxins) to impose restrictions on certain products for intra Community trade and exports, in application of the principle that the EU should not export that which it does not consider fit for the Internal Market.

A more complete description of the competence of MS and how it is exercised is given in their individual submissions.

2.6 Commission Mechanism for Risk Analysis

Risk Assessment

Scientific Committees

In 1997, the Commission adopted a series of measures to rebuild confidence in the process by which it obtained scientific advice from its independent advisory committees on matters relating to consumer and public health.

The scientific committee system of the Commission responds not only to the need for excellence and independence, but also to the fact that public confidence depends on transparency.

Excellence is achieved by ensuring that the Members of the Committees are drawn from amongst the most experienced and qualified scientists in the domains of interest. Members are selected through a fully open, worldwide, public call for expressions of interest and an independent evaluation against published criteria.

As concerns *independence*, Members of the Committees are required to make annual declarations of any financial or other interests, which could be considered to prejudice the independence of their advice. Members and ad hoc experts are also required to declare such interests at the beginning of all meetings in relation to specific questions on the agenda. Annual declarations of interest are made available to third parties with the consent of the Member concerned. Independence is further enhanced by the freedom of each committee to determine how it will manage specific questions and to select external experts that it considers necessary.

The *transparency* of the process has greatly benefited by use of the Internet. The names and affiliations of members, and draft plenary agendas and plenary minutes are available on the Directorate General for Consumer Health and Safety's home page on the Commission's Europa server (http://europa.eu.int.com/dg24/health/sc/index_en.html). The Committees' opinions are also made available on the home page as soon as possible, generally within a few days of their adoption. They include any minority opinions expressed by individual Members. Finally, the procedure includes an important safeguard to ensure that the Committees advice is not strictly confined to the questions put. The Committees have an explicit requirement to draw the attention of the Commission other problems or new risks for consumer health.

The Commission considers that the current arrangements of 8 specific scientific committees (Food, Veterinary Public Health, Animal health and welfare, Animal Nutrition, Plants, Toxicity and Ecotoxicity, Cosmetics and other non food products, Medicinal products and medical devices) co-

ordinated by the Scientific Steering Committee provide a sound basis not only for ensuring that the needs of excellence, independence and transparency are satisfied but also that it is able to fulfil its international obligations as concerns matters which depend on science based risk assessment.

Risk Management

EU legislation is based on the provisions of the Treaties. The initiative for food safety measures, both routine and emergency, is largely conferred on the Commission, which makes proposals as appropriate, taking into account opinions of scientific committees, reports from its own control service (the Food and Veterinary Office - FVO) and from international organisations. The Commission's proposals are discussed with the MS, who may themselves consult interested parties in their own countries. The Commission will consult Institutions, which have a statutory role in the Community such as the Economic and Social Committee and the Committee of the Regions as well as other stakeholders.

These stakeholders fall into two categories –official bodies which are consulted formally by the Commission (e.g. Consumers Committee, Veterinary Advisory Committee) and other organisations representing sectoral interests (NGOs, lobby groups, special interest groups).

After consultation, legislation is adopted by the MS themselves in Council, acting with the European Parliament, or by the Commission after consultation of the MS, depending on the category of legislation (primary or implementing respectively).

In most cases, there is sufficient scientific basis to take measures aiming to achieving a high level of protection in the European Communities. However, when the lack of scientific information precludes a detailed risk assessment and where there are reasonable grounds for concern that potential hazards may affect human health, the **precautionary principle** has been accepted as a risk management strategy. The Commission has recently adopted a paper on the precautionary principle (COM (2000) 1 final), but this has not yet been discussed or agreed by the MS.

Risk managers need to be aware of the uncertainties and the insufficiency of the data, their inconclusive and imprecise nature and, when necessary, the diverging opinions of scientists, before taking decisions. Judging what is an "acceptable" level of risk for society is a *political* responsibility. In all cases, the decision-making procedure should be transparent and should involve all interested parties as early as possible and to the extent reasonably possible.

Measures should be, *inter alia*, **provisional, proportional** to the chosen level of protection, **non-discriminatory** in their application, and **consistent** with similar measures already taken. They should be based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis), subject to review in the light of new scientific data, and capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

In the decision making process in the EU, **other legitimate factors** relevant to the health protection of consumers and to the promotion of fair practices in food trade can also be taken into account. Examples of such factors are environmental considerations, animal welfare, sustainable agriculture, and consumers' expectation regarding product quality, fair information and definition of the essential characteristics of products and their process and production methods.

Risk Communication

The Commission has established web sites, which are fully accessible, free of charge, to the public. On these sites are published reports of inspections to MS and third countries, scientific committee

agendas and opinions, speeches given by the Commissioners and senior officials, policy documents and legislation. Press releases are made each time information becomes available on measures, proposals, policy development, and other key events which affect health.

III. Activities of the Commission in Addressing Food Safety Issues

The Commission has adopted a White Paper on Food Safety (COM(1999) 719 final of 12 January 2000), which is available on the Commission's web site (http://europa.eu.int/comm/dg24/health/afh/index_en.html#8). It sets out the Commission's strategy to build on the existing high food safety standards. This Paper will be discussed with the Member States over the coming months.

An effective food safety policy must recognise the inter-linked nature of food production. It requires assessment and monitoring of the risks to consumer health associated with raw materials, farming practices and food processing activities; it requires effective action to manage this risk; and it requires the establishment and operation of control systems to monitor and, where necessary, to enforce such action. Each element forms part of a cycle: thus, developments in food processing can require changes to existing regulations, whilst feedback from the control systems can help to identify and manage both existing and emerging risks. The impact of and interaction with environmental policy must also be considered. These facts therefore demand a comprehensive and integrated approach to food safety.

The White Paper identifies five key elements:

- Setting up a European Food Safety Authority
- Food safety legislation
- Controls
- Consumer information
- International dimension.

3.1 European Food Safety Authority

The Commission proposes to establish an independent European Food Authority as the most appropriate response to the need to maintain and improve the existing high level of food safety. This Authority, if agreed to by the MS, would be entrusted with a number of key tasks embracing independent scientific advice on all aspects relating to food safety, operation of rapid alert systems, communication and dialogue with consumers on food safety and health issues as well as networking with national and international agencies and scientific bodies.

The principles for its operation will be independence, excellence and transparency. It must therefore be guided by the best science, be independent of industrial and political interests, be open to rigorous public scrutiny, be scientifically authoritative and work closely with national scientific bodies.

The Authority will not have regulatory powers, at least at the beginning. It will therefore continue to be the responsibility of the Commission to decide on the appropriate response to risk assessments provided by the Authority. Nevertheless, the Authority should have a legal existence and personality separate from the current EU Institutions in order to carry out its role in terms of risk assessment and risk communication independently.

3.2 Food Safety Legislation

3.2.1 New Legislative Proposals

The setting up of the independent Authority would be accompanied by a wide range of measures to improve and consolidate legislation covering all aspects of food products from "farm to table". There have been enormous developments in the past decades, both in the methods of food production and processing, and in the controls required ensuring that acceptable safety standards are being met.

An improved legal framework will be proposed which will cover the whole of the food chain, including animal feed production. It will confirm that primary responsibility for safe food production lies with to industry, producers and suppliers. The ability to trace products through the whole food chain and to take rapid, effective, safeguard measures in response to health will be important elements. The use of scientific advice will continue to underpin Food Safety policy, whilst the precautionary principle will be used where appropriate.

The safety of food of animal origin begins with safe animal feed. Proposals in this sector will ensure that only suitable materials are used, and that the use of additives is effectively controlled. The feed manufacturing industry should be subjected to the same rigorous requirements and controls as the food-producing sector. Steps will be taken to address those areas where the existing legislation in this sector needs to be improved to provide adequate protection.

The issue of BSE and related diseases merits special attention. The Commission has addressed this problem by a proposal for a Directive, to cover all measures to control BSE and other transmissible spongiform encephalopathies. Until the adoption of this proposal, provisional measures will be taken, which will include rules on removal of specified risk materials, in combination with a provisional geographical classification of BSE status.

Existing eradication and control programmes for zoonoses will continue. Zoonoses monitoring will be better exploited.

3.2.2 Hygiene

Over the years, the Community has developed extensive requirements for the hygiene of food. However, these were adopted to meet the needs of the Internal Market. This has resulted in a series of different hygiene regimes according to whether the food is of animal or plant origin. Some areas are not covered, such as production of food of plant origin at the farm level. A Regulation will be proposed, to introduce consistency and clarity throughout the food production chain.

Food operators should bear full responsibility for the safety of the food they produce. The implementation of hazard analysis and control principles and the observance of hygiene rules, to be applied at all levels of the food chain should ensure this safety.

3.2.3 Other Issues

A series of initiatives will be taken to cover areas such as limits of contaminants and residues, and legislation on additives, flavourings, packaging and irradiation, and implementation rules and amendments for novel foods (including development of harmonised labelling provisions).

3.3 Food Safety Controls

Legislation will be proposed to recast the different control requirements, based on the general principle that all parts of the food production chain must be subject to official controls.

Experience has shown that there are wide variations in the manner in which Community legislation is implemented and enforced. This means that consumers cannot be sure of receiving the same level of protection across the Community, and makes it difficult for the effectiveness of national authority measures to be evaluated. Proposals will be developed for a Community framework for the development and operation of national control systems. In support of Community-level controls, more rapid, easier-to-use, enforcement procedures will be developed. Controls on imports at the borders of the Community will be extended to cover all feed and foodstuffs, and action taken to improve co-ordination between inspection posts.

3.4 Consumer Information

Consumers must be kept well informed. The Commission, together with the proposed new European Food Authority, would strengthen the dialogue with consumers to encourage their involvement in the new Food Safety policy. Consumers have the right to expect information on food quality and constituents that is helpful and clearly presented, so that informed choices can be made. Proposals on the labelling of foods, building on existing rules, will be brought forward.

3.5 International Dimension

The key principle for imported foodstuffs and animal feed is that they must meet health requirements at least equivalent to those set by the Community for its own production.

The Community has already negotiated a number of bilateral international agreements on sanitary measures, which include the recognition of the equivalence of sanitary measures applied by third countries. The possibility of further agreements will be explored, and the Community will endeavour to ensure that all legislation affecting issues falling under the SPS Agreement provides for the possibility to recognise equivalency outside bilateral agreements.

3.6 Research

EU activities in support of food safety include research programmes under the Framework Programme currently Key Action 1 (Food, Health and Nutrition) of the Quality of Life programme. Details are available on the Cordis website at ftp://ftp4.cordis.lu/pub/life/docs/a_wp_en_200001.pdf>. Work is also under progress on developing and calibrating GMO detection and tracing techniques.

ANNEX I

Communication from the Commission on the Precautionary Principle

I. Summary

The issue of when and how to use the precautionary principle, both within the European Union and internationally, is giving rise to many debates, and to mixed, and sometimes contradictory views. Thus, decision-makers are constantly faced with the dilemma of balancing the freedom and rights of individuals, industry and organisations with the need to reduce the risk of adverse effects to the environment, human, animal or plant health. Therefore, finding the correct balance so that the proportionate, non-discriminatory, transparent and coherent actions can be taken requires a structured decision-making process with detailed scientific and other objective information.

The Communication's fourfold aim is to:

- Outline the Commission's approach to using the precautionary principle.
- Establish Commission guidelines for applying it.
- Build a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully.
- Avoid unwarranted recourse to the precautionary principle, as a disguised form of protectionism.

It also seeks to provide an input to the ongoing debate on this issue, both within the Community and internationally.

The precautionary principle is not defined in the Treaty, which prescribes it only once - to protect the environment. But *in practice*, its scope is much wider, and specifically where preliminary objective scientific evaluation, indicates that there are reasonable grounds for concern that the potentially dangerous effects on the *environment, human, animal or plant health* may be inconsistent with the high level of protection chosen for the Community.

The Commission considers that the Community, like other WTO members, has the right to establish the level of protection - particularly of the environment, human, animal and plant health, - that it deems appropriate. Applying the precautionary principle is a key tenet of its policy, and the choices it makes to this end will continue to affect the views it defends internationally, on how this principle should be applied.

The precautionary principle should be considered within a structured approach to the analysis of risk, which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk.

The precautionary principle, which is essentially used by decision-makers in the management of risk, should not be confused with the element of caution that scientists apply in their assessment of scientific data.

Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or processes have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty.

The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty**.**

Decision-makers need to be aware of the degree of uncertainty attached to the results of the evaluation of the available scientific information. Judging what is an "acceptable" level of risk for society is an eminently *political* responsibility. Decision-makers faced with an unacceptable risk, scientific uncertainty and public concerns have a duty to find answers. Therefore, all these factors have to be taken into consideration.

In some cases, the right answer may be not to act or at least not to introduce a binding legal measure. A wide range of initiatives is available in the case of action, going from a legally binding measure to a research project or a recommendation.

The decision-making procedure should be transparent and should involve as early as possible and to the extent reasonably possible all interested parties.

Where action is deemed necessary, measures based on the precautionary principle should be, *inter alia*:

- *Proportional* to the chosen level of protection.
- *Non-discriminatory* in their application.
- *Consistent* with similar measures already taken.
- *Based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis.
- *Subject to review,* in the light of new scientific data.
- Capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

Proportionality means tailoring measures to the chosen level of protection. Risk can rarely be reduced to zero, but incomplete risk assessments may greatly reduce the range of options open to risk managers. A total ban may not be a proportional response to a potential risk in all cases. However, in certain cases, it is the sole possible response to a given risk.

Non-discrimination means that comparable situations should not be treated differently, and that different situations should not be treated in the same way, unless there are objective grounds for doing so.

Consistency means that measures should be of comparable scope and nature to those already taken in equivalent areas in which all scientific data are available.

Examining costs and benefits entails comparing the overall cost to the Community of action and lack of action, in both the short and long term. This is not simply an economic cost-benefit analysis: its scope is much broader, and includes non-economic considerations, such as the efficacy of possible options

and their acceptability to the public. In the conduct of such an examination, account should be taken of the general principle and the case law of the Court that the protection of health takes precedence over economic considerations.

Subject to review in the light of new scientific data, means measures based on the precautionary principle should be maintained so long as scientific information is incomplete or inconclusive, and the risk is still considered too high to be imposed on society, in view of chosen level of protection. Measures should be periodically reviewed in the light of scientific progress, and amended as necessary.

Assigning responsibility for producing scientific evidence is already a common consequence of these measures. Countries that impose a prior approval (marketing authorisation) requirement on products that they deem dangerous *a priori* reverse the burden of proving injury, by treating them as dangerous unless and until businesses do the scientific work necessary to demonstrate that they are safe.

Where there is no prior authorisation procedure, it may be up to the user or to public authorities to demonstrate the nature of a danger and the level of risk of a product or process. In such cases, a specific precautionary measure might be taken to place the burden of proof upon the producer, manufacturer or importer, but this cannot be made a general rule.

II. Introduction

A number of recent events have shown that public opinion is becoming increasingly aware of the potential risks to which the population or their environment is potentially exposed.

Enormous advances in communications technology have fostered this growing sensitivity to the emergence of new risks, before scientific research has been able to fully illuminate the problems. Decision-makers have to take account of the fears generated by these perceptions and to put in place preventive measures to eliminate the risk or at least reduce it to the minimum acceptable level. On 13 April 1999 the Council adopted a resolution urging the Commission inter alia " *to be in the future even more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer-related activities and develop as priority clear and effective guidelines for the application of this principle"*. This Communication is part of the Commission's response.

The dimension of the precautionary principle goes beyond the problems associated with a short or medium-term approach to risks. It also concerns the longer run and the well being of future generations.

A decision to take measures without waiting until all the necessary scientific knowledge is available is clearly a precaution-based approach.

Decision-makers are constantly faced with the dilemma of balancing the freedoms and rights of individuals, industry and organisations with the need to reduce or eliminate the risk of adverse effects to the environment or to health.

Finding the correct balance so that proportionate, non-discriminatory, transparent and coherent decisions can be arrived at, which at the same time provide the chosen level of protection, requires a structured decision making process with detailed scientific and other objective information. This structure is provided by the three elements of risk analysis: the assessment of risk, the choice of risk management strategy and the communication of the risk.

Any assessment of risk that is made should be based on the existing body of scientific and statistical data. Most decisions are taken where there is sufficient information available for appropriate preventive measures to be taken but in other circumstances, these data may be wanting in some respects.

Whether or not to invoke the Precautionary Principle is a decision exercised where scientific information is insufficient, inconclusive, or uncertain and where there are indications that the possible effects on the environment, or human, animal or plant health may be potentially dangerous and inconsistent with the chosen level of protection.

III. The Goals of this Communication

The aim of this Communication is to inform all interested parties, in particular the European Parliament the Council and Member States of the manner in which the Commission applies or intends to apply the precautionary principle when faced with taking decisions relating to the containment of risk. However, this general Communication does not claim to be the final word - rather, the idea is to provide input to the ongoing debate both at Community and international level.

This Communication seeks to establish a common understanding of the factors leading to recourse to the precautionary principle and its place in decision making, and to establish guidelines for its application based on reasoned and coherent principles.

The guidelines outlined in this Communication are only intended to serve as general guidance and in no way to modify or affect the provisions of the Treaty or secondary Community legislation.

Another objective is to avoid unwarranted recourse to the precautionary principle, which in certain cases could serve as a justification for disguised protectionism. Accordingly the development of international guidelines could facilitate the achievement of this end. The Commission also wishes to stress in this Communication that, far from being a way of evading obligations arising from the WTO Agreements, the envisaged use of the precautionary principle complies with these obligations.

It is also necessary to clarify a misunderstanding as regards the distinction between reliance on the precautionary principle and the search for zero risk, which in reality is rarely to be found. The search for a high level of health and safety and environmental and consumer protection belongs in the framework of the single market, which is a cornerstone of the Community.

The Community has already relied on the precautionary principle. Abundant experience has been gained over many years in the environmental field, where many measures have been inspired by the precautionary principle, such as measures to protect the ozone layer or concerning climate change.

IV. The Precautionary Principle in the European Union

The Community has consistently endeavoured to achieve a high level of protection, among others in environment and human, animal or plant health. In most cases, measures making it possible to achieve this high level of protection can be determined on a satisfactory scientific basis. However, when there are reasonable grounds for concern that potential hazards may affect the environment or human, animal or plant health, and when at the same time the available data preclude a detailed risk evaluation, the precautionary principle has been politically accepted as a risk management strategy in several fields.

To understand fully the use of the precautionary principle in the European Union, it is necessary to examine the legislative texts, the case law of the Court of Justice and the Court of First Instance, and the policy approaches that have emerged.

Legal Texts

The analysis starts with the legal texts, which explicitly or implicitly refer to the precautionary principle (Annex I, Ref. 1).

At Community level the only explicit reference to the precautionary principle is to be found in the environment title of the EC Treaty, and more specifically Article 174. However, one cannot conclude from this that the principle applies only to the environment (Annex I, Refs. 2 and 3). Although the principle is adumbrated in the Treaty, it is not defined there.

Like other general notions contained in the legislation, such as subsidiarity or proportionality, it is for the decision-makers and ultimately the courts to flesh out the principle. In other words, the scope of the precautionary principle also depends on trends in case law, which to some degree are influenced by prevailing social and political values.

However, it would be wrong to conclude that the absence of a definition has to lead to legal uncertainty. The Community authorities' practical experience with the precautionary principle and its judicial review make it possible to get an ever-better handle on the precautionary principle.

Case Law

The Court of Justice of the European Communities and the Court of First Instance have already had occasion to review the application of the precautionary principle in cases they have adjudicated and hence to develop case law in this area. (see Annex I, Refs. 5, 6 and 7)

Policy Orientations

Policy orientations were set out by the Commission in the Green Paper on the General Principles of Food Safety and the Communication of 30 April 1997 on Consumer Health and Food Safety, by Parliament in its Resolution of 10 March 1998 concerning the Green Paper, by the Council in its Resolution of 13 April 1999 and by the Joint Parliamentary Committee of the EEA (European Economic Area) in its Resolution of 16 March 1999 (Annex I, Refs. 8-12).

Hence the Commission considers that the precautionary principle is a general one which should in particular be taken into consideration in the fields of environmental protection and human, animal and plant health.

Although the precautionary principle is not explicitly mentioned in the Treaty except in the environmental field, its scope is far wider and covers those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection .

V. The Precautionary Principle in International Law

At international level, the precautionary principle was first recognised in the World Charter for Nature, adopted by the UN General Assembly in 1982. It was subsequently incorporated into various international conventions on the protection of the environment. (cf. Annex II).

This principle was enshrined at the 1992 Rio Conference on the Environment and Development, during which the Rio Declaration was adopted, whose principle 15 states that: *"in order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation"*. Besides, the United Nations' Framework Convention on Climate Change and the Convention of Biological Diversity both refer to the precautionary principle. Recently, on 28 January 2000, at the Conference of the Parties to the Convention on Biological Diversity, the Protocol on Biosafety concerning the safe transfer, handling and use of living modified organisms resulting from modern biotechnology confirmed the key function of the Precautionary Principle (see Annex II).

Hence this principle has been progressively consolidated in international environmental law, and so it has since become a full-fledged and general principle of international law.

The WTO agreements confirm this observation. The preamble to the WTO Agreement highlights the ever-closer links between international trade and environmental protection1[1.] A consistent approach means that the precautionary principle must be taken into account in these agreements, notably in the Agreement on Sanitary and Phytosanitary Measures (SPS) and in the Agreement on Technical Barriers to Trade (TBT), to ensure that this general principle is duly enforced in this legal order.

Hence, each Member of the WTO has the independent right to determine the level of environmental or health protection they consider appropriate. Consequently a member may apply measures, including measures based on the precautionary principle, which lead to a higher level of protection than that provided for in the relevant international standards or recommendations.

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) clearly sanctions the use of the precautionary principle, although the term itself is not explicitly used. Although the general rule is that all sanitary and phytosanitary measures must be based on scientific principles and that they should not be maintained without adequate scientific evidence, a derogation from these principles is provided for in Article 5 (7) which stipulates that: "*in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organisations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.*"

Hence, according to the SPS Agreement, measures adopted in application of a precautionary principle when the scientific data are inadequate, are provisional and imply that efforts be undertaken to

1. "The parties to this agreement ... recognising that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing to in a manner consistent with their respective needs and concerns at different levels of economic development ...".

elicit or generate the necessary scientific data. It is important to stress that the provisional nature is not bound up with a time limit but with the development of scientific knowledge.

The use of the term "more objective assessment of risk" in Article 5.7 infers that a precautionary measure may be based on a less objective appraisal but must nevertheless includes an evaluation of risk.

The concept of risk assessment in the SPS leaves leeway for interpretation of what could be used as a basis for a precautionary approach. The risk assessment on which a measure is based may include non-quantifiable data of a factual or qualitative nature and is not uniquely confined to purely quantitative scientific data. This interpretation has been confirmed by the WTO's Appellate body in the case of growth hormones, which rejected the panel's initial interpretation that the risk assessment had to be quantitative and had to establish a minimum degree of risk.

The principles enshrined in Article 5.7 of the SPS must be respected in the field of sanitary and phytosanitary measures however, because of the specific nature of other areas, such as the environment, it may be that somewhat different principles will have to be applied.

International guidelines are being considered in relation to the application of the Precautionary Principle in Codex Alimentarius. Such guidance in this, and other sectors, could pave the way to a harmonised approach by the WTO Members, to drawing up health or environment protection measures, while avoiding the misuse of the precautionary principle which could otherwise lead to unjustifiable barriers to trade.

In the light of these observations, the Commission considers that, following the example set by other Members of the WTO, the Community is entitled to prescribe the level of protection, notably as regards the environment and human, animal and plant health, which it considers appropriate. In this context, the Community must respect Articles 6, 95, 152 and 174 of the Treaty. To this end, reliance on the precautionary principle constitutes an essential plank of its policy. It is clear that the choices made will affect its positions at international and notably multilateral level, as regards recourse to the precautionary principle.

Bearing in mind the very origins of the precautionary principle and its growing role in international law, and notably in the agreements of the World Trade Organisation, this principle must be duly addressed at international level in the various areas in which it is likely to be of relevance.

Following the example set by the other members of the WTO, the Commission considers that the Community is entitled to prescribe the level of protection, notably as regards environmental protection and human, animal and plant health, that it considers appropriate. Recourse to the precautionary principle is a central plank of Community policy. The choices made to this end will continue to influence its positions at international level, and notably at multinational level, as regards the precautionary principle.

VI. The Constituent Parts of the Precautionary Principle

An analysis of the precautionary principle reveals two quite distinct aspects: (i) **the political decision to act or not to act as such,** which is linked to the **factors triggering** recourse to the precautionary principle; (ii) in the affirmative, **how to act, i.e.** the **measures** resulting from application of the precautionary principle.

There is a controversy as to the role of scientific uncertainty in risk analysis, and notably as to whether it belongs under risk assessment or risk management. This controversy springs from confusion between a prudential approach and application of the precautionary principle. These two aspects are complementary but should not be confounded.

The prudential approach is part of risk assessment policy which is determined before any risk assessment takes place and which is based on the elements described in 5.1.3; it is therefore an integral part of the scientific opinion delivered by the risk evaluators.

On the other hand, application of the precautionary principle is part of risk management, when scientific uncertainty precludes a full assessment of the risk and when decision-makers consider that the chosen level of environmental protection or of human, animal and plant health may be in jeopardy.

The Commission considers that measures applying the precautionary principle belong in the general framework of risk analysis, and in particular risk management.

6.1 Factors Triggering Recourse to the Precautionary Principle

The precautionary principle is relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inclusive nature of the scientific data.

It should however be noted that the precautionary principle could under no circumstances be used to justify the adoption of arbitrary decisions.

6.1.1 Identification of Potentially Negative Effects

Before the precautionary principle is invoked, the scientific data relevant to the risks must first be evaluated. However, one factor logically and chronologically precedes this evaluation, namely identification of the potentially negative effects of a phenomenon. To understand these effects more thoroughly it is necessary to conduct a scientific examination. The decision to conduct this examination without awaiting additional information is bound up with a less theoretical and more concrete perception of the risk.

6.1.2 Scientific Evaluation

A scientific evaluation of the potential adverse effects should be undertaken based on the available data when considering whether measures are necessary to protect the environment, the human, animal or plant health. An assessment of risk should be considered where feasible when deciding whether or not to invoke the precautionary principle. This requires reliable scientific data and logical reasoning, leading to a conclusion which expresses the possibility of occurrence and the severity of a hazard's impact on the environment, or health of a given population including the extent of possible damage, persistency, reversibility and delayed effect. However it is not possible in all cases to complete a comprehensive assessment of risk, but all effort should be made to evaluate the available scientific information.

Where possible, a report should be made which indicates the assessment of the existing knowledge and the available information, providing the views of the scientists on the reliability of the assessment as well as on the remaining uncertainties. If necessary, it should also contain the identification of topics for further scientific research.

Risk assessment consists of four components - namely hazard identification, hazard characterisation, appraisal of exposure and risk characterisation (Annex III). The limits of scientific knowledge may affect each of these components, influencing the overall level of attendant uncertainty and ultimately affecting the foundation for protective or preventive action. An attempt to complete these four steps should be performed before decision to act is taken.

6.1.3 Scientific Uncertainty

Scientific uncertainty results usually from five characteristics of the scientific method: the variable chosen, the measurements made, the samples drawn, the models used and the causal relationship employed. Scientific uncertainty may also arise from a controversy on existing data or lack of some relevant data. Uncertainty may relate to qualitative or quantitative elements of the analysis.

A more abstract and generalised approach preferred by some scientists is to separate all uncertainties into three categories of – Bias, Randomness and True Variability. Some other experts categorise uncertainty in terms of estimation of confidence interval of the probability of occurrence and of the severity of the hazard's impact.

This issue is very complex and the Commission launched a project "Technological Risk and the Management of Uncertainty" conducted under the auspices of the European Scientific Technology Observatory. The four ESTO reports will be published shortly and will give a comprehensive description of scientific uncertainty.

Risk evaluators accommodate these uncertainty factors by incorporating prudential aspects such as:

- Relying on animal models to establish potential effects in man.
- Using body weight ranges to make inter-species comparisons.
- Adopting a safety factor in evaluating an acceptable daily intake to account for intra- and inter-species variability; the magnitude of this factor depends on the degree of uncertainty of the available data.
- Not adopting an acceptable daily intake for substances recognised as genotoxic or carcinogenic.
- Adopting the "ALARA" (as low as reasonably achievable) level as a basis for certain toxic contaminants.

Risk managers should be fully aware of these uncertainty factors when they adopt measures based on the scientific opinion delivered by the evaluators.

However, in some situations the scientific data are not sufficient to allow one to apply these prudential aspects in practice, i.e. in cases in which extrapolations cannot be made because of the absence of parameter modelling and where cause-effect relationships are suspected but have not been demonstrated. It is in situations like these that decision-makers face the dilemma of having to act or not to act.

Recourse to the precautionary principle presupposes:

- ***identification of potentially negative effects resulting from a phenomenon product or process***
- ***scientific evaluation of the risk which because of the insufficiency of the data, their inconclusive or imprecise nature, makes it impossible to determine with sufficient certainty the risk in question.***

6.2 Measures Resulting from Reliance on the Precautionary Principle

6.2.1 The Decision Whether Or Not To Act

In the kind of situation described above - sometimes under varying degrees of pressure from public opinion - decision-makers have to respond. However, responding does not necessarily mean that measures always have to be adopted. The decision to do nothing may be a response in its own right.

he appropriate response in a given situation is thus the result of an political decision, a function off the risk level that is "acceptable" to the society on which the risk is imposed.

6.2.2 Nature of the Action Ultimately Taken

The nature of the decision influences the type of control that can be carried out. Recourse to the precautionary principle does not necessarily mean adopting final instruments designed to produce legal effects that are open to judicial review. There is a whole range of actions available to decision-makers under the head of the precautionary principle. The decision to fund a research programme or even the decision to inform the public about the possible adverse effects of a product or procedure may themselves be inspired by the precautionary principle.

It is for the Court of Justice to pronounce on the legality of any measures taken by the Community institutions. The Court has consistently held that when the Commission or any other Community institution has broad discretionary powers, notably as regards the nature and scope of the measures it adopts, review by the Court must be limited to examining whether the institution committed a manifest error or misuse of power or manifestly exceed the limits of its powers of appraisal.

Hence the measures may not be of an arbitrary nature.

Recourse to the precautionary principle does not necessarily mean adopting final instruments designed to produce legal effects, which are subject to judicial review.

VII. Guidelines for Applying the Precautionary Principle

7.1 Implementation

When decision-makers become aware of a risk to the environment or human, animal or plant health that in the event of non-action may have serious consequences, the question of appropriate protective measures arise. Decision-makers have to obtain, through a structured approach, a scientific evaluation, as complete as possible, of the risk to the environment, or health, in order to select the most appropriate course of action

The determination of appropriate action including measures based on the precautionary principle should start with a scientific evaluation and, if necessary, the decision to commission scientists to perform an as objective and complete as possible scientific evaluation. It will cast light on the existing objective evidence, the gaps in knowledge and the scientific uncertainties.

The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty.

7.2 The Triggering Factor

Once the scientific evaluation has been performed as best as possible, it may provide a basis for triggering a decision to invoke the precautionary principle. The conclusions of this evaluation should show that the desired level of protection for the environment or a population group could be jeopardised. The conclusions should also include an assessment of the scientific uncertainties and a description of the hypotheses used to compensate for the lack of the scientific or statistical data. An assessment of the potential consequences of inaction should be considered and may be used as a trigger by the decision-makers. The decision to wait or not to wait for new scientific data before considering possible measures should be taken by the decision-makers with a maximum of transparency. The absence of scientific proof of the existence of a cause-effect relationship, a quantifiable dose/response relationship or a quantitative evaluation of the probability of the emergence of adverse effects following exposure should not be used to justify inaction. Even if scientific advice is supported only by a minority fraction of the scientific community, due account should be taken of their views, provided the credibility and reputation of this fraction are recognised.[2]

The Commission has confirmed its wish to rely on procedures as transparent as possible and to involve all interested parties at the earliest possible stage[3]. This will assist decision makers in taking legitimate measures which are likely to achieve the society's chosen level of health or environmental protection

2. cf The WTO Appellate Body report on hormones, paragraph 194 : « In some cases, the very existence of divergent views presented by qualified scientists who have investigated the particular issue at hand, may indicate a state of scientific uncertainty ».

3. A considerable effort has already been made notably as regards public health and the environment. As regards the latter, the Community and the Member States have demonstrated the importance they attach to access to information and justice by signing the Aarhus Convention of June 1998.

An assessment of the potential consequences of inaction and of the uncertainties of the scientific evaluation should be considered by decision-makers when determining whether to trigger action based on the precautionary principle.

All interested parties should be involved to the fullest extent possible in the study of various risk management options that may be envisaged once the results of the scientific evaluation and/or risk assessment are available and the procedure be as transparent as possible.

7.3 The General Principles of Application

The general principles are not limited to application of the precautionary principle. They apply to all risk management measures. An approach inspired by the precautionary principle does not exempt one from applying wherever possible these criteria, which are generally used when a complete risk assessment is at hand.

Thus reliance on the precautionary principle is no excuse for derogating from the general principles of risk management.

These general principles include:

- Proportionality
- Non-discrimination
- Consistency
- Examination of the benefits and costs of action or lack of action
- Examination of scientific developments.

7.3.1 Proportionality

The measures envisaged must make it possible to achieve the appropriate level of protection. Measures based on the precautionary principle must not be disproportionate to the desired level of protection and must not aim at zero risk, something, which rarely exists. However, in certain cases, an incomplete assessment of the risk may considerably limit the number of options available to the risk managers.

In some cases a total ban may not be a proportional response to a potential risk. In other cases, it may be the sole possible response to a potential risk.

Risk reduction measures should include less restrictive alternatives which make it possible to achieve an equivalent level of protection, such as appropriate treatment, reduction of exposure, tightening of controls, adoption of provisional limits, recommendations for populations at risk, etc. One should also consider replacing the products or procedures concerned by safer products or procedures.

The risk reduction measure should not be limited to immediate risks where the proportionality of the action is easier to assess. It is in situations in which the adverse effects do not emerge until long after

exposure that the cause-effect relationships are more difficult to prove scientifically and that – for this reason – the precautionary principle often has to be invoked. In this case the potential long-term effects must be taken into account in evaluating the proportionality of measures in the form of rapid action to limit or eliminate a risk whose effects will not surface until ten or twenty years later or will affect future generations. This applies in particular to effects on the eco-system. Risks that are carried forward into the future cannot be eliminated or reduced except at the time of exposure, that is to say immediately.

Measures should be proportional to the desired level of protection.

7.3.2 Non-Discrimination

The principle of non-discrimination means that comparable situations should not be treated differently and that different situations should not be treated in the same way, unless there are objective grounds for doing so.

Measures taken under the precautionary principle should be designed to achieve an equivalent level of protection without invoking the geographical origin or the nature of the production process to apply different treatments in an arbitrary manner.

Measures should not be discriminatory in their application.

7.3.3 Consistency

Measures should be consistent with the measures already adopted in similar circumstances or using similar approaches. Risk evaluations include a series of factors to be taken into account to ensure that they are as thorough as possible. The goal here is to identify and characterise the hazards, notably by establishing a relationship between the dose and the effect and assessing the exposure of the target population or the environment. If the absence of certain scientific data makes it impossible to characterise the risk, taking into account the uncertainties inherent to the evaluation, the measures taken under the precautionary principle should be comparable in nature and scope with measures already taken in equivalent areas in which all the scientific data are available.

Measures should be consistent with the measures already adopted in similar circumstances or using similar approaches.

7.3.4 Examination of the Benefits and Costs of Action and Lack of Action

A comparison must be made between the most likely positive or negative consequences of the envisaged action and those of inaction in terms of the overall cost to the Community, both in the long- and short-term. The measures envisaged must produce an overall advantage as regards reducing risks to an acceptable level.

Examination of the pros and cons cannot be reduced to an economic cost-benefit analysis. It is wider in scope and includes non-economic considerations.

However, examination of the pros and cons should include an economic cost-benefit analysis where this is appropriate and possible.

Besides, other analysis methods, such as those concerning the efficacy of possible options and their acceptability to the public may also have to be taken into account. A society may be willing to pay a higher cost to protect an interest, such as the environment or health, to which it attaches priority.

The Commission affirms, in accordance with the case law of the Court that requirements linked to the protection of public health should undoubtedly be given greater weight than economic considerations.

The measures adopted presuppose examination of the benefits and costs of action and lack of action. This examination should include an economic cost/benefit analysis when this is appropriate and feasible. However, other analysis methods, such as those concerning efficacy and the socio-economic impact of the various options, may also be relevant. Besides the decision-maker may, in certain circumstances, by guided by non-economic considerations such as the protection of health.

7.3.5 Examination of Scientific Developments

The measures should be maintained as long as the scientific data are inadequate, imprecise or inconclusive and as long as the risk is considered too high to be imposed on society. The measures may have to be modified or abolished by a particular deadline, in the light of new scientific findings. However, this is not always linked to the time factor, but to the development of scientific knowledge.

Besides, scientific research should be carried out with a view to obtaining a more advanced or more complete scientific assessment. In this context, the measures should be subjected to regular scientific monitoring, so that they can be re-evaluated in the light of new scientific information.

The Agreement on Sanitary and Phytosanitary Measures (SPS) provides that measures adopted in the context of inadequate scientific evidence must respect certain conditions. Hence these conditions concern only the scope of the SPS Agreement, but the specific nature of certain sectors, such as the environment, may mean that somewhat different principles have to be applied.

Article 5(7) of the SPS agreement includes certain specific rules:

- The measures must be of a provisional nature pending the availability of more reliable scientific data. However this provisional nature is linked to the development of scientific knowledge rather than to a time factor.

- Research must be carried out to elicit the additional scientific data required for a more objective assessment of the risk.

- The measures must be periodically reviewed to take account of new scientific data. The results of scientific research should make it possible to complete the risk evaluation and if necessary to review the measures on the basis of the conclusions.

- Hence the reasonable period envisaged in the SPS Agreement includes the time needed for completion of the necessary scientific work and, besides, the time needed for performance of a risk evaluation based on the conclusions of this scientific work. It should not be possible to invoke budgetary constraints or political priorities to justify excessive delays in obtaining results, re-evaluating the risk or amending the provisional measures.

Research could also be conducted for the improvement of the methodologies and instruments for assessing risk, including greater integration of all pertinent factors (e.g. socio-economic information, technological perspectives).

The measures, although provisional, shall be maintained as long as the scientific data remain incomplete, imprecise or inconclusive and as long as the risk is considered too high to be imposed on society.

Maintenance of the measures depends on the development of scientific knowledge, in the light of which they should be re-evaluated. This means that scientific research shall be continued with a view to obtaining more complete data.

Measures based on the precautionary principle shall be re-examined and if necessary modified depending on the results of the scientific research and the follow up of their impact.

7.4 The Burden of Proof

- Community rules and those of many third countries enshrine the principle of prior approval (positive list) before the placing on the market of certain products, such as drugs, pesticides or food additives. This is one way of applying the precautionary principle, by shifting responsibility for producing scientific evidence. This applies in particular to substances deemed "a priori" hazardous or which are potentially hazardous at a certain level of absorption. In this case the legislator, by way of precaution, has clearly reversed the burden of proof by requiring that the substances be deemed hazardous until proven otherwise. Hence it is up to the business community to carry out the scientific work needed to evaluate the risk. As long as the human health risk cannot be evaluated with sufficient certainty, the legislator is not legally entitled to authorise use of the substance, unless exceptionally for test purposes.

- In other cases, where such a prior approval procedure does not exist, it may be for the user, a private individual, a consumer association, citizens or the public authorities to demonstrate the nature of a danger and the level of risk posed by a product or process. Action taken under the head of the precautionary principle must in certain cases include a clause reversing the burden of proof and placing it on the producer, manufacturer or importer, but such an obligation cannot be systematically entertained as a general principle. This possibility should be examined on a case-by-case basis when a measure is adopted under the precautionary principle, pending supplementary scientific data, so as to give professionals who have an economic interest in the production and/or marketing of the procedure or product in question the opportunity to finance the necessary research on a voluntary basis.

Measures based on the precautionary principle may assign responsibility for producing the scientific evidence necessary for a comprehensive risk evaluation.

VIII. Conclusion

This Communication of a general scope sets out the Commission’s position as regards recourse to the precautionary principle. The Communication reflects the Commission’s desire for transparency and dialogue with all stakeholders. At the same it is provides concrete guidance for applying the precautionary principle.

The Commission wishes to reaffirm the crucial importance it attaches to the distinction between the decision to act or not to act, which is of an eminently political nature, and the measures resulting from recourse to the precautionary principle, which must comply with the general principles applicable to all risk management measures. The Commission also considers that every decision must be preceded by an examination of all the available scientific data and, if possible, a risk evaluation that is as objective and comprehensive as possible. A decision to invoke the precautionary principle does not mean that the measures will be adopted on an arbitrary or discriminatory basis.

This Communication should also contribute to reaffirming the Community's position at international level, where the precautionary principle is receiving increasing attention. However the Commission wishes to stress that this Communication is not meant to be the last word; rather, it should be seen as the point of departure for a broader study of the conditions in which risks should be assessed, appraised, managed and communicated.

ANNEX II

Legal and Other Bases for EC Decisions on Precautionary Measures

The legislative texts

Ref. 1

The EC Treaty, incorporating provisions already introduced by the Maastricht Treaty of 1992, and more specifically Article 174 thereof, states:

- "2. Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay …
- 3. In preparing its policy on the environment, the Community shall take account of:
- available scientific and technical data, …
- the potential benefits and costs of action or lack of action …"

Ref. 2

Article 6 of the EC Treaty provides that "*environmental protection requirements must be integrated into the definition and implementation of the Community policies and activities referred to in Article 3, in particular with a view to promoting sustainable development*".

Ref. 3

Hence, Article 95(3) of the EC Treaty provides that: *"The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective"*.

Ref. 4

The first paragraph of Article 152 of the EC Treaty provides that: *"A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities"*.

Case Law

Ref. 5

In its judgement on the validity of the Commission's decision banning the exportation of beef from the United Kingdom to reduce the risk of BSE transmission (Judgements of 5 May 1998, cases C-157/96 and C-180/96), the Court held:

"Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent." (Grounds 99). The next section fleshes out the Court's reasoning: *"That approach*

is borne out by Article 130r(1) of the EC Treaty, according to which Community policy on the environment is to pursue the objective inter alia of protecting human health. Article 130r(2) provides that that policy is to aim at a high level of protection and is to be based in particular on the principles that preventive action should be taken and that environmental protection requirements must be integrated into the definition and implementation of other Community policies."(Grounds 100).

Ref. 6

In another judgement concerning protection of consumer health (Judgement of 16 July 1998, case T-199/96), the Court of First Instance cites the above passage from the BSE judgement (see Grounds 66 and 67).

Ref. 7

Recently, in the Order of 30 June 1999 (Case T-70/99), the President of the Court of First Instance confirmed the positions expressed in the above mentioned judgements. Note that this judgement contains an explicit reference to the precautionary principle and affirms that *"requirements linked to the protection of public health should undoubtedly be given greater weight that economic considerations."*

Policy Orientations

Ref. 8

In its Communication of 30 April 1997 on consumer health and food safety (COM(97) 183 final), the Commission states: *"the Commission will be guided in its risk analysis by the precautionary principle, in cases where the scientific basis is insufficient or some uncertainty exists".*

Ref. 9

In its Green Paper on the General Principles of Food Law in the European Union of 30 April 1997 (COM(97) 176 final), the Commission reiterates this point:

"*The Treaty requires the Community to contribute to the maintenance of a high level of protection of public health, the environment and consumers. In order to ensure a high level of protection and coherence, protective measures should be based on risk assessment, taking into account all relevant risk factors, including technological aspects, the best available scientific evidence and the availability of inspection sampling and testing methods. Where a full risk assessment is not possible, measures should be based on the precautionary principle."*

Ref. 10

In its Resolution of 10 March 1998 on the Green Paper, the European Parliament states:

"European food law is based on the principle of preventive protection of consumer health;

stresses that policy in this area must be founded on a scientifically based risk analysis supplemented, where necessary, by appropriate risk management based on the precautionary principle;

invites the Commission to anticipate possible challenges to Community food law by WTO bodies by requesting the scientific committees to present a full set of arguments based on the precautionary principle."

Ref. 11

The Joint Parliamentary Committee of the EEA (European Economic Area) adopted a Resolution on Food Safety in the EEA on 16 March 1999. In this connection, on the one hand, it *"emphasises the importance of application of the precautionary principle"* (point 5) and, on the other, *"reaffirms the over-riding need for a precautionary approach within the EEA to the assessment and evaluation of applications for the marketing of GMOs intended to enter the food chain…" (point 13).*

Ref. 12

On 13 April 1999, the Council adopted a Resolution urging the Commission, inter alia, *"to be in the future even more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer-related activities and develop as a priority clear and effective guidelines for the application of this principle"*.

ANNEX III

The Precautionary Principle in International Law

The Environment

Although applied more broadly, the Precautionary Principle has been developed primarily in the context of environmental policy.

Hence, the Ministerial Declaration of the Second International Conference on the Protection of the North Sea (1987) states that "*in order to protect the North Sea from possibly damaging effects of the most dangerous substances, a precautionary approach is necessary which may require action to control inputs of such substances even before a causal link has been established by absolutely clear scientific evidence*". A new Ministerial Declaration was delivered at the Third International Conference on the Protection of the North Sea (1990). It fleshes out the earlier declaration, stating that "*the participants ... will continue to apply the precautionary principle, that is to take action to avoid potentially damaging impacts of substances that are persistent, toxic and liable to bioaccumulate even where there is no scientific evidence to prove a causal link between emissions and effects*"

The Precautionary Principle was explicitly recognised during the UN Conference on Environment and Development (UNCED) in Rio de Janeiro 1992 and included in the so-called Rio Declaration. Since then the Precautionary Principle has been implemented in various environmental instruments, and in particular in global climate change, ozone depleting substances and biodiversity conservation.

The precautionary Principle is listed as Principle 15 of the Rio Declaration among the principles of general rights and obligations of national authorities:

"In order to protect the environment, the precautionary approach should be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".

Principle 15 is reproduced in similar wording in:

1. 1. The preamble of the Convention of Biological Diversity (1992):

2. (…) *Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimise such a threat (…)*

3. 2. In article 3 (Principles) of the Convention of Climate Change (1992):

4. (..) The Parties should take *precautionary measures to anticipate, prevent or minimise the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost.* To achieve this, such policies and measures should take into account different socio-economic contexts, be comprehensive, cover all relevant sources, sinks and reservoirs of greenhouse gases and adaptation, and comprise all economic sectors. Efforts to address climate change may be carried out co-operatively by interested Parties.

In the Paris Convention for the protection of the marine environment of the north-east Atlantic (September 1992), the precautionary principle is defined as the principle "*by virtue of which preventive measures are to be taken when there are reasonable grounds for concern that substances or energy introduced, directly or indirectly, into the marine environment may bring about hazards to human health, harm living resources and marine ecosystems, damage amenities or interfere with other legitimate uses of the sea, even when there is no conclusive evidence of a causal relationship between the inputs and the effects.*"

Recently, on 28 January 2000, at the Conference of the Parties to the Convention on Biological diversity, the Protocol on Biosafety concerning the safe transfer, handling and use of living modified organisms resulting from modern biotechnology confirmed the key function of the Precautionary Principle. In fact, article 10, paragraph 6 states: "*Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimise such potential adverse effects"*.

Besides, the preamble to the WTO Agreement highlights the ever-closer links between international trade and environmental protection.

The WTO SPS Agreement

Although the term "Precautionary Principle" is not explicitly used in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), the Appellate Body on EC measures concerning meat and meat products (Hormones) (AB-1997-4, paragraph 124) states that it finds reflection in Article 5.7 of this Agreement. Art 5.7 reads: "*In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available scientific information, including that from the relevant international organisations as well as from sanitary and phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.*"

The Appellate Body on Hormones (Paragraph 124) recognises…." that there is no need to assume that Article 5.7 exhausts the relevance of a precautionary principle". Moreover, Members have the "right to establish their own level of sanitary protection, which level may be higher (i.e. more cautious) than that implied in existing international standards, guidelines and recommendations". Furthermore, it accepts that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned." The Appellate Body on Japan-Measures affecting agricultural products (AB-1998-8, paragraph 89) clarifies the four requirements, which must be met in order to adopt and maintain provisional SPS measures. A Member may provisionally adopt an SPS measure if this measure is:

1) Imposed in respect of a situation where "relevant scientific information is insufficient".

2) Adopted "on the basis of available pertinent information".

Such a provisional measure may not be maintained unless the Member which adopted the measure:

1) "seek(s) to obtain the additional information necessary for a more objective risk assessment."

2) "review(s) the … measure accordingly within a reasonable period of time."

These four requirements are clearly cumulative and are equally important for the purpose of determining consistency with the provision of Art 5.7. Whenever one of these four requirements is not met, the measure at issue is inconsistent with Art 5.7. As to what constitutes a „reasonable period of time“ to review the measure, the Appellate Body points out (Paragraph 93), that this has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review *and* the characteristics of the provisional SPS measure.

ANNE*X* IV

The Four Components of Risk Assessment

An attempt to complete as far as possible these four components should be performed before action is taken.

Hazard identification means identifying the biological, chemical or physical agents that may have adverse effects. A new substance or biological agent may reveal itself through its effects on the population (illness or death), or on the environment and it may be possible to describe the actual or potential effects on the population or environment before the cause is identified beyond doubt.

Hazard characterisation consists of determining, in quantitative and/or qualitative terms, the nature and severity of the adverse effects associated with the causal agents or activity. It is at this stage that a relationship between the amount of the hazardous substance and the effect has to be established. However, the relationship is sometimes difficult or impossible to prove, for instance because the causal link has not been established beyond doubt.

Appraisal of exposure consists of quantitatively or qualitatively evaluating the probability of exposure to the agent under study. Apart from information on the agents themselves (source, distribution, concentrations, characteristics, etc.), there is a need for data on the probability of contamination or exposure of the population or environment to the hazard.

Risk characterisation corresponds to the qualitative and/or quantitative estimation, taking account of inherent uncertainties, of the probability, of the frequency and severity of the known or potential adverse environmental or health effects liable to occur. It is established on the basis of the three preceding and closely depends on the uncertainties, variations, working hypotheses and conjectures made at each stage of the process. When the available data are inadequate or non-conclusive, a prudent and cautious approach to environmental protection, health or safety could be to opt for the worst-case hypothesis. When such hypotheses are accumulated, this will lead to an exaggeration of the real risk but gives a certain assurance that it will not be underestimated.

EUROPEAN UNION

Competence for food legislation policy and implementation in the European Union is shared between the European Commission and the Member States. In order to have a clear overview of the situation, the reader should begin by reading the submission of the European Commission.

AUSTRIA

I. Synthesis

Due to the federal structure of Austria food legislation is organised by the central level while its implementation is primarily the responsibility of the governors of the 9 provinces. Basis is the Food Act of 1975 with its amendments, which also establishes the implementation of food relevant Community law. Co-ordination for risk analysis rests with the Federal Ministry of Social Affairs and Generations (from April 1st, 2000 on before: Federal Chancellery). A long established system provides for scientific contributions as well as for consideration of other legitimate factors by scientists and representatives of all stakeholders.

To reinforce public confidence additional or improved measures to address food safety issues are promoted. Generally that means following a preventive approach, e.g. hygienic production methods based on HACCP, monitoring of residues, effective information of the public. Consumer concerns have in particular to be met in the area of novel foods; notably those derived from GMOs; for that purpose not only safety issues but also other legitimate factors have to be taken account of. Clear labelling is required to permit consumers' choice. Conclusions to be drawn from new scientific evidence have to be disseminated widely and rapidly by the usual media addressing consumers but taking advantage also of the potentialities of the Internet age.

II. Overview of the Food Safety System

2.1 Government

Austria is a federal republic divided into nine provinces (Länder), each with its own provincial assembly (Landtag). The federal parliament has two chambers; the National Council (Nationalrat) and the Federal Council (Bundesrat), it decides on amendments to the Food Act, which is a federal law.

The Federal Ministry of Social Affairs and Generations (in following text: the Ministry) is the country's supreme health authority. It is responsible for formulating health policy, including matters of food safety, for drafting legislation and general directives, and for the technical supervision of health services and training. The Governor of each province implements the directives of the Federal Ministry.

2.2 Legal Instruments

2.2.1 Foodstuffs Legislation

The aim of this legislation is to protect consumers against health risks and from misleading marketing practises. The Food Act of 1975 with its amendments deals with trade in foodstuffs, „consumption products" (Verzehrprodukte), additives, cosmetics and consumer goods. „Consumption products" are substances that are intended to be eaten, chewed or drunk but are not used primarily for

nutritional purposes and are not medicines. „Consumer goods“ includes a wide range of articles and materials, such as packaging materials intended for use with foodstuffs, clothing and furniture textiles.

The Food Act defines amongst others the notions of "harmful to health" and "falsely designated".

The Federal Ministry of Social Affairs and Generations issues ordinances, in particular to lay down MRLs for pesticides in foods or to ensure that the principles of food hygiene are observed.

2.2.2 Food of Animal Origin

While most regulatory aspects of food of animal origin are covered by the Food Act some areas are under the responsibilities of the Veterinary Service of the Ministry and concomitantly covered by veterinary legislation. This applies in particular to meat hygiene, meat inspection, and poultry hygiene and residue control.

2.2.3 Mechanism for Risk Analysis

For drafting legislation pertaining to chemical safety of food the Ministry has installed specifically a department of toxicology. It is involved in the consultation process and co-ordinates research in relation to risk assessment, except for matters of hygiene. This research is undertaken by experts who are known for their experience and qualification and who are independent from economic interests in their capacity as university scientists. Research is funded by several ministries. Expertise is also provided by specialists of the Federal Institutes of Food Investigation, mainly in the field of exposure assessment.

The Austrian Codex Commission (Codex Alimentarius Austriacus) advises the Minister; it has to be heard for drafts of legislative acts (regulations). Its members which are appointed for 5 year periods are scientists with specific knowledge in one or more of the relevant fields; most of the scientists are independent university experts, but there are also some who are nominated by stakeholder organisations. Other members of the commission are representatives of the ministries concerned and of the stakeholder organisations, including several from the consumers’ side. This commission may consult other experts. The rules of procedure are similar to the Codex Alimentarius Commission to which it was a model.

Consequently so-called other legitimate factors relevant to health protection and promotion of fair practises in food trade are considered where appropriate. In this context the possibilities of good production practises are taken account of to establish a level of protection as high as reasonably achievable.

It is evident that especially in cases of urgency sufficient scientific data for a final evaluation are sometimes not available but that existing data indicate potential hazards. In conformity with a strict interpretation of the Food Act the principle of precaution is followed. Austria is in agreement with the EU wide interpretation of this principal.

Furthermore like all legislative drafts, also those relating to food safety are circulated for comments and examination to all interested parties.

These consultation processes allow for interactive exchange of information's and opinions.

Similar to the procedure for chemical safety of food the consultation for food hygiene legislation is co-ordinated by another department of the Ministry, the department of food matters.

For advice of the Minister the Standing Committee on Hygiene with a membership composition comparable to the Austrian Codex Commission and involving specialised scientists and representatives of all relevant stakeholder organisations has been set up in 1975.

2.2.4 Control of Foodstuffs

The Provincial Governors are responsible for the surveillance of trade in the commodities covered by the Federal Food Act taking into full consideration EU-legislation. To perform this task they may call on the services of qualified persons of various kinds of specialisation and may, under certain conditions, delegate their duties to individual municipalities. The Federal Ministry for Social Affairs and Generations may issue ordinances regulating the training of supervisory staff. It issues annual rules for the surveillance of trade in the commodities concerned. The Provincial Governors, who must implement these rules, are required to submit an annual report on the subject to the Minister.

The supervisory authorities can seize commodities, as well as containers and advertising material, whenever there is reason to suspect that they are spoiled or harmful to health, contravene legal provisions, etc. A specified legal procedure has to be followed in connection with seize commodities and their confiscation.

In their inspection of meat and meat products, veterinarians are obliged to take into account the provisions of the Federal Food Act and the ordinances issued under it.

For the purpose of testing official samples 5 Federal Institutes for Food Investigations and 3 provincial institutes were established. When, in the course of their duties, any of these institutes find that legal provisions have been violated they are required to notify the competent authorities without delay. Beyond that, to the Institute in Vienna has been assigned in relation to public health the task of research, in particular in the areas of nutrition, food science and food hygiene. (see annex)

III. Activities in Addressing Food Safety Issues

Food safety is increasingly a subject of public concern. At the same time investigations and control are becoming ever more complex. With limited resources ways have to be sought to concentrate public laboratory activities at specialised and appropriately equipped institutes implementing consolidated monitoring programs. Their participation in international corporations for the development of new or improved analytical methods is continuously further strengthened.

Taking note of the importance of modern hygienic production methods and their control based on HACCP, stakeholders are encouraged to develop guidelines for their respective sectors. A series of such guidelines to which Ministry experts made contributions are already published. High priorities have guidelines in the restaurant and catering sector. To intensify their efficacy and for better protection of the employees a number of recommendations are distributed in foreign languages to personal coming from outside the EU (Croatian, Serbian, Turkish, and Chinese). Particular attention is also given to updating the training of the food inspectors.

Like in other countries consumers are reluctant in accepting GMOs or products derived from GMOs. Account has to be taken of both safety concerns and various reservations to environmental impacts

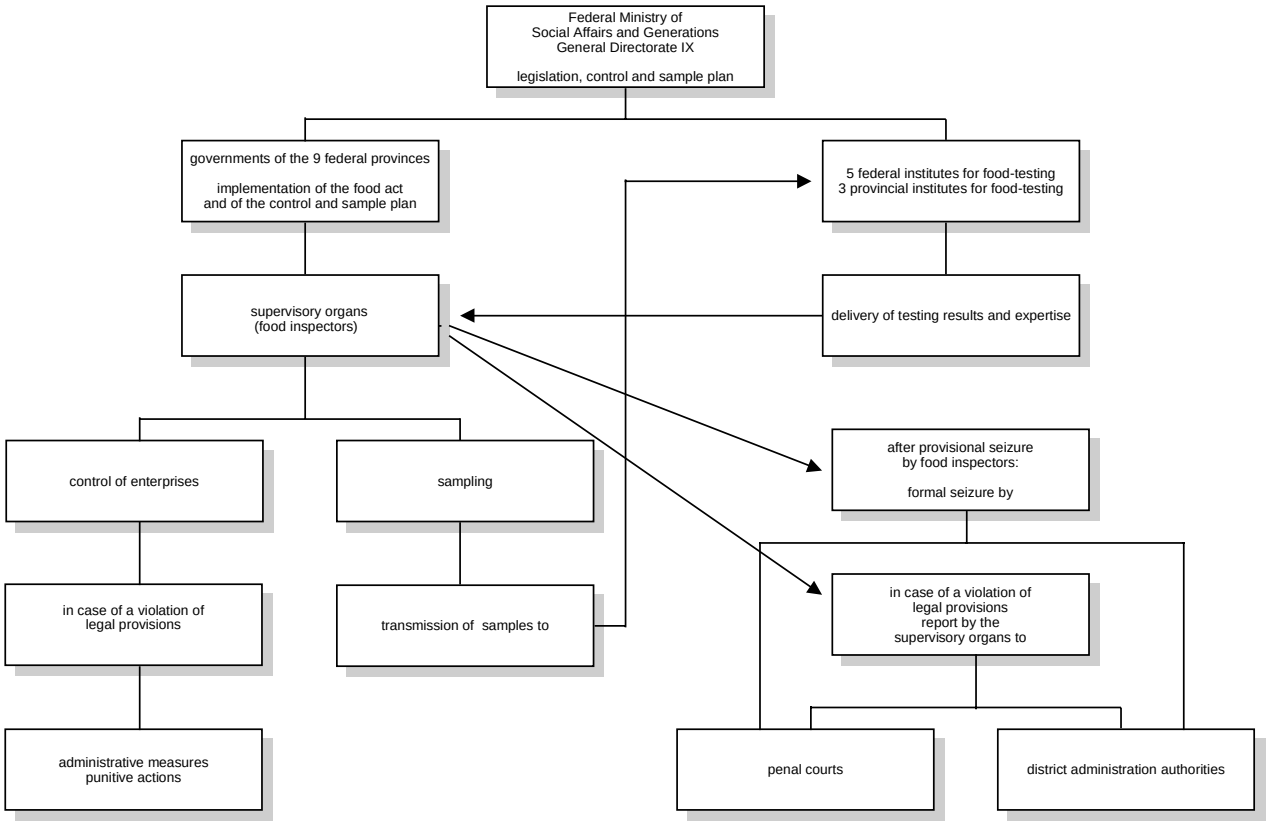
and other legitimate factors. The way forward is to provide for „consumers' choice" by informative labelling and clear criteria for safety evaluation and product composition. As for labelling it has clearly to state what it means, using the term „genetically modified", and should refrain from referring to „(modern) biotechnology". EU legislation for safety requirements and labelling is covering already a wide spectrum of products. One field which is in preparation for harmonisation, but was considered urgent by consumers and distributors in some countries, are products labelled „without GT" or „GT-free". Pending future international harmonisation Austria has defined these products in 1998 by means of a guideline within its territory.

For many years intense communication is provided for between interested parties in the process of developing legislation. These Improvements are continuously pursued, in particular taking advantage of modern information technology.

Another important task is to go beyond the communication between representatives of interested groups. That is to address consumers and people working in the field of food marketing and processing directly. A number of brochures and leaflets describing where problems exist, what to do about them, and what the legal provisions might be have been widely distributed, notably concerning food hygiene. In addition to such measures for the future already existing systems of information by Internet will be rapidly expanded.

ANNEX

Structure of the food control in Austria



BELGIUM

I. Introduction

The Compendium on Belgium's food safety system first notes that the current rules and regulations are, for the most part, either EU regulations or legislation transposing EU directives into national law.

The food safety system is based on a range of laws, combined with royal and ministerial implementing orders.

Responsibilities are currently shared between the health and agriculture ministries. Individual departments have specific powers, take part in international negotiations, prepare regulations and monitor their enforcement. Comprehensive reform of the system is under way (see below).

The Compendium then presents the risk assessment system, which is based on consultations with scientific committees or boards whose members are appointed by government. Stakeholders are not represented. When giving their opinions, the committees and boards draw on international guidelines.

Risk management is based on risk assessment but also takes other relevant factors into account, on a case-by-case basis. The precautionary approach is not prescribed by regulation, but it is applied in practice. Consultation with stakeholders is not mandatory, as a rule; when it does take place, consensus is sought.

The description of risk communication covers a range of matters such as the rapid information exchange system, labelling, traceability, and the register of genetically modified organisms and communication with consumers.

The Compendium finally lists three significant new developments: (i) the establishment of a federal food safety agency; (ii) the establishment of a system for monitoring contamination in the food chain; and (iii) the introduction of a more comprehensive traceability system covering the whole of production and marketing.

Parliament passed the law establishing the federal food safety agency on 4 February 2000, and preparatory work is going ahead actively. The agency, which will come under the health minister, has a single objective: monitoring food safety throughout production and marketing. It will take an overall approach to supervision of the food chain and will operate independently, transparently, with its own budget and in conjunction with similar agencies in other countries.

II. The Food Safety System in Belgium

2.1 General Principles

In Belgium the bulk of current rules and regulations are either EU regulations, which apply directly, or legislation transposing EU directives into national law.

The food safety system is based on a range of legislation, prepared by the executive (government) and passed by Parliament[1]. The most significant components are:

- The Law of 24 January 1977 dealing with **consumer health protection** in respect of **foodstuffs** and other products.
- The Law of 5 September 1952 on the **inspection and sale of meat.**
- The Law of 15 April 1965 on the inspection and sale of fish, poultry, rabbits and game.
- The Law of 11 July 1969 concerning pesticides and inputs for agriculture, horticulture, forestry and stockbreeding.
- The Law of 2 April 1971 on the control of organisms harmful to plants and plant products.
- The Law of 21 June 1983 concerning **medicated animal feed.**
- The Law of 15 July 1985 concerning the use of artificial hormones and anti-hormones, adrenergic blocking agents and growth stimulants for livestock.
- The Law of 20 July 1991 providing a framework for orders concerning **genetically modified organisms.**
- The Law of 28 March 1975 on the sale of agricultural, horticultural and fisheries products.

These provisions set the framework and guidelines for the Belgian system. They also provide the basis for transposing EU directives into Belgian law and for setting penalties for infringements of EU regulations, which apply directly.

The legislation and orders pursuant thereto further regulate the consultation of scientific committees or boards responsible for risk assessment, and consultative committees covering all stakeholders.

The legislation sets the general regulatory framework and delegates powers of implementation to the executive.

It also provides for enforcement, and sets penalties for infringements. The penalties may be fines or terms of imprisonment handed down by courts of law. In some cases, however, the executive may first propose an administrative settlement, and only when payment of the administrative fine is refused will the matter be referred to the courts. In other cases, when the prosecuting office does not pursue a matter referred to it, the executive may set administrative fines.

1. Parliament may also initiate and pass legislation without consulting the executive.

Responsibilities are shared between the health and agriculture ministries. Within each ministry, various departments have specific powers[2]. Within the limits of their powers, these departments perform regulatory and inspection functions. In this connection they:

c. Take part in international negotiations on quality standards and flow and risk management policy.

d. Prepare implementing regulations (royal orders[3] and ministerial orders[4]).

e. Monitor compliance.

2.2 Risk Assessment

As a general rule, the regulations call for scientific committees or boards to be **consulted** as part of the risk assessment procedures. They include:

1) The *Conseil Supérieur d'Hygiène Publique*, which gives opinions on health and toxicological issues, the acceptability of additives, contaminants and pesticides, and nutritional matters.

2) The *Comité d'Agréation des Pesticides à Usage Agricole* (which includes an expert committee on ecotoxicology), which assesses the acceptability of agricultural pesticides for human health and the environment.

3) The *Conseil de Biosécurité*, which gives opinions on matters relating to genetically modified organisms (public health and environmental aspects).

The first two are made up of scientists appointed by the government for unspecified terms; the relevant minister makes regular adjustments to membership. The *Conseil de Biosécurité* is made up of representatives of the competent authorities, appointed by the King for a four-year term, renewable. It calls in experts to examine scientific issues relating to biosecurity. The scientific members come from public institutions, universities and specialist colleges in Belgium. Stakeholders are not represented on these committees and boards.

The committees and boards are consulted by the government **before food safety rules are approved**, and may also give opinions on the need to issue or amend regulations on their own initiative, and make general recommendations.

The opinions go to the minister(s) concerned. As a general rule they are **not binding** on the risk manager and publication is not systematic or mandatory, except for opinions of the *Conseil de Biosécurité* concerning genetically modified organisms.

In a number of cases the regulations set basic specifications for references to the committees and boards. This is the case in particular for references concerning additives, pesticides and biocides, pesticide residues, materials in contact with foodstuffs, and genetically modified organisms.

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2. In order to enhance the system's transparency and effectiveness, on 4 February 2000 Parliament passed a law establishing a federal food safety agency (AFSA), which will come under the federal health minister (see Section III below).

3. A royal order is signed by the King. It may be amended or terminated by another royal order, or by a law.

4. A ministerial order is signed by the relevant minister. It may be amended or terminated by another ministerial order, a royal order or a law.

The boards and committees make risk assessments on the basis of international guidelines. As a general rule they draw extensively on the recommendations and opinions of international expert committees such as EU science committees, the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), the European Committee for Standardisation (CEN) and the expert groups set up by OECD. For novel foods, assessments are made in line with a European Commission recommendation based on an opinion issued by the EU Scientific Committee for Food.

2.3 Risk Management

When taking decisions, and in particular when framing regulations, the risk manager takes account of factors other than those arising from risk analysis. There is no exhaustive list of criteria to be taken into consideration by risk managers because assessment is made on a case-by-case basis, but they include:

- Good practice in manufacturing, agriculture and veterinary science
- Environmental criteria
- Animal welfare and health
- Legitimate concerns and interests of consumers
- Fair trading
- Economic implications
- Feasibility and implementation.

The precautionary principle as such is not prescribed in regulations and so far no administrative circulars have required or recommended its application. But when we consider how risk managers reach their decisions, it can be seen that this approach is in fact used, in line with the European Commission's report on the application of the precautionary principle.

Consultations with stakeholders are not mandatory, with some exceptions. When consultations do take place, before decisions are reached, a consensus is sought.

Regulations, which are binding, are taken via royal or ministerial orders, and published in the Official Journal (*Moniteur Belge*).

Interpretations of regulations are usually issued in administrative circulars. These interpretations do not have the force of law and may be contested in court.

Inspection findings may be contested in court.

Self-inspection by firms is increasingly required under compulsory safety measures, the HACCP system and good practice guides (relating to health or farming, for instance). It may also involve approved or accredited outside bodies. In all these cases, government departments check that self-inspection is properly performed (inspection of inspection).

Market monitoring takes place in a number of cases, including:

- Pesticides and residues
- Additives
- Contaminants (dioxins, PCBs, aflatoxins, etc.)
- Biological contaminants (salmonella, listeria, etc.)
- Veterinary medicines (hormones, antibiotics, etc.)
- Livestock feed.

The traceability principle is mandatory as far as slaughter in the production of beef (per cow) and pork (per batch) via the SANITEL system, a veterinary database, and to consumer level in organic farming and integrated agricultural production (fruit and vegetables).

2.4 Risk Communication

The **European Union information exchange** system in cases of serious immediate danger keeps the authorities informed of major consumer health problems arising in Europe; they can then take the necessary steps without delay. The system also identifies persistent problems, so that regulations can be introduced or amended and inspections stepped up to deal with them.

Compulsory **labelling**, and optional nutritional labelling, provides consumers with information on various important health-related matters: best before date, lists of ingredients to identify allergens, etc. False or misleading information may not be supplied, and any claims, in particular claims relating to health or effects on the metabolism, must be scientifically proven.

Traceability is another excellent way of informing consumers. It is to be strengthened when already required, and made compulsory when it is currently optional. The use of quality labels or marks (such as organic farming labels, denoting absence of pesticide residues) is also a means of risk communication.

The **register of authorised GMOs**, with case-by-case information, is available on a website. Several government websites can provide information on this subject: sujet: http://health.fgov.be, http://minsoc.fgov.be, http://biosafety.ihe.be.

Last, **government leaflets** (on food preparation, on GMOs), workshops and information days (in December 1998 the agriculture and health ministries arranged an information day on GMOs) and press releases (in particular warning people not to consume particular batches of goods) are also part and parcel of communication with the public and stakeholders.

III. Future Projects

Following the contamination of part of the food chain by dioxins and PCBs in Belgium in 1999, the government took a number of significant decisions: to establish a federal food safety agency *(Agence fédérale pour la Sécurité alimentaire* -- AFSA), to set up a contamination surveillance system (CONSUM), and to extend traceability.

3.1 Federal Food Safety Agency (AFSA)

Parliament passed the law establishing the federal food safety agency on 4 February 2000, and it was published in the *Moniteur Belge* on 18 February 2000.

Government and private-sector experts are working on the royal orders to implement the law, setting out the procedural stages in the switchover from the current system to the new one.

The **chief objective** of the Agency is to integrate and co-ordinate inspection of the entire food chain in a single structure, in order to end the current dispersal of powers and responsibilities and to facilitate the identification of health problems and risks and appropriate measures to tackle them. This will provide better guarantees of food safety and protect the consumer. More effective control and inspection should restore and build up people's confidence in the food that they eat both nationally and internationally.

Fundamental to the Agency's approach is:

- Transparency: reports and research on all stages in the food chain, and on foodstuffs, must be accessible.

- Comprehensiveness: inspection and control of all facets and stages in the food chain will be in the hands of a single agency.

- A single objective: inspecting food safety.

- Independence: the Agency's members must act on the basis of objective criteria and solely for purposes of safeguarding public health, regardless of pressure groups.

- Budget autonomy, to safeguard the Agency's independence and continuity.

- International co-operation, with bodies with similar objectives elsewhere.

AFSA will report to the federal health minister and will have **responsibility** for:

- Monitoring, inspecting and analysing food products and their ingredients at every stage in the food chain.

- Monitoring and analysing production, processing, storage, transport, sale and import and export of food products and their ingredients, and inspection of sites used for the production, processing, packaging, storage and sale thereof.

- Approvals and authorisations.

- Developing systems for identifying and tracing food products and their ingredients in the food chain, and inspection.

- Collecting, collating, managing, storing and disseminating information relevant to its objective.

- Developing and implementing policy on prevention, public awareness and information.

- Monitoring compliance with legislation at all stages in the food chain.

AFSA will have a **consultative committee** to advise it on all matters relating to the Agency's policy. The committee, including stakeholders, will give opinions on request, or on its own initiative.

AFSA will have a **scientific committee** made up of national and international experts in fields covered by the Agency. The committee will conduct reviews and give opinions, on its own initiative and on request. **It must be consulted** on all proposed regulations on subjects relevant to the Agency. The experts will be appointed by the government.

AFSA will have a permanent contact point where consumers may obtain objective information and lodge individual complaints about food quality and safety.

3.2 CONSUM Programme

In order to guard against fresh contamination of the food chain by PCBs and dioxins, the Belgian authorities have instituted a contaminant surveillance system, CONSUM. This risk management programme is intended to allow early detection of contamination (preventive aspect) and swift and effective responses when contamination is identified (corrective aspect).

The surveillance system will be designed to detect PCB contamination affecting 2 per cent of foodstuff manufacturers, with 99 per cent reliability, and to detect contamination affecting 5 per cent of batches manufactured in a given plant with 95 per cent reliability.

To achieve these objectives, commodities and feedstuffs will be subjected to intensive monitoring. It is estimated that 12 000 items will need to be sampled, including 10 000 for Belgian production alone. In addition, "critical" commodities and additives have been defined: in these cases, there will be permanent surveillance, and all operators in the sector are identified.

In addition to the surveillance, a system for tracing commodities, additives, preliminary mixes and feed compounds is to be introduced. On the farming side, monitoring will take place at the initial processing stage. Samples will be taken from slaughterhouses, dairies, eggplants and aquaculture units.

Farms where contamination is identified will be subject to restrictions and assigned C Status. This status will be marked on livestock papers, and will not be lifted until the farm has been cleared.

On the processing and distribution side, further monitoring, on top of that required by EU Directive 96/23, will be performed. All the findings will be managed in a single database open to all stakeholders.

Scenarios are to be prepared and tested to ensure an optimum response to contamination in the food chain.

CONSUM is an ambitious programme designed to ensure safety in the food and feed chain. It is based on integrated risk management principles, focusing chiefly on preventing contamination entering the food chain.

3.3 Traceability

The traceability of risk products and feed compounds must be radically improved in order to allow swift intervention when the need arises. This means registering risk operators and also intermediaries dealing in feedstuffs for cattle, sheep, pigs and poultry. Dealers will require ministry authorisation, which may be withdrawn if false returns or breaches of procedures are identified.

Operators must retain a sealed sample from each batch delivered, for official inspection over the following six months, and systematically supply PCB and/or dioxin analysis reports, depending on the type of product, with each delivery to customers. Any positive test finding must be reported to the appropriate official service.

Operators, concentrate manufacturers and dealers must also register all transactions precisely so that links can be established immediately between contaminated feed and herd numbers listed in the veterinary department's SANITEL system.

This system, already operational for cattle and pigs, will be extended to poultry.

GMO traceability in the food chain is also being launched. A network of three federal laboratories has been established to conduct analyses, co-ordinated by the *Conseil de Biosécurité*. Belgium's proposal to establish a similar network across all 15 EU countries has been accepted. The aim is to have a co-ordinated network of reference laboratories for GMOs and derivatives available to all the competent authorities.

DENMARK

I. Summary

The structures in food production, distribution and trade are changing dramatically these years, and the consumer awareness of possible health concerns related to food has become evident. With the purpose of facing these developments adequately a major reorganisation of the Danish food safety system has been implemented recently.

All responsibilities for food safety ”from stable to table” has been brought together in a new Ministry of Food Agriculture and Fisheries, and legislation on food and animal diseases has been concentrated in two new major laws on these topics.

The goals of the reorganisation is to enforce the capability to ensure that foods being marketed does not bring consumer safety at risk, and to enhance an equal and sufficient control and supervision level throughout the whole country. The major steps towards implementing these goals have been to set up The Danish Veterinary and Food Administration and to reorganise the control-system completely into eleven regional authorities controlling aspects from animal health to the final marketing of foods.

The Veterinary and Food Administration is organised as a comprehensive institution covering the three elements in the risk analysis process, i.e. risk assessment, risk management and risk communication. Different departments have their specific responsibilities in this framework, but this model of organisation also supports functional interaction.

The major objective of the administration is to protect consumers against risks and to safeguard the health and welfare of livestock and maintain Denmark’s high veterinary standards.

The reorganisation of the control system has been set up to increase efficiency and equality in food control throughout the country. The larger units being set up comprise a higher level of expertise altogether, and is capable of dealing with all issues from stable to stable. Key elements in the control philosophy is auto-control and HACCP-principles, and a strong emphasis on the fact that responsibility of marketing sound food products lies with the suppliers, and not with the authorities – their function is to monitor if the operators handle their processes and products correctly to be in accordance with prevailing legislation.

Safety, transparency, traceability and credibility are basic elements in Danish food policy, and risk management procedures includes legal obligations to involve consumers and other stakeholders. Food policy decisions are taken on the basis of solid scientific assessment, the precautionary principle and consideration of other legitimate factors.

II. Overview of Food Safety Systems

Introduction

Denmark used to have a rather complicated structure in food legislation as well as in the organisation of control-systems and political responsibility, which historically reflected a rational distribution of work in relation to the prevailing structure in food production and distribution. Meat, milk products and fish were major export commodities from Denmark, and consequently controlled by central authorities, while other foods were basically produced and consumed in local or regional areas, and therefore controlled by municipal authorities.

In the latest decades the development in structures for production, distribution and retail trade has changed dramatically. The average size and complexity of food manufacturing plants is constantly growing. Nowadays one production plant frequently supplies the whole country with specific products, and major supermarket chains dominates retail trade in food. These new structures do not go along with a local inspection structure, where different measures would often be taken on equal products.

In addition it became apparent, that major food safety problems can be handled more efficient if legislation, administration and control activities are organised along the "stable to table" philosophy. Food safety problems have to be solved as close to the source as possible.

On this background the Danish government decided on 30 December 1996 to establish a new **"***Ministry of Food, Agriculture and Fishery***"**. All responsibilities concerning veterinary and food safety was transferred to the new ministry, and a major reorganisation at all levels has been carried out to achieve the goals. Major steps has been

- To streamline and modernise legislation on food and veterinary issues.
- To organise a central advisory and administrative body covering veterinary and food issues from stable to table.
- To reorganise and modernise the inspection system fundamentally.

A number of laws covering specific aspects of food safety have been repealed, and the relevant provisions have been established in the new *Food Law of 1 July 1998*, and the *Law on Animal Disease and Infection of 2 June 1999.* These laws establish the basic framework for food safety and safety of animal health, and contains a number of provisions on the basis of which the minister of food can establish more detailed rules of a legal nature, when appropriate. These laws include provisions enabling the Minister of Food to implement legislative acts issued by the European Community, and to administrate Community regulations.

The very purpose of the food law appears in the first paragraph, which states:

> *"The purpose of the law is to guarantee the consumers healthy foods of high quality, to protect the consumers against misleading when foods are marketed, to promote healthy eating habits, and by these means ensure food producers and traders reasonable and equal conditions, and to promote Danish exports of food." (Unauthorised translation)*

An illustration of how the Danish government intends to focus strongly on implementing the purpose of the law can be illustrated by the "White Paper on Food Safety", which the government issued in January 1998.
(See home page http://www.fdir.dk/vis.cgi/white_paper)

The General Framework

A major step towards enforcing food safety in Denmark is a complete reorganisation of the administrative structure and the control system. The new Ministry of Food, Agriculture and Fisheries has been organised as follows:

The Ministerial Department ⟹

- The Danish Veterinary and Food Administration
- The Danish Plant Directorate
- The Danish Directorate for Fisheries
- The Danish Directorate for Food, Fisheries and Agro-Business
- Various Research institutions

On 1 July 1997 the Danish Veterinary and Food Administration was set up as a merger of the former National Food Agency and The Veterinary Directorate. Merging these two institutions was based on a firm belief that an organisation based on the *"stable to table"* philosophy would give the best opportunities to enforce Danish food safety in the short run, and in addition increase the capability to face emerging challenges.

The new administration (see organisation chart below) is responsible for food safety, including nutritional issues, as well as for animal health issues. The overall objective of the Danish Veterinary and Food Administration is to:

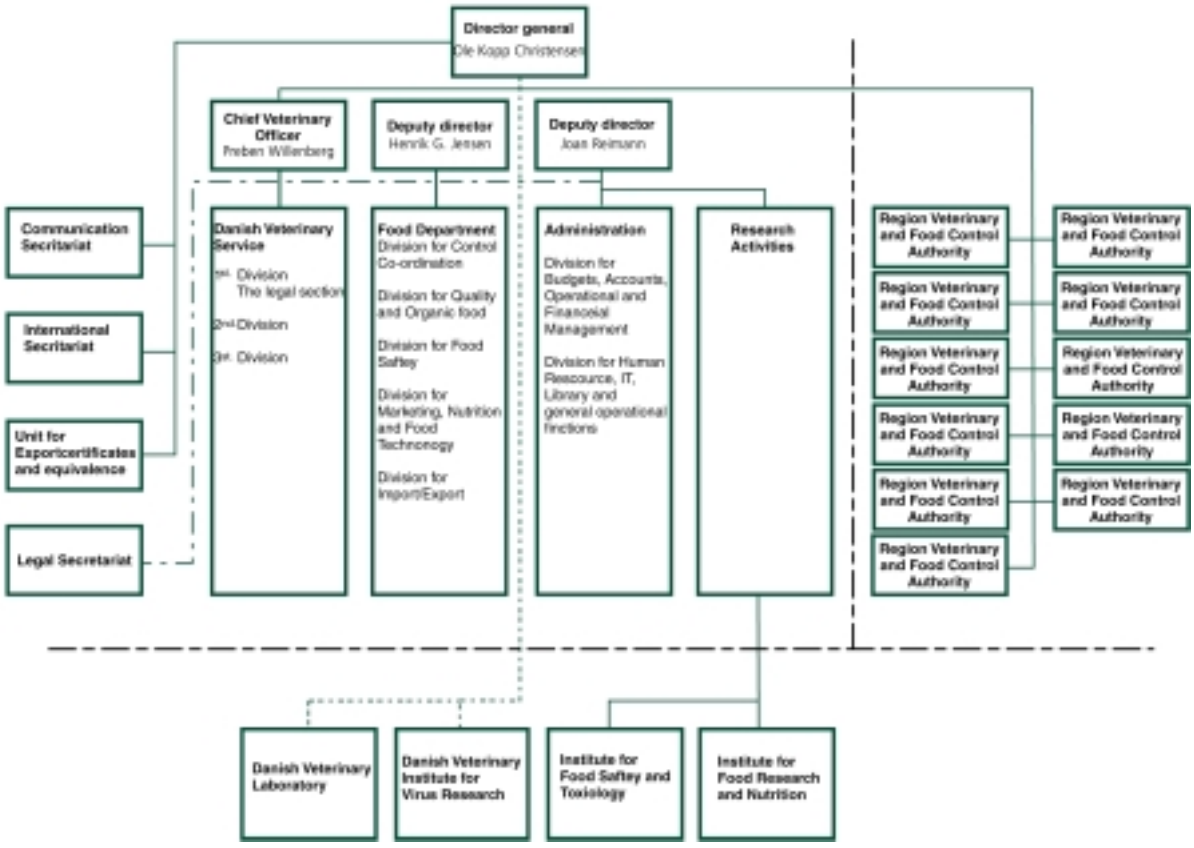
- Protect consumers against risks and secure truthful labelling of products, and to promote sound eating habits.
- Safeguard the health and welfare of livestock and maintain Denmark's high veterinary standards.

Specific objectives are to:

- Ensure that food is healthy and uncontaminated.
- Provide consumers with information on food and nutrition.
- Ensure the consistent and effective control and inspection of all food at every stage in the production chain.
- Promote development of high-quality food.
- Promote development of sustainable food production.
- Promote Danish food exports.
- Create a sound scientific basis for all activities through research and testing.
- Guard against the influx of dangerous livestock diseases and maintain contingency capabilities.
- Ensure openness concerning the administration's activities.
- Ensure uniform conditions for both producers and retailers.

Ministry of Food, Agriculture and Fisheries

Danish Veterinary and Food Administration



Risk Assessment bodies are Labortories and Research Facilities below the dotted line.

The new veterinary and food administration has been organised inspired by the three elements in the Risk Analyses Principles, which are Risk Assessment, Risk Management and Risk Communication. This will appear from the above organisation chart of the administration.

Risk Assessment Bodies:

- *The Institute of Food Safety and Toxicology* advises on safety in the context of food additives, nutrients, pollution, pesticide residues, natural plant toxins, pathogenic micro-organisms, antibiotic resistance, starter cultures, novel foods etc. These consulting activities are backed up by the institute's own research into toxicology as well as safety in the fields of microbiology and genetic engineering. It is also involved in risk assessment projects carried out by the EU, OECD and FAO/WHO. The Institute furthermore undertakes investigations designed to study and prevent the links between diet and various diseases.

- *The Institute of Food Research and Nutrition* collect information and give advise on a number of issues. One task is to document the content of energy-providing nutrients, vitamins, other secondary substances and additives in food, and to carry out diet surveys and advise on nutritional matters and the operating of large-scale kitchens. An other major activity is compiling data on contamination of food with heavy metals, minerals, mycotoxins, dioxins, PCBs, nitrosamines, etc., from all sources, including packaging materials. A third activity is to organise inspection surveys of a number of animal products concerning their composition, residues of veterinary drugs and microbiological quality. The Institute acts as reference laboratory for food inspection and is extensively involved in the development of new methodologies.

- *The Danish Veterinary Laboratory and The Danish Institute for Virus Research* are specialised in animal diseases, of which especially Zoonosis are of particular relevance to food safety. In the serum laboratory a special unit, The Zoonosis Centre, has been set up to monitor the incidence of zoonosis in the veterinary sector and advice on the efforts to combat problems like salmonella and camphylobacter in livestock, which may lead to pathogenic contamination of food.

Risk Management is the responsibility of The Food Department and the Veterinary Service.

Concerning legislative matters the Veterinary and Food Administration in general advise the ministerial department, and on specified items legal orders can be issued by the administration itself. The responsibilities include participation in preparatory work on legislation in The European Community, national provisions etc.

On the implementation side, the veterinary and food administration is responsible for guiding and instructing the regional inspection authorities in the whole country, which are responsible for the inspection of production, wholesale and retail companies "from stable to table" (see below).

The Food Department

The Food department is responsible for the administration of legislation related to food enterprises, labelling, marketing and product regulations, food technologies including genetically modified foods, radiation etc., food additives, microbiological and chemical food contamination, organic food, quality labelling etc. General nutritional issues also belong to this department.

A key-function of this department is to develop strategies and principles for the regional control system, including training requirements and collection of data, establishing national control campaigns etc.

The Veterinary Service

The Veterinary Service is responsible for animal health matters and for the authorisation of veterinarians.

The animal health responsibilites include monitoring, inspecting and combating indigenous livestock diseases and zoonosis as well as veterinary emergency services in the context of exotic livestock diseases and import and export of livestock and animal products (excluding foods) and aqua-culture products.

Other major responsibilities are the use of veterinary medicines, agreements on health counselling, animal welfare, animal husbandry and zoo-technology.

Risk Communication

Risk communication is an integrated part of the whole organisation, but activities are co-ordinated by the Communication secretariat, which in close co-operation with relevant units in other departments produce information material to consumers, issue press information's etc. concerning day to day "hot news" with relevance to consumers.

Food Inspection from Stable to Table

By far the widest ranging step in the reorganisation of the Danish food safety system is a complete reshuffle of the inspection system. The following authorities previously carried out the control and supervision tasks:

- The municipal food inspection units.
- The regional Veterinary Service.
- The meat inspection units.
- The border Veterinary Service.
- The Danish Directorate for Fisheries, (part of the fish inspection service).
- The Danish Plant Directorate, (part of the inspection of fruit, vegetables, potatoes and cheese).

After having placed the responsibility in one ministry, The Ministry of Food, Agriculture and Fishery, all inspection responsibilities has by 1 January 2000 been centralised in eleven *Regional Veterinary and Food Control Authorities.*

Consumers, food enterprises and livestock owners now have a single point of contact with the food authorities. The Regional Veterinary and Food Control Authorities are knowledge centres providing information, guidance and inspection concerning legislation, etc. throughout the veterinary and food area.

The purpose of this restructuring is to ensure a streamlined, efficient inspection from stable to table. A unified inspection system makes it possible to inspect at the level where maximum effect can be achieved, to ensure wholesome food of high quality for the consumers.

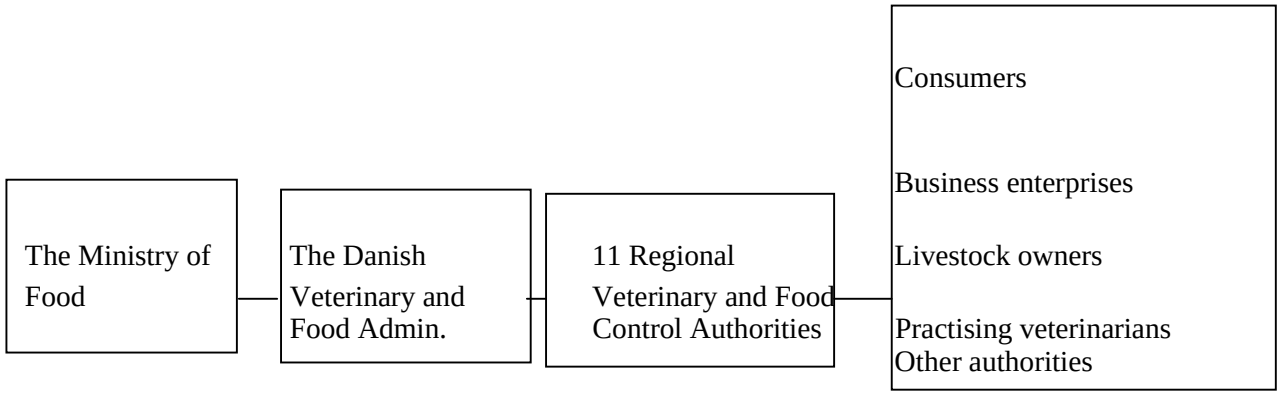
The benefit of centralising the expertise in large units is to enhance the quality of food inspection. The regional governmental structure shall:

- Provide a consistently high level of consumer protection nation-wide.
- Ensure consistent inspection of business enterprises of the same type.
- Provide for more uniform decisions at national level.

The Regional Veterinary and Food Control Authorities are established under the auspices of the Danish Veterinary and Food Administration, which has to co-ordinate their activities, but the regional authorities are autonomous bodies undertaking the direct contact with consumers, business enterprises, practising veterinarians and livestock owners within the region.

In principle, the structure is the same for all Regional Veterinary and Food Control Authorities. They are headed by a regional manager and consist of a food department, a veterinary department, a laboratory and a secretariat.

Interfaces between users, Regional Veterinary and Food Control Authorities, the Danish Veterinary and Food Administration and the Ministry of Food, Agriculture and Fisheries



The Regional Veterinary and Food Control Authorities are an integrated part of the national administration, and have the same principal objectives and goals as the Administration (described above).

The purpose of the centralisation of food inspection is to enhance consumer safety. All levels in the production process are important to consumer safety. The regional authorities handle food inspection at all levels from stable to table, from the animals at the farm via the abattoir to the food industry, and during shipping and transport, until the goods are in the shop. Consumer considerations have been the cornerstone of the modernisation of the food inspection service.

Inspection shall be carried out at all levels all levels. At farms with livestock production the control authority will inspect e.g. use of medicine for the animals and residual medicine level, occurrence of salmonella and other food-borne diseases, animal welfare issues, import of livestock, etc.

At abattoirs and in food production facilities inspection is carried out concerning compliance with health regulations and whether the enterprises' auto control meets the requirements. Retail outlets and restaurants are inspected in a similar way and samples are taken and analysed at the laboratory of the regional authority. Organic production and quality labelling schemes are subject to special inspection.

The 11 Regional Veterinary and Food Control Authorities will cooperate on activities like major inspection campaigns to ensure an effective and consistent campaign nation-wide.

The responsibility for food quality rests with the food producers, shops and restaurants. The food products must be clean and safe, and correctly labelled. The Regional Veterinary and Food Control Authority can always be contacted concerning any questions about food and livestock.

The consumers may also contact the regional authority if they suspect that illness is due to food bought on the market, or they discover other irregularities.

The Regional Veterinary and Food Control Authority authorises, approves or registers food enterprises, which is a legal obligation for those who want to handle food on a commercial basis. The authority inspects the enterprises' import, production, storage and labelling of foods. This gives the food enterprises a single point of contact with the food authorities.

Concerning livestock owners the regional authority provides information and guidance on animal husbandry regulations, and undertakes the following tasks in connection with animal husbandry:

- Preventing and combating contagious livestock diseases such as swine fever or BVD.
- Preventing and combating diseases carried from animals to humans, e.g. salmonella.
- Monitoring the welfare of livestock.

Especially combating zoonosis is an important element in the stable to table philosophy, which is a cornerstone in the Danish organisation.

The **major control principles** can be summarised as follows:

- The basic responsibility for only marketing products in accordance with the prevailing legislation lies with the business enterprises.
- Auto control is a fundamental obligation to all enterprises.
- Inspection focuses on procedures and routines in the enterprise. Analytical testing is primarily being used as verification of the capability to handle food correctly.
- Inspection frequency and intensity is adapted to risk level and detected problems.
- Inspection is carried out as early in the supply-chain as possible.
- Prevention is the goal of inspection, but sanctions are used when compliance with legislation are inadequate.
- Inspection intensity is the same for products to the national market and for export.

III. Activities Related to Food Safety

Basic Principles in Danish Food Legislation.

Safety, transparency and credibility are leading principles in food policy making by the Danish government. The basic element is solid scientific evaluation of substances, processes etc., which is carried out in the national institutes, and in active co-operation with institutes in other countries and international bodies established by FAO/WHO, OECD, The European Community etc. Denmark is a strong supporter of international co-operation on assessing the ever-increasing number of potential problems, which must be scientifically evaluated.

When legal or administrative steps are taken on the background of scientific opinions, decisions will be based on the **precautionary principle.** This implies that doubt in the scientific judgement should always be handled to the benefit of the consumer. If science cannot, on the basis of the existing data, draw any clear conclusion, the uncertainty may lead to the conclusion that the involved substance or process cannot be authorised, or its use is being restricted to an extend, which is consistent to the chosen level of protection of the consumer.

Further to the basic demand of scientific justification and invoking the precautionary principle, *other legitimate factors* are taken into account. These are factors of a general concern to the consumer, which would often be of an ethical or preventive nature. An example of these other factors is the basic principle that chemical substances in food should only be used to the lowest extend possible no matter whether it is food additives, pesticides or other substances being added directly or found as residues from other sources. A specific example of a preventive nature is that antibiotic growth promoters should be phased out because of the risk of creating severe resistance problems in the population. Animal welfare is another example of factors taken into account. A third factor is the consumers "right to know". If consumers are concerned about the use of specific processes or other conditions related to food, full information should be given to enable the consumer to make an informed choice of their food.

Traceability is a vital factor in modern Danish legislation covering the food chain from table to stable. If problems are detected in food, it is of major importance to be able to trace the relevant products in case they constitute an immediate risk, and solving the problem as close to the source as possible is the most cost effective and efficient way to react.

*Transparency and consumer-involve*ment is of bearing importance in Danish decision making processes. Second to the fact that Denmark is a very open society, where the government is always responsible to the Parliament (and can be dismissed by a majority at any time), where the media is very actively following questions on food safety, and where the public has access to files in the administration etc., there are formal procedures on how to involve consumer-organisations and other stakeholders in the process.

A basic instrument is that the administration is obliged by law to ask stakeholders - consumer organisations, the producer and trade organisations and other relevant authorities - to *submit written comments* when new legislation is being prepared. This counts for national legislation as well as preparations of directives etc. from the European Community. In addition meetings are being organised if requested. These opinions will be considered in the further planning of proposals, and in addition they will be described in memorandums to the political decision makers at government as well as Parliament level, which enables a genuine political consideration of stakeholders opinions.

A second instrument covering food legislation in general is The Advisory Board on Food, which has members representing central stakeholder organisations. This body express their opinion on food issues in general as well as proposals for legislation in particular, and has the function of giving direct advise to the Minister of Food.

Codex Alimentarius issues are being handled in a special system of Codex committees, which is comprised of a National Codex Advisory Body dealing with principal Codex issues, and a number of specialised committees covering the major horizontal Codex committees. Any organisation being registered as a hearing partner within the food legislation is invited to participate in the Codex work.

Further information on Danish food safety issues can be found on the homepages of the Veterinary and Food Administration, see www.foedevaredirektoratet.dk This homepage includes links to the homepage of The Ministry of Food, Agriculture and Fisheries, where general information on the ministry can be found.

FINLAND

I. Synthesis

Finland wishes to point to the following important key principles and activities of the Finnish food safety approach, with some examples. In certain cases such as salmonella control, experience has been gained over 30 years, in some other areas such as application of modern biotechnology, more experience still needs to be gained.

Control from the Stable to the Table

In order to control risks in food production it is essential to take systematic, active and preventive measures at the early stages of the food chain in primary production and at the level of agricultural production inputs, e.g. animal feed, fertilisers, pesticides and on the farm. Salmonella control in animal feed as well as the Finnish Salmonella Control Programme (SCP) for food products of animal origin are examples of an efficient farm to table food safety approach, with emphasis on the control of primary production. Salmonella is found to a degree of less than 1% on Finnish farms. At later stages in the food chain, the processing of agricultural products is controlled to minimise the contamination and deterioration of foods during distribution and marketing. Finally, the task of market surveillance is to ascertain the quality of foods offered for sale to consumers. Market surveillance guarantees the wholesomeness of foodstuffs and responds to consumer complaints.

Application of Precautionary Principle

The increase of antibiotic resistance to bacteria is a serious global health threat. By mutual agreement Finnish farmers, as well as the feed and food industry last year suspended the use of antibiotic growth promoters in animal production. This precautionary measure is a part of the national policy to keep the pool of antibiotic resistance bacteria as low as possible by reducing the use of antibiotics wherever possible. This policy is shared by all sectors, including agriculture, veterinary and human medicine.

The precautionary principle has been applied in Finnish food legislation in matters related to food allergens. Mandatory labelling of common allergens causing anaphylactic reactions has been practised for all foodstuffs. The high prevalence of coronary heart disease has been lowered by decreasing the salt intake of the population. In order to encourage consumers to avoid highly salted foods and to promote low salt products, national labelling regulations relating to labelling of salt have been stipulated.

Consumer Perceptions

Despite the implementation of less strict EU legislation on the use of colours in foodstuffs, the use of these colours has hardly increased at all. Foodstuffs are still mainly being coloured with natural colours. It is quite obvious that consumer perception has greatly influenced the behaviour of the Finnish food industry and food trade. Furthermore, Finland is fully implementing the EU legislation concerning modern biotechnology. The authorities have actively informed the consumer and NGOs concerned of their

activities. Finland's policy has been to act as openly as possible. This also concerns policy on the labelling of GM-products. At the moment, the Finnish feed and food industry is avoiding the use of GM- and GM-derived products because of consumer concerns.

Co-Operation in a National Food Safety Strategy

One example of fruitful co-operation in Finland is the national food quality strategy, in which the entire production chain, from agricultural producers and industry to advisory bodies, trade, research and administration, is working systematically together to ensure high quality of foodstuffs. The aim is to adopt internationally approved environmental management and quality standards in agriculture, the food industry and trade by the year 2006. The intention is also to improve the competitiveness of agriculture and food production. In short, the challenge is threefold: quality, competitiveness and safety of food and agricultural production.

II. Overview of Food Safety Systems

2.1 The Control of Agricultural Production Inputs in Relation to Food Safety

Risk Management

The control of agricultural inputs - animal feed, seeds, propagating materials, fertilisers and pesticides - is organised on three different levels.

The Ministry of Agriculture and Forestry (MAF) is responsible for risk management, e.g. legislation and policy-making as well as direction and supervision of control. The ministry yearly approves control plans and participates in developing control systems. In policy making, the ministry is assisted by specific groups for each sector (feed, fertilisers, pesticides, and seed). The members consist of the interest groups concerned, e.g. other authorities, farmers' organisations, consumer organisations, relevant industry etc. In certain cases, e.g. pesticide approval, decisions are delegated to the pesticide board representing the authorities concerned.

The main responsibility for the implementation of control is given to the Plant Production Inspection Centre (PPIC) as the official national control organisation in the field of agricultural production inputs. PPIC is in charge of the control relating to the production, marketing and use as well as the import and export of agricultural production inputs. PPIC thereby carries out *risk management* measures as well as, to a certain extent, *risk assessment*.

At the regional and local level the control work is carried out by authorised inspectors and samplers as well as by regional agricultural authorities all over Finland (Rural Departments of the Employment and Economic Development Centres). The PPIC co-ordinates this work and practical control activities are based on annual control plans provided by the PPIC. In addition, the PPIC is assisted in import control by the National Board of Customs.

Risk Assessment

Is carried out by independent scientists and experts from national research institutes and authorities. The authorities, scientist and experts are consulted on approval procedures (e.g. feed additives, pesticides), on setting limits for undesirable products and substances in feed and any other questions, as well as in the preparation of legislation.

2.2 Food Control

Risk Management

In Finland food control is organised on four levels, comprising ministries, the administrative level of the central government, provincial governments and municipal food control authorities. The Ministry of Trade and Industry is responsible for food legislation concerning food safety and quality matters as well as their market control. The Ministry of Agriculture and Forestry takes overall responsibility for the control of primary production and the hygiene of foodstuffs of animal origin. The Ministry of Social Affairs and Health deals mainly with the hygiene of foodstuffs of non-animal origin and the hygiene of all foodstuffs at retail and catering level. The ministries assume overall responsibility for the development of food legislation.

The central administrative level is occupied by two enforcement authorities: the National Food Administration (NFA) and the National Veterinary and Food Research Institute (NVFRI). They are in charge of co-ordinating national food control services. NFVRI has enforcement responsibilities for the control of the production, processing and export of foods of animal origin, whereas NFA has enforcement responsibilities on all other foods and market control. The practical enforcement is carried out by local municipal authorities under the direction of provincial governments. Local municipal authorities take care of the control of intra-Community trade in foodstuffs of animal origin within the meaning of the Directive 89/662. The regional and local authorities exercise power only in their respective territories, whereas NFA and NVFRI are competent throughout the whole country. Some 40 municipal laboratories are recognised as official food control laboratories within the meaning of the Directive 93/99. The customs authorities and veterinary border inspection have responsibility for the control of foodstuffs of non-animal and animal origin respectively, imported from third countries.

Risk Assessment

So far systematic risk assessment has not been assigned specifically to any organisation in Finland. Hazard identification originates in most cases from food law enforcement authorities or from international fora. Continuous food surveillance provides data on the existing microbiological quality and levels of contaminants in foods. An important source of information is the ongoing market surveillance joint programme between the National Food Administration and the Customs authorities, in which both domestic and imported foods are included. Dietary surveys are carried out by the National Health Institute, which continuously monitors the dietary habits of consumers. Based on this information, intake estimates are drawn up. Recent intake estimations have been completed on food additives and PAH-compounds. Finally, hazard evaluation and risk estimation is performed by combining the available data. The key elements of the Finnish risk assessment are the co-operation of the authorities and widespread use of available data.

2.3 Risk Communication

Risk communication is carried out by all involved parties in co-operation with all the appropriate authorities and stakeholders. The principle of openness prevails.

Firstly, the transparency of all government activities is guaranteed by the Act on Openness of Government Activities. Everyone in Finland has the right to obtain information from official documents in the public domain. The act applies to all documents delivered to an authority and those prepared by an authority, including letters, applications, decisions, statements etc. Official documents are in the public domain unless specifically provided otherwise. Under the Constitution, documents may be kept secret only where provided by an Act. Furthermore, the Act imposes on the authorities the obligation to inform

the public of their activities. Control results are published regularly; e.g. all feed control results are published quarterly.

The National Food Administration (NFA), the National Health Institute and the National Veterinary and Food Research Institute co-operate in risk communication by e-mail and via extranet with all partners in environmental health control. The information material is disseminated to the regional and municipal authorities and to the media as soon as the first signs of a food related hazard is detected. If a food related issue is coming up for public debate, authorities often choose proactive communication and inform the public at once in an open way.

Press releases are compiled and co-ordinated with all the authorities participating in a food related issue. The press releases are delivered to the media by e-mail. In a risk situation the Internet is used effectively: all the press releases are published on the NFA web site and a special, interactive Internet site will be opened. NFA gets regular feedback from consumers via the web-site.

NFA has a toll-free information telephone for consumers containing the contact information of the local food control officers. Consumers can also listen to the latest press releases online. To make the food control work visible the National Food Administration organised in co-operation with other national, regional and municipal authorities and food research institutes a National Food Control Day in 1992, 1995 and 1998. The open doors in laboratories, lectures concerning food and food-related risks and special events proved very popular. The national and regional media covered the events exceptionally well.

A folder on health hazards has been compiled. The authorities have made guidelines for regional and local food control authorities for eventual health hazard situations. The folder explains how, what and where to inform in actual food- or health-hazard situations.

According to several research reports, 85 -90% of Finnish consumers trust government authorities as a source of information in food related issues. Consumers appear to trust the food control authorities, which also act and communicate openly at local level.

III. Activities in Addressing Food Safety Issues

3.1 Developing National Food Safety Frameworks

To improve the national co-ordination of food control at the central government level a project has been initiated to merge National Food Administration and the enforcement unit of the National Veterinary and Food Research Institute. The new organisation would be in charge of the enforcement for the control of all kinds of foods, including meat inspection. The new organisation would also be active in national food safety evaluation as well as directing the regional and local authorities. The new agency will eventually start in early 2001. Recent experiences from other EU member states will be considered in the planning.

3.2 Food Control from the Stable to the Table

Salmonella Control in Feed and Food of Animal Origin

Salmonella control in animal feed as well as the Finnish Salmonella Control Programme (SCP) for food products of animal origin are examples of the ‘farm to the table' food safety approach with an emphasis on the control of primary production. The fight against Salmonella (all serotypes) in feed over 30 years has been successful. There is a high level of hygiene in animal feed which has also been maintained after Finland's accession to the EU and the free movement of goods in the EU. There is no

doubt that this is one reason why there is such a low level of salmonella findings on Finnish farms today, below 1%. In recent years the feed industry has established its own control programmes in order to safeguard the high level of animal feed hygiene in co-operation with the national feed control authority.

The SCP is a binding legal measure stipulated in European legislation. All salmonella serotypes are included into the programme. The main objective of the SCP is to keep the level of salmonella contamination in beef, veal, and pig meat as well as poultry meat and table eggs clearly below 1% at the national level. This is carried out by taking 3,000 random samples per animal species, which makes it possible to detect at the population level a prevalence of salmonella of 0.1% with a confidence level of 95%. Breeding and production animals, carcasses and cut meat are included in the sampling scheme. Positive findings always trigger a corrective action. At farm level actions vary from culling to basic biosecurity measures according to the serotype detected. At establishment level actions are aimed to prevent the spread of contamination by destroying or heat-treating the contaminated products together with enforced cleaning and disinfecting procedures.

Finland requires equivalent guarantees concerning Salmonella contamination of meat and table eggs delivered from other member States or third countries and of that produced in Finland. Programmes approved by the European Commission are considered equal (the Swedish and Norwegian ones), while others have to examine consignments for Salmonella with negative results before dispatch.

The SCP has met its goals since it was launched in 1995. A cost-benefit analysis showed about a 1:5 return for the meat and a 1:20 return for the table egg control programme. Voluntary programmes concerning Campylobacter in poultry meat production and EHEC in milk and beef production are currently being piloted.

Cadmium in Fertilisers

Certain components of fertilisers such as heavy metals do, however, cause concern from an environmental and public health point of view. The uptake of heavy metals by plants introduces these toxic elements into the food chain. Finland has one of the lowest tolerance levels for cadmium in the world. For this reason derogation from the Community fertiliser legislation was accorded to Finland on joining the EU. According to the Accession Agreement Finland had the right to keep the existing limit value in force during the four-year transition period. The derogation was prolonged in 1998 for another three years during which the European Commission has to carry out a proper risk assessment of cadmium in fertilisers at EU level. In this process Finland's aim is to introduce the limit-value in the acquis.

3.3 Regulation of Modern Biotechnology

Finland is implementing fully the EU legislation concerning modern biotechnology. Modern biotechnology has been intensively discussed in public in recent years. The authorities have actively informed the consumer and involved NGOs in their activities. Finland's policy has been to act as openly as possible, including in the labelling of GM-products. At the moment, the Finnish feed and food industry is avoiding the use of GM- and GM-derived products.

3.4 Precautionary Principle

Finland suspended last year the use of antibiotics as growth promoters in animal production. The reason was the fear of possible transfer of resistant bacteria from animals to humans and the common aim in Finland is to keep the pool of antibiotic resistance bacteria as low as possible. The use of antibiotics

should be reduced where possible. This policy is shared by all sectors, agriculture, veterinary and human medicine.

The suspension of the use of antibiotic growth promoters was carried out voluntarily by the feed industry. The Ministry of Agriculture and Forestry took several measures in order to reduce the use of antibiotics in feeds in co-operation with farmers, the feed and food industry as well as with the research and extension services. The overall good health situation of animals in Finland, research on alternative products, improvement of animal feed composition and housing have made this development possible.

A precautionary approach has long been applied in Finnish food legislation, especially in questions relating to food allergens. Mandatory labelling of common allergens causing e.g. anaphylactic reactions has been practised in all foodstuffs. Similar labelling rules have now been proposed in the EU and international fora. Control of allergens has been introduced as a part of in-house HACCP systems in the food industry and especially in the catering sector. Registration of severe reactions due to inaccurate labelling or product faults has been introduced. Products and labelling are monitored and inspected regularly.

The high prevalence of coronary heart disease has been partly lowered by decreasing the salt intake of the population. Previously, salt was considered as food additive in national food legislation with maximum permitted levels in specific products, which were the main sources of salt intake. In order to encourage consumers to select low salt products (which are also low in sodium), mandatory national labelling rules are still in force. Due to these precautionary actions, combined with consumer information, salt intake has decreased markedly, especially in consumer risk groups.

Another example of the application of the precautionary principle is the control/management of adding vitamins and minerals to foods. If the fortification were free the producers could add nutrients to foodstuffs without limitations. The individual food products as such may contain safe amounts of added nutrients, but the cumulative intake could lead to the excessive intake of nutrients and give rise to health concerns. In the evaluation, the safety margin should be observed. For folate and vitamins A and D as well as for minerals like iodine, selenium, iron, copper and zinc, the safety margin is considered to be narrow. More research is also needed to confirm that the excessive intake of one nutrient does not harmfully affect the metabolism of other nutrients.

In order to apply the precautionary principle, the addition of nutrients to foodstuffs is regulated by law. Two mechanisms exist: either general permission or individual authorisation for a food product. The intake of nutrients by different population groups has to be evaluated before the addition can be authorised. A valid reason for the addition of nutrients has been regarded as being to correct proven insufficient intake or deficiency of a nutrient in a population group.

3.5 Regulatory Enforcement and Compliance

Monitoring and Surveillance of Food Borne Infections and Intoxications

Monitoring, surveillance and reporting of food borne infections and intoxications became mandatory when Finland, together with eleven other European countries, started the WHO/Euro Surveillance and Monitoring Programme. According to the guidelines laid down by the National Board of Health in 1980, the local health and food control authorities were to establish permanent joint groups for the surveillance of communicable diseases. During the early years some 60 to 80 outbreaks were reported annually. Most of the outbreaks at that time were reported to be caused by foods of animal origin. After the mid-eighties the number of reported outbreaks declined gradually and reached a steady level, some 30 outbreaks annually in the nineties. A remarkable under-reporting seemed obvious.

In 1997 the Ministry of Social Affairs and Health introduced new guidelines for surveillance and reporting. These guidelines involve an immediate preliminary notification from the local authorities to the National Public Health Institute when an outbreak is suspected. Effective co-operation between the local authorities responsible for the surveillance of communicable diseases, health protection and food control is to be established. This joint group is responsible for immediate sampling, co-ordination of countermeasures, communication between authorities, reporting of the case and communication to the public. By means of the preliminary notification the national authorities are made aware of the case and are able to use their expertise to assist the local authorities. Finally, the data are recorded in the national food poisoning register kept by the National Food Administration.

Thanks to the new system the number of reported outbreaks has dramatically increased. In 1997, a total of 68 outbreaks were reported. In 1998 the number rose to 95. During the past years the proportional share of foods of animal origin as a source of outbreaks has diminished and the role of sprouts, berries and other fresh produce has become almost as important as meat, milk, fish and products thereof. Along with this trend ”new” pathogens such as EHEC, Listeria and calici virus have emerged. Due to the early detection of the causative agents, effective countermeasures have been introduced. Two cases can be mentioned as examples.

In 1998 there was a campaign to increase the consumption of beans. Due to insufficient soaking and cooking, the lectins of the beans were not inactivated, which resulted in several cases of intoxication. The causative agent was soon identified and appropriate instructions were given to the catering business. In addition, warnings concerning sufficient soaking and boiling were added on packages which are marketed to the consumers. Calici viruses have recently caused several food poisonings in Finland. Due to the tightened monitoring, berries originating from Central and East European countries were identified as carriers of the viruses. Consequently, the National Food Administration gave instructions on sufficient heat treatments of the berries, which has resulted in a remarkable decrease in the number of reported calici cases.

3.6 Addressing Socio-Economic Concerns

Voluntary Restrictions on the Use of Food Colours

Before the accession of Finland to the European Union in 1995 there was remarkable public concern over the effects of EU legislation on food quality. In the public debate special attention was paid to the seemingly liberal EU legislation on food colours, and especially the azo dyes. Many of the azo dyes had been earlier permitted, but banned since 1979 due to suspected allergic effects. Consequently, Finnish consumers had been used only to natural food colours and they did not expect their food to be very bright coloured. Consumer organisations clearly indicated their dislike for the harmonisation of Finnish food additive legislation with the relevant Community rules.

Knowing the consumer expectations the Finnish food industry, followed by the food marketing chains, declared that they would refrain from the use of azo colours or the marketing of products containing them in the future. This was done despite the fact that the technical properties of azo dyes are superior to natural colours.

New harmonised food additive legislation, based on EU directives, has been applied in practice for three years. The effect of the new legislation on the use and intake of additives has been recently monitored. The survey concentrated on analysing most important food groups and additives from the intake perspective.

Despite the less strict legislation the use of colours has hardly increased at all. Foodstuffs are still mainly being coloured with natural colours (carotenes, caramel colour, carmine, chlorophyll and vegetable

carbon). Azo dyes are only sporadically found in foodstuffs, and exclusively in imported products. The concentrations on colours amount on average to just a few percent of the permitted maximum levels.

It is quite obvious that consumer perception has greatly influenced the behaviour of the Finnish food industry and food trade. This development is in our view a good example of addressing socio-economic concerns.

3.7 Communication and Consultation

In practice, the regulatory process involves a consultation process concerning all interest groups. Openness prevails, as explained above in point 2.2 (risk communication). The process is also carried out for information purposes as well as to assist the later implementation of regulations. In addition, the ministries possess permanent advisory boards such as the Advisory Board on Food of the Ministry for Trade and Industry. Furthermore, it is common practice by the ministries to create working groups for actual matters and problems. At the moment there are working groups in action, such as an interministerial working group on antibiotic resistance. In these boards or working groups, concerned authorities, scientists and experts as well as other interest groups such as industry and NGOs, are invited to take part.

3.8 Other Activities

Quality Data Bank

The Association of Rural Advisory Services and the Agricultural Data Processing Centre have begun to build an information bank for the benefit of the whole food chain. The newest information technology and the Internet will be used to gather information for stakeholders in the food chain in order to develop activities, show the origin of foodstuffs and their production method for domestic and foreign consumers. The documented information will form a part of quality systems. The basis of the quality data bank is formed by information on production methods provided by Finnish farms. Information is progressively added for later stages of the food chain and information on safety of products will be included as well.

Sophisticated Food Additive Intake Assessment Method

For the intake studies of food additives, a stepwise exposure assessment method was developed. It starts from the theoretical maximum exposure, but is further refined to a more sophisticated exposure assessment of individuals. The recent exposure estimate has been targeted especially at children from one to six years.

The selection of food additives started with a market survey. The usage of food additives, based on label information, was checked in over 1000 products. The products for laboratory analyses were chosen according to the market shares of the food products. Information on market shares was provided by the Finnish food marketing chains. The intention was to include in the survey those food products, which contribute most to the intake of food additives. The food products to be analysed cover at least 50% of the Finnish market. The weighted mean of the results was used for intake estimates. The sampling method, called the TOP 10-method, was developed especially for this study. It provides more exact information than any earlier method. The results of this survey are used in consumer information both by the food control authorities and health care centres.

The recent survey indicates that food additive intakes by children aged from 13 months to six years were on average at a safe level. Correlated with weight (compared to the ADI value) the children

had the highest intake of additives at two to four years of age. However, based on this and earlier studies, nitrite and benzoic acid intakes of children under three years seem to be problematic. The main sources of nitrites are sausages and benzoic acid juice concentrates. A three year old child can consume only one frankfurter a day without exceeding the nitrite ADI value or similarly drink only one large glass of fruit juice a day without exceeding the benzoic acid ADI value.

High consumers were identified with the 95th percentile of food additive intake. In regard to benzoic acid and nitrite, intake by high consumers in the age groups of 13 months to five years exceeded the ADI values. The intake of benzoic acid by high consumers was 101-160% of the ADI value when the actual weight of each child was used. The intake of nitrite was 121-189% of the ADI value, depending on the age point. The intake of other evaluated food additives was at acceptable and even very low levels in the high consumption group.

FRANCE

I. Introduction

- **France has opted to separate risk assessment and risk management**

The French Food Safety Agency (AFSSA) is responsible for providing scientific opinions for purposes of risk assessment.

Three government services, the *Direction générale de l'Alimentation* in the Ministry for Agriculture and Fisheries, the *Direction générale de la Concurrence, de la Consommation et de la Répression des Fraudes* in the Ministry for Economic Affairs, and the *Direction générale de la Santé* in the Health Ministry, are responsible for food safety within their respective spheres. They prepare regulations as necessary and conduct the relevant inspections for risk management purposes, under the authority of their Ministers.

The whole of the food chain is subject to inspection. The French approach places emphasis on multidisciplinarity and cross-cutting skills. At *département* level, prefects often make use of skills pools involving the various local inspection services to ensure that inspections are complementary and functionally organised. Risk assessment and risk management are both performed on an independent and transparent basis.

- **France has opted for a form of organisation under which inspection services can cover the whole of the food chain -- "from spade to fork"**

This comprehensive approach to inspection, together with the epidemic disease monitoring networks and product traceability, are the keystones of the French food safety system.

- **France, like the European Commission, considers that the precautionary principle may be applied under current international law when the scientific data available are incomplete or non-existent, pending further research findings**

France advocates a prudential approach in risk assessment policy while reserving application of the precautionary principle to risk management, notably in areas of scientific uncertainty, when the potential consequences of the risk are significant.

- **France argues that other relevant factors may be taken into account**

In France's view, factors other than scientific ones, responding to the expectations of civil society and consumers, should also be taken into account where appropriate (non-restrictive list: technical feasibility, economic impact, scope for inspection, animal welfare, environmental impact).

II. The French Food Safety System

1. Institutional Structures

In France, responsibility for regulating and inspecting food safety lies with three ministries:

- Agriculture and Fisheries
- Consumer Affairs (Ministry for Economic Affairs)
- Health.

They are responsible for framing regulation and for conducting inspections. Regulations are prepared by the central services of these ministries.

Field inspections are conducted in each *département* by the devolved services of the three ministries, established across the whole country. These are the local veterinary services of the *Direction générale de l'alimentation* (DGAL) in the Ministry for Agriculture and Fisheries, the local services of the *Direction générale de la concurrence, de la consommation et de la répression des fraudes* in the Ministry for Economic Affairs (responsible for consumer affairs), and the local health and social affairs services of the Health Ministry.

Within their respective spheres, these government services:

- Follow the work of OECD, the Codex Alimentarius, the Council of Europe and WHO.
- Draw on scientific expertise and take part in defining research policy on food safety and nutrition.
- Manage health alerts on a co-ordinated basis.
- Jointly validate guides to sound health and hygiene practices.

As a general rule:

- DGAL monitors safety in the agricultural and food sectors, more particularly with regard to animal foodstuffs.
- DGCCRF monitors food safety and product conformity.
- Inspections relating to drinking water or infections in humans are conducted by the devolved services of the Health Ministry.

These services have agreed protocols on the efficient organisation of inspections and work together to secure optimum inspection coverage.

Skills pools involving all government services concerned with food safety may be set up locally. Inspection services must be capable of "covering the ground" in all spheres.

The French approach thus places emphasis on multidisciplinarity and cross-cutting skills.

A. Direction Générale de l'Alimentation (DGAL)

DGAL is part of the Ministry for Agriculture and Fisheries. It exercises the Ministry's powers relating to plant and animal health and quality inspection of agricultural products and foodstuffs. Its area of competence is hence focused on hygiene, the organisation of quality systems, animal and plant health and, more broadly, safety in the food sector.

Its activities have a number of objectives:

Acting throughout the Food Chain

At the upper end of the food chain, DGAL intervenes in the fields of plant quality and health, and animal health and welfare.

DGAL frames policy on plant protection and health, and monitors implementation, in particular with regard to plant pests; it is responsible for bio-vigilance, with regard to experimentation and dissemination of genetically modified organisms (GMOs). It is concerned with authorisations to market phytopharmaceuticals, fertilisers, growth media, silage preservatives and agrofood disinfectants.

Similarly, it frames regulations on animal health and in particular epidemic disease monitoring and livestock disease control. It frames and implements regulations concerning veterinary pharmacy, the use of substances administered to animals, and feedstuff production and quality. It implements regulations concerning the identification and monitoring of animal movements, and animal welfare.

At all stages in the food chain, DGAL frames, implements and assesses hygiene regulations. It is concerned with primary production, health approval for units processing foodstuffs intended for human consumption, foodstuff transport and distribution, and collective catering.

DGAL takes part in framing regulations on product traceability.

It defines microbiological criteria, frames and implements surveillance and inspection plans relating to biological and phytochemical contaminants, environmental contaminants and mycotoxins, residues from veterinary medicine and prohibited substances that may occur in foodstuffs.

Last, it takes part in the management of health alerts and food poisoning outbreaks.

Bringing together trade and institutional actors, co-ordinating partners' activities concerning food quality and safety

For this purpose, DGAL takes part in mobilising scientific expertise and in defining research policy in its particular sphere. It directs the network of public and private laboratories involved with food and veterinary matters, and co-ordinates national health certification policy, for domestic trade and exports.

It serves as the secretariat for various committees and boards: in the plant sphere, the toxicology board, the approval committees and the bio-vigilance committee. It also serves as the secretariat for the *Conseil National de l'Alimentation* of the *Commission du Génie biomoléculaire*, and directs the section of the *Commission nationale des labels et de la certification de conformité* (CNCL) which is responsible for the approval of certification agencies.

It contributes to the validation of guides to sound health and hygiene practices proposed by trade bodies. It co-ordinates inspection criteria, and develops and validates the quality assurance procedures of

its veterinary inspection services. DGAL oversees the coherence and scheduling of the monitoring and inspection plans carried out by local veterinary services, and assesses the findings.

It promotes standardisation and accreditation in the food sphere.

Contributing to international recognition of the French food health model

DGAL follows the work of the European and Mediterranean Plant Protection Organisation (EPPO), FAO work under the International Plant Protection Convention (IPPC) and the work of the International Office of Epizootics (OIE).

Within the European Union it sits on the standing veterinary committee, and is responsible for follow-up to the Agreement on the Application of Sanitary and Phytosanitary Measures. It takes part in the European Commission's negotiations with non-Member countries on sanitary and phytosanitary matters.

It draws on the findings of the French veterinary health system to lift sanitary barriers to exports, and negotiates sanitary conditions for the import and export of animals and animal products.

Last, it co-ordinates operations by border inspection posts, and manages alerts from Community networks covering imports of animal foodstuffs. This co-ordinating work is in conjunction with the customs department.

DGAL has a staff of 190 at central level, and 4 300 in devolved services, across 100 local veterinary services and 22 regional plant protection services.

The local veterinary services, at *département* level, are concerned with enforcing regulations and conduct inspections relating to animal health, the environment and food safety.

The regional plant protection services in the regional agriculture and forestry directorates are concerned with controlling plant pests and protecting consumers and the environment through sustainable and more environmentally-friendly farming.

For operations extending beyond single *départements*, DGAL relies on the national veterinary health investigation teams.

B. Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF)

DGCCRF is part of the Ministry for Economic Affairs, Finance and Industry. It deals with the safety, conformity and quality of all consumer goods: composition, additives, authorised processing, labelling, trading practices, and so on.

Its main task is to ensure fair dealing between operators and fair dealing for consumers.

For this purpose it has a staff of 4 100 (including 2 000 investigators across the whole country) in its central services, 101 local directorates at *département* level, and specialist units for expert inspections and analysis. Eight laboratories, in the product inspection network, perform analyses requested during regular inspections or samples taken on local initiative.

DGCCRF frames circulars defining or improving the rules governing foodstuff safety and conformity (name, labelling, composition, etc.), inspects these products at all levels, in particular with

regard to hygiene, and has powers to investigate and bring proceedings. When a crisis or serious danger arises, it may prohibit the marketing of risk products or order firms to change manufacturing conditions.

It checks product conformity against labelling, verifies the substance of quality claims, and investigates false or misleading practices. It further checks that consumer safety requirements are observed: inspecting for additives, microbiological and chemical contaminants, etc.

Last, in all cases, it ensures that quality marks are properly employed via inspections and standing consultations with trade groups and consumers.

For inspection purposes its officials, under the authority of the public prosecutor, have wide powers such as right of entry to all business or production premises, rights to obtain and keep any papers relevant to the performance of their duties, and the right to seize or distrain products, in particular when they are dangerous.

C. Direction Générale de la Santé (DGS)

The Health Ministry conducts health monitoring by collating data (hospital statistics, pathology registers), collaborating with hospital specialists, referral centres, centres for poisoning treatment, toxico-vigilance centres and the National Health Monitoring Institute. This enables it to detect outbreaks of food poisoning.

DGS may request the French Food Safety Agency to assess food products that may entail risks for consumer health.

The Health Ministry also monitors the framing of regulations relating to foodstuffs and drinking water.

In addition, under the Public Health Code, all advertising for the general public, concerning products presented as being beneficial to health, including foodstuffs, must receive prior approval by the Health Ministry.

At devolved level, the health and social affairs directorates (DDASS) in each *département* inspect drinking water and food hygiene, in particular in collective catering.

2. Regulatory Framework

French foodstuffs law has built up over time and covers all sectors of production.

French regulations are based on EU provisions (regulations and directives) and on two fundamental enactments, France's Consumer Code and Rural Code, which are complementary in requiring monitoring of foodstuffs.

All products sold in France must comply with the safety regulations, whether made in France or imported. Importers are responsible for the safety of products which they sell in France, on the same basis as the producers. Importers must determine safety through inspection and through guarantees from suppliers.

EU Provisions

Virtually all provisions on food safety stem either from EU regulations (applying directly in France) or directives (transposed into national law by decrees and orders). The EU provisions concerned are listed in the preamble prepared by the Commission.

Consumer Code

Stemming from the Law of 1 August 1905 and the Consumer Safety Law of 21 July 1983, the Consumer Code is concerned with the product itself and its conformity with the regulatory framework in respect of safety, composition and mandatory accompanying information, in particular via labelling. It imposes safety as a general obligation and requires trade operators to ensure product conformity (self-inspection).

Rural Code

The Rural Code requires health and quality inspection of foodstuffs and the production thereof. It accordingly includes sanitary conditions in production premises among the matters to be inspected by government officials. Mandatory requirements for given categories of plant are certified by health approval. The Code has been strengthened in particular by the Law of 8 July 1965, on modernisation of the meat trade, the Law of 10 February 1994 on the marketing and import of products, and by the Framework Law of 9 July 1991 on product safety and traceability.

On the basis of these two Codes, two decrees were issued in 1971 and 1991 defining fundamental food hygiene rules for establishments involved in the production, transport, distribution, import and export of animal and plant foodstuffs. These regulations have been supplemented by numerous implementing orders, often transposing EU provisions. They are sectoral, concerning given categories of products (meat, processed meat products, dairy products, processed fruit and vegetables, etc.) or horizontal, regulating aspects of concern for all foodstuffs (microbiological criteria, transport, storage, collective catering, etc.).

The whole national regulatory framework is fully consistent with the European Union's drive to ensure high levels of safety.

Consultations may be launched on the framing of regulations; these may be scientific consultations, in which case the French Food Safety Agency is mainly involved, or consultations with partners in the trade or consumers. In the latter case, consultations are conducted via ad hoc working parties in the ministries concerned, or more formally within the National Consumer Council (CNC).

3. Risk Assessment

A new centre of expertise: the Agence française de sécurité sanitaire des aliments (AFFSA)

A Law of 1998 established a new expert scientific body, the French Food Safety Agency. Coming under the Ministries responsible for health, agriculture and consumer affairs, AFSSA is a key player in the new approach to the assessment and analysis of food health and nutritional risks.

The Agency must be consulted about any changes to laws or regulations relating to food safety, and may propose to the relevant authorities any measures that it considers appropriate to safeguard public health. It publishes its opinions and recommendations. It is now the national body for assessing food health and nutritional risks, combining various analysis and assessment units. It is responsible for helping to secure food health safety, from commodity production to distribution to the end consumer.

Expertise will be concentrated in consultative committees of specialists in areas including food and water hygiene, nutrition, special foodstuffs, animal feed and veterinary medicine.

AFSSA, which is also a research and technical support centre, is able to draw on 13 national laboratories, three of which are EU reference laboratories, with international reputations.

The establishment of the Agency stems from an internationally accepted approach, the separation of risk assessment and risk management.

4. Risk Management

In France risk management comes under the Ministries responsible for agriculture, consumer affairs and health.

Senior officials in the three ministries concerned co-ordinate regularly to shape approaches to risk management and monitor the implementation of agreed measures, in particular regarding inspection. They signed a co-operation protocol in September 1999 to deal with areas where they interact, to share information and to co-ordinate operations in the form of joint investigations.

The centralisation of risk management decisions, the organisational approach and co-ordination enhances the effectiveness of inspection services for emergency operations.

Inspections may be conducted on the basis of:

- Surveillance and monitoring plans.

- National or local programmes, reflecting the characteristics of farms and firms and potential risks in given products.

- Information obtained in particular from consumers or health authorities in other countries.

In all, nearly 8 000 people in France are involved in food health monitoring. Officials have numerous and varied powers of inspection, relating chiefly to production facilities, products themselves and the investigation of incidents concerning food.

In the field, local risk management decisions lie with highly skilled specialist officials, independent of sectoral interests and of local elected authorities.

Production Facilities

Food safety has to be monitored as far upstream as possible. Inspection teams accordingly check production conditions and self-inspection by firms. In addition, businesses manufacturing animal foodstuffs require health approval. Each facility is inspected before it can open, and then at regular intervals.

Production Inspection

Products are inspected throughout the process: manufacture, transport, storage and distribution. Conditions of storage (in particular temperature), composition and health characteristics are verified. These inspections are based on documentary checks or laboratory analysis of samples taken at every stage. DGCCRF has 8 laboratories and DGAL can draw on the network of local veterinary laboratories and the AFSSA network of reference laboratories.

Inspections of products and facilities also extend to animal feed.

Penalties

Inspection officials have powers to record and report infringements of regulations pursuant to the Consumer Code and the Rural Code. Various types of penalties, separately or together, may result from an inspection:

- A regulatory warning, which takes the form of a letter requiring the person or firm concerned to rectify the infringements noted within a reasonable time.
- An official report to the public prosecutor.
- A seizure or distraint order, which may be issued by inspection staff when they suspect or consider that goods are unfit for human consumption or dangerous.
- Closure by administrative order, when hygiene conditions are not complied with and public health risks may ensue. It will be ordered by the local mayor or the prefect, following a report by the head of a government inspection service or by the Minister of Agriculture, depending on the type of facility.
- Withdrawal of goods which are suspected to be dangerous.

Emergency Handling of Health Risks

In spite of government inspections, incidents may still occur. For consumer safety purposes, inspection services must be informed as swiftly as possible, and the authorities must have as accurate an assessment of the risk as possible and take the necessary steps to remove the danger.

For health monitoring, information has to circulate. Handling emergency health risks involves, for the authorities, permanent monitoring, effective collaboration between inspection services, and effective procedures for withdrawing suspect items.

Alerting Sources and Channels

Sources are varied, and may be a local or central government service, the EU alerting network, another country's embassy, or an international body. Scientists, the media, consumer associations and trade bodies may also give the alert.

The health monitoring arrangements established under the Law of 1 July 1998 include the Health Monitoring Institute (*Institut de veille sanitaire* -- IVS), which is based on the interregional epidemiology units and local directorates for health and social affairs. IVS has three functions:

- Health monitoring and observing health trends.
- Giving the alert, and recommending appropriate measures to the authorities.
- Identifying the causes of changes in health, in particular in emergencies.

These arrangements have, for instance, allowed the identification of groups of cases of listeria poisoning in humans, with co-ordinated measures taken as quickly as possible to find the foodstuffs causing the contamination.

5. Risk Communication

In France risk communication is the responsibility of the ministries in charge of food safety risk management. The communications units of the ministries or services concerned, depending on the level of risk in question, issue press releases warning consumers that products dangerous to health are on the market.

The French Food Safety Agency has to publish the scientific opinions that it issues concerning risk assessments.

In addition, consultative structures such as the national food and consumer boards provide opportunities, outside times of emergency, for exchanging information and establishing consensus on the broad lines of food policy, as between trade bodies, government and consumers.

III. French Activities in Addressing Food Safety Problems -- Emerging Issues

1. Recent Developments in France

See Section II.3 above: Establishment of the French Food Safety Agency (AFSSA) in March 1999, pursuant to the Law of July 1998. The Agency is responsible for risk assessment.

2. Regulation of Modern Biotechnology

Regulation of biotechnology is based on the relevant EU provisions. Risk assessment is conducted by an independent board, the *Commission du génie biomoléculaire*, and the Food Safety Agency AFSSA, whose powers extend to feedstuffs. The government is currently preparing to introduce a system for tracing GM foodstuffs (documentary traceability), to be supplemented by the provision of GMO identification sequences. A bio-vigilance scheme, at present focusing largely on monitoring the environmental effects of GMOs, has been set up. It will establish a historical record of commercial GMO dissemination in the environment. Supplemented by provisions concerning traceable use of GMOs in agrofood sectors, the French scheme will provide a consistent policy for managing potential risks related to GMOs.

3. Precautionary Approaches and Principle

France, like the European Commission, considers that the precautionary principle may be applied under current international law (Article 5.7 of the Agreement on the Application of Sanitary and Phytosanitary Measures; Agreement reached in Montreal at the end of January 2000 on cross-border trade in modified living organisms) when the scientific data available are incomplete or non-existent, pending further research findings, when the potential consequences of the risk are significant.

France advocates a prudential approach in risk assessment policy while reserving application of the precautionary principle to risk management, notably in areas of scientific uncertainty.

GERMANY

I. Synthesis

Germany is a federal republic with a federal constitution, the Basic Law. It consists of 16 federal Länder, each of which possesses its own constitution, its own government and its own parliament.

Legislation in the area of food and food safety is largely the accomplishment of the Federal Government. The Länder, on the other hand, are responsible for the implementation of the food regulations, in other words for the inspection services. In cases where the Federal Government fails to avail itself of its legislative competence, the Länder are entitled to issue their own legal regulations.

For many years now, Germany has had at its disposal a body of food legislation, which is especially oriented towards protecting consumers from damage to their health and from being misled. These regulations are constantly being developed further on the basis of the principle of preventive health protection. In keeping with this principle, foods in Germany may pose no risk to human health. The consumer must also be protected from deceit and he or she must be properly informed. In addition, there are numerous regulations, which serve to guarantee that foods are of a high quality.

Nowadays, German food legislation is shaped in many areas by Community law. In continuing to develop its food laws, the legislator allows itself to be guided by three fundamental principles:

1. Consumer health protection. In other words, protecting the consumer from health risks posed by foodstuffs must take absolute precedence over all other interests including economic ones.

2. Preventive consumer health protection, and therefore the application of the principle of prevention, should not only be developed further within the European Union but should become the foremost guiding principle internationally as well.

3. Consumers must be informed comprehensively, openly and honestly especially where labelling is concerned so that they are in a position to decide which foods they wish to purchase, on the basis of clear information.

Furthermore, a sufficiently high degree of quality in foods must be guaranteed in the interest of the consumer.

II. Overview of Germany’s Food Safety System

Risk Assessment

The official risk assessment of food in the Federal Republic of Germany is carried out primarily by the Federal Institute for Health Protection of Consumers and Veterinary Medicine. This Federal Institute is a scientific authority which falls within the Federal Ministry for Health's sphere of responsibility and has at its disposal scientists specialised in fields such as pharmacology and toxicology,

nutritional science, food chemistry, veterinary medicine, food hygiene and food technology and who, alongside their research activity in the field, are also involved in the risk assessment process.

The assessment of risks by the Federal Institute for Health Protection of Consumers and Veterinary Medicine involves investigating dangers posed by microbial, chemical and physical contamination of animal stocks used in the production of food and in foods themselves (food ingredients, food additives, substances migrating from materials coming into contact with foods, pesticide residues, residues from veterinary drugs, contamination by environmental chemicals) as well as nutritional and microbiological risks.

In addition to the dangers that can be posed by foods themselves in the narrow sense of the term, the risks which can be posed by articles having a gustatory or stimulating effect, tobacco products, cosmetics and other commodities are also assessed.

The Federal Institute for Health Protection of Consumers and Veterinary Medicine bases its risk assessment not only on the study of the relevant literature but also on its own research and expertise - for example the results of its own national food inspection activities coupled with the findings of its national laboratories and the European Union's reference laboratories - and, most of all, on external expertise. Where it is technically advisable to do so, the individual Land authorities responsible for food inspection are also involved in the process. In specific areas, the Federal Institute for Health Protection of Consumers and Veterinary Medicine also relies on the advice of its own scientific committees (the Plastics Commission, the Cosmetics Commission, and the Commission on Novel Foods among others). In other fields, close collaboration takes place with expert bodies outside of the Federal Institute for Health Protection of Consumers and Veterinary Medicine, for example with the German Research Association's Senate Commission on the Testing of the Health Safety of Foods, and with the federal research institutions within the sphere of responsibility of the Federal Ministry of Food, Agriculture and Forestry and the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. Furthermore, on special issues, ad hoc expert meetings are convened, working groups set up and scientific hearings conducted. Experts from the consumer side are also included in the expert discussions.

The results of the Federal Institute for Health Protection of Consumers and Veterinary Medicine's risk assessment mainly serves as a basis for the risk management efforts undertaken by the national legislator and those who issue ordinances, the food inspection services as well as the European authorities. The findings of the Federal Institute's risk assessment activities are also channelled into that institute's actions in the area of risk prevention in areas where it is competent (for example in the case of marketing authorisation decisions, especially those relating to veterinary drugs and pesticides, measures pursuant to the Ordinance on Novel Foods and the like). Its assessments are also of importance for measures taken by the food industry.

Risk Management

A. Legislation

1. Institutional Framework

Germany is a federal republic with a federal constitution, the Basic Law. It is made up of 16 federal Länder each of which possesses its own constitution, government and Parliament. The *"Länder"* themselves are further divided into *"Kreise"* (counties) or *"Gemeinde"* (local authorities) and in some cases in *"Bezirke"* (districts). The counties and local authorities have their own parliaments (county council, local board) and their own administrative bodies (local authority of the county, local government).

2. Legislation

a) The relationship between the Federal Government and the Länder and, in particular, the division of legislative competence between the Federal Government and the Länder is regulated by the Basic Law.

Food law is largely federal law since the provision of living conditions of uniform quality and the preservation of legal and economic unity makes federal regulation in this area necessary in the interest of the State as a whole. In cases where additional objectives are pursued by means of food legislation, for example market regulation objectives, the competence then lies with other ministries.

The Länder do, however, collaborate in the Federal Government's legislative efforts in the area of food law by means of the Bundesrat, the Länders' legislative body.

b) The competence for food-related legislation within the Federal Government lies with the Federal Ministry for Health in so far as health protection and protection of the consumer from deceit are concerned. Responsibility for specific contaminants in foods, however, falls to the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety whereas quality regulations for foods (such as wine, fruits and vegetables, eggs, milk and meat) fall within the competence of the Federal Ministry of Food, Agriculture and Forestry.

c) German food law is comprised of laws, ordinances and administrative regulations based thereon.

- Food laws are largely prepared by the Federal Government. They are adopted by the legislature, the German Bundestag, with the consent of the Bundesrat.

- Ordinances are issued by the responsible ministry and - to the extent that these are affected - prepared in agreement with other relevant ministries and subject to the consent of the Bundesrat. Ordinances can only be issued if the law makes provision for this in the form of a delegation of the power to issue ordinances, which must specify the content, purpose and scope of the regulation.

Administrative regulations serve to ensure uniformity in administrative practice.

3. Food Regulations

The most important law in the area of food safety in Germany is the Law on Foods and Commodities of 15th August 1974. As the central umbrella and framework law, it brings together the general legal regulations governing, above all, foods and certain commodities. The Law on Foods and Commodities essentially contains the general regulations whereas the special provisions are contained in ordinances.

The Law on Foods and Commodities and other food-related laws (such as the Meat Hygiene Act, the Poultry Meat Hygiene Act as well as the Wines Act) contain the main legal bases for food safety in Germany. Other laws such as the Drug Law, the Plant Protection Act, the Chemicals Act and the Foodstuffs Act contain provisions, which also serve to protect human health.

4. The Law on Foods and Commodities

The material regulations of the Law on Foods and Commodities are based on Germany's long-established principles regarding food legislation which have proved their worth, have been refined continually throughout the years and - where necessary - supplemented by new concepts. In the process, preventive health protection has been consistently given a more prominent role.

a) General protective regulations

According to the Law on Foods and Commodities, it is prohibited to manufacture for other persons, or to place on the market, any foods, which are likely to damage human health. It is also forbidden to manufacture, process or place on the market for other persons, products which can be mistaken for foods in such a way that a risk to health could occur as a result of the fact that they can be mistaken for foods.

The legal provisions therefore contain a comprehensive prohibition aimed at protecting the health of consumers from concrete dangers, which might arise in the food trade. The mere fact that a food is capable of causing damage to health suffices to prohibit its marketing without there being a need for certainty that the damage will definitely occur.

b) The delegation of powers for health protection purposes

The Law on Foods and Commodities contains many clauses, which delegate the power to issue ordinances in order to avert health risks. Prohibitions or restrictions can already be issued by means of an ordinance whenever this is deemed necessary to prevent a health risk. This makes it possible to act way in advance of a concrete danger to health, without a concrete ability to cause damage to a person's health having to exist. Action can already be taken in those cases where scientific findings presume that a danger exists without having to wait for proof of its existence. These clauses delegating the power to issue ordinances to this effect are therefore in keeping with the precautionary principle.

c) Prohibitions coupled with a reservation on the granting of permission

In Germany, what is known as the "prohibition principle" applies to food additives and to the processing of foods using ionising radiation. This means that additives are admissible in the manufacture of foods or foods may only be subjected to ionising radiation if this is expressly authorised by means of an ordinance issued by the Federal Ministry for Health.

The legal provisions governing food additives and the treatment of foods with ionising radiation are in keeping with the internationally debated "precautionary principle". These are furthermore supplemented by a legal provision which specifies that additives authorised by ordinance for use in the manufacture of foods as well as the authorisation of the use of ionising radiation for the treatment of individual foods must be indicated on the labelling in each case. This information is intended to enable the consumer to decide whether he or she is willing to purchase foods manufactured using additives or with the aid of ionising radiation.

The regulations contained in the Law on Foods and Commodities with regard to pesticide residues and other agents, as well as on substances with a pharmacological action, are also in keeping with the precautionary principle.

d) Food monitoring

The regulations on food monitoring introduced in 1994 have placed Germany in a position to recognise the danger posed by undesirable substances which may be hazardous to health (such as pesticides, heavy metals and mycotoxins) at an early stage and assess the risks involved. The aim is also to improve the necessary provision of information about residues and the contaminants in foods for the public.

e) The import and export of foods

Foods which are imported into Germany are subject to German food regulations. In the case of Member States of the European Union as well as for States Parties to the Treaty on the European Economic Area, the freedom of the movement of goods is guaranteed under the provisions of the Treaty on European Union and the Treaty on the European Economic Area.

Foods for export are also subject to the German food regulations, especially those legal regulations that have been issued for the purpose of health protection. In such cases, an exception can only be made if other requirements have to be fulfilled in the country of destination and if necessary, plausible reasons can be given why the products meet these requirements.

5. Public Hearing

Prior to the issuing of food legislation and ordinances, experts from scientific, consumer and the affected business circles are heard. This ensures public participation in legislative projects regarding the manufacture and placing on the market of foods, as well as the latter's advertising here in Germany.

B. Food Inspection

Even in the area of food inspection, the implementation of which falls within the competence of the Länder, the Law on Foods and Commodities provides the general legal framework. Food inspection serves to monitor the observance of food regulations and thus to protect human health and to protect the consumer from deceit. Establishments handling food products are inspected at regular intervals on the basis of sampling and inspection plans. These inspections, which are conducted without prior notice, cover all food groups and all types of establishments ranging from manufacturing establishments to sales outlets to the consumer. The inspections cover all operating rooms, all objects which come into contact with foods and vehicles used in the transport of foods, as well as the measures taken by the firm itself within the framework of its own internal inspections (HACCP). As a result, food inspection embraces all of the areas, which form part of the food chain.

Establishments, which manufacture, process or place easily perishable foods on the market are supervised with special care. The test results from samples taken there are recorded and transmitted in the form of a report to the local administrative authority.

A veterinary examination of live cattle is conducted immediately before the animals are slaughtered. A subsequent examination of the meat determines its wholesomeness. In such cases, the meat is judged to be wholesome, not wholesome or wholesome after handling and labelled accordingly. Any meat, which leaves the abattoir as subjected to additional tests before it reaches the consumer: during transport, storage, further processing and when it is placed on the market.

In the case of easily perishable goods of animal origin such as meat, milk, fish, eggs and products manufactured from them, the authorities of the individual Länder conduct food hygiene inspections to check the implementation and application of the specific product-related hygiene provisions

(for example those contained in the Meat, Poultry, Milk and Fish Hygiene Ordinances). The veterinary checks begin with the animal stocks and extend for example to the abattoirs and cutting plants, milk treatment and processing plants as well as those establishments which process fish.

The competence of the Länders' food inspection services also extends to the examination of tobacco products, cosmetics and other materials and objects such as packaging paper, foil, plastics and containers in which food is stored.

Risk Communication

Food Monitoring

The legal regulations on food inspection introduced in 1994 placed Germany in a position to identify dangers to health posed by undesirable substances in foods in good time and to assess the risks they imply. One of the aims of these regulations is also to ameliorate the information accessible to the public about residues and contaminants in foods. In doing so, food monitoring makes its contribution in the area of risk communication.

Furthermore, the Federal Ministry for Health, the Federal Centre for Health Education and the Federal Institute for Health Protection of Consumers and Veterinary Medicine make use of the various media to educate and inform consumers about foods and nutrition.

GREECE

I. Synthesis

1.1 The EU Institutions (Parliament, Council, Commission and Committees)

1.2 The Greek Ministries of Food Safety System in Cooperation with the EU Institutions.

– Ministry of Agriculture Fisheries and Forestry

– Ministry of Finance (General Chemical State Laboratory)

– Ministry of Health

– Ministry of Development (Department Of Commerce)

– Ministry of Public Order

1.3 The Legislation in Food

1.3.1 Primary and Implementing Legislation

The EC in cooperation with competent authorities of the Ministries of MS, make draft proposals to be forwarded and adopted by the Council or the Parliament.

1.3.2 Legislation Applicable to the MS

The competent authorities are responsible for application and transposition of the EU food law to the National practice.

1.4 The State Responsibilities

1.4.1 Animal Feed Control

Central and regional services are responsible for the controls, sampling and analysis of feedstuffs. Local committees are responsible for administrative and penal measures in the case of non-conformity.

1.4.2 Foodstuffs of Animal Origin

Different local authorities carry out the official controls, mainly by the veterinary services. A network of analytical laboratories is established throughout of the country.

1.4.3 Foodstuffs of Plant Origin

Official inspection authorities mainly from the Agricultural Ministry exercise the controls. The samples are forwarded to the appropriate analytical laboratories.

1.4.4 Exports – Imports

The exports of food are regulated by bilateral agreements. The imports include phytosanitary and Veterinary health controls.

1.5 Food Risk Analysis Mechanism in Greece.

The mechanism includes a number of Scientific Committees for excellence, independence and transparency be ensured in the food risk assessment. Beyond them many other NGOs, consumer groups etc take part in the risk management and risk communication.

II. Other Activities in Food Safety Issues

The establishment of the HELLENIC FOOD AUTHORITY under the recent Law N2741/28-9-99.

Overview of the Greek Food Safety System

2.1 EU Institutional Structure (see EU food safety system)

2.2 Greece Institutional Structure

Greece participates in the EU Parliament with 26 national representatives, in the EU Council with one representative. The Greek Permanent Representation for EU in Brussels is in a continuous cooperation and coordination in different actions.

The Ministries which participate in food safety system in Greece with the main actions are as follows:

2.2.1 Ministry of Agriculture

- General Directorate of Plant Production (With a network of regional authorities and laboratories).

Action: Phytosanitary issues, Quality control, standardization and safety of foodstuffs of plant origin, controls of pesticide residues, contaminants, nitrates, checks of food industry establishments, labeling rules, Novel Foods, contribution to National Organizations (Codex Alimentarius, UN/ECE etc.

- General Directorate of Animal Production (With a network of regional authorities and laboratories).

Actions: Quality control and standardization of feedstuffs. Control of feedstuff residues, material used in animal nutrition, labelling rules, undesirable substances, inspection, sampling, analysis, etc.

- General Directorate of Veterinary (With a network of regional authorities and laboratories).

Actions: Sanitary issues of foodstuffs of animal origin, veterinary checks and food industry establishments, materials prohibited as feedstuffs for public or original health reasons, antibiotics and feedstuffs for specific health purposes etc.

2.2.2 Ministry of Finance

- General Chemical State Laboratory (With a network of regional authorities and laboratories).

Actions: chemical analysis of foodstuffs for imports – exports, National Codex Alimentarius, Transposition of the EU legislation into National law in food additives, Novel food issues etc. Chemical control, labeling control, packaging control etc.

2.2.3 Ministry of Health

- General Directorate of Public Health (With a network local authorities).

Actions: Hygienic control of food industry installations and instruments, legislation on toxicological and microbiological examination of food acts on hygienic food control.

- Hygienic School of Athens for education of personnel of Public health authorities and Nutrition.
- Central Health Council part of which is the Food Committee.
- National Organisation for medicines, scientific councils for dietary products.

2.2.4 Ministry of Development (Department Of Commerce) (With a network local authorities)

- General directorate of consumers protection.
- Directorate of analyst laboratories
- Action: Acts on market control issues (including foodstuffs issues), inspection of retail shops of foodstuffs, sampling of foodstuffs for analyst laboratories.
- Commission for administrative penalties.

2.2.5 Ministry of Public Order (With a network of local authorities)

- Directorate of market inspection.

Action: inspection of food market (especially for foodstuffs of animal origin). Inspection of retail foodshops and wholesale markets. Application and enforcement of the foodstuffs legislation and impose of sanctions.

2.3 Food Legislation

2.3.1 Primary and Implementing Legislation.

The European Commission (EC) in cooperation with the competent authorities of the Ministries of each member state (MS) makes legal proposals to be forwarded to the European Council and European Parliament for adoption.

2.3.2 Application of Legislation from Greece

The transposition and the coordination of the EU food law with the National law is the responsibility of the competent authorities of each Ministry. The Regulations are directly applicable in Greece probably accompanied with explanatory ministerial Decisions, and amendments of the existed food law. The transposition of the Directives takes place with Presidential Decisions of interministerial Decisions, or other administrative actions.

The Recommendations and Opinions have no binding force, so they are taken into account when explanatory decisions are made for food control application.

2.4 State Responsibilities

2.4.1 Animal Feed

Controls on feed (inspection, sampling and analysis) are carried out by the competent authorities of the Ministry of Agriculture. There are regional services throughout the country, which are responsible for inspection and sampling. The samples are sent to the local laboratories for analyses and for safety evaluation. The local feedstuff committees are responsible for the administrative and penal measures taken in the cases of infringements in co-operation with the co-responsible services of the Department of Commerce.

2.4.2 Foodstuffs of Animal Origin

The controls of rules for raw materials, production conditions, the competent authorities of the Ministry of Agriculture carry out hygienic requirements, microbiological criteria, labeling and packaging. The same authorities are responsible for the storing, handling and transport in cooperation with competent authorities of the Ministry of Health and Department of Commerce. All relevant establishments as slaughterhouses, cutting and processing plants, egg processing and packaging plants etc. are registered and approved.

Different local authorities depending on the purposes of control carry out the official controls for safety assessment. The samples are forwarded to the proper laboratories for analyses. The Ministry of Agriculture authorities is responsible for production conditions until the product arrives to the retail market (Veterinary Services). In the places of super markets and restaurants, as final products of animal origin, the responsibility for application of the rules belongs to the Ministries of Agriculture, Commerce, Health and Public Order. In any case the cooperation and coordination of the control services is important for the effectiveness of the control.

For the control of safety of drinking waters, the competent authority of the Ministry of Health is fully responsible, with its local authorities throughout the country.

2.4.3 Foodstuffs of Plant Origin

The Ministry of Agriculture exercises the controls in foodstuffs of plant origin. The official safety controls are made from the farm as good agricultural practice, production conditions (use of agrochemicals), defined standards, processing conditions, labeling, packaging until the retail-market. The local services exercise the inspection, sampling, and forward then to the appropriate analytical laboratories for check on pesticides residues, heavy metals, nitrates, mycotoxins etc. Next in the retail market the official controls are exercised by the Ministry of Health, General Chemical State Laboratory and Department of Commerce, doing inspection, sampling, analytical work etc. In any case the competent authorities according to the national law may take administrative and penal measures.

2.4.4 Exports – Imports of Foodstuffs

Exports are meant with the third countries (outside of (EU). Those are regulated by bilateral agreements. So the official controls are responsible for the meeting of requirements, of the importing country, and they are exercised by different competent authorities of the above mentioned, depending on the product exported and the degree of processing.

For imports the official control of safety requirements are those of internal market regulated by EU. The official competent authorities in imports are mainly from the Ministry of Agriculture (Phytosanitary controls, Quality controls, Safety controls, and Veterinary controls) and the General Chemical State Laboratory.

2.5 Food Risk Analysis Mechanism in Greece

2.5.1 Risk Assessment

There are some permanent Scientific Committees as the Phytosanitary Committee, Veterinary Committee and the Public Health Committee and the occasional advisory Committees. The targets of the scientific committees system for food risk assessment arise from the necessity for excellence, for independence and for transparency which means consumers confidence. The members of scientific committees are high experienced scientists from Research Laboratories and from the Universities. For the Novel foods and biotechnological products there is a General Biotec Committee and case by case Committees depending on the product assessed and on the specific conditions and methods used. So in Greece there are three assessment bodies, for agricultural products, for Chemical products and for Medical, drug products and products for specific Nutrition.

The research institutions of the country also play an important statutory role in food risk assessment system, especially in emergency cases. Such institutes are the Institution of Public health the Institution of Food Hygiene the Institution of Agricultural research.

2.5.2 Risk Management, Risk Communication and Rapid Alert System

The above mentioned Committees and Institutions also play an important role in food risk management and risk communication. Beyond of these committees, there are many others as NGOS, special groups and of interest, Consumers Committees or Institutes, Green Peace branches in Greece etc. Where there are scientific uncertainties the acceptable level of risk for the consumers or for the environment is a political responsibility. The precautionary measures are taken after the proposals of scientific groups of experts aiming to achieve a high level of protection of consumers. The press and the media also play a very important role in the risk communication system.

In the EU there is an alert notification system for products or foods carrying a serious risk. The contact point for the Commission (EC) in Greece is the General Chemical State Laboratory from which the notification is dispersed to the competent authorities and groups of interest through out the country.

III. Activities of Greece in Addressing Food Safety Issues –Hellenic Food Authority

A new one authority is established under the recent Law No 2741/28-9-99, intended to undertake and co-ordinate all the above mentioned actions on food safety issues in order to:

- Create a unique confrontation of food safety in Greece.
- Promote effectiveness in consumers confidence
- Co-ordinate actions with the new coming European Food Authority.

IRELAND

I. Synthesis

Introduction

Food production is vital to the Irish economy with Agri-Food products accounting for over one-third of net foreign exchange earnings. A growing consumer demand for safe food, as well as exacting export market requirements, are the driving forces for high standards in food safety.

The Historical Context

Up to recent times food safety policy and implementation was dealt with in Ireland through a number of Government Ministries, and implemented either directly by those Ministries or through Agencies operating under their control. A large number of local and regional agencies were involved in and delivered food safety services at that level. Furthermore, Ireland, as a member of the European Union, is part of the Union's Food Safety System. This overview of the Irish food safety system must therefore be read against the background of the role of the European Union.

The Establishment and Role of the Food Safety Authority of Ireland

In March 1996, the Government initiated a review of Ireland's food safety system. Resulting from this the Food Safety Authority of Ireland (FSAI) was established as a statutory, independent and science-based body. The FSAI is responsible for (a) providing policy advice to regulators in relation to food safety issues, (b) ensuring the co-ordinated and seamless delivery of food safety services to an agreed high standard by the various state agencies involved, and (c) promoting communications, education and information on food safety matters. The advisory function of the FSAI is carried out through a Scientific Committee consisting of 15 members appointed for their expertise.

The enforcement of food safety legislation relating to on farm activities was not included within the scope of the enforcement measures encompassed by the FSAI. Such legislation is enforced by the Department of Agriculture, Food and Rural Development in relation to farm animals and by the Department of the Marine and Natural Resources in relation to fish and other marine life.

Food Safety Promotion Board

An Agreement between the Government of Ireland and the Government of the United Kingdom and Northern Ireland provides for a "cross-border body" dealing with certain food safety functions with a mandate covering both parts of Ireland. At the time of writing the future role of this Board is dependent on progress in the current talks on the Northern Ireland situation.

Role of the Ministries

As regards the policy and legislative function (risk management functions), four Government Ministries are primarily responsible, i.e., the Departments of Health and Children; of Agriculture, Food

and Rural Development; of the Marine and Natural Resources; and of Environment and Local Government.

In settling policy there is no express legislative requirement to consult with and have regard to the advice of the FSAI in determining that policy and regulating for it. However the requirements in administrative law of objectiveness and reasonableness, and the political determination to regulate following sound independent advice, means that this is the practice. All documents relating to policy determination and regulation are also subject to freedom of information legislation, thus ensuring transparency.

II. Introduction

Food production is vital to the Irish economy with Agri-Food products accounting for over one-third of net foreign exchange earnings. The raw materials for Ireland's food come chiefly from extensive grassland farming systems. The greater proportion of production is exported so the industry is export oriented. A growing consumer demand for safe food, as well as exacting export market requirements, are the driving forces for high standards in food safety. Quality and safety of products are most important.

In Ireland responsibility for the determination of food safety policy (risk management) rests with a number of Ministers of the Government, with the Minister for Health and Children taking a co-ordinating role. Scientific advice upon which such policy decisions are taken (risk assessment) is obtained from the Scientific Committee of the Food Safety Authority of Ireland, a committee composed of independent experts. Food Safety services (risk management) are delivered through a number of different Government Departments and agencies at national, regional and local level. The Food Safety Authority is responsible for ensuring the co-ordinated and seamless delivery of food safety services to an agreed high standard by those agencies. The Food Safety Authority is also responsible for promoting communications, education and information on food safety matters (risk communication).

Ireland, as a member of the European Union, is part of the Union's Food Safety System. The contribution by the Commission of the European Union sets out the factual description of the institutional structure and regulatory framework of the Union's Food Safety System and highlights the already extensive role which the Union has in the determination of food safety policy and regulation in Ireland, and in auditing compliance with those requirements. This overview of the Irish food safety system must therefore be read against the background of the role of the European Union.

III. The Historical Context

Up to recent time's food safety policy and implementation were dealt with in Ireland through a number of Government Ministries, and implemented either directly by those Ministries or through Agencies operating under their control. Four Government Ministries were primarily involved, the Department of Health and Children, the Department of Agriculture, Food and Rural Development, the Department of the Marine and Natural Resources, and the Department of Environment and Local Government.

The Department of Health and Children's role related primarily to horizontal measures (the general rules for food safety and their implementation at retail level though Health Boards and Local Authorities), the Department of Agriculture, Food and Rural Development's role related to specific sectoral measures concerning food derived from non-marine animals (for example the specific rules governing controls on the use of medicines, pesticides, biocide plant protection products, and other substances, the application of measures relating to zoonotic diseases in food animals, the production and inspection of animal feed, meat and meat products, eggs and egg products, and milk for both home and

export markets, etc), the Department of the Marine and Natural Resource's role related to those vertical issues concerning food derived from the marine (for example the specific rules governing fish and fishery products, live bivalve molluscs, etc.), and the Department of Environment and Local Government's role related to the implementation of certain food safety measures through regional government (Local Authorities). A large number of local and regional agencies were involved in and delivered food safety services at that level, namely the Local Authorities and Health Boards.

IV. The Establishment and Role of the Food Safety Authority of Ireland

In March 1996, the Government initiated a review of Ireland's food safety system and an Interdepartmental Group was established by the then Government to conduct that review. It submitted a report to Government in September 1996 recommending, amongst other things, the establishment of an independent food safety organisation. The Government, in its "Action Programme for the Millennium", considered that customer confidence, both at home and abroad, in Irish food products needed to be paramount. It maintained that Ireland must be in a position to give independent and verifiable assurances as to the quality and purity of its food products. It therefore proposed the establishment of the Food Safety Authority of Ireland (FSAI) as a statutory, independent and science-based body, overseeing all functions relating to the food safety regulation of the food industry. The Food Safety Authority of Ireland was set up under interim legislation on 1st January 1998 pending enactment of primary legislation. On 1st January 1999, the Authority was formally established under the Food Safety Authority of Ireland Act, 1998.

Ensuring Compliance with Food Safety Legislation

The Act (a) established the Authority as an independent body accountable to the Minister for Health and Children, (b) transferred all responsibility for ensuring compliance with food safety legislation to the FSAI, (c) conferred powers on the Authority (which included those powers available under existing food safety legislation, as well as additional new enforcement powers), (d) provided that the existing food control enforcement arrangements at local and national level would remain in place, but would be carried out under 'contract' to the FSAI by the various public bodies involved in food safety services delivery, and (e) provided mechanisms for the FSAI to keep food safety service delivery under review and to report to the Minister for Health and Children in relation to such matters, in particular on the scope for better co-ordination and delivery of the food inspection services.

The enforcement of food safety legislation relating to on farm activities was not included within the scope of the enforcement measures encompassed by the FSAI. Such legislation is enforced by the Department of Agriculture, Food and Rural Development in relation to farm animals and by the Department of the Marine and Natural Resources in relation to fish and other marine life.

Provision of Independent Scientific Advice on Food Safety matters

The Act also provided for the establishment of a Scientific Committee of the FSAI consisting of 15 members. This enabled the FSAI, either on its own initiative or at the request of a Minister, to provide scientific advice on any issue relating to Food Safety. The members of this Committee are appointed by the Minister for Health and Children on a periodic basis following consultation with the Board of the FSAI. All material produced is open to public inspection through Freedom of Information legislation. Thus the competence of the expertise, their independence and the transparency of the process is ensured.

This Scientific Committee has established a number of specialist sub-committees in the various areas of food safety. Their task is to prepare the work of the main committee and advise it on the various

issues involved. To these sub-committees independent experts in fields appropriate to the sub committees' remit are appointed.

Promoting Communications, Education and Information on Food Safety Matters

With regard to communications, education and information, the FSAI was also given a key role in (a) establishing and managing public relations and promotional activities, and (b) developing and implementing policy on communications, education (training) and information for consumers, industry and food safety enforcement officers, etc. To this extent it is therefore responsible for Risk Communication.

Service Contracts

The FSAI operates by means of service contracts with the agencies currently engaged in the enforcement of food safety legislation. These agencies act as agents of the Authority in the performance of their contracts, and the Authority publishes details of these contracts. It may also publish reports on any matter related to its remit and functions and in particular it must publish an annual report, which will be laid before each of the Houses of Parliament. These arrangements are designed to ensure a much greater degree of transparency and information about food safety generally and about the operation of the control system. The FSAI has finalised the details of its first service contracts with food control agencies at central and local level. These contracts are with the (a) the Department of Agriculture, Food and Rural Development, the Department of the Marine and Natural Resources, and the Department of Environment and Local Government, and (b) the regionally based Health Boards, the Local Authorities, and the Director of Consumer Affairs. (There is no contract with the Department of Health and Children, as it has no executive functions in relation to food safety)

Structure

Led by a Chief Executive, the FSAI is controlled by a Board, which consists of ten members, each of whom has been appointed by the Minister for Health and Children. To ensure that the Authority has access to the views of all the stakeholders involved in the production and consumption of safe food, the Act requires that a Consultative Council of 24 members be set up, 12 members appointed by the Government and 12 members appointed by the Board. As regards the staff of the Authority, the organisation itself is a multidisciplinary one, and has recruited many specialists, for example public health doctors, veterinarians, food scientists, environmental health specialists, microbiologists, public relations specialists and administrators.

Broadly speaking therefore the FSAI is responsible for (a) providing policy advice to regulators in relation to food safety issues, (b) ensuring the co-ordinated and seamless delivery of food safety services to an agreed high standard by the various state agencies involved in the delivery of such services, and (c) promoting communications, education and information on food safety matters.

V. Food Safety Promotion Board

In addition to the above, and under the terms of an Agreement between the Government of Ireland and the Government of the United Kingdom and Northern Ireland, a "cross-border body" dealing with food safety issues was established with a mandate covering both parts of Ireland. To implement this Agreement, the British-Irish Agreement, Act 1999 was enacted on 22 March 1999 and provides for the

establishment of a "Food Safety Promotion Board". At the time of writing the future role of this Board is dependent on progress in the current talks on the Northern Ireland situation.

The Food Safety Promotion Board has/would have an all island remit in relation to six particular food safety related functions, namely (a) Promotion of Food Safety, (b) Research into Food Safety, (c) Communication of Food Alerts, (d) Surveillance of Food Borne Diseases, (e) Promotion of Scientific Co-operation and Linkages between Laboratories, and (f) Developing cost-effective facilities for specialised laboratory testing. These functions, formerly exercised by the Dept. of Health and Children and/or Food Safety Authority of Ireland, will/would in future be exercised by the Food Safety Promotion Board.

VI. Role of the Ministries

As regards the policy and legislative function (risk management functions), the four Government Ministries mentioned above as primarily responsible, i.e., the Department of Health and Children, the Department of Agriculture, Food and Rural Development, the Department of the Marine and Natural Resources, and the Department of Environment and Local Government, retain their policy and regulatory functions. In this respect the Department of Health and Children's role relates primarily to horizontal measures (the general rules for food safety and their implementation at retail level though Health Boards and Local Authorities), the Department of Agriculture, Food and Rural Development's role relates to specific sectoral measures concerning food derived from non-marine animals (for example the specific rules governing controls on the use of medicines, pesticides, biocide plant protection products, and other substances, the application of measures relating to zoonotic diseases in food animals, the production and inspection of animal feed, meat and meat products, eggs and egg products, and milk for both home and export markets, etc), the Department of the Marine and Natural Resource's role related to those vertical issues concerning food derived from the marine (for example the specific rules governing fish and fishery products, live bivalve molluscs, etc.), and the Department of Environment and Local Government's role relates to the implementation of certain food safety measures through regional government (Local Authorities).

In settling policy there is no express legislative requirement to consult with and have regard to the advice of the FSAI in determining that policy and regulating for it. However the requirements in administrative law of objectiveness and reasonableness, and the political determination to regulate following sound independent advice, means that this is the practice. All documents relating to policy determination and regulation are also subject to Freedom of information legislation, thus ensuring transparency.

ITALY

I. Synthesis

General Organisation

The Italian monitoring and management system for foodstuffs safety guarantees the implementation of EU provisions and introduces some additional elements for foodstuff safety and control under the subsidiary principle.

At the central level the Ministry of Health, through the Department for Food, Nutrition and Veterinary Public Health (DANSPV), performs guidance, co-ordination and verification tasks on the activities performed at the local level. The national production system in the foodstuff sector requires a health authorisation granted at the local level by the Regional authorities and by their subordinate operational bodies (Local Health Unit- LHUs).

Official Control

The Ministry of Health, through the DANSPV, manages the National and EU alert system and co-ordinates its activities at the local level. Moreover, permanent operational monitoring systems have been set up as far as foodstuff security is concerned, performing checks on the whole production chain from feedingstuffs to foodstuff control and to the processing stages.

In particular, national monitoring programmes on veterinary drug residues, environmental contaminants and any possible illegal use of substances (such as hormones) have been in place for numerous years, as well as control programmes on pesticide residues in products of plant origin and microbiological contamination in food of animal origin.

The local control activity is performed by the Regional authorities and by the Autonomous provinces by means of their subordinate operational bodies in the veterinary and health fields (LHU Prevention Departments, Istituti Zooprofilattici Sperimentali, Local Prevention Bodies – PMPs -, Regional Authorities for Environment Protection – ARPAs).

The control on imported foodstuffs is carried out by health bodies directly dependent on the Ministry of Health (Border Inspection Posts, Harbour or Airport Inspection offices). Intra-community trade is dealt with by the Veterinary Offices for the Enforcement of EU provisions (UVACs), also dependent on the Ministry of Health. The control activity aimed at safeguarding foodstuff quality, also with a view to preventing and suppressing food frauds and adulterations, is performed by the Ministry of Agriculture and Forestry by means of its subordinate structures (Central Inspection Service for Fraud Repression– ICRF – and its peripheral sections).

Developing Sectors

The sectors currently being developed and requiring a special attention by the national control authorities are the novel food sector and food ingredients deriving from GMOs, feedingstuffs and residues in foodstuffs, new contaminants. Lacking indisputable scientific elements, the national health authorities rely on the precautionary principle as an appropriate tool to safeguard public health.

Future Prospects

The control system on food safety currently in place in Italy appears to comply with the criteria adopted or under adoption at the EU level. In the future the above described system is likely to be strengthened and upgraded in view of adjusting the standards of food safety and consumers' protection to the guidelines supplied by the EU Commission White Paper.

II. General Principles and Organisation of Food Safety Systems

In Italy the safeguard of food safety relies mainly on the official control activity performed by the Ministry of Health with its central and local offices, and by the Regional authorities and Autonomous Provinces through their local bodies. Within the Ministry this issue (included the whole veterinary planning and the management of peripheral offices) is completely dealt with by the Department for Food, Nutrition and Veterinary Public Health. Mercantile checks on the agricultural and food chains, aiming at safeguarding the quality of products, have been entrusted to the Ministry of Agriculture and Forestry, which acts through its central and peripheral offices.

The official control activity is regulated both by the EU provisions transposed into the Italian legislation and by previous legal provisions of national origin. The provisions of national origin have been issued since the 60s and represent a general legal basis for the safeguard of food safety. The national legislation also contains specific requisites for numerous activities concerning foodstuffs, subsequently matched and completed by the latest EU provisions.

Council Directive 83/397/EEC, transposed into the national legislation by D.L.vo n. 123 of 3 March 1993 led to the harmonisation of official control activities on foodstuffs in EU Member States. The purpose of the official control is to verify and guarantee the compliance of foodstuffs with the provisions aimed at preventing risks for public health, protecting the interests of consumers and ensuring fair trade transactions.

The official control activities cover national products and products of foreign origin intended to be placed on the market in the national territory, as well as those forwarded towards EU Member States or exported towards Third Countries. These activities cover all the stages of the food production chain, from primary production to the placing on the market of the product (production, processing, storage, transportation, sale, administration, importation) and consist of one or more of the following activities: inspection, control of the hygiene conditions of the personnel, examination of written papers, of any other document and of the assessment systems put in place by the firm, with the relating results.

The official control on the national territory is performed by the Regional authorities through their local structures, under the guidance and co-ordination of the Ministry of Health (Department for Food, Nutrition and Veterinary Public Health). The official control on food of animal origin is performed on the basis of EU Directives (vertical directives) transposed into the Italian legislation. The scope of the control system is the following:

a) Direct intervention on production.

- Authorisation of plants (also by means of on-the-spot inspections) aimed at assessing the suitability of the production process and the safety in the application of new technologies, by means of controlled experiments with a view to validating the procedure, in collaboration with the National Health Institute and the national reference laboratories for emerging issues.

- Checks aimed at assessing the systems and procedures put in place by producers, either as random verifications of the safety standards in the production chain, or on request, in the event that possible hazards to health arise that could undergo targeted measures.

- Precautionary measures withdrawing the authorisation or stopping the activity of plants, in order to prevent unmanageable or non-managed health hazards from endangering public health.

b) Assessment, modification and validation of the system by means of regional audits aimed at ascertaining the overall functioning of local controls, the way they are organised, the effectiveness and efficiency of the actions planned on the basis of proposals and provisions, with a view to directly highlight the local concerns, assessing the implementation of the central information, assessing the production in terms of safety and ensuring that the connected hazards are acceptable and managed by means of the production chain and of the control activities .

c) Guidance and co-ordination by means of specific provisions (monitoring plans, validation of manuals, official control on the chain) and of general provisions on methods to prevent health and hygiene hazards at the national and international levels (circular letters, ordinances) on the basis of validated or detailed statistical data.

Decree of the President of the Republic of 14 July 1995 defined the character and frequency of official controls in the national territory to be performed by the Regional authorities and by the Autonomous provinces by way of annual programmes, in order to uniform and rationalise the official control activity in the national territory.

The Ministry of Health directly performs checks on commodities imported from Third Countries through its subordinate peripheral Offices: Border Inspection Posts (PIFs) for food of animal origin and Harbour or Airport Inspection Offices (USMA) for other products. In order to guarantee the fair implementation of the zootechnical and veterinary legislation within the Single Market (Directive 89/608/EEC) the Ministry of Health relies on the Veterinary Offices for the Enforcement of EU Provisions (UVACs).

The official control performed on the national territory is part of a more general framework of activities intended to guarantee food safety, also including own-checks to be performed by the food industry in compliance both with the vertical directives (food of animal origin) and with Directive 93/43/EEC. In this field the Ministry of Health forwards guidelines to the local Authorities, which have in their turn to verify the fair implementation of own-checks, and supplies food industry operators with indications and instructions.

Control Bodies

Numerous bodies, both at the central and at the local levels, are in charge of supervising and performing the different aspects of official control on foodstuffs and drinks, in compliance with D.L.vo n. 123 of 3 March 1993 (Directive 89/397/EEC).

The Ministry of Health operates at the central level through the Department for Food, Nutrition and Veterinary Public Health (DANSPV), at the local level through its own peripheral offices, that is the Harbour and/or Airport Inspection Offices (USMAs) and the peripheral veterinary offices, Border Inspection Posts (PIFs) and Veterinary Offices for the Enforcement of EU Provisions (UVACs). According to the legislation in force for the safeguard of foodstuffs and drinks from the hygiene point of view, the Ministry of Health has to assure uniform health conditions and guarantees in the whole national territory by means of provisions, guidance and co-ordination of the regional administrative activities.

The central authority is in charge of issuing uniform technical provisions on quality and soundness standards for foodstuffs, on additives and colouring agents and their use, on the hygiene and health features of materials and objects intended to come into contact with foodstuffs, as well as on the authorisation and use of pesticides and the fixing of pesticide residues in foodstuffs.

The Ministry of Health has administrative tasks in the field of international relationships and is in charge of carrying out international prophylaxis through its Harbour, Airport and Border Offices, also in the veterinary field, as well as control activities on food imports. Moreover, it is in charge of supplying uniform and simultaneous guidelines for all those multi-regional, national or international interventions to perform which the Ministry relies on the Carabinieri NAS (Anti-adulteration and Health divisions of the Carabinieri).

The National Health Institute (ISS) works in the field of scientific research for the safeguard of public health, performs analytical checks and technical examinations of patents and projects in the hygiene and health fields; it draws up technical provisions for drugs, foodstuffs, products and activities in the hygiene and health fields, promotes and organises meetings, technical-scientific refresher and training courses for Italian health operators. In particular, the Institute performs confirmatory analyses on foodstuffs and on other products in the food sector.

In the field of food hygiene, the ISS supplies the laboratories of PMPs and of the IZSs with criteria and methods for trials on foodstuffs, co-ordinates their technical activities and supervises them as far as the public health field is concerned. The laboratories of the ISS operating in the field of foodstuffs and drinks are the Foodstuff Laboratory, the Veterinary Medicine Laboratory and the Toxicology Laboratory. Other labs of the ISS participate in these activities to a lesser extent. The National Health Council (CSS) has counselling tasks on the various foodstuff safety issues.

The Regional Authorities and Autonomous provinces operate at the local level, by means of the Veterinary Services and the Food Hygiene and Nutrition Services, co-ordinated by the LHU Prevention Departments. All the analytical and lab tests are performed by the Istituti Zooprofilattici Sperimentali, supported by the PMPs and the ARPAs. The Regional authorities and Autonomous provinces are instructed, among other things, of performing planning, guidance, co-ordination and control functions on the activities of the LHU bodies and departments in the field of food safety and veterinary health.

Among the tasks of the Local Health Units are those concerning:

a) The hygiene of production, processing, distribution and placing on the market of foodstuffs and drinks.

b) The prophylaxis and veterinary policy, inspection and veterinary surveillance on animals intended for human consumption, on slaughterhouses and processing plants, on food of animal origin, on animal reproduction, breeding and health, on veterinary drugs.

These tasks are performed respectively by the Hygiene Services and the Veterinary Services.

The Ministry of Agriculture and Forestry_operates at the central level through its Central Inspection Service for Fraud Repression (ICRF) and is in charge of the economic safeguard of agricultural products, by means of mercantile checks.

The Central Inspection Service for Fraud Repression (ICRF)_operates throughout the national territory through its peripheral offices, which rely on the laboratories equipped to perform checks on products of plant origin (PMPs – Local Prevention Bodies). From the scientific and technical point of view the Ministry of Agriculture and Forestry is supported by its subordinate Experimental Research Institutes for Agriculture (10 in the national territory), which deal with the various aspects of agrarian research (zootechny, plant pathology, fruit growing, horticulture, cereal growing, viticulture, citrus-fruit growing, food preserves, mechanisation and so on), and which already perform experimentation in the plant biotechnology sector in compliance with the "National Biotechnology plan".

Among the experimental Institutes there is the National Nutrition Institute, which offers its collaboration for research and for lab trials on products of plant origin and supports the ICRF. At the regional level there are the regional Plant Protection Services, which perform checks on plant diseases and quarantine noxious organisms (not present in the national territory) at the authorised entry points and in the territory of competence (firms, importers, exporters, tree nurseries). Such services are co-ordinated by the central Plant Protection Service of the Ministry of Agriculture and Forestry, which is in charge of transposing EU provisions in this sector into the Italian legislation (Directive 77/93/EEC and further amendments), in order to harmonise checks in the territory, as well as of the relationships with the International Bodies (FAO or EPP) and the competent Authorities of Third Countries. For checks and analyses on plants the Plant Protection Services rely on their own laboratories and, in many instances, on laboratories of the Agrarian Universities specialised in the various agrarian branches.

Check on Imports from Third Countries

Products of Animal Origin

Health guarantees on imports from Third Countries are established by the EU Commission by way of Directives and Decisions. In Italy, checks on imports of products of animal origin are performed by the 30 Border Inspection Posts (PIF) which make, together with the 249 BIPS located in the 14 other EU Member States, checks on every single consignments intended for the European Union. These BIPs directly depend on the Ministry of Health.

Checks are performed systematically, on each consignment, in order to ascertain that health and trade certificates are correct and the identity of the product. The inherent qualities of the product are on the other hand randomly checked, with a different frequency according to the kind of good and to the Country of origin.

If veterinary inspectors deem it opportune, or in compliance with specific instructions supplied by the Ministry or by the EU, the physical/material check is integrated by laboratory trials. Further to the veterinary check on imports, goods can be imported into the EU or rejected outside the EU territory. If necessary, further to checks carried out on imported products of animal origin, the EU alert system can be started up.

Products of Plant Origin

For products of plant origin the EU provisions (Directive 77/93/EEC and further modifications) currently regulated only checks on plant diseases, which are performed in Italy by the regional Plant Protection Services throughout the territory and at the authorised entry points. The activity of the services is co-ordinated and harmonised by the central Plant Protection Services of the Ministry of Agriculture and Forestry.

As far as food safety is concerned, the official control on entry points is performed by the Harbour, Airport and Border Inspection Offices of the Ministry of Health. These offices, in the territory falling under their competence, are instructed to perform international and public health prophylaxis, and in particular they survey imports of goods, mainly of plant origin, intended for human consumption, and of plant protection products.

In order to perform their tasks, the Harbour, Airport and Border Inspection Offices rely on the public laboratories making trials for the official control on foodstuffs (PMPs, IZSs and ARPAs). There are 33 offices currently operating and distributed on a regional basis. The EU alert system can be started up also further to checks on products of plant origin.

Checks on EU Consignments

In the light of the Single Market EU Directives envisage that veterinary checks on animals and on products of animal origin are performed at the place of origin. Even though this system is grounded on the confidence in the guarantees supplied by the dispatcher country, the Directives foresee that random and non-discriminatory checks can be performed in the Country of destination. Besides these routine checks there are, moreover, those stemming from the implementation of measures safeguarding public or animal health. The co-ordination of these checks is entrusted to the UVACs, directly dependent on the Ministry of Health.

Pursuant to the EU Directives, if during a check at the place of destination or during transportation an animal consignment turns out to be affected with a zoonosis or a disease, or if presenting any other problem liable to seriously jeopardise human or animal health, the consignment has to be destroyed or, in some cases and if possible, has to be rejected to the despatching country prior authorisation of the competent authorities. After each rejection, 5 consignments of the same kind and origin are subjected to a systematic control. The situation gets back to normal only if such checks turned out to be favourable.

EU and National Alert System

The EU alert system_was set up by Directive 92/59/EEC concerning the general safety of products, transposed into the Italian legislation (for food safety) by D.L.vo n. 123 dated 3 March 1993. The alert system, whose goal is the safeguard o consumers' health, aims at preventing a contaminated product (deemed as such in a EU Member State or at an EU border and withdrawn from trade or rejected) from being introduced or from staying on the market of another EU Member State, in the event that it can

seriously and immediately jeopardise consumers' health. The EU Commission receives and forwards to EU Member States the notifications on food hazards; the Member States perform the necessary verifications case by case, and adopt the subsequent precautionary provisions.

For each Member State the EU Commission has appointed the link body for this sector; in Italy, the contact body is the Department for Food, Nutrition and Veterinary Public Health of the Ministry of Health (DANSPV). At the national level, the alert notifications of EU origin and those forwarded by the local authorities in charge of food control on the territory are co-ordinated by the Ministry of Health (DANSPV).

The national alert system consist of a network connecting the various central and peripheral structures acting in the food surveillance sector, that is the above mentioned control bodies. According to circumstances, professional associations, firms operating in the food sector and consumers' associations get involved in the process.

Control Activity Aimed at Risk Assessment and Management in Specific Sectors

Novel Food and Food Ingredient Sectors

The biotechnology field, for its complex nature, is dealt with by various national Administrations. The GMO sector is dealt with by various Departments of the Ministry of Health. A Commission instructed of assessing the notifications and applications for placing novel foods on the market (EC Reg. 28/97) was created at the DANSPV. Considering the delicacy of such issues, the Italian Commission always acted with the utmost care.

Risk Assessment

This careful approach is justified by the scarce data reported in some cases in the dossiers submitted by some firms. In fact, it is necessary to carry out also long term inquiries in order to guarantee the absence of health hazards prior to marketing. This entails from one side an increase in studies and verifications aimed at thoroughly examining the consequences of genetic modifications of food, from the other the setting up of post-marketing monitoring programmes with a view to identifying any possible hazard stemming from such foodstuffs. For this reason the Italian Commission always delivered unfavourable opinions on the placing on the market of these products.

Risk Communication

The delicacy of this issue, which also involves the safeguard of ethical problems in some populations, requires targeted actions. Moreover, it also calls for a high level of consumer's information and a correct labelling of such products.

Risk Management

For the above mentioned reasons various actions were taken at the national level. These actions entail:

a) Involving other Ministries with a view to achieving a wider and global assessment of problems relating to environmental impact and transgenic farming management. This assessment will enable us to guarantees the traceability of such products once the authorisation stage envisaged by Directive 90/220 comes to an end.

b) Assessing ethical aspects and of socio-economic impact of new technologies that, in the long term, indisputably affect health.

c) Appropriately informing the public opinion by means of specific World Wide Web pages.

d) Drawing up an operational protocol for pre-marketing and post-marketing monitoring of novel foods.

e) Drawing up and performing monitoring at the points of entry in order to be aware of importation flows into the national territory, and of the compliance of labelling along the food chain of genetically modified maize and soy by-products.

f) Implementing the official control to evaluate the compliance of labelling of these products intended for the final consumer.

Plant Protection Product

The main activity of the Ministry of Health – DANSPV – in collaboration with the local authorities in the field of plan protection products aims at regulating and monitoring various tasks, whose ultimate goal is granting the placing on the market of efficient active substances safe for man, animals and the environment.

The above mentioned activities concern the experimentation on new active substances or new uses, the delivery of specific authorisations for production plants, sale premises, users' licence, ministerial registration of plant protection products, planning and management of annual control plans for residues in foodstuffs.

As far as the placing on the market is concerned, the authorisation for the plant protection product is delivered by the Ministry of Health, further to a favourable assessment of papers according to EU uniform assessment criteria. The Ministry relies on a National Consultative Commission, consisting of 25 members and 20 experts.

Hazards to man, animals and the environment deriving from the use of pesticides are assessed in advance on the basis of international criteria. The plant protection product is classified and labelled in compliance with EC Directives relating to dangerous compounds, and users are properly notified the risk and care advises. As far as the fixing of maximum residue levels is concerned, this is done upon assessment of consumers' exposure on the basis of long and short- term intake.

The control of residues of plant protection products is performed on products of plant origin, in cereals and in some products of animal origin according to a national plan (Decree 23 December 1992) including the verification of national and EU maximum levels (Directives 76/895/EEC, 86/362/EEC and 90/642/EEC).

Veterinary Medicines

The safety of food deriving from animals treated with veterinary medicines is safeguarded by specific provisions implementing EU Directives 90/677, 92/18 and 93/40 amending Directive 81/851 and 81/852, as well as national provisions transposing such Directives – D. L.vo 119 dated 27 January 1992 and D. L.vo 66 dated 4 February 1993.

The registration of veterinary drugs is the task of the DANSPV of the Ministry of Health, and requires the submission of precise pharmacological and toxicological protocols, to be attached to the application for registration of each veterinary medicine.

The search for residues in foodstuffs aims both at ascertaining their presence from the quality and quantity point of view and at possibly establishing the interval to observe in order to rule out any possible hazard to human health.

The evaluation of veterinary medicines is carried out on the basis of a scientific advice delivered by a Consultative Commission of experts in the toxicology and residue sectors. At the end of such an examination the possible suspension interval is established for each medicine, taking into account the EU Maximum Residue Levels laid down in Regulation 2377/90 and its further modifications.

The suspension interval has to be determined in order to grant to consumers that the presence of drug residues in foodstuffs deriving from treated animals is lower than the limits envisaged by EU provisions. After the Commission has delivered a favourable opinion, the drug is authorised to be placed on the market by a proper decree stating the suspension intervals and the other fundamental data.

The surveillance on veterinary medicines is strictly connected with the detailed examination of the distribution regime envisaged by article 32, indent 3 of D.L.vo 119/92: a triple–copy, non-renewable veterinary prescription. The sale of veterinary medicines prescribed for treating animals intended for human food production and presenting a suspension interval is only permitted upon submission of a non-renewable veterinary prescription in triple copy respectively for the veterinarian, the pharmacist and the Local Health Unit.

The owners and the persons in charge of animals intended for food production have to keep a record stating the essential data for the purchase, storage and administration of veterinary drugs for which a triple-copy prescription is required.

Feedingstuffs

In Italy the production of feedingstuffs was regulated since 1963, by Law 281 dated 15 February 1963, setting up conditions for the preparation and placing on the market. Subsequently, Council Directive 90/167/EEC dated 26 March 1990, transposed into the Italian legislation by D. L.vo 90 of 3 March 1993 laid down the EU level conditions for preparing, placing on the market and using medicated feedingstuffs in Member States.

The approval or registration of all feed mills supplies the competent Authority with additional and more effective control or intervention opportunities in the event of an illegal or incorrect use of substances in feedingstuffs. Within the specific framework of the national food safety system, various monitoring plans were set up over the years aimed at evaluating feedingstuff quality.

Decreto Legislativo 460, date 23 November 1998, transposing Council Directive 95/53/EC laying down conditions for the official control in the feedingstuff sector defined a co-ordinated control programme between the Ministry of Agriculture and Forestry and the Ministry of Health.

In any event, a health surveillance plan has operated in Italy since 1985 (Circular Letter of the Ministry of Health n. 34, dated 9 August 1985), performed by the local control bodies on a routine, permanent and annual basis. The health surveillance in the sector in performed on the production, placing on the market and use of feedingstuffs, single additives, premixtures, integrated feedingstuffs, medicated premixtures and medicated feedingstuffs on the national territory, and is carried out on all the operators of this chains, and therefore on producers (feed mills), distributors (zootechical stores and wholesalers) and on animal breeders. During the surveillance operations, the local control bodies collect feedingstuff samples to be sent to the Istituti Zooprofilattici Sperimentali to be tested for antibiotics, chemiotherapics, additives, hormones, aflatoxins, lead, mercury, fluorine, nitrites, pesticides and other contaminants, for bacteriological and chemical trials and for radio nuclides. Currently the local control bodies and the IZSs gather data and forward them to the central Authorities.

Food for Particular Nutritional Uses

Those products for particular nutritional uses not yet covered by specific EU provisions are authorised by the Ministry of Health – DANSPV upon opinion delivered by a Consultative Commission of experts, examining also general aspects of dietetics and nutrition.

The Food Laboratory at the National Health Institute performs analytical trials on all the products to be authorised within three months of delivery of this authorisation; for products non requiring an authorisation the label is examined and, if necessary, the relating scientific papers. All the plants producing and packaging food for particular nutritional uses require an authorisation upon favourable outcome of a prior inspection.

Residues in Animals and in Products of Animal Origin

In Italy there is a National Plan for Residues in animals and in food of animal origin (EU Directive 96/23/EC). This plan aims at examining and underlining the reasons for risks stemming from residues in foodstuffs and in products of animal origin in farms, slaughterhouses, fish plants, egg and milk gathering points. The samples are tested by the IZSs according to the EU provisions and international standards.

Pesticide Residues in Products of Plant Origin

This sector is covered by a National Plan for Residues of plant protection products in products of plant origin, in cereals and in some products of animal origin, (Decree of 23 December 1992), comprising the verification of the national and EU maximum levels (Directives 76/895/EEC, 86/362/EEC and 90/642/EEC). tests are performed by the laboratories of the National Health Service (SSN) on samples of national and non-national products randomly taken mainly from wholesalers and retail stores.

Waste of Animal Origin

This sector provides for the disposal, processing and placing on the market of proteins deriving from waste of animal origin. The legal provision complies with EC Directive 90/667. Processing plants are under permanent veterinary supervision and are periodically inspected by inspectors of the Ministry of Health and by inspectors of the regional veterinary service. A particular attention was dedicated to the verification of requirement compliance with EU Decision for BSE.

Consumers' Exposure to Food Additives and Contaminants

The NHI is performing inquiries in order to ascertain whether the intake of food additives or of some contaminants via foodstuffs entail or not an exceeding of the ADI (for additives) and of the PTWI (for contaminants). This is done in order to acquire the necessary evaluation criteria to ascertain whether possible modifications to the provisions in force are needed.

Materials and Objects Intended to Come into Contact with Foodstuffs

Provisions were adopted limiting the use of phthalates in plastic materials and in rubber used to manufacture materials and objects intended to come into contact with food or used for manufacturing children's items, and controls were increased, by extending them to paints used for food containers, with a view to verifying the compliance with the restriction envisaged, in particular for BADGE.

Quality Safeguard in the Agricultural and Food Sector

The search for high quality standards in each sector of the agricultural and food chain can decisively contribute in improving the hygiene of products. The general goal is to upgrade the procedures and modes of placing on the market of agricultural products having an impact on the environments by means of a series of actions at the multi-regional level. Specific targets cal for a modernisation of manufacturing facilities, the decrease in costs by introducing new technologies and the increase in resources for the environments by means of biological farming.

Within the framework of the activity performed by the Ministry of Agriculture and Forestry we should mention the Operational Multi-Regional Programme, already implemented in the 1996-99 period in order to improve the processing and marketing structures in the agro-industrial sector.

As far as quality fostering is concerned, a specific regulation calls for the participation of the Regional authorities in detecting the products and geographical areas to be involved.

In the agricultural and food sectors two kinds of agreement were identified: the *labels of origin* (Protected Denomination of Origin, Protected Geographical Indication and Specificity Certificate) and *labels of quality*, issued by Bodies or Associations having their own statute and a regulation enabling them to certify the requisites of the product.

III. Future Activity in the Field of Food Safety

Development of Structures in Charge of Food Safety

The control system on the food chain currently in force in Italy presents the following peculiar features:

- It belongs to the National Health Service (SSN) (the national, head level is represented by the Ministry of Health, whereas the intermediate, regional level and the basic, local level belong to the SSN).

- Its has a unified organisation: the Veterinary Service is in charge of checking all the stages of the production chain for food of animal origin (meat, milk and by-products, fish and so on), starting from checks on feedingstuffs and on veterinary drugs, to checks on animal welfare, animal health, to the hygiene of agricultural products, until the distribution, placing on the market and sale (stores, supermarkets, restaurants, canteens, and so on) of finished foodstuffs. A real from-the-farm-to-the-fork approach.

- It has a widespread distribution on the territory: At the basic level the Veterinary Services and the Services for Food Hygiene and Nutrition have a widespread distribution on the whole national territory; each of the 223 Local Health Units of the SSN has its own Veterinary Service and Public Hygiene Service, organised into operational areas.

The system described appears to fulfil the criteria currently adopted or under adoption by the EU Commission (DG SANCO) and by some Member States, where all the competencies in the field of food safety control are entrusted to the Ministry of Health or to its subordinated Units.

Provisions on Biotechnology

Section II describes the approach adopted at the national level for biotechnology and its products.

PrecautionaryPrinciple

As to foodstuffs consumed daily by all the population levels (children, elderly people, pregnant women), the risk assessment has to be grounded on the precautionary principle when possible long-term detectable effects cannot be ruled out and by means of appropriate targeted epidemiological studies.

In some instances the lack of sufficient documents and of long-term studies on such products cannot guarantee the risk assessment. In Italy the precautionary principle was applied by the recent Decree of President of the Republic n. 128 dated 7 April 1999, prohibiting the use of GMOs in baby foods.

Communication and Consultation

The policy recently started up at the EU level (with the restructuring of the General Directions) called for the participation of consumers in evaluating, managing and submitting proposals in the food safety sector.

This process envisages an increase in the information to be supplied to users (consumers, professional organisations and so on), and has been already started up also at the national level in EU Member states. It is aimed at increasing consumers' confidence in public institutions.

In Italy Law 281 of 30 July 1998 set up the National Council of Consumers and Users to the Ministry of Industry, Trade and Craftsmanship.

Such Council held its second general policy conference in Milan on 13/14 December 1999: “Consumers, new subjects between the State and the market”.

During this conference various issues of public interest were dealt with, among which “Nutrition. Product safety and consumers’ health”, “Quality of products and of the environment” and “Services of public interest and competition”. This conference supplied the opportunity of presenting some early undertakings, as well of defining an overall programme for the next few years aiming at creating a modern and qualified relationship network between all the public and private subjects involved.

Moreover, in 1999, a national campaign of communication and information on food safety was performed on the national territory, in compliance with an EU Commission announcement and under the supervision of the Ministry of Health.

NETHERLANDS

I. Synthesis

The food safety system of the Netherlands is very much connected with the food safety legal system of the European Union. It provides the consumer with a high level of protection. It is based on solid principles of risk assessment, risk management and risk communication. The risk assessment is carried out by independent risk assessment bodies, whose procedures and decision's are open and transparent. Detailed data on food intake are at its disposal, enabling quite precise exposure estimates for its risk assessment.

Current legislation covers food additives, flavours, residues of materials into contact with foodstuffs, food irradiation, contaminants, food hygiene, novel foods, pesticides, veterinary drugs, veterinary public health, animal feed, substances for the decontamination of food and micro-nutrients. This legislation includes legislation in the framework of the EU food safety legal system as well as national regulations for areas, which are not yet harmonised in the EU.

Risk management decisions are taken at EU-level or at the national level by specially designated bodies or by a ministerial decision. The Netherlands has a long tradition of consultation with stakeholders (food producers, food retailers and consumer organisations). Draft national and European Community legislation is extensively being discussed in one of the consultative bodies. The Netherlands values strongly the inclusion of other legitimate factors, for example issues related to production processes, in the risk management discussion. Key issues for the risk analyses of foods derived from modern biotechnology are the following: pre market approval, freedom of choice for the consumer and open and transparent procedures.

Food safety systems should be strengthened in some specific fields in answer to international developments. A high level of consumer protection and the precautionary principle should be the leading starting-point. The HACCP-principle should be extended to the primary sector and the animal feed sector. Enforcement activities need a better international collaboration and international strategies for monitoring, detection and inspection need to be strengthened and adjusted.

At last the Netherlands emphasises the increasing importance of risk communication activities to the consumer at the national and the international level.

II. Overview of Food Safety Systems in the Netherlands

1. Legal Instruments

Food safety provisions are laid down in the following legislative texts:

1. The Commodity Act

2. The Pesticides Act

3. The Veterinary drugs Act

4. Meat Inspection Act

5. The Animal Waste rendering Act

2. Risk Assessment Bodies

The Health Council of the Netherlands

The Health Council is composed of independent, scientific experts in the relevant disciplines. The Health Council provides the Government with advice on important health related issues, such as the use of antibiotics in animal feed, the prevalence and prevention of food borne infections and on the safety of novel foods.

The Board for the Registration of Pesticides

The Board for the Registration of Pesticides and the Commission for the Registration of Veterinary Drugs are also risk management bodies. The Board is supported by a secretariat comprising of an l scientific staff. The secretariat co-ordinates the risk assessment and advises the Board on decisions for the registration of pesticides.

The Commission for the Registration of Veterinary Drugs

A bureau comprising of a scientific staff supports the Commission. The bureau co-ordinates the risk assessment and advises the Commission on the proposals for registration of veterinary drugs.

The National Institute for Public Health and the Environment (RIVM)

This is a government institute which carries out applied and fundamental research on health related issues.

The National Institute for the Quality of Agricultural Products

This is a government institute which, carries out scientific research on the quality of agricultural products. The institute concentrates its research on contaminants and veterinary drugs, including toxicological aspects

All reports and evaluations from the above institutes are available for the public. Also minutes of meetings are in the public domain.

3. Risk Assessment

Risk assessment is carried out at the national level by one of the risk assessment bodies mentioned under 2, by a risk assessment body of the European Commission or by a risk assessment body from FAO/WHO.

Food additives, Flavours, Residues of materials into contact with foodstuffs, food irradiation and certain contaminants (aflatoxins, nitrate). Risk assessments for these categories of substances or treatments are being carried out by the Scientific Committee for Food as part of a European-community procedure (see EC-document).

In case a national assessment has to be made on specific subjects the National Institute for Public Health and the Environment will carry out the risk assessment. This is especially the case for certain contaminants, which are not yet included in European community legislation or for irradiated foods, which are not yet evaluated in a European community-procedure.

Food Hygiene

The government requests advise from the Health Council of the Netherlands on important issues, like the prevention of food borne infections. Risk assessment of pathogens is carried out by the National Institute of Public Health and the Environment.

Substances used for the Decontamination of Food

Risk assessment is being carried out as part of a national procedure. The National Institute of Public Health and the Environment will carry out the assessment. Substances have to be safe as a residue, but also the possible reaction products of the chemical in contact with the food have to be safe.

Novel Foods

The risk assessment is part of a European-procedure. Risk assessment of novel foods or novel food ingredients is first carried out by a member state. The initial assessment report is then being discussed in a Community procedure. The risk assessment body for novel foods in the Netherlands is the Health Council. Novel feedingstuff are being assessed on a voluntary basis for their safety for humans and animals by the National Institute for the Quality of Agricultural Products.

Functional ingredients, if they are novel are considered novel ingredients and consequently do require a safety assessment.

Pesticides

Risk assessment for pesticides takes place according to European legislation. Pesticides can only be brought on the market after an assessment of its safety for humans and the environment, as well as their efficacy for agricultural use. Risk assessment for pesticides is being carried out by specific institutes, like the National Institute for Public Health and the Environment. Based on these assessments the secretariat drafts the management decisions for adoption by the Board for the Registration of Pesticides.

Veterinary Drugs

Risk assessment of veterinary drugs takes place according to European legislation. Veterinary drugs can only be put on the market after an assessment of its efficiency and its safety for humans, animals and Environment. The risk assessment is carried out by specific institutes, mainly, by the National Institute for Public Health and the Environment and the National Institute for the Quality of Agricultural Products.

Veterinary Public Health

Risk assessment concerning veterinary public health takes place according to European legislation. Risk assessment is being carried out as part of a European procedure. Risk assessment in the Netherlands is carried out by the National Institute of Public Health and the Environment.

Animal Feed

According to European legislation the use of harmful substances and additives in animal feed has to be approved before this feed is put on the market. The assessment of these products in the Netherlands is the responsibility of the Bureau for the Registration of Veterinary Drugs (BRD), respectively the Agency for Product Registration (BPR). Government research institutes employ the scientists involved in the evaluation. Moreover the use of certain substances in animal feed is restricted, respectively forbidden.

4. Exposure

The Netherlands has a systematic approach for the assessment of the exposure of the consumer to chemicals in food. The level of protection is aimed at protecting not only the average consumer but also the heavy user and the vulnerable groups of the population. The Netherlands have quite precise and updated data on food consumption at their disposal since national food consumption surveys are being carried out every five years since the late 1980. In the surveys specific questions are included to enable the estimation of the intake of special categories of substances, for example on sweeteners. The exposure estimations are part of the risk assessment and form the basis for the risk management process. The most recent national survey was in 1998/1999. This survey allowed the establishment of food consumption trends. A separate very recent survey covered the immigrant population groups.

5. Risk Management Bodies

1. The Consultative Committee on the Commodity Act. This is a formal Expert committee comprising of the stakeholders: representatives of consumer organisations, industry and trade, which discuss issues and proposals, related to the Commodity Act.

2. The Board for the Registration of Pesticides.

3. The Board is composed of persons from different disciplines, but does not include stakeholders. The Board is being assisted by a secretariat with scientific staff. The Board decides on the registration of pesticides.

4. The Commission for the Registration of Veterinary Drugs.

5. The Commission is comprised out of government officials. A bureau with scientific staff is assisting the Commission. The Commission advises the ministers of Agriculture and Health on the registration of veterinary drugs.

6. Risk Management

Risk management is being carried out at the national level or as part of a European Community procedure. If risk management is carried out at the national level decisions are taken at the ministerial

level or by one of the risk management bodies as mentioned under 5. The Netherlands has a long tradition of consultation with stakeholders (food producers, food retailers and consumer organisations). Draft national and European community legislation are extensively discussed in the Consultative Committee on the Commodity Act.

Food additives, Flavours, Residues of materials into contact with foodstuffs, food irradiation and certain contaminants (see under risk assessment).

For these categories of substances and treatments EU-legislation exists (see document of the European Commission). Risk management decisions are taken at EU level.

Contaminants

In addition to Community regulations the Netherlands has national provisions for Dioxins in milk, PCB's, heavy metals (Cd, Pb, Hg and As) in a number of foodstuffs and a guideline level for the mycotoxin deoxynivalenol (DON) (tricothecenes) in cereal grains. Besides the establishment of national or European provisions for contaminants risk management is aiming at lowering the presence of contaminants in foods by source oriented measures. For instance the Netherlands have very strict rules for the exposure of contaminants from waste incinerators in order to decrease the emission of dioxins in the Environment and on foods.

Food Hygiene

Risk management for food hygiene is a shared responsibility of the Ministers of Health and Agriculture. The Ministry of Health is primarily responsible for legislation and setting of standards for the whole food chain. The Ministry of Agriculture is primarily responsible for legislation and standards concerning the quality of meat. The stakeholders and consumer organisations are consulted in several fora, mostly the Consultative Committee on the Commodity Act. Codes of hygiene, including HACCP are being set up by the different sectors of the industry and trade. These codes have to be approved at the ministerial level, after consultation of the Consultative Committee on the Commodity Act. Until now there have been accepted about 26 of these codes. Good hygienic practice is the bases for obtaining good hygienic quality. Decontamination of food with chemical substances is not allowed.

Novel Foods

All novel food applications (national and EU) and novel food policy, especially with regard to labelling requirements, are being discussed in the Consultative Committee on the Commodity Act. Final decisions are taken at the ministerial or at EU-level.

Pesticides

The registration of pesticides is harmonised in the European Union. Decisions on active substances are taken at EU-level. Decisions on the pesticides are taken at national level. As far as the national procedure is concerned the Board for the Registration of Pesticides decides on the registration of a pesticide.

Veterinary Drugs

Risk management of veterinary drugs is harmonised in the European Union. In case a risk is identified the concerned Member State informs the Commission and the other Member States. This information leads either to actions taken on a European level, or to new European legislation.

Decisions on the approval of a veterinary drug are taken at ministerial level on advice from the Commission for the Registration of Veterinary Drugs.

Veterinary Public Health

Risk management (veterinary legislation) is partly harmonised within the European Union. As regards zoonoses, several national plans of action have been developed to reduce the level of infection. Examples are scrapie in sheep, salmonella in poultry and poultry products and para tbc in cattle. Animal waste is rendered in compliance with EU standards to obtain a safe product. Specified risk materials in relation to BSE are incinerated.

Animal Feed

In the Netherlands since 1992 a voluntary system of Good Manufacturing Practice is used in the production and trade of animal feed. The aim is to guarantee the quality in the total animal production chain. Since the dioxin-crisis this system is extended to the oils and fats sector. According to European legislation, in order to control the implementation, the national control system has to meet certain conditions. These conditions apply to the national production as well to imports from third countries. The Animal Feed Quality Service of the Dutch Animal Feed Board (KDD) controls the national production of animal feed. The National Inspection Service for Livestock and Meat (RVV) controls the import of animal feed and feed additives. The General Inspection (AID) Service has the general control responsibility.

Substances Used for the Decontamination of Food

Decontamination substances are only permitted when its necessity is included in a code of hygiene for the specific product category. Up till now there are no substances allowed for this purpose.

Food Irradiation

The Netherlands allows the following food categories to be irradiated (dried fruit, dried vegetables, spices, shrimps, froglegs, poultry (restricted to poultry products for the elderly), pulses, grainflakes, food additives and flavours. Food irradiation may only be used when there is a clear public health advantage. It may only be used when good hygienic practice is realised and should never be used to cover inadequate hygiene.

Micro-Nutrients

Enrichment of food with micro-nutrients is very much a national policy. No EU-legislation for these substances exists. Countries do have very different ways of ensuring an adequate intake of some essential micro-nutrients, and at the same time taking measures to prevent intake levels to exceed safe levels. Essential micro-nutrients in this respect are folic acid, vitamin A and D and iodine.

The Netherlands does in principle allow the enrichment of food with micro-nutrients up to 100% of the recommended daily allowance in a daily portion. For some micro-nutrients addition to food is restricted as the safe exposure level can easily being exceeded.

7. Risk Communication

The decisions and advises of the risk assessment and risk management bodies are made available for the public. For novel food, a website is being elaborated, which will give information on the procedure, the applications, the dossiers, the evaluations of the Health Council, the rational of the decision taken and the progress in the national and the EU procedure.

As mentioned, under 5, all risk management aspects are being discussed with the stakeholders in the different fora. An important one is the Consultative Committee on the Commodity Act. The minutes of these discussions are, in principle, available for the public.

General communication on issues related to food and to food safety is left to the Dutch Nutrition Centre. This institute is financed by the ministry of Agriculture, Nature management and Fisheries and the ministry of Health, Welfare and Sport. The Nutrition Centre provides information, education and communication on food and nutrition issues to intermediates and the general public.

There have been special education activities and campaigns on modern biotechnology. In elaboration is a big campaign on modern food production methods and on questions of consumers about food.

In case of food incidents, apart from the stakeholders, especially the consumer organisations and the Dutch Nutrition Centre are informed by the ministries of Health and of Agriculture and kept up-to-date on the developments regarding the incident.

8. Current Affairs and New Developments

Food safety has been a core policy objective for decades, resulting in a high level of consumer protection. An extensive system of legislation and standards now exists and has been harmonised to an important extent within the European Union.

A few of the important developments are:

1. The food safety policy is being realised by monitoring the safety of products throughout the entire food production chain. This not only entails applying the HACCP principle to the production of end products, but also applying that principle right from primary production sources and the animal feed producers.

2. In February this year the European commission published a Communication on the Precautionary Principle. This document is currently in discussion in the Council of the European Union.

3. Because of growing international trade, globalisation and increasing agricultural production, alternative demands have to be met with regards to the enforcement of food safety (monitoring, inspection and control). These developments make the verification of food safety and quality as well as fraud increasingly difficult to detect. Just one hitch in the early stages of production and the entire process can be jeopardised. This emphasises the need for stronger international collaboration. Strategies for monitoring, detection and inspection have

to be adjusted in order to meet the requirements following current trends. Attention should be paid explicitly to the animal feed producing sector, being at the beginning of the food production chain.

4. Although scientific aspects play a major role in food safety policy other consumer interests should not be neglected. The consumer is becoming increasingly aware of issues related to the production process itself. Ignoring these issues would only contribute to increase a growing tension among consumers.

5. Good communication about food safety between government authorities, commercial enterprises and the public is one of the great challenges for the years to come. The perceptions of consumers with regard to what is safe for them to buy do not always concur with the government's proposals for objective standards.

6. A policy on functional food and food supplements will be of paramount importance in the coming years. Key issues are: health and medical claims and the interpretation thereof, safety issues, efficacy requirements, additional information to be provided on the label, formulation of conditions of use.

7. Present legislation on veterinary matters is not adapted to the contemporary production-systems and the actual food safety risks. The legislation does not confer the responsibility for food safety to producers themselves. In view of modernisation of the European veterinary legislation several measures have been taken: the industry introduced an integrated chain-system, by which information is exchanged between farms and slaughterhouses, respectively specific hygiene codes and HACCP in a restricted measure.

9. Biotechnology and Legislation

Key policy issues are the safety of food from genetically modified organisms (GMOs), and freedom of choice for the consumer.

Legislation regarding GMOs has largely been based on European community legislation.

The scientific requirements for the assessment of the safety of GMOs for approva hve been established by the European Union.

The Netherlands applies the Precautionary Principle in dealing with the issue of food safety. The Netherlands supports maximal freedom of choice for the consumer. This freedom of choice is partly achieved by providing the consumer with information through labels on foodstuffs as to whether or not the product has been derived from a GMO. Current (EU) legislation does not provide the consumer with a complete freedom of choice for GMO products. Product labelling is compulsory unless GMO-DNA or GMO-proteins cannot be detected in any given product. As a result, these particular products do not have to provide any labelling information. This exception to the rule is based on the desire that legislation should be enforceable. In order to fill this gap, the Netherlands has also passed legislation in which the term "produced without genetechnology" has been introduced. This will create a reasonable freedom of choice system for the consumer. Furthermore, government authorities are stimulating the development of GMO-free food chains.

The Netherlands is also in favour of as much openness and transparency as possible. Applications, files and evaluation reports are generally accessible for the general public unless in conflict with proprietary rights of food producers.

The active involvement of stakeholders is considered to be of great importance. All applications for approval are submitted to the Consultative Committee on the Commodity Act. The Netherlands will review its policy on GMOs in a systematic way in a public debate to be organised in 2000 and 2001.

10. The Precautionary Principle and New Foods and New Food Ingredients

There is an increased concern by consumers, politicians and parliament on the issue of scientific uncertainties. Consumers are increasingly reluctant to accept scientific uncertainty. Consumers even demand a zero-risk. This of course is impossible. The Netherlands is however of the opinion that it is important to deal with these concerns and acknowledge that there is a need to deal in a more precise and more explicit manner with scientific uncertainties.

The Precautionary Principle offers such an instrument. It offers a structured approach to deal with scientific uncertainties. More-over it has something comforting in it.

In essence it states that when there is scientific uncertainty "do not do it"; choose the safe side. But, under certain conditions, like balancing with economic costs, it should not be discriminatory and it should not be used as a barrier to trade (see also the document of the European Commission).

The Netherlands is of the opinion that there is a need for such an instrument in order to fine- tune the approach to scientific uncertainties.

This section below shows the application of the Precautionary Principle when screening new foodstuffs and new ingredients:

1. GMOs, or products derived from GMOs, may only be introduced into the market if their level of safety has been assessed by an independent organisation. GMOs are not inherently safer or less safe than products, which have been, prepared traditionally, however the safety assessment includes subjective elements for evaluation, whereby a check by an independent authority is necessary.

2. GMOs should not contain (active) antibiotic-resistant marker genes. By adding antibiotic-resistant genetic material in GMO-plants it is possible to introduce on a large scale transferring antibiotic resistance in man, animals and the Environment. Although the chances of transferring antibiotic resistance to other organisms is very limited, it is however still possible. The Netherlands therefore considers as a precautionary measure that generating GMOs with antibiotic-resistant genes into the market should be consistently reduced to zero.

3. Preventative measures must be taken in order to avoid additional risk to allergy patients with the introduction of foodstuffs, which include genetically modified products into the consumer market. Despite the relatively low risk of allergenic effects, it is still imperative that this aspect be assessed during each application for a new foodstuff. The Netherlands is basically opposed to a policy in which the problem of allergenicity by GMOs is being solved by means of compulsory labelling requirements.

11. Regulatory Enforcement and Compliance

The enforcement of food standards is the responsibility of the Inspectorate for Health Protection, Commodities and Veterinary Public Health and the National Inspection Service for Livestock and Meat. The Government promotes the development of private certified systems in the production chain. All

sections of the production chain should be covered, inclusive by-products and waste. The enforcement concentrates on the inspection of the food safety systems of the producers.

The Netherlands is also participating in the Rapid Alert System of the European Union, which facilitate the circulation of information on serious food emergencies. Within the ministries of Health, Welfare and Sports and of Agriculture, Nature management and Fisheries there are centres for reporting on food incidents. An overall interdepartmental committee on food emergencies is being created.

12. Socio-Economic Concerns

Besides food safety concerns consumers have other concerns related to aspects of the products or the production methods. These concerns are of increasing importance for their confidence in food and their food buying decisions. Such concerns can lead to request specific labelling provisions or even to a call for a ban on certain products. Existing examples in the Netherlands are the regulation on products from organic farming and regulations on products with particular aspects of animal welfare.

Such concerns are also of importance for products of biotechnology. Examples: environmental concerns (environmental impact of biotechnology); animal welfare; ethical concerns; like the integrity of the animal when crossing the species barrier and religious concerns. The Netherlands is of the opinion that these concerns should be dealt with in the risk management, resp. the risk analysis process.

PORTUGAL

I. Summary

Legal aspects are harmonised within the EU perspective. Three Ministries, Agriculture, Economy and Health run the food safety system.

The *Ministry of Agriculture* controls the food quality inspectorate and a reference laboratory belonging to the Directorate General for Fiscalization and Control of Food Quality, that is CISC active in certification. Another Directorate General for Veterinary is responsible for the fiscalization of slaughterhouses, sanitary inspections, animal feed and veterinary public health. Scientific and analytical support for these activities is obtained through the National Laboratory for Veterinary Research. Regional branches of this ministry are also active for some purposes.

The *Ministry of Economy*, through the Inspectorate General for Economic Activities is the competent authority for economic fraud, including food falsification, and is called by the inspectors of the Ministry of Agriculture when legal action is necessary.

In cases of founded suspicion of eventual negative effects in public health, the intervention of the *Ministry of Health* is mandatory. This system is now subject to change with the currently ongoing structuring of a National Agency under the Minister for Consumer Protection.

For the GMO matters the Government appointed a Consulting Board composed by senior officers of the Ministries involved and independent scientists.

Concerning the precautionary approaches and principles, Portuguese experience comes mainly from dealing with BSE and the tendency has been in the sense of reducing strongly the levels of acceptance in cases of incomplete or not completely adequate information.

Communication, consultation and the discussion of socio-economic concerns only recently became socially useful and are not yet the object of fully organised approaches. Several sectoral discussions have taken place. The National Commission for the Environment and Sustainable Development, a body affiliated with the Parliament is performing a board national audition.

II. Draft Overview of the Portuguese Food Safety System

Institutions involved in law and regulation making are the Parliament (Assembleia da Repùblica) the regional Assemblies of the Autonomic Regions (Azores and Madeira local Parliaments), the Government and the Regional Governments for Azores and Madeira, for minor regulations local (Municipal) authorities. *As* Laws and Regulations have been harmonised within an EU perspective this part of the compendium can be taken from the contribution prepared by the European Commission in informal consonance with the Member Countries.

Concerning the application of Laws and Regulations the competencies are organised similarly in the Central and Autonomic Governments and, in both cases also include local (Municipal) authorities in some cases

Competencies are split among Ministries, with involvement of Agriculture (Ministério da Agricultura, do Desenvolvimento Rural a das Pascos), of Economy (Ministério da Economia) and Health (Ministério da Saùde).

The Ministry of Agriculture is responsible for setting the standards for food and feed including permitted contaminant and residue levels, and also for animal health and welfare. Two Directorates are involved:

DGQFCQA (Directorate General for Fiscalization and Control of Food Quality) active in the control of the quality of food, in standardisation and in certification, and also running a reference laboratory for official control of the quality of foodstuffs; for veterinary matters, including fiscalization of slaughterhouses, sanitary inspections, animal feed and veterinary public health, competencies belong to D.G. Veterinary that does have any dedicated laboratories and obtains scientific and technical support from the National Laboratory for Veterinary Research (Loboratòrio Nacional de lnvestigçào Veterinària)

For some matters Regional Directorates of the Ministry of Agriculture are also active, supported by regional laboratories. The inspectors of the Ministry of Agriculture when they find infringements of the Law can fine the infringement, but further legal action needs the intervention of the Inspectorate General for Economic Activities (IGAE; Inspecçào Geral das Actividа des Econòmicas) this belongs to the Ministry of Economy and is the authority in all aspects of economic fraud, including falsification of food or non-compliance's with quality standards. This Inspectorate General also has Regional branches but they do not coincide in number and territorial jurisdiction with those of the Ministry of Agriculture. If any of the aspects of non-conformity with standards can have public health implications, the direct involvement of the Ministry of Health is mandatory.

The Co-ordination between inspection bodies belonging to different Ministrios, in the absence of a formal inter-ministerial body, is exclusively informal. Presently this situation is under change.

A new body with broad competencies under the Ministry for Consumer Protection is being structured, but the timing for change is also being studied. In matters concerning novel food with GMO origins, the competencies are also shared with the Ministry of Environment and the participation of the Ministry of Health is mandatory, independently of any founded suspects about health risks. For these cases, as there are no national Laboratories currently involved in GMO analysis; external expertise is obtained by the Competent Authorities through associated laboratories, that are also represented at a Consulting Board of DGQFA.

At least one of these laboratories actively participates in European Networks and ring trials for analytical methods for GMO food control.

For the GMO matters, the Ministries involved decided, with support from the Ministry of Science and Technology, to appoint a Consulting Board with representatives from the Ministries of Agriculture (3 representatives), Environment (2 representatives), and Health (2 representatives), plus four independent scientists (a molecular geneticist, a specialist in Health, a plant biologist and a plant breeder) appointed by the Ministry of Science and Technology.

Concerning the precautionary approaches and principles, Portuguese experience comes mainly from dealing with BSE and the tendency has been in the sense of reducing strongly the levels of acceptance in cases of incomplete or not completely adequate information.

Communication, consultation and the discussion of socio-economic concerns only recently became socially useful and are not yet the object of fully organised approaches.

The National Commission for the Environment and Sustainable Development, a body affiliated with the Parliament is performing a board national audition.

Several sectoral discussions have taken place organised both by academic and civic organisations, and the media are showing consistent interest, in some cases, trying to transmit views from diverse sectors of opinion in a more balanced way.

SPAIN

I. Synthesis

Review of Present Systems and Activities

Institutional Structure and Regulatory Framework

Food safety: Right to protection of health (Art. 43.1 of the Spanish Constitution)

Competent Authorities and Legal Grounds for Competencies

The above competencies are exercised directly by health authorities (Ministry of Health and Consumer Affairs) at various levels (central, regional/autonomous, municipal/local) with the participation of other authorities (Ministry of Agriculture, Fisheries and Food, National Consumer Institute, Ministry of the Environment, Ministry of Economy/Secretary of State for Trade...) which, like the territorial levels described, indirectly affect food safety throughout the chain of production.

The participation of the different authorities listed in food safety management obviously calls for *interterritorial and intersectoral co-ordination*.

Legal framework for food - Competent authorities' regulatory sources and capacities.

Fewer and fewer areas are regulated exclusively by national initiatives, the most general source of domestic legislation being *Community Law*. The *Codex Alimentarius* is also acquiring greater importance as the inspiration for legal provisions in the field of food safety. Finally, *domestic legislative initiatives* are also taken.

The Spanish State's own framework of competencies also lays down specific precepts with respect to the regulatory capacity of the authorities involved in food safety management. The Central Government is responsible for drafting the so-called *base regulations* which may, in certain cases, be enlarged upon by territorial authorities.

Executive - as opposed to regulatory - competencies relating to the official control of foodstuffs are vested in the regional authorities, with the exception of border health patrol (control at Border Inspection Points, PIFs)

Risk Analysis

Food safety management in the framework of (risk assessment, management and communication).

Risk Assessment

The risk assessments used are international or authored by the technical-scientific institutes under the aegis of the competent authorities. Such institutions also provide analytical coverage for the system, in particular by conducting reference-finding activities. The ideal pursued is comprehensively oriented assessment based on criteria of excellence, independence and transparency.

Risk Management

This activity is conducted by health authorities, with the participation from time to time of other stakeholders, with a dual approach consisting of generating and maintaining appropriate regulatory standards (*legal framework*) and verifying process and product conformity to such legal standards (*official control/inspection)*.

Risk management comprises programmed activities and contingent and urgent activities to respond to risk situations. Support is provided in the form of the following elements: General Health Registry of Food and Industries, the Epidemiological Surveillance System, reference laboratories and a qualification system to certify their technical competence and, especially, the Co-ordinated System for the Rapid Exchange of Information/Food Alert Network. The domestic system, in turn, is integrated into the Community "RAPEX/RASFF" system network.

In practice, the precautionary principle forms a part of risk management, although it may be construed to be related to assessment or even to communication. It is applied under certain clearly defined circumstances and translates, as far as risk management is concerned, into the adoption of regulatory or enforcement measures or both.

Risk Notification

Notification is based on transparency but not limited to transparency and accessibility to risk assessment reports (risk notification policy).

Risk notification strategy is systematised in the following points: notification should not precede assessment and management; it is undertaken at the request of risk managers, who notify the risks directly or through institutional notification cabinets, keeping stakeholders systematically informed and limiting notification to the population at large through the media to situations where such information impacts health protection favourably and effectively or is required to quell unwarranted social alarm; notifications must be accessible and intelligible for the target audience.

The systematised strategy is implemented by favouring media access to information generated by managers and systematically informing recognised food industry (*FIAB*) and consumer (*Consumers and Users Council*) representatives.

Future Activities and Approaches in the Treatment of Food Safety Questions

- Creation of a *Spanish Food Safety Agency*, as mandated by Spanish Parliament.
- Nation-wide follow-up and implementation of measures stemming from the application of the *European Commission's White Paper on Food Safety.*
- Strengthening and updating existing frameworks by, among others, enacting a *Food Act* addressing the creation of a *specific body to handle public alert situations.*

II. Review of Present Systems and Activities

2.1 Institutional Structure and Regulatory Framework

Food safety should be strictly understood to mean prevention of human disease carried or caused by food. Article 43.1 of the Spanish Constitution guarantees the right to protection of health and mandates public authorities to organise and safeguard public health through preventive measures and any necessary services (Art. 43.2).

2.2 Competent Authorities and Legal Grounds for Competencies

The competencies for protecting public health by overseeing food safety or harmlessness for consumption are exercised directly by Health Authorities (Art. 6.3, among others, of General Health Act 14/1986) at several levels:

- Central Government (Ministry of Health and Consumer Affairs).
- Autonomous territorial or regional governments.
- Municipal or local governments.

Action affecting agribusiness products, processes, industries and establishments involves the participation of other authorities which, like the territorial levels described (central, autonomous/regional, local/municipal), indirectly impact food safety, given, moreover, the concurrence of *other legitimate factors* in food safety management, such as:

- Consumer protection competencies in non-health related areas that have a direct influence on food safety and health protection (Ministry of Health and Consumer Affairs National Consumer Institute and territorial consumer authorities) (General Act 26/1984 on the Protection of Consumers and Users).
- Direct competencies relating to the initial links in the food chain (animal health, primary production and means of production) (Ministry of Agriculture, Fisheries and Food - MAPA -, territorial agricultural authorities).
- Direct competencies relating to the regulation, governance and insurance of foodstuff fitness and quality (MAPA, territorial agricultural authorities).
- Competencies in environmental matters with a direct bearing on food safety (Ministry of the Environment and the respective territorial authorities).
- Other authorities are also involved, if not in the management of the official control of foodstuff safety, at least in the legal governance of the food sector, although the impact of their activity on food safety management is less immediate than that of the non-health authorities mentioned above. Examples would be ministerial departments such as Industry, Economy/Secretary of State for Trade, or Public Administration... see Interministerial Food Commission - CIOA - below. The Ministry of the Interior (Directorate General of Police, Economic and Financial Delinquency Brigade) also provides relevant support in this regard.

The legal powers or grounds on which the above authorities or institutions exercise competencies that have a direct or indirect bearing on food safety are addressed in the respective regulatory legislation, namely:

Royal Decrees on structure and functions, in the event of Central Government ministerial departments:

- Ministry of Health and Consumer Affairs
- Ministry of Agriculture, Fisheries and Food
- Ministry of the Environment

Royal Decrees on transfer of competencies/functions from the central to the autonomous regional governments.

Statutory instruments addressing the system of local government (Town Halls).

The participation of all the authorities involved in food safety management obviously calls for co-ordination, both:

- ***Interterritorial***: Between the Central Government and the regional authorities competent within their respective territories.
- ***Intersectoral:*** Among the various authorities at the same territorial level with concurrent competencies because of subject area.

The forum for *interterritorial co-ordination* - insofar as food safety-related health protection is concerned - is the National Health System Interterritorial Council (CISNS), which is broken down into several levels according to political, technical or hierarchical criteria.

Similarly, non-health authorities ensure interterritorial co-ordination through their respective Sectoral Conferences: respectively, Agricultural, Consumer Affairs and Environmental Sectoral Conferences, as well as the National conference on Agriculture and Agricultural Development and the specific forum on animal health, Follow-up National Committee on Animal Diseases' Eradication and Control Programmes.

Intersectoral co-ordination, in turn, deals primarily with issues relating to the drafting and interpretation of food regulations within the Interministerial Food Commission (CIOA).

The most prominent fora focusing essentially on risk management are the Joint Commission for Pesticide Residues - involving Health and Agriculture -, and the Commission for the Management of the National Surveillance Residues Programme or PNIR, which is both interterritorial and intersectoral, involving Health-Agriculture and the respective regional authorities.

There are also *mixed* models, albeit in very specific areas, that addresses both intersectoral and interterritorial co-ordination. Such is the case of the National Biosafety Commission and its Collegiate Body, as far as the assessment of GMO-related environmental and health risk is concerned (enforcement of Directives 91/219/EEC and 90/220/EEC).

All the co-ordination fora mentioned are institutionalised as provided in the respective legislation.

2.3 Legal Framework for Food

While the drafting and enforcement of food regulations and the adaptation of foodstuffs and processes to the existing legal framework are considered in the section on risk management below, essentially in connection with legislation directly or indirectly intended to ensure the harmlessness of foodstuffs for consumption, this section describes the ***sources*** of competencies and the ***regulatory capacities*** of competent authorities.

It is not always possible in practice to ascertain whether a provision is directly and exclusively geared to ensuring the safety of foodstuffs. This explains the participation of different authorities in the drafting of regulations, although their respective responsibilities and involvement are not necessarily equally distributed. It is, in any event, important to note that the Spanish Constitution itself contains a paragraph exclusively devoted to laying the grounds for health legislation in the area in question (Art. 149.1.16).

Generally speaking, it may be said that there are fewer and fewer areas regulated exclusively by national initiatives, the most general source of domestic legislation being **Community Law** (Regulations, Directives and Decisions), which may either be directly applied or transposed into the Spanish body of law.

The **Codex Alimentarius** is also acquiring greater importance as the inspiration for legal provisions in the field of food safety, directly or through transposition of EU legislation. The more so in view of the role of *Codex Alimentarius* standards in the management of SPS and TBT Agreements within the framework of the World Trade Organisation.

Though no exhaustive or systematised discussion is intended, certain chapters in domestic legislative initiatives may be highlighted, such as health training for food handler people, the establishment of microbiological criteria in areas that have not yet been harmonised at the Community level, the existence of tolerance limits for certain abiotic contaminants not regulated by the EU, as well as a number of aspects in connection with diet foods, substances designed to be in contact with food as representative examples.

The Spanish State's own framework of competencies also lays down specific precepts with respect to the regulatory capacity of the authorities involved in food safety management. Drafting of the so-called *base regulations* is incumbent upon the Central Government, with direct responsibility attributed to the Ministry of Health and Consumer Affairs either exclusively or in conjunction with other departments, in particular the Ministry of Agriculture, Fisheries and Food, which assumes the primary if not exclusive responsibility for all matters involving quality and animal health, even where they may have an indirect impact on food safety and aptness for consumption.

Such *base regulations* may, in certain cases, be enlarged upon by territorial authorities, although as a general rule the regulatory capacity of the latter is limited to issues affecting organisational and structural questions associated with enforcement more than the substance of the regulations themselves.

In conclusion, the Central Government is responsible for incorporating Community provisions into the domestic body of law and, as appropriate, of converting the existing *Codex Alimentarius* regulations into domestic provisions in areas not covered by Community legislation. It should be recalled that international relations fall under the exclusive competence of the Central Government. The Central Government is also responsible for drafting domestic regulatory measures (on foodstuffs) of an exclusive or basic nature that are not derived from supra- or international sources, although the exercise of this competence is subject to the notification procedures in place in the EU (*General, Directive 98/34/EC; Labelling, Directive 79/112/EC; Hygiene, Directive 93/43/EC and Contaminants, Regulation 315/93/CE*), geared to detecting potential hidden obstacles to trade in domestic regulations.

In short, given the unquestionable preponderance of Community-inspired and framework legislation in the area of food safety, a more detailed discussion of this question may be found in the respective section of the Compendium drawn up by the European Commission.

While competency for drafting regulations on food is nearly exclusively incumbent on the Central Government, the same may not be said of EXECUTIVE COMPETENCE FOR THE OFFICIAL CONTROL OF FOODSTUFFS. This is incumbent upon territorial authorities - regional and local - with certain incidental exceptions, most significantly border health patrol (control at Border Inspection Points or PIF, which is incumbent on the Ministry of Public Administration, under the functional co-ordination of the Ministry of Health and Consumer Affairs. PIF inspection of raw materials, feed for animals and animal health and plant protection issues not directly related to human consumption are likewise subject to central functional co-ordination through the MAPA).

Summarising: enforcement of the official control of foodstuffs (geared primarily to monitoring and guaranteeing their safety for consumption, but also to combating fraud and safeguarding consumers' non-health interests) are incumbent upon territorial governments, while the Central Government is responsible for co-ordinating criteria and initiatives in this regard, as well as for analytical reference tasks in the above-mentioned fora for interterritorial co-ordination.

2.4 Risk Analysis

Preliminary Considerations:

Competent Spanish authorities share the criterion set out in the *Codex Alimentarius* procedures manual whereby RISK ANALYSIS, taken as a whole, covers **risk assessment, risk management and communication of risk.**

Competent authorities assume that risk assessment and risk management need to be functionally separated but also that the essential interactive elements between assessment and management needs to be recognised.

2.5 Risk Assessment

The risk assessment sources used by risk management authorities, often international (European Commission scientific committees, Council of Europe, WHO and/or FAO, ICMSF, ILSI, OECD... ad hoc queries), increasingly tend to address most of the food safety problems that arise with the added benefit, in virtually all cases, of being internationally accepted assessments.

The above does not, however, preclude resorting to domestic risk assessment commissioned from technical and scientific institutes under the aegis of the competent authorities but not directly involved in the risks assessed. The following are the most prominent institutions in this respect:

- The Ministry of Health and Consumer Affairs' “Carlos III” Health Institute, through its specialised centres:
  - National Food Centre
  - National Microbiology, Virology and Immunology Centre
  - National Environmental Health Centre
  - Health Technologies Assessment Agency.
- Research and Quality Control Centre, pertaining to the Ministry of Health and Consumer Affairs' National Consumer Institute.
- The Ministry of Agriculture, Fisheries and Food's National Agrarian Research Institute.
- The Ministry of Agriculture, Fisheries and Foods' Spanish Institute of Oceanography.
- A number of institutes under the aegis of the Ministry of Education and Culture's Higher Council for Scientific Research (CSIC).
- National Investigation Centre on Animal Health (Valdeolmos) as well as Animal Health and Production Reference Labs (Algete y Santa Fe).

The above institutions, in addition to their assessment activities, provide analytical coverage for the system, in particular by conducting reference-finding activities.

Preliminary risk assessment activities are also carried out in some of the co-ordination fora discussed in the preceding section. Such is the case of the national Biosecurity Commission, whose GMO assessment is conducted at this assessment level, whereas its Collegiate Body assumes responsibility for management of the risk assessed, although the approach is general rather than food-specific (the latter is covered under Regulation 258/97/EC *et sequentes*, implemented by the Ministries of Health and Consumer Affairs and Agriculture, Fisheries and Food).

In specific cases, preliminary risk assessment tasks are commissioned from *ad hoc* groups whose membership includes experts in the field, enlisted from different fora (e.g., the conference on a consensus about *Listeria* in foodstuffs, organised by the Ministry of Health and Consumer Affairs as early as 1992).

The ideal pursued is comprehensively oriented assessment based on criteria of excellence, independence and transparency. The need to ensure that assessors are free from the influence of management considerations is stressed. "Transparency" is not considered to be synonymous with "risk notification", as will be sustained below.

In any event, it is always preferable for risk assessment to be conducted at the supranational level since the provisions generated should, in principle, be recognised both regionally in Europe and internationally.

2.6 Risk Management

This activity is conducted by health authorities, with the participation from time to time of other stakeholders (other non-health authorities, agribusiness industry federations or associations, health service

professionals' associations and so on). The Ministry of Agriculture, Fisheries and Food is directly involved in risk management in the initial phases of the food chain (control of feed and feed ingredients, prime materials and its imports; control of the use of plant protection products at the source and follow-up on their LMRs; sanitary control of livestock production in connection with disease that can be transmitted to human beings; authorisation and control of the use of animal health substances, etc.).

A dual approach is taken to risk management:

a) Generate and maintain the appropriate regulatory standards (*legal framework*).

b) Verify process and product conformity to such legal standards (o*fficial control/inspection*), providing for nimble intervention mechanisms to restrict any incident detected both spatially and temporally and thereby prevent consumer access to unsafe or potentially unsafe foodstuffs that may constitute a serious or immediate health hazard (*Co-ordinated System for the Rapid Exchange of Information/Food Alert Network)*.

Both as regards regulatory measures and action associated with enforcement and management of the Food Alert Network, the p*recautionary principle* is an alternative that is always open to be deployed as necessary, as discussed below.

The preceding sections briefly describe the **risk management regulation drafting process, which** is increasingly if not - in the near future - exclusively based on the strict assessment of existing risks. The system whereby food regulation drafting competencies and responsibilities are distributed has likewise been discussed. As far as risk management is concerned, however, mention should also be made of the possibility of articulating and adopting immediately applicable precautionary and temporary measures which at times do not need to be validated as regulatory legislation, since they may be revoked once the cause that prompted their adoption disappears. Possible examples are the adoption of safeguard measures under Community standards or, in the absence of the latter, in response to strictly domestic initiatives, although subject to justification to Community authorities.

As far as the **application of the legal framework for food** or more precisely, enforcement of that framework with respect to the actors involved along with the identification and resteering of alleged infringements, is concerned, risk management is synonymous with the various expressions of official control of foodstuffs at whatever governmental level. It has already been noted that the enforcement competencies - with the exception of enforcement at PIFs - is incumbent upon autonomous regional authorities, from which it may be readily deduced that interterritorial co-ordination is extremely important. In this respect, Central Government co-ordination of criteria and initiatives is clearly a risk management task.

Special reference should be made to the arrangements regarding competencies and functions at Border Inspection Points or PIFs, a food risk management element that is essential to import and export control. Border health patrol, pursuant to constitutional principles (Art. 149.1.16), is exclusively a Central Government competency. Control of food safety at the border (also external EU borders) is articulated via a network of 37 PIFs in ports and airports, subject to the functional co-ordination of the Ministry of Health and Consumer Affairs.

Risk management draws on:

- Programmed activities
- Contingent and urgent activities to respond to risk situations.

The former comprises of the obligations laid down in Directives 89/397/EEC and 93/99/EC relating to the official control of foodstuffs and respective additional measures. Pursuant to such provisions, Spain conducts yearly overall control programmes, which primarily address questions relating to food safety, but also combat fraud and include other activities intended to protect consumer interests.

According to the above directives and the Commission's respective yearly recommendations adopted in the framework of those directives, Spain also systematically participates in co-ordinated Community programmes.

In addition to these actions - which are mandatory for by all EU Member States - others likewise intended to cover Community imperatives, although outside the directives on official control, are taken. The most representative (and of particular interest because they constitute control measures geared to the aptness for consumption and involving the initial links in the food chain) of these are the ongoing programmes implemented under the PNIR (see back) and the *Pesticide Residues Control* Programmes, implemented both at the source and on the marketplace.

Finally, there are the actions scheduled under exclusively domestic initiatives, namely: Prospective Programmes for Assessment of Foodstuffs on the Market (likewise useful, albeit indirectly, in risk assessment, insofar as they provide information, on occasion, about unprecedented risks).

Risk management support, in addition to the co-ordination mentioned above, is provided pursuant to the respective legal grounds:

- Databases on industries, establishments and potentially high-risk products (*General Health Registry of Food and Industries*). These databases are used to programme control action and facilitate traceability and alert management.
- *Epidemiological Surveillance System*, closely related, in this regard, to food alert management.
- *Reference Laboratories and Acreditation System* to certify the technical competence of laboratories participating in official control of foodstuffs.
- *Co-ordinated System for the Rapid Exchange of Information/Food Alert Network:* this is one of the activities envisaged in the event of contingent and urgent risks, nimble intervention mechanisms able to restrict any incident detected both spatially and temporally to prevent consumers from having access to unsafe or potentially unsafe foodstuffs that may constitute a serious or immediate health hazard.

In Spain, the *co-ordinated system for the rapid exchange of information or food alert network,* as a system for managing serious and immediate risks, is unquestionably a part of risk management, irrespective of the connections among the three elements that constitute overall risk analysis (assessment, management and communication) since risk assessment or, where lacking, the precautionary principle, is instrumental in the adoption of the decision to set off the alert notification procedure. The management of a given episode, in turn, determines the risk notification strategy to be deployed, since it is assumed that such notification necessarily involves more than transparency and accessibility of the scientific reports ensuing from the assessments, as discussed below.

Although the Co-ordinated System for the Rapid Exchange of Information is prior in Spain to the existence of Community legislation in this regard, today the legal grounds and procedural reference for the system are to be found in the Directive on General Product Safety (92/59/EC) and its respective instruments for application.

It is structured around a Network of Contact Points (consisting essentially of regional health authorities and the Federation of Food and Beverage Industries, which may be selectively expanded, depending on the case, to other points such as Border Health Patrol Services ***(1)***, the Ministry of Defence, the Ministry of Agriculture, Fisheries and Food and the National Epidemiology Centre) under the co-ordination of the Ministry of Health and Consumer Affairs' General Directorate of Public Health. ***(1)*** *The Border Health Patrol Services have a specific Alert Notification Network among P.I.F.s with respect to third country products, likewise co-ordinated by the Ministry of Health and Consumer Affairs.*

The national system, in turn, is integrated into the Community "RAPEX/RASFF" network, likewise based on Directive 92/59/EC and managed by the European Commission's Directorate General for Consumer Policy Health and Consumer Health Protection. The connection between the domestic and Community networks is the Ministry of Health and Consumer Affairs' Directorate General of Public Health, which co-ordinates communication between the two.

The system operates under criteria of speed and maximum selectivity - in terms of substance and geography - of information flows. The content of the notifications circulated is not made public systematically, but subject to established criteria in the framework of a risk notification policy or strategy.

2.7 The Precautionary Principle

The precautionary principle is most appropriately considered under and, in practice, forms a part of risk management, although it may also be regarded to be associated with assessment and even to communication.

If food safety is to be the result of the combination of a number of health and non-health interests which, while legitimate, are subsidiary to the guarantee of a high level of health protection, the precautionary principle may be invoked and applied under the following general circumstances:

- Non-existent, insufficient, outdated or controversial risk assessment.
- Insufficient information as far as the actual or potential exposure to a risk is concerned, even where the risk is adequately assessed.
- Material or temporary unfeasibility of analytically proving the absence of risk in products or processes associated with others in which the existence of an adequately assessed risk has been substantiated.
- Inability to reach the same level of protection with any other alternative than the precautionary principle.
- Cost-effectiveness appraisal.

Resorting to the precautionary principle in risk management translates into the adoption of regulatory or enforcement measures or both.

In any event, the principles considered in the adoption of such measures are proportionality - although the difficulty of making proportionality compatible with insufficient information has to be assumed *a priori* -, absence of arbitrary discrimination, maximum possible time and space restriction, coherent, as appropriate, with the precautionary nature of the measures in question. Such considerations are subordinate to the ultimate objective, namely health protection, in objective terms (impossibility of managing "zero risk").

A balance must be struck between the concept "evidence" and "precautionary principle". In the face of sufficiently and unfavourably assessed risk, managers must not be required to assume the full burden of proof as prior justification for any precautionary measure, concluding that otherwise the only justification for the action taken is the precautionary principle. The adoption of such measures based, for instance, on exclusively epidemiological evidence, may be justified without invoking the precautionary principle.

2.8 Risk Communication

This is understood to necessarily be based on transparency. It is, however, assumed not to be limited to transparency and accessibility to risk assessment reports, but rather to necessarily conform to structured strategies in the context of a risk communication policy.

The fundamental objective is not related as much to facilitating the information ensuing from scientific assessment in a way that is intelligible to all stakeholders as it is to conveying to those stakeholders and in particular consumers any necessary, sufficient and - it goes without saying - truthful information they may need with respect to any risk being reviewed under the management process. In this regard, risk notification supplements management itself in cases where citizen participation is requisite to full attainment of the risk management safety objective pursued.

Risk notification strategy is systematised in the following points:

- Notification should not precede assessment and management.

- Risk notification is undertaken at the request of risk managers, who establish the information process timetable and content. They notify the risks directly or through institutional (ministerial) notification cabinets, identifying and maintaining, in any event, unambiguous notification sources in order to prevent the co-existence of divergent information. Similarly, valid interlocutors among the parties concerned are identified and maintained.

- Risk notification can and should be stratified, in the sense of keeping stakeholders systematically informed and limiting notification to the population at large through the media to situations where such information impacts health protection effectively and favourably or is required to quell unwarranted social alarm.

- In any event, risk notification must be accessible and intelligible for its target audience, which often calls for prior conversion of terminology to common language, a task that may require risk managers to resort to communications specialists for counsel.

The above-systematised strategy is put into practice by health risk managers following the lines of action listed below:

- Favouring media access to the information generated by managers, both as regards the follow-up of individual incidents and the programming of joint sessions to analyse risk notification strategy.

- Systematically reporting to the Federation of Food and Beverage Industries (FIAB), in addition to promoting joint analysis and risk management in the food industry (26 sectoral guides published).

- Appearing from time to time to the Consumer and User Council, the senior consumer associations' representative body in Spain, without prejudice to the incidental information that may be provided in each case.

III. Future Activities and Approaches in the Treatment of Food Safety Questions

Three main aspects comprise this chapter on future trends:

a) Creation of a Spanish Food Safety Agency.

b) Nation-wide follow-through and implementation of measures stemming from the application of the *European Commission's White Paper on Food Safety*.

c) Strengthening and updating existing frameworks by, among others, enacting a *Food Act* covering a specific scope (neither exclusively nor exhaustively geared towards safety) and containing basic principles which, while co-existing with other instruments of the same status cited above in this Compendium but with a more general scope, will respond to the multifaceted nature of food and will address, *inter alia*, the creation of a *specific body to handle public alert situations*, with the involvement of the Government, the food industry, distributors and consumers.

3.1 Adaptations in the framework of the working world: Spanish Food Safety Agency

Last year the Government was mandated by Spanish Parliament to create a body of this nature. Based on the present structures of the Ministries of Health and Consumer Affairs and Agriculture, Fisheries and Food and other institutions related to the processing and monitoring of foodstuffs, it should, while both honouring the executive enforcement competencies assumed by the Autonomous Regions and enlisting their participation, pursue the following objectives:

- Articulate co-operation mechanisms among all the public authorities responsible for the control of foodstuff health and hygiene, ensuring homogeneous inspection and control processes.

- Keep abreast of the latest technical and scientific know-how in the areas of foodstuff and nutrition hygiene and control.

- Maintain any relevant technical and scientific relations, within the bounds of the system of competencies, with similar European Union bodies and those of its Member States.

- Encourage updating of basic regulations on foodstuffs.

This mandate is to be implemented taking account of the profile ultimately defined for the Food Safety Agency or Authority to be instituted in the European Union, given that the domestic agencies will be networking with the Europe-wide body. Initially, then, it would be advisable for the domestic agency to be vested with at least risk assessment responsibilities.

The articulation of other functions must necessarily be in agreement with the framework of competencies established by the Spanish Constitution, Autonomous Region Statutes and the decrees on transfer, all of which calls for cautious reflection before establishing a working model intended to last for

any length of time. The structural design and explicit definition of the functions of the future Spanish agency is, therefore, presently under review.

SWEDEN

I. Synthesis

Food that poses a potential risk to health should never be accepted.

A basic requirement is that no one should be exposed to diseases such as e.g. salmonella through eating food. People must feel that they can trust the food in terms of quality and content, and that the products they buy are safe.

There is a clear connection between the way farming and animal husbandry is managed and the quality of the food produced. High quality standards must be maintained along the entire chain of production.

The official control needs to be improved and the responsibility of the feed manufacturing industry should be clarified. Traceability and the safety for animal feed are important elements.

Labelling is also of importance. Sweden emphasises the need of information about allergens and intolerance against specific substances.

The precautionary principle must be the guiding principle for all matters concerning food.

Consumer interest must be strengthened. All consumer-related issues must include ethical end environmental considerations. One example is consumer anxiety over genetically modified food and how such food should be labelled.

II. Overview of the Food Safety System in Sweden

2.1 Institutional Structure

2.1.1 Ministry of Agriculture, Food and Fisheries

Swedish ministries are generally relatively small compared with their counterparts abroad. The day-to-day business of government administration is instead handled by independent, central government agencies. Within its sphere of operations the Ministry of Agriculture, Food and Fisheries is the principal for a number of agencies of varying sizes. The Ministry is responsible for providing the Government with the factual information required making decisions. The agencies are responsible for implementing government decisions and ensuring that they are complied with. They also provide expert knowledge in various matters.

The Ministry of Agriculture, Food and Fisheries has a wide area of responsibility, including foodstuffs and animal welfare.

2.1.2 The Swedish National Food Administration (NFA)

The National Food Administration (NFA) is the central administrative agency for matters concerning food.

The National Food Administration:

- Issues food standards and other food regulations.
- Carries out and co-ordinates food control in Sweden.
- Provides information on important matters concerning food.
- Promotes changes in dietary habits aimed at improving health.
- Carries out investigations and applies scientific studies on food and dietary habits and develops methods for food control.

There are also several other Government agencies with responsibilities in related areas include:

- National Board of Agriculture (agriculture, including animal health and welfare, the veterinary services and animal feed).
- National Chemicals Inspectorate (pesticide registration and use, control of chemicals).
- Medical Products Agency (registration of drugs for human and veterinary use).
- Environmental Protection Agency (environmental pollution and protection).
- National Board for Consumer Policies (consumer information, marketing).
- National Institute of Public Health (diet and health, alcohol, diseases).
- National Board of Health and Welfare (health statistics and health services).
- Institute of Infectious Disease Control (epidemiology and control of food-borne diseases).
- National Veterinary Institute (animal diseases, feed control, national zoonosis centre).
- National Board of Fisheries.

2.2 Legal Instruments

Sweden joined the European Union on 1 January 1995 and has harmonised its food legislation with that of the European Community (EC). Sweden takes part in the development of new EC legislation in the food area. EC regulations apply directly in Sweden and EC Directives are transposed into National Food Administration Ordinances, e.g., the regulation of novel foods.

In Sweden, food legislation is made at three levels:

- The **Food Act** issued by the **Swedish Parliament** is a frame law, containing definitions and principles concerning inter alia food composition, handling, labelling, offering for sale, personnel hygiene, food premises, supervision/ control, penalties and appeals.

- The **Food Decree** issued by the **Government** develops the rules of the Food Act in some greater detail and gives the National Food Administration the power to issue further regulations in the food area and to approve food premises in certain types of establishments.

- **Ordinances** issued by the **National Food Administration** contain detailed regulations on inter alia food standards, labelling, food handling, additives, contaminants, supervision and in-house control, food premises, personnel hygiene, drinking water, veterinary food control, export control, import control, food control laboratories and material for food contact use.

2.3 Food Control

2.*3.1 National Level*

The NFA is responsible at the national level for enforcing the Food Act and regulations issued under the provisions thereof. It inspects slaughterhouses, dairies, egg product establishments, export-controlled establishments and other very large food-producing establishments and also food premises in railway carriages, aircraft and certain ships. It also initiates food control projects, which are carried out by the local authorities and follows up the results of food control carried out at the municipal level.

The NFA registers the importers, which gives them and the municipal authorities the possibility to inform and to supervise.

The co-operation between the Swedish Customs and the control authorities is effective. The Customs receives the register of importers. As a preventive measure, a blacklist of exporters is used. The blacklist could help strengthening the official control and gives also the control authorities access to the Swedish Customs computerised system for imported food.

2.3.2 Municipal Level

In each municipality a committee, usually the Environment and Health Protection Committee, is responsible for control of all food handling establishments, except those under the supervision of the NFA. These include food production establishments, wholesalers, and retailers, catering establishments, waterworks and imports. The municipal authorities are also responsible for import control of food from countries outside the EU at border inspection posts.

2.3.3 Import from Countries outside the EU

The Swedish Board of Agriculture approves the import from countries outside the EU. **Food of animal origin** must be imported from EU-approved establishments in the country of origin. Control of salmonella is made on all meat, except for heat-treated meat.

The meat must also be controlled at the border inspection posts when it passes the EU border. When the meat passes the Swedish border, a preliminary entry needs to be sent to the border inspection post.

Import of honey requires a certificate from a food authority in the country of origin and the designation of “pure honey” needs to be certified. The import is carried out at border inspection posts.

Food of plant origin from countries outside the EU requires an import certificate from NFA. It concerns peanuts, Brazil nuts, figs, cacao, coconuts, products with Soya protein and water. Peanuts and Brazil nuts require an aflatoxin certificate.

Import of mushrooms from certain countries outside the EU is only allowed at border inspection posts. An export certificate from the country of origin and a certificate, which shows that a cesium control has been made, are required.

2.4 Risk Analysis

2.4.1 Risk Assessment

Transparency

Sweden has a tradition of an ”open” government and the right of public access to information on the workings of governmental agencies is established in our constitution. Consumer confidence in the food supply is vital for agriculture and the food industry and trade. One way of helping establish and maintain such confidence is by giving consumers and other interested parties access to information on how decisions on food safety matters are made and the results of food control activities.

2.4.2 Risk Management

Application of the precautionary principle

The precautionary principle must be the guiding principle for all matters concerning food. The European Commission has recently adopted a paper on the precautionary principle (COM (2000) 1 final). The definition of the principle is also discussed in the Codex Committee on General Principles.

Risk managers need to be aware of the uncertainties and the insufficiency of the data, their inconclusive and imprecise nature and, when necessary, the diverging opinions of scientists, before taking decisions. Judging what is an unacceptable level of risk for the society is a *political* responsibility.

When establishing maximum limits for contaminants of various types in foodstuffs, Sweden has applied risk management and set the limits to provide a wide margin of safety. In some cases, for example certain pesticides, these limits are lower than the limits considered acceptable from the purely toxicological point of view. In this way and through the active enforcement of the regulations the consumer’s exposure to foreign substances should be minimised.

Consultation of stakeholders

Stakeholders in Sweden, e.g. NGOs, consumer organisations, the industry, other authorities, are consulted (normally by a written procedure) in the regulatory process. The Swedish Government always considers the outcome of the consultation in the decision-making process. The consumer organisations have a considerable impact on the decisions concerning genetically modified food and other food issues.

2.4.3 Risk Communication

The National Food Administration has an important role in providing information. It has its own web site with the latest news and other information. Mass media is an important channel in reaching the consumers. Press releases are one considerable tool. Information activities are also directed to consumer organisations, the food industry and trade, catering organisations, municipalities and other national authorities.

III. Activities in Addressing Food Safety Issues

3.1 The Consumer in Focus

Today's consumers expect a great deal from the products they buy. All food should be produced in ways that are friendly to animals and the environment. Consumers in Sweden and other EU member states are becoming more aware of these issues, and increasingly disposed to question the quality of food and the way it is produced. Consideration for the environment and for the way animals are treated are factors which have made Sweden to one of the leading nations in the common European market in terms of consumer-oriented agriculture and food production.

Sweden's efforts in relation to consumer issues in the EU are aimed at strengthening the consumer's position in the market, promoting their interests and enhancing their influence in an integrated Europe. Sweden will also continue to pursue and further develop its own consumer policies. EU regulations for the protection of consumer rights must be improved and strengthened.

3.2 Developing National Food Safety Frameworks

In December 1998, the EU banned the use of medically approved ***antibiotics*** to stimulate growth. This was a great success for Sweden and an important first step for the EU. Sweden will continue to pursue the antibiotics issue. The objective is the banning of the regular use of antibiotics in animal feed throughout the EU.

Sweden fully supports a continued ban on the use of ***hormones*** and the import of meat from animals that have received hormone treatment.

Sweden will take active steps to reinforce and improve ***animal protection***. Using the Swedish Animal Protection Act as a point of departure, an improvement of animal protection in Europe as well will be sought.

It is essential that Sweden continue to take active measures to control ***salmonella.*** The prevalence of salmonella in Sweden is minimal; a unique condition directly attributable to a well-developed, effective monitoring system that protects the consumer from diseases that can be communicated from animals to humans through our food. To provide better protection for consumers, a more pro-active attitude towards the salmonella issue combined with common community regulations will be needed.

One of the most important measures in preventing communicable diseases is adequate collection and disposal of ***animal carcasses*** and other high-risk animal waste. With the exception of thinly populated areas in the northernmost part of Sweden, the burial of animal waste or the deposition of animal waste on refuse dumps is no longer allowed in Sweden.

UNITED KINGDOM

I. Summary

The principal legislative instruments for the control of food safety and standards in the UK are the Food Safety Act 1990, and equivalent legislation in Northern Ireland, and the Food Standards Act 1999. In addition, a large body of detailed food legislation has been developed by the European Union and its predecessor over the last 40 years. This legislation is either directly applicable in national law or has been implemented in the United Kingdom under the Food Safety Act and Northern Ireland legislation. A key feature of the Act is the "due diligence defence" which requires a person to take "all reasonable precautions and exercise due diligence", when dealing with food. The onus is therefore very much on the producer and seller of food to ensure that food is safe. Enforcement of most food legislation is undertaken by local authorities.

The UK operates a well-established risk analysis system in dealing with food safety hazards, which has as its main components risk assessment, risk management and risk communication. This is undertaken in an increasingly open and transparent manner involving consumer input and is underpinned by extensive research and surveillance programmes. The UK has access to a range of independent advisory committees in operating the risk analysis system and takes a precautionary approach to the management of risk where the scientific evidence is considered to be incomplete and the possible damage to human health, considerable. It always endeavours however to ensure that its decisions are proportionate to the risk, paying due regard to costs and benefits and avoiding over regulation.

Prior to April 2000, responsibility for the development and implementation of food safety and standards policy within the UK Government rested with the Ministry of Agriculture, Fisheries and Food and the Department of Health in England, and the equivalent Government departments in Northern Ireland and in the devolved administrations in Scotland and Wales. However, from 1 April 2000, this was passed to a new Government Department, the Food Standards Agency. The Agency is a UK body accountable to Parliament through Health Ministers and through the equivalent devolved authorities in respect of the Scottish Parliament and National Assembly for Wales.

The Food Standards Agency operates at arms length from Ministers under the day-to-day responsibility of a Chairman, Deputy Chairman and a Board of 12 members. Its decision making processes are open, transparent and consultative and it acts independently of specific sectorial interests at all times. It publishes its advice to Government and explains the basis on which decisions are made. These take full account of UK obligations arising from domestic and international law. It endeavours to use the best available scientific advice and ensures that the policies its develops are of practical relevance and proportionate to the risk. It also provides information to consumers to enable them to make informed choices about the food that they buy. The Agency concentrates particularly on the communication of risk through publicity, advice, education and training. In achieving this, it works closely with the public and other stakeholders. It intends to develop and improve the current risk procedures and the science base which underpins these having taken over the Government's food research and surveillance programmes. It will participate fully in the development of future international food safety systems.

II. National Food Safety Systems and Activities

Introduction

Responsibility for the development and implementation food safety and standards policy within the UK Government has resided with the Food Standards Agency from the beginning of April 2000.

The report which recommended the establishment of this Agency (Food Standards Agency Report – An Interim Proposal, by Professor Philip James, 1997) highlighted the loss of public confidence in food safety that had occurred over the previous 10 years as the main driving force for this. It reported on the findings of public surveys showing that consumer concern focused on four principal areas:

a) *The microbiological safety of food*: the *E. coli* and salmonella outbreaks – along with BSE– highlighted particular concerns about the safety of meat, but other problems, such as listeria, had given rise to wider public concern that the modern systems of farming, food processing, distribution and retailing may be operating with inadequate safeguards.

b) *The chemical safety of food:* long-standing concerns about the safety of chemicals in foods including veterinary drug residues, pesticide residues, heavy metal contamination, and the use of food additives had been heightened by more recent scares over phthalates in infant formulae and substances in food with oestrogenic activity that could be affecting sperm counts. The problems were not felt to be confined to food produced on land; but also included algal toxins in fish and the use of chemicals in fish farming. More recently, concern about contamination from dioxins entering the animal feed supply has highlighted both the significance of the whole feed chain and the international dimension of food safety systems.

c) *Genetically modified organisms, novel foods and processes*: many people are apprehensive about new developments in genetic modification and about technologies which introduce new characteristics (in plants in particular) where consumer benefits are not clear, and the environmental impact uncertain. The introduction, for example, of genetically modified soya and maize and their potential use in a wide range of foods continues to be a matter of concern to many consumers.

d) *The nutritional quality of the diet*: the public perceives correctly that nutrition is of major importance for their health, but many are confused by the information conveyed through labelling. The consensus among the scientific community on the effect of food on health tends not to be reflected in the media, itself poorly served by reliable and independent sources of information. There is widespread public demand for more information about new products on which to base meaningful choices.

In combination, these issues have raised the level of awareness and concern about the safety and quality of food in the UK and moved the topic towards the centre of public debate and media attention. The general presumption by consumers in the past**,** that food is as safe as it can be, has been undermined by a number of factors including media 'scares', poor information and a sometimes weak appreciation of both the underlying science and relative risk. Retailers, prompted by the 'due diligence' requirement of the GB Food Safety Act and Northern Ireland legislation, and the commercial pressure to maintain their market position, require increasingly rigorous production protocols and traceability across the whole supply chain. Primary producers are striving to meet the higher standards required by regulations, farm assurance schemes and retailer protocols at a time of extreme economic pressure. Government is challenged with developing policies that are fully informed, proportionate to the risk, effectively communicated, credible and reliable.

Consequently there is an unprecedented demand for sound knowledge, with fully informed risk assessments and risk management options, effectively communicated, as a basis for meaningful policies and better practices, leading to the provision of safer food.

This requires:

- The use of surveillance, research and other intelligence gathering methods to assist the risk assessment process.

- The closer integration of science, practice and stakeholder interests across the whole food chain to aid the risk management process.

- More effective risk communication of the outcomes through publicity, advice, education, and training.

Legislative Base

The Food Safety Act 1990, and equivalent legislation in Northern Ireland, and the Food Standards Act 1999, are now the overarching primary legislative tools for the control of food safety and standards in the UK. The Food Standards Act amended the Food Safety Act and Northern Ireland legislation to provide for the establishment of the Food Standards Agency.

The Agency is a UK body accountable to Parliament through Health Ministers and through the equivalent devolved authorities in respect of the Scottish Parliament and National Assembly for Wales. It operates at arm's length from Ministers under the day to day responsibility of a Chairman, Deputy Chairman and a Board consisting of 12 members. The Agency is the primary source of policy advice to the Government as a whole and to the devolved authorities in relation to food safety and associated areas. These functions were previously vested with the Ministry of Agriculture Fisheries and Food (MAFF) and Department of Health (DH) in England and the equivalent Government departments in Northern Ireland and in the devolved administrations in Scotland and Wales. The Agency is also able to advise on the development of policy by other Government departments on matters relevant to the Agency's own area of responsibility, for example activities on the farm that may have an impact on food hygiene such as the occurrence of food borne zoonoses and the use of veterinary products.

The general functions of the Agency are to:

- Develop policies on food safety, food standards and other related matters and to provide advice, information and assistance to enforcement authorities.

- Provide advice and information to the general public on matters connected with food safety, food standards and nutrition.

- Obtain, compile and review information in connection with food safety, food standards and related matters. This will include monitoring developments in science and technology and other relevant fields and undertaking, commissioning or coordinating research.

- Set and monitor enforcement standards and to audit local authority application of these.

These general functions also apply to the safety of animal feeding stuffs, with a view to protecting human health.

The Food Standards Act gives the Agency the power to obtain information about any aspect of food production or supply, food sources, or the use of animal feedingstuffs.

The White Paper (The Food Standards Agency – A Force for Change), which was published in 1998, set out the UK Government's plans for the Agency and described the guiding principles on which it would operate. These are as follows:

a) The essential aim of the Agency is the protection of public health in relation to food.

b) The Agency's assessments of food standards and safety are to be unbiased and based on the best available scientific advice.

c) The Agency is to make decisions and take action on the basis that:

- Its decisions and actions should be proportionate to the risk; pay due regard to costs as well as benefits to those affected by them; and avoid over-regulation.
- It should act independently of specific sectoral interests.

d) The Agency is to strive to ensure that the general public has adequate, clearly presented information in order to allow it to make informed choices. In doing this, the Agency must aim to avoid raising unjustified alarm.

e) The Agency's decision making processes is to be open, transparent and consultative, in order that interested parties, including representatives of the public:

- Have an opportunity to make their views known.
- Can see the basis on which decisions have been made.
- Are able to reach an informed judgement about the quality of the Agency's processes and decisions.

f) Before taking action, the Agency is to consult widely, including representatives of those who will be affected, unless the need for urgent action to protect public health makes this impossible.

g) In its decisions and actions, the Agency is to aim to achieve clarity and consistency of approach.

h) The Agency's decisions and actions must take full account of the obligations of the UK under domestic and international law.

i) The Agency is to aim for efficiency and economy in delivering an effective operation.

In summary, the Food Standards Agency has powers across the whole food chain. It is dedicated to putting the consumer first, to being open and accessible and to acting as an independent voice. In fulfilling its remit, the Chairman and Board have decided that the Agency will:

- Base its decisions and advice on the best evidence available.
- Consult widely before it makes recommendations unless urgent action is essential.
- Obtain independent expert advice from its advisory committees.
- Commission research to support its functions.
- Be prompt in making public its advice to Government.

The Food Safety Act for England, Wales and Scotland, and the equivalent one for Northern Ireland, brought together and updated all food legislation and implemented some European legislation requirements. A key feature of this legislation is the 'due diligence defence' which requires a person to have taken 'all reasonable precautions and exercised due diligence' when dealing with food. The reasonableness of the action taken in any particular set of circumstances is judged on a case by case basis taking account of the resources available to the business concerned.

A significant body of detailed food legislation has been developed by the European Union and its predecessor over the last 40 years and this now embraces most areas, which have a bearing on food safety. Under the provisions contained in the various European treaties, this legislation is either directly applicable in national law, or must be implemented by the Member States. This is described more fully in the separate document provided by the European Commission.

UK Food Safety Systems

The challenge for the policy process is to gain a full appreciation of the hazards to food safety, and to develop an understanding of their extent, the causal and transfer mechanisms, and the health consequences of these, and to use this knowledge to develop appropriate control procedures where these are needed. To be able to do this, all appropriate information - scientific, commercial and consumer - needs to be obtained and considered. Using this approach, a structured risk analysis procedure was developed and put into operation in the UK some years ago.

Risk Analysis

The risk analysis system used in the development of UK policy has evolved with the understanding and development of this concept internationally. This has lead to the development of a national system embracing risk assessment, risk management and risk communication, and based firmly on scientific principles and analysis.

There is a formal separation between the risk assessment and risk management functions. This approach minimises the possibility that the technical assessment of risk might be distorted by consideration of other, non-scientific issues such as limitations on the precise form that any resulting action might take.

This separation creates one potential difficulty however. This is that the risk assessors need to be made fully aware of all the questions to which answers are required before the various options for managing the risk can be properly examined. It is therefore essential that the scope of the risk assessment is defined as closely as possible at the outset.

Risk Assessment

Risk assessment is carried out by the advisory committees of independent experts that provide advice to the Agency. A list of these is given in the Annex. Most members of these advisory committees are appointed as independent scientific, medical (or other technical) experts on the basis of their special skills and knowledge. The Committees also contain one or more public interest members who are appointed for their knowledge of consumer and other matters.

In assessing the risks, the advisory committees consider all relevant scientific data. The committees are also made aware of relevant risk assessments carried out elsewhere, including internationally, where these are likely to be relevant.

Risk Management

Chemical risk management considerations are the responsibility of the Food Advisory Committee (FAC) although the Board of the Agency also has a role here. The FAC is composed of members with a diverse range of backgrounds, which enables it to be able to tackle a wide range of food issues. The FAC does not tend to deal with complex technical matters in relation to, say toxicology or carcinogenicity, but relies on risk assessments provided by the appropriate independent expert group. The primary role of the FAC is that of considering the management of risks that have been identified and assessed elsewhere. It does this by considering the nature of the risk, assessing the options and advising the Agency on the appropriate course of action. The options considered may reflect wider considerations, such as Codex standards, or risk management decisions and policy development in other countries.

Risk Communication

Risk Communication is an integral part of the UK risk analysis process, and covers both the risk assessment and risk management stages. The Agency devotes significant resources to this activity, including the establishment of a major Website of up-to date national and international food safety information, regular Press Releases and briefings, and publication of a large number of information documents designed for the lay person covering a range of food safety issues. In addition to these specific issues, the increasing openness and transparency of the UK risk analysis system contributes significantly to the overall communication of risk.

Openness and Transparency

Both the expert committees on risk assessment and the FAC have taken a number of steps in the last few years to operate in an open and transparent manner. This includes the declaration (and disclosure) of members interests, publication of agendas of meetings, discussion papers, minutes of meetings, Reports of Assessments and Conclusions, and Annual Report of the Activities of the Committee. A number of expert committees also produce a regular newsletter which conveys the work of the committee to the lay reader. More recently, the committee that advises on novel foods has decided to publish all future applications that it receives on its website. Only a small amount of information which is classified as commercially sensitive will be excluded from this arrangement. All those with an interest can then make their views known to the committee before it reaches its conclusions. These various openness arrangements are important in involving stakeholders in the decision-making process from an early stage.

Formal and informal consultation processes involving all stakeholders contribute to the formulation and implementation of new policies, regulations and techniques. Where substantial policy initiatives are proposed, consultation is extensive and highly transparent with considerable effort being made to include all relevant interests in the process.

Consumer Representation

In addition to the above consultation procedures, the UK also consults consumer interests on a wide range of food issues. This is done in a variety of different ways including through meetings, formal consultation letters and advisory committee websites (see previous page, first paragraph of, "Openness and Transparency"). The Agency will be reviewing these procedures with the aim of enhancing consumer input to the decision making process wherever possible.

Research and Surveillance

In order to improve the scientific base, which underpins the food risk analysis carried out in the UK, the Agency spends around £25million annually on research. This research is commissioned via open competition following the publication of clearly defined and focused research requirements. The various research programmes are reviewed regularly and evaluated by external experts to ensure that they remain relevant and appropriate.

The Agency also spends around £5 million per year on surveillance of the food supply in order to assess the appropriateness of its policies and to identify emerging problems. This work is also used to inform the risk assessment and risk management processes, for example, by providing data on the dietary exposures of the UK population to certain chemicals.

Summary and Conclusions

The development of food safety systems in the UK is dynamic and has evolved rapidly over the last decade. The establishment of the Food Standards Agency in April 2000 marked the latest stage in this process. It is focussing particularly on:

- Co-ordination of food safety activity throughout the food chain.
- The involvement of all stakeholders in the development of policy.
- The continued development of policies that are based on sound science, practical relevance and are proportionate to the risk.
- The provision of information to consumers to enable them to make informed choices.
- The development and implementation of food policy in a way that is both open and inclusive.
- The maximising of efficiency and economy in policy delivery.

ANNEX

Current Advisory Committees are:

1. Advisory Committee on Microbiological Safety of Food (ACMSF).
2. Advisory Committee on Novel Foods and Processes (ACNFP).
3. Advisory Committee on Pesticides (ACP).
4. Committee on Medical Aspects of food and Nutrition Policy (COMA).
5. Committee on Medical Aspects of Radiation in the Environment (COMARE).
6. Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT).
7. The Committee on Carcinogenicity and The Committee on Mutagenicity.
8. Food Advisory Committee (FAC).
9. Spongiform Encephalopalthy Advisory Committee (SEAC).
10. Veterinary Products Committee (VPC).
11. Scientific Committee on Nutrition.

HUNGARY

I. Executive Summary

In the New Millennium Hungarian food industry is facing great challenges. Requirements regarding food safety and product quality are more and more definite in the pre-accession period.

The legal background of the Hungarian food-safety system is based on the relevant EC legislation thus fully harmonised with the provisions of the EC. The *Food Act* which determines the conditions of the production and marketing of raw, semi-processed and processed food intended for public consumption states that the protection of consumer health and interests and fairness of market competition should be ensured.

The official food control tasks are allocated between three Ministries and their institutes/ organisations. The official control of animal health, quality and food hygiene requirements for processed food for domestic consumption and export moreover for fresh fruits and vegetables is carried out by the *Veterinary and Food Control Service* operating in every county and in the capital under the umbrella of the Ministry of Agriculture and Regional Development. Their work is supported by the National Food Investigation Institute (OÉVI).

The official control of those issues related to public health and human epidemics is carried out by the *National Public Health and Medical Officer Service* (NPH-MOS) having institutes and offices in each county and certain cities. Their work is supported by central expert institutes as well. This organisation is responsible for the Ministry of Health.

Certain food safety but rather food quality issues are handled by the General Inspectorate for Consumer Protection reporting to the Ministry of Economic Affairs which is responsible for the consumer protection. The work of these three organisations is co-ordinated by an inter-ministerial committee.

II. Introduction - Food Industry, Processing and Retail

In the New Millennium the Hungarian food industry is facing great challenges. Requirements regarding food safety and product quality are more and more definite in the pre-accession period.

Hungary has a long tradition in producing and processing agricultural raw materials. The Hungarian horticultural products have achieved good reputation for their excellent sensory properties. Food industry is one of the most important sectors of the national economy. The food sector, producing 4 % of the GDP has a vital role in processing 75 % of the agricultural raw material and distributing properly processed high quality products to the final consumers. Currently there are more than 8000 food manufacturing businesses in Hungary. Out of these large and medium size companies are responsible for more than 80 % of the total production of the food industry.

In the ‘80s much effort was taken on traditional quality control practices to provide good properties, large and medium size companies mostly had comprehensive traditional internal inspection and testing systems focused on product testing. Food industry has been essentially privatised in the ‘90s mainly by multinationals. The high interest for quality management issues in the food industry resulted in

a rapidly growing number of people understanding requirements, the significance of proper specifications, etc. which has created a business culture in which food safety management systems could develop. Quality management principles and preventive, proactive approach were introduced to provide uniform, reliable quality and food safety.

In the retail sector the market share of the retail chains having large stores is rapidly increasing which will have a driving effect in improving food safety and quality standards and practices in the industry. In the catering sector (cca. 43.000 units) the fast food business, both restaurant chains and small independent outlets, have developed very quickly. A wide range and variety of traditional restaurants from hotel restaurants to local pubs, ethnic restaurants to salad bars have been established by new owners having significant differences in professional background and experience. The traditional institutional catering system has virtually collapsed. A few large companies with central kitchens represent this sector where major changes may be expected.

III. Legal Framework

The legal background of the Hungarian food-safety system is based on the following acts, enacting clauses and related decrees, which are fully harmonised with the provisions of the EC:

- *Food Act*, Act XC of 1995 on Foods, and its joint executive decree No. 1/1996. (I.9.) FM-NM-IKM last amended by 45/1999. (IV.30.) FVM-EüM-GM joint decree.
- *Veterinary Act*, Act XCI of 1995 and decree: 41/1997. (V.28.) FM on the execution of the Act, entitled “The Veterinary Procedural Regulations”.
- *Gene-technological Act*: Act XXVII of 1998 and its executive decree: 1/1999. (I.14.) FVM and 44/1999. (IV.30.) FVM decree.
- Consumer Protection Act: Act CLV of 1997.
- 4/1998. (XI.11.) EüM decree on the "permissible level of microbiological contamination in foods".
- 12/1998. (XII.11.) EüM decree on the "permissible rate of radioactive contaminants in food".
- 2/1999. (II.5.) EüM decree on the "Tolerable residue limits of veterinary drugs in foods".
- 17/1999. (VI.16.) EüM decree on the "Tolerable residue limits of chemicals in foods", amended by 57/1999. (XI.26.) EüM decree.
- 17/1999. (II.10.) FVM-EüM joint decree "About the food-hygienic conditions of food's manufacturing and trade".
- 59/1999. (XI.26.) EüM decree - "About the public health regulations of food trading on markets, and market-halls”.

The *Food Act* which determines the conditions of the production and marketing of raw, semi-processed and processed food intended for public consumption states that the protection of consumer health and interests and fairness of market competition should be ensured.

The Act declares that for food production only such materials may be used which are not harmful to human health and meet the legal requirements. In the course of the production and

transportation of foods technical, technological, public health and food hygiene conditions shall be applied that ensure that the foods meet the public health, food hygiene and quality requirements. Food producers are obliged to comply with the provisions concerning the chemical, physical, microbiological characteristics of food.

The Food Act declares that the Hungarian Food Code (Codex Alimentarius Hungaricus) is the collection of obligatory provisions and recommended guidelines concerning raw and processed foods. The volumes of the Hungarian Food Code contain the following:

- Volume I shall contain the mandatory provisions governing foods produced or marketed in Hungary. These provisions are based on the legislation of the European Communities.

- Volume II shall contain the recommended specifications drawn up by taking into account the recommendations of international organisations and the local circumstances in Hungary.

- Volume III (Collection of Official Methods for Food Analysis shall contain the mandatory methods based on the legislation of the European Communities, recommended nationally adapted European standard, other standards and guidelines.

IV. National Food Control System; Responsible Institutions

The official food control tasks are allocated between three Ministries (see Table) and their institutes/ organisations (see Table). The official control of animal health, quality and food hygiene requirements for processed food for domestic consumption and export moreover for fresh fruits and vegetables is carried out by the *Veterinary and Food Control Service* operating in every county and in the capital under the umbrella of the Ministry of Agriculture and Regional Development. Their work is supported by the National Food Investigation Institute (OÉVI).

The official control of those issues related to public health and human epidemics is carried out by the *National Public Health and Medical Officer Service* (NPH-MOS) having institutes and offices in each county and certain cities. Central expert institutes support their work as well. This organisation is responsible for the Ministry of Health.

Certain food safety but rather food quality issues are handled by the General Inspectorate for Consumer Protection reporting to the Ministry of Economic Affairs which is responsible for the consumer protection.

The work of these three organisations is co-ordinated by an inter-ministerial committee.

1. Veterinary and Food Control Service

The structure of the Hungarian Veterinary and Food Control Service is shown in Tables. It serves as an executive authority supported by specialised central institutes. This executive professional system has been governed and supervised by the Department of Animal Health and Food Control of the Ministry of Agriculture and Regional Development. There are Municipal Veterinary and Food Control Stations as executive offices in all the 19 counties and one in the capital moreover the laboratories concerned.

The Specialised Central Institutes are:

- **National Food Investigation Institute:** The institute is devoted to the food-safety control. It is specialised on the subjects of general and specific nature such as food-hygienic control of export-licensed abattoirs for both red and poultry-meat and related meat processing plants, as well as cooling-freezing plants. Its activity is supported by specialised laboratories (microbiology, food contaminant's analytical-toxicology, compositional food chemistry, food and environmental radiological control). It supervises the county station's laboratories via round-tests and other laboratory quality assurances systems. For supporting the above-mentioned activities the National Food Investigation Institute has taken part for 5 years in the British Food Analytical Performance Assessment Scheme (FAPAS) and other international laboratory quality control programmes (e.g. International Atomic Energy Agency (IAEA)). It serves as a radiological control centre managing the related district radiological laboratories as well. It supervises 5 district Milk Safety and Quality Control Laboratories. It introduces the control system for novel foods in particular for foods containing or derived from GMOs and related risk analysis. It acts as an international food safety contact point for FAO, WHO, CAC.) It works in close co-operation with the public health service. It organises also food-safety-training programmes. It performs continuously the food-safety-related risk-analysis and -assessment in any food sector.

- **Central Veterinary (Diagnostic) Institute and its 5 district subsidiaries:** The institute is devoted to every aspect of veterinary epidemiological control, complex diagnostic of mammalian-, avian-, fish-, wild-game-, bee-species related diseases via pathology, pathohistology, virology, bacteriology, serology-immunology, parasitology, toxicology, planning of disease eradication, sentinel and surveillance epidemiological programmes, urgent local inspections and sampling of animal disease and death-cases. It contributes to the development of new diagnostic methods and improving the specificity and effectiveness of the procedures. It organises specialised training programmes. It serves as an international animal epidemiological contact point (OIE, FAO, WHO). The institute contributes to the eradication of zoonoses. It maintains the computer centre for the National Veterinary Information and Data Handling Network.

- **Control Institute for Veterinary Vaccines, Animal Drugs and Feeds:** This institute is responsible for the control of any batches of home produced or imported veterinary vaccines for licensing, maintains permanent contacts with international vaccine-banks. It surveys the approbational documentation of any veterinary drugs intended to be introduced; it performs general and specific documentary, pharmacological or toxicological check before to be licensed by the Ministry of Agriculture and County Development. It controls any feed ingredients, species identification of imported meat- or fishmeal, medicated feeds, feed-additives, premixes, compositional characteristics of feed-concentrates and ready-to-eat composed-mixed feeds.

Veterinary and Food Control Stations (19 + 1 establishments)

These offices are serving as subsidiaries of the Division of Veterinary and Food Control Service of the Ministry of Agriculture and Regional Development and empowered to the official sphere of authority on the following areas:

I. Animal health and disease control;

II. Food-safety, -hygiene and quality control.

The sphere of operation covering the territory of the given county is divided into 3-5 state veterinary districts.

A. In case of certain animal disease or related circumstances the official veterinarian orders quarantine-measures and steps forwarding the eradication (separate closing of animal groups, prohibition or release animal for transport, stemping-out, emergency slaughtering, disinfection, treatment, vaccination, animal welfare, economic compensation) and reporting to the higher ranking authorities. It contributes to the eradication of zoonoses as well. Some veterinarians fulfil service at certain border inspection posts for controlling both: inter country trade of live animals and food consignments of animal origin. The Station co-operates with the municipalities and public health authorities for eradicating the epidemic-endemic of animal diseases and food safety-control. The Station performs sentinel or surveillance sampling of animal herds.

B. The Stations are in charge of official licensing of establishing any food processing plant, food store (list of products, mode of production, structure, capacity, organisation of work, safeguarding). Ante- and post-mortem meat inspection, animal transport related veterinary documentary check, animal welfare at the farm and at the reception side of slaughterhouse and at stunning and bleeding, official monitoring sampling for chemical contaminant's control.

Documentary check for residue-, tap water-, hygienic status-control, maintenance of HACCP-system, furthermore eradication programmes for rodents and insects. Controlling the rendering plants. Food-hygienic status control of food-shops, -stores, -markets is performed and hygienic surveillance of specific food-consignments in trading e.g. shelf-life and quality in particular food safety is evaluated. Surveying the methods of closed collection and destruction of condemned foods. Food-quality control related measures en locos and via laboratory test is carried out as well. Laboratory of the Veterinary and Food Control Station performs real-time investigations (microbiological, immunological, analytical, antimicrobial control, radiological, food-compositional and -quality related characteristics); furthermore round-test laboratory quality assurance related samples issued by the central reference laboratory.

The above-mentioned Hungarian food-hygienic and -safety authorities are about to introduce and apply the principles of r*isk analysis* for planning their programmes and actions. The participating experts are selected on the basis of their professional excellence, independence, transparency, legitimacy, appropriateness, efficiency, accountability and feasibility. In case of newly emerging food-safety problems and in order to establish the guaranty of food-safety the authority co-operates with other official institutions involved in food safety matters and with the representative organisations of the public sector e.g. Consumer Protection Service, Society of the Food-Hygienic Experts, Society for Environmentally Influenced Health Matters.

The **Risk Management** of the Hungarian food-safety authority is considered to be as a complex decision making procedure: surveying and evaluating any information and the possibility of taking legal actions. The aim of it to gain the most favourite and affective preventive and/or defending procedure.

The **Risk Communication** such modes of communication and publication which considering the available microbiological, chemical-toxicological, economical, cost/benefit ratio, psychological, etc. information which will give public related correct share of information.

The **Risk Analysis** related main aims are: to establish food-safety policy, updating the regulations and executive official bodies, consultations, establish effective and oriented monitoring systems and complex evaluation, innovative approach, impact on the political decision-makers, consider sound scientific advice and establish wide-scale consultations with all interested parties and information-transfer.

2. National Public Health and Medical Officer Service

The Ministry of Health is responsible regarding food safety and nutrition for the effects of unsafe food and unhealthy nutritional habits on the population as a whole so its aim is to prevent food-borne diseases.

The *National Public Health and Medical Officer Service* is responsible for the prevention and investigation of food-borne diseases. Please find attached Tables on the national reporting system of food-borne diseases in Hungary.

The *National Public Health and Medical Officer Service (NPH-MOS)* works under the umbrella of the Ministry of Health. This service is responsible for the prevention and investigation of food-borne diseases. This service deals with the nutritional aspects, too. It operates in three levels.

- The head of the whole National Public Health and Medical Officer Service is the *Chief Medical Officer*, who is appointed by the Minister of Health.

- The *Office of the Chief Medical Officer* is responsible for the food control activity of the whole NPH-MOS in Hungary.

- A scientific research institute, called Institute of *Food Hygiene and Nutrition* belongs to the Service. Beside its scientific and research activity, task of the Institute is to examine and licence food additives, some special health-related foods (e.g. foods for special diets, functional foods, novel foods), the imported foodstuffs from the health aspect and it issues guidelines. This Institute is the contact point for WHO in nutritional and food safety issues, and it is the surveillance centre of food-borne diseases and food contamination.

- Each of the 19 counties in Hungary and the capital has a *regional public health institute*. The main role of the regional institutes is to control and co-ordinate the work of the local institutes, but they have their own tasks, too. Laboratories belong to each regional institute.

- The local environmental health institutes regularly licence, register and control all food enterprises (food industry, catering sector, restaurants, food retailing).

At the Public Health and Medical Officer Service mainly medical health officers (they are medical doctors by profession) and environmental health inspectors work specialised in environmental and epidemiological studies including food control and nutrition. In the national and regional institutes lots of different specialists (chemists, engineers, microbiologists, nutritionists, etc.) work.

The medical health officers and the environmental health inspectors such as the above-mention veterinarians have right to take certain measures. They can prohibit the placing on the market of food suspected of being infected or toxic, and seize food if it is proved to be dangerous or spoiled. They can order some necessary measures to improve the health condition of the premises or to prevent food poisoning. They prohibit the employment of food handlers suffering from certain diseases that might be transmitted through food. There is a personal penalty for contravention and a stricter penalty for food companies, if they proved to be guilty related to food quality, or their product is infected, toxic, spoiled or fraud.

Risk analysis (in food control): The National Public Health and Medical Officer Service and the officers of the Veterinary and Food Control Stations take into consideration the principles of the Risk Analysis regarding their food control activity. The high-risk premises are controlled more frequently than the premises at law risk. The NPH-MOS and the Veterinary Service has every year an action plan for

controlling and investigating of " hot" topics with special high risk or actual problems of food safety. In some fields a special monitoring systems exist as well. Nevertheless there is a lot to be done in order to follow an effective risk analysis procedure, and to develop a comprehensive monitoring system for all question related to food safety.

According to the food-borne disease investigating and reporting mechanisms data on food-borne infections and intoxication collected according to two legally controlled reporting system.

- The first one is the *reporting system of food-borne infections and intoxication.* Each proved or suspected food-borne outbreak or incident has to be reported to the local NPS-MOS and will be investigated, regardless of the number of ill persons or the causative agents. The results of the investigation have to be reported to the National Institute of Food Hygiene and Nutrition. In Hungary there is a *Rapid Report System (RR)* of food-borne disease, too (please find indicated in Table XX). A real-time notification is carried out to the regional and to the national level by means of telecommunication in case of: 30 or more people are ill, more than 10 people are hospitalised, death in connection with food consumption, illness of foreign person, botulism, intoxication caused by toxic chemicals or toxic plants (except mushroom), intoxication from mushroom, which was bought in shop, on open-air market or from a peddler.

- The second one is the *reporting system of noticeable communicable diseases.* Under this reporting system data of all cases of noticeable communicable diseases, including food-borne infections is reported. These infections are reported by the physicians, and in most cases are confirmed by NHS-MOS laboratories. The local NHS-MOS institutes investigate the origin of each infection.

V. General Inspectorate for Consumer Protection

The General Inspectorate for Consumer Protection (hereinafter the GICP) (see Tables) directed by the Ministry of Economic Affairs was created by the Hungarian Government on the basis of the General Commercial Authority for Market Surveillance in 1991. With regard to the sphere of official consumer protection and market surveillance in Hungary this institution disposes of the corresponding competency throughout the country. The central inspectorate in the capital and the 19 county inspectorates operate countrywide. From 1st of March 1998 the activities of the General Inspectorate are basically determined by the Consumer Protection Act (Act CLV 1997).

The essential tasks of the General Inspectorate, related to the products and consumer services, are as follows:

- Protection of life, health and safety of consumers.

- Protection of consumers' interests.

- The provision of adequate information to consumers.

- Taking part in consumer protection education.

The duties of the GICP in detail are the following:

- Inspection of the safety of products and services.

- Assisting the enforcement of the legal regulations adapted in conformity with those of the EU in relation to market surveillance.

- Supervision of the enforcement of the regulations of the Consumer Protection Act.
- Performing duties related to advertising supervision.
- Operation of the Central Market Surveillance Information System, helping in this way to detect those products which may have a risk to life and safety of consumers.
- Fact-finding investigation of consumers' complaints and taking the relevant measures as a result of those.
- Providing information to consumers in printed form and the publication of the results of comparative tests.

The GICP and the county inspectorates under its direction perform, on the basis of an annual schedule, specific and ad hoc inspections covering, as required, the whole country or certain counties only. Parts of the inspections are carried out repeatedly and regularly as a kind of monitoring activity. The controls and investigations of the GICP are mainly carried out on site, or in its own laboratories or by the accredited laboratories of other institutions.

On both a national and local level controls and inspections are performed concerning several thousands of products and many tens of thousands of outlets every year by the officials of the GICP and their colleagues from the 19 county consumer protection inspectorates and the proper official measures are taken if necessary. As an average, the GICP handles over 10.000 complaints from the citizens each year.

The GICP co-operates with the specialised inspectorates, authorised partner institutions and the civil consumer protection organisations (NGO), e.g. with National Association for Consumer Protection.

Since 1999 the GICP has provided home to the Co-ordination Secretariat of the Transnational Rapid Information Exchange System on Dangerous Products (TRAPEX), an organisation established according to the RAPEX-system functioning well in the EU, linking the consumer protection authorities of the 9 countries of Central-Eastern European Region that are expected to join the Community.

Recently at the General Inspectorate the development of the data registration system has been accelerated. Within this framework the GICP and RCPI process and keep records on the data and documents obtained during their market surveillance activity in the Central Market Surveillance Information System (CMSIS). The database contains the data suitable for product or service identification (accurate name, origin, name and address of manufacturer/distributor as well as the number and date of the valid administration decision). The computer system of CMSIS works in an on-line system with the regional inspectorates and partner authorities. It will be necessary to connect the computer systems of GICP and partner authorities as soon as possible in order that the issued licences, expert appraisals be accessible for all authorities.

GICP informs the citizens on the conclusions and experiences of its market surveillance inspections. For realising this aim our periodical is published in every two months in 10500 copies and available free of charge and serves as a fair information for consumers.

The General Inspectorate for Consumer Protection (GICP) and the county inspectorates place special emphasis in their activity on supervising food safety, a most fundamental factor in the protection of consumer health and safety.

Based on the corresponding laws and regulations, inspectorates for consumer protection are obliged to supervise products from the consumer's point of view upon entering the market, that is to verify

the existence of the needed certificates and examination results of the product, and detect any damage caused in the course of storing or trading.

Risk Analysis

Is markedly significant in inspections, which must be used in trade as well as on manufacturing spots. Institutions for consumer protection are sensitive to such issues and they demand the establishment of corresponding systems and control their operation.

The system on dangerous products operates via the Central Market Surveillance Information System. Its effectiveness depends on all other authorities informing it about noticing any dangerous produces about to enter the market or in trade.

The role of the Ministry of Economic Affairs is above all to establish appropriate laws in line with EU legislation and to monitor continuously the related activities.

It is thus of the greatest importance to have consumers informed. The legal basis for that lies partly in the Act on Consumer Protection and partly in the regulation on the scope of GICP activity and competence. As constituted, the largest proportion of consumer protection and infringement fines are to cover the organisation and insurance of consumer information through GICP as well as civil consumer protection organisations (NGOs).

The Ministry is assuming a major share in this activity as it operates the fund, which is the financial resource for civil organisations to compete for tenders with the purpose of promoting consumer information.

Thus it has become possible to publish leaflets and hold conferences which contribute to informing consumers and drawing attention to hazards. Some organisations have provided consumers with detailed documents written by excellent experts to call attention to the dangers, appropriate handling, storing and processing of certain foods. these activities fully satisfy the risk analysis principle as well as the requirement for the protection of consumer health on the grounds of prudence.

Furthermore, the Ministry has set up an Advisory Board for Consumer Protection in which civil organisations are largely represented. Consumers are informed about the prevailing regulations and other relevant issues via the Board. The Ministry and the GICP are represented in all current committees for food safety, detecting hazardous materials, and prevention and for operating monitor systems. So they contribute to providing information to consumers as much as possible.

Scientific Boards and Expert Groups

A joint Food Safety Advisory Board of the Ministry of Agriculture and Regional Development and the Ministry of Health was established in 1997. Within this board, apart from the officials of the Ministries in charge, representatives of the food control authorities, the expert institutes, the Complex Food Science Committee of the Hungarian Academy of Sciences and the food industry are included. The task of the Board is to analyse the food safety status of the country, to develop a food safety strategy and provide scientific advice to the government, and to ensure that the policy and the actions are based on sound scientific advice. This board will co-ordinate national activities relating to risk assessment. It can influence the public opinion by elaborating and issuing statements. A statement was carried out regarding the implementation of the HACCP systems and the minimally processed, sous-vide type foodstuffs. A comprehensive analysis and evaluation of the quality assurance and food safety situation was completed by the Board and the draft report on the state of play of the food safety in Hungary will be published soon.

Special Activities Relating GMOS

The gene technology is regulated by the *Act No. XXVII of 1998 on gene-technological activity* (came into force 1st January 1999) and by the ministerial *decree* No. 1/1999. (I.14.) FVM *on the implementation* of the rules of the Act No. XXVII of 1998 in the field of agriculture and food industry.

The basis of these two regulations is the relevant EC legislation. Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms, Council Directive 98/81/EEC amending directive 90/219, and Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms have been taken over, respectively. However the scope of the Hungarian regulations is much broader than that of the EU's. The Hungarian regulations cover all kind of genetically modified organisms with the exception of humans. The other special Hungarian regulations - e.g. the Seed Act, Food Act, Feed Act, etc.- are well harmonised to the EU legislation.

According to the above-mentioned regulations, *permission* is required for the following activities:

- To establish gene technological laboratory.
- To modify natural living organism.
- To use of GMOs in a contained system.
- To release GMOs into the environment.
- To commercialise GMOs on the market.
- To export and import GM products.

Institution*s* which are responsible for permitting gene technological activities:

- Independent Gene-Technological Scientific Advisory Committee – (which gives opinion and prepares conditions of decision to the competent authorities; consisting 17 representatives of the competent ministries, the Hungarian Academy of Sciences, the National Committee on Technological Development and of the non-governmental organisations for protection of environment and human health).
- Authorities of Gene-Technological Activities under the control of the competent ministries (give permissions, control of application, require labelling, etc.).

The authorising responsibility is shared by the following ministries:

- Ministry of Agriculture and Regional Development
- Ministry of Environment Protection
- Ministry of Economic Affairs
- Ministry of Health.

Before making the decision the competent ministries have to send every GM application to the Advisory Committee. The Committee examines the application and gives an opinion and conditions for the request, to accept or to reject it. The final decision is made by the competent ministry. The Committee's examination considered the risk assessment allowing the ministries' control.

On behalf of the Hungarian Government the Minister of Environment Protection signed the Biosafety Protocol this year. After the proclamation of the Protocol by the Hungarian Parliament or Government the ministries have to amend the Hungarian regulations and adopt the procedures of Protocol, e.g. risk assessment under Annex II.

Ministerial Support for the Industry

The development of the HACCP based model management system was started with a HACCP analysis for food safety hazards, contamination and quality problems having each as a clearly separated module. This analysis identified the minimal technical content on which control has to be applied within the quality management system. The HACCP work had been completed in the same time as the development of ISO 9002 system was carried out. The control, monitoring and verification activities and corrective actions were built into the procedures of the ISO 9002 system.

The model system was followed by a range of company financed projects followed by and expanded national HACCP model scheme where the establishment and introduction of quality assurance systems are financed from the national budget. A specific sectorial application of the HACCP including guidelines, a documentation software module and training courses were also developed. The HACCP approach helped production management to develop measurable, motivating performance standards to improve efficiency.

The results of the range of this projects proved that an integrated product development, marketing and HACCP approach can be used for vertical diversification of raw materials and for initiation of the restructuring of the management systems of food manufacturers working in transition economies or in developing countries.

Involvement of Industry in Decision Making

The proposed activities of the Federation of Hungarian Food Industries are based on a PHARE Business Support Project submitted to the European Commission last year by the Confederation of the Food and Drink Industries of the EU.

The Hungarian Federation has the right and possibility to take part in the preparatory procedure of legislation concerning the food industry in co-operation with the relevant ministries and other authorities.

The representatives of the Federation are invited members of the following committees: EU Harmonisation Working Group of the MARD, Hungarian Food Code Committee and its subcommittees, Hungarian National Committee of Codex Alimentarius and its subcommittees, Committee of the "Quality Food from Hungary" trademark, Committee of the HACCP programme projects etc.

Precautionary Principle

The precautionary principle is a new approach regarding food safety issues, which has to be further defined in order to apply it by those responsible for the enforcement. The health authorities are in favour of this approach nevertheless the lack of legal background would not enable the relevant authorities to apply it in practice without legal actions taken against them by not respecting the principle of the free movement of goods. Basically the protection of consumer health should be the driving force for those responsible for control and enforcement. According to this approach e.g. energy drinks having unwanted effects on certain consumer groups as it has been approved by EU scientists formally were not allowed to be marketed in Hungary. Further improvement and definition of this principle at regional and international level and development of testing methods is needed in order to apply it.

Future Need and Challenges

The efforts of the industry, the government and the authorities in the near future need to focus on the following:

- National Food Safety Strategy developed by the Food Safety Advisory Board for improving the food safety at national level based on the survey carried out.
- Several sector specific GMP documents developed by industry groups after consulting the relevant authorities.
- Training staff of the food control authorities on HACCP and other food safety management systems.
- Information and training to be provided for industry regarding the practical methods of auditing food safety in factories.
- Methods and training to be developed on the validation and verification of HACCP systems.
- Co-operation to be strengthened between industry experts, trade associations and authorities.
- Massive productions of publicity material on food safety, hygienic practices etc. for industry, caterers and for the public.
- Improvement of food safety awareness and knowledge of the public by means of a special food safety information campaign.

ICELAND

I. Synthesis

The responsibility for food control in Iceland is divided between three ministries; the Ministry for the Environment, the Ministry of Agriculture and the Ministry of Fisheries. Ministerial departments or agencies which co-ordinate inspection carried out by local authorities and/or approve inspection bodies are the Environmental and Food Agency, the Veterinary Services and the Directorate of Fisheries.

A consultative committee, the Food Council, co-ordinates direct food control in order to prevent overlapping in the control functions of the three bodies.

Policies and Guidelines

The main principles of the Icelandic food legislation are the protection of public health, to avoid misleading practices and to inform consumers about the composition and quality of foodstuffs. Iceland aims at a high level of protection of public health based on the precautionary principle where a full risk assessment is not possible. The public should not be exposed to disease-causing food borne bacteria through handling and eating food, nor should it be exposed to pesticide residues in fruit and vegetables.

Consumers' interest and knowledge must be strengthened through information; dialogue and education and consumer concerns should be evaluated together with scientific advice and principles. Consumer related issues should include ethical, social and environmental considerations.

Correct and precise labelling is important, especially in cases of allergies and sensitivities to certain substances. Labelling should also give consumers information on which to base an informed choice of which products they want to buy. Accordingly, a national regulation on the labelling and approval of GM foods is imminent.

Central and local food control authorities meet regularly and have established working groups to co-ordinate the control and deal with specific tasks such as guidelines for inspections. Control programs are carried out each year and several hygiene guidelines have been issued. The local food control authorities report their control plans and the results for the food control annually to the central authorities.

II. Overview of Food Safety Systems

1. Structure of Control

2.1 Ministries

Based on the Food Act (93/1995) three ministries are responsible for food control in Iceland: the Ministry for the Environment, the Ministry of Agriculture and the Ministry of Fisheries.

The Ministry for the Environment has the main responsibility for food legislation and control of domestic and imported retail foods. The responsibility of the Ministry of Agriculture concerns import and

export of animal products, control of slaughtered animals and health inspections of cultivated fish whereas the Ministry of Fisheries is responsible for the control of fishery products, except for retail sales.

In accordance with the Food Act a consultative committee, the Food Council, has been established. The Environmental and Food Agency of Iceland, the Directorate of Fisheries and the Chief Veterinary Officer nominate its members. The Food Council was established in order to ensure the collaboration of the parties responsible for food policy and food control at the central (state) and local (municipal) level and its duties are harmonisation of food legislation and food control, co-ordinate direct food control and prevent overlapping in control functions, and initiate training and information on foods and food control, administrated by the three ministries.

3. The Environmental and Food Agency and Local Authorities

3.1 The Environmental and Food Agency (EFA)

EFA was established in 1982 by combining the activities of other institutions, which served a similar purpose. The Agency is professionally independent and reports to the Ministry for the Environment.

The Agency supervises and co-ordinates the control of hygiene, food, chemicals, environmental protection and pollution control and operates a laboratory in service of hygiene and food control in the country.

EFA´s activities are organised under the following offices:

The Laboratory, who's principal objective is to provide analytical services to the national hygiene and food control system. Its main activities relate to microbiological and more recently to chemical studies (e.g. pesticides).

The Office of Food deals with matters relating to food and hygiene legislation and the control of hygiene and production, distribution, sale and import of foodstuffs. Control of fish and fish products and veterinary control in abattoirs is not included in the responsibilities of this office.

The Office of Environmental Protection deals with matters regarding the pollution of land, marine, air and water and licensing potentially polluting activities.

The Office of Chemicals Control supervises the import, production and use of hazardous substances and preparations for domestic purposes and the control of hygiene.

The main responsibilities of the EFA are to work on and adopt implementing legislation, supervise and co-ordinate the control, prevent overlapping in control functions, act in an advisory capacity, promote courses, initiate training and instructions, guidelines for food businesses and inspectors and consumer information and education.

The only direct control functions of the EFA are control of imported foods, control in dairy plants in co-operation with local inspectors and monitoring pesticide residues in fruit and vegetables. An important part of control functions is the organisation of control programs, with participation of the control areas, and registration of food related diseases/outbreaks. The EFA is also responsible for laboratory testing of samples and guidelines for evaluating results from testing of microbiological parameters.

The central import control function of the EFA is funded by the state budget and the cost of sampling of fruit and vegetables and analysing pesticides is the predominant part of the budget.

3.2 Local Authorities

Iceland is divided into 10 control areas and a municipal public health board is responsible for organising and co-ordinating food control in each area. Local inspection and licensing is carried out by inspectors who are responsible to the municipal public health boards. In each of the 10 areas one of the inspectors is the Director of the environmental and public health inspection, including the food control.

One of the main Icelandic regulations on the implementation of food control is the, "food regulation" (522/1994). The regulation defines the responsibilities of the official food control on a local level. Based on its provisions local authorities are responsible for licensing food business operators. All businesses must have an internal control based on the HACCP principles.

The main responsibility of local authorities is to control that provisions of the relevant acts and regulations are carried out and, in case of infringements, to take appropriate measure. Local officials/inspectors are responsible for priorities and preventive measures and it is their task to act in case of outbreaks of food borne diseases, often in co-operation with the EFA.

According to the provisions of regulation 294/1995 inspectors have to be certified by the Minister for the Environment. They must have an education in environmental and public health control, or have a university degree or a similar education in related subjects, supported by special courses or work experience. Based on the provisions of the "food regulation" the EFA is responsible for approving the qualifications of inspectors in food control.

The cost of food control at local level is covered by the local authorities as far as it is not covered by control fees

3.3 Co-ordination and Co-operation

The EFA and the local authorities have written guidelines for food businesses. Several methods are used for co-ordination and co-operation between the local authorities and the EFA:

- For co-ordination EFA has a two-day meeting twice a year, with the participation of local inspectors, where different subjects are discussed, such as new regulations and results from co-ordinated control programs.

- During the last years introducing/implementing the internal control in food businesses has been the main priority of the local authorities. During that time seminars have been held in order to co-ordinate actions from the local authorities.

- EFA and the local authorities have had meetings and seminars on internal control and HACCP principles for food business employees. In these meetings the provisions on internal control of regulation 522/1994 have been presented and discussed.

- In connection with evaluation of the food businesses internal control, experts from EFA have engaged audits to some food businesses together with the local control. The aim is to co-ordinate implementation and control in different control areas.

- Several checklists have been issued.

- A group of experts from EFA and inspectors from local authorities meet on a regular basis. This group is mostly discussing measures on internal control and has made hygiene guidelines for different food businesses. This work will be a foundation for quality control manuals for the local authorities.

- Control programs are carried out each year and several hygiene guidelines have been issued.

3.4 Food Borne Diseases

The main problem in Iceland related to food borne diseases is the growing incidence of campylobacteriosis. Before 1996 the incidence rate was low, but started increasing in 1996-1997 and even more in 1998 and 1999. At the same time the incidence of salmonellosis is low, with only a couple of outbreaks with a relatively high number of cases in 1987 and 1996.

3.5 Pesticide Residues in Fruit and Vegetables

An official monitoring programme for pesticide residues in fruit and vegetables was initiated in 1991. Around 320 samples are now analysed each year. Samples are analysed by a GC/MSD multimethod based on ethyl acetate extraction, covering 40 pesticides. In the year 1999 a total 301 samples were examined, 241 imported and 60 domestic samples. About 47% of the samples contained pesticide residues and 3% contained pesticide residues over Maximum Residue Limits (MRL´s). The MRL´s are based upon EU-directives

3.6 Biotechnology

At the present time there is only partial legal basis for regulation of GM foods, i.e. foods consisting of or containing theoretically viable genetically modified organisms. The Act on Genetically Modified Organisms (18/1996) ensures that production and use of genetically modified organisms takes place in an ethically and socially justified manner in accordance with the principle of sustainable development, without detrimental effects on health and the environment and with special regard to the geographical position of Iceland in the northern hemisphere. The act does not cover products of genetically modified organisms. However, a national regulation, now in draft, with a legal basis in the Food Act will be ratified later this year. The draft regulation is in accordance with the decision of the Icelandic government of May 1999, that GM foods shall be labelled in Iceland in acknowledgement of consumer's right to information on which to base an informed choice. The labelling provisions of the draft regulation require that products containing 1% or more of genetically modified ingredients shall be labelled as GM products. The draft regulation also contains provisions for approval of GM foods based on EU´s regulation no. 258/97 on novel foods and novel food ingredients.

3.7 Definition of the Degree of Urgency and Priorities

The definition of the degree of urgency for the control of foodstuffs is communicated through circular letters, the initiation of control programs and through discussions at regular meetings of EFA experts and inspectors from the local authorities. Priorities are derived from observations of hygiene conditions, developments in the food businesses and epidemiological data. EFA has for instance initiated control programs of seasonal specialities, which are considered to pose potential health risks. In recent years the internal control in food businesses and evaluation of critical control points has been a priority

project of EFA and the local authorities. At the import control the priority project is the pesticide control in fruit and vegetables, the follow up of RAPEX announcements and the evaluation of labelling of ingredients, especially additives. Microbiological quality of foods has also been tested, e.g. imported spices.

3.8 Responsibilities and Activities, Hazardous Products

The EFA is responsible for contacting the local authorities and/or the public if necessary, when informed of any hazardous food products.

When dealing with food borne outbreaks EFA collaborates with local authorities. Because of the import control EFA is connected to the customs authorities database, and therefore, and because of how small the Icelandic market is, it is easy to see if products are in distribution in Iceland. If it becomes necessary to withdraw products from the market it is done in co-operation with the local authorities.

3.9 Evaluating the Effectiveness of the Control of Foodstuffs

The central authority has obligations according to the relevant acts and regulations to supervise and co-ordinate the local control. In order to fulfil its obligations the central authority is involved in:

- Control programs.
- Collecting local control reports for the past calendar year and plans for the next year. EFA compiles the data and reports back to all local control units.
- Checking results/situation in approving the internal control of food businesses in each control area, and co-ordinates that work by courses, seminars and meetings.
- Compiling data on sampling by inspectors and evaluating results from laboratory testing.
- Comparing data on sampling and test results between control areas, foods and/or food categories.

3.10 Scientific and Advisory Committees

The following committees/councils have an assisting or advisory function:

- The Food Council
- The Committee on Food Additives
- The Contaminant Committee
- The Committee on Food Analysis
- The Committee on Genetically Modified Organisms.

The Food Council has an advisory function on food legislation and food control as described under point 1. The council is also involved in training and production of information material for officials in food control and for food businesses.

The Committee on Food Additives evaluates applications on the use of food additives and has an advisory function to EFA on questions related to the use and control of food additives.

The Contaminant Committee has an advisory function to EFA on contaminant legislation and import control of pesticides and other contaminants.

The Committee on Food Analysis has an advisory function on quality control and methods used in laboratories responsible for food analysis.

The Committee on Genetically Modified Organisms has an advisory function to the Ministry of the Environment and EFA on legislation and questions related to the control of the use and marketing of genetically modified organisms.

4. The Veterinary Services

The Veterinary Services is a separate department in the Ministry of Agriculture. The Chief Veterinary Officer (CVO) is the administrator of the Veterinary Services. The Veterinary Services comprises in addition to the CVO of one Deputy CVO, nine Veterinary Inspectors and seventeen Districts Veterinary Officers (DVO) reporting to the CVO. The DVO´s under the supervision under the CVO are responsible for the monitoring of the health of slaughter animals, slaughtering, processing in slaughterhouses and meat cutting plants. They are also supervising the health of milking cows and the facilities on the holdings for milk production. The CVO is responsible for import and export of animal products.

5. The Directorate of Fisheries and Inspection Bodies

The Icelandic authorities have recently reformed the control system by insisting on accreditation of those inspection bodies, which are approved by the Directorate of Fisheries. This ensures that the inspection bodies show impartiality in their inspection work and that consulting and other activities are completely separate from the surveillance role.

Accredited inspection bodies acting on behalf of the Directorate of Fisheries have as from 1 January 1998 performed inspections of processing establishments. The inspection bodies regularly submit the results of their inspections to the Directorate of Fisheries, which handles all actions that need to be taken as a consequence of their results. The accreditation, means that the inspection bodies' activities are so defined that they are solely engaged in a surveillance role under the responsibility of the Directorate of Fisheries and operating in accordance with predefined procedures. Inspection bodies are intended to operate completely independently from the parties being inspected and are therefore not permitted to offer them consulting services or take part in production or sales of fish products in any manner. Inspection bodies are expected to demonstrate their competence and impartiality by accreditation.

5.1 Directorate of Fisheries

- The Directorate of Fisheries is responsible for approving inspection bodies cf. Act no. 55/1998 providing that the set conditions have been fulfilled (e.g. accreditation) and to rescind approval if these conditions cease to be fulfilled.

- The Directorate of Fisheries is responsible for licensing producers providing that conditions have been fulfilled, cf. Act no. 55/1998, and rescinding their licences if these conditions cease to be fulfilled.

- The Directorate of Fisheries is professionally responsible for the interpretation of Icelandic Regulations being consistent with EU Directive 91/943 and any others which are relevant.

5.2 Inspection Manual for Fishery Products

By far the largest task given to the Directorate of Fisheries, in the implementation process of the new system, was the writing of a new inspection manual for fishery products.

In the making of the manual the provisions of Council Directive 91/493/EEC, laying down the health conditions for the production and the placing on the market of fishery products, and derived and related EU acts, were analysed and classified into seven categories. These categories are Own Health Checks, Premises and Equipment, Processes, Personnel, Pest Control, Cleaning and Disinfection, and Substances. These seven categories include all requirements on activities concerning health conditions from catch to processing and placing on the market. Within these categories the requirements were grouped into objects of inspection. The objects of inspection contain the requirements identified by reference to EU Acts. The requirements were interpreted and items of inspection derived including method of inspection, procedures, limits and rating of non-conformity.

5.3 Responsibility

- The Directorate of Fisheries is responsible for approving inspection bodies cf. Act no. 55/1998 providing that the set conditions have been fulfilled (e.g. accreditation) and to rescind approval if these conditions cease to be fulfilled.

- The Directorate of Fisheries is responsible for licensing producers providing that conditions have been fulfilled, cf. Act no. 55/1998, and rescinding their licences if these conditions cease to be fulfilled.

- The Directorate of Fisheries is professionally responsible for the interpretation of Icelandic Regulations being consistent with EU Directive 91/943 and any others which are relevant.

5.4 Inspection Bodies - Role and Tasks

- An inspection body shall undertake inspection of the health conditions for the production and the placing on the market of fisheries products, including the inspection of hygiene, premises, equipment and own checks in fish processing establishments which are licensed as producers by the Directorate of Fisheries, cf. Act no. 55/1998.

- An inspection body shall supply the Directorate of Fisheries with regular information on the state of the licensed producer. In order that this information is presented in the most standardised format possible, the Directorate of Fisheries has already developed inspection materials such as Inspection Manual for Fishery Products, inspection forms and check lists.

- An inspection body shall operate in accordance with the ÍST EN 45004; 1995 standard and is defined according to Art. 4.2.1 as a type A inspection body and accredited by the Metrology and Accreditation Service, cf. provisions of Regulation no. 450 / 1997 on surveillance framework and working methods of accredited inspection bodies in the fish industry.

- An inspection body shall be operated as a private company, which charges its clients, i.e. licensed producers, an inspection fee.

5.5 Responsibility

- An inspection body shall base its inspections, cf. EN 45004, on the requirements made of producers as stated in relevant Icelandic Regulations, together with the interpretation and presentation of individual provisions as made by the Directorate of Fisheries in inspection manuals.

- The inspection body shall provide the Directorate of Fisheries with information about the activities and state of companies, cf. Act no. 55/1998.

- An inspection body may not impose unfair conditions upon its clients, or refuse to provide service to specific parties, except in the case of financial default or the failure by that company to fulfil minimum legal requirements.

An inspection body may not impose unfair conditions upon its clients, or refuse to provide service to specific parties, except in the case of financial default or the failure by that company to fulfil minimum legal requirements.

JAPAN

I. Synthesis

A healthy life is one of the most important qualities of human existence and food is the primary source in ensuring this state of well being. As such, Japan is addressing the issue of food safety as a national priority.

Health crisis management is crucial in controlling the outbreak and spread of infectious diseases caused by food and drink and in preventing the harmful effects of chemical substances. In order to avoid health hazards, Japan is comprehensively promoting various measures, including the appropriate surveillance and guidance from the production stage through distribution to consumption, the establishment of rapid-response arrangements when a health hazard does occur, and the thorough investigation of the causes of such incidents. Japan is also supporting further research on the long-term effects on the human body of chemical substances, such as dioxin and endocrine disrupters. Furthermore, with the increase in the distribution of a wide variety of imported food products into Japan, we are making efforts to enhance related surveillance arrangements.

In order to establish comprehensive measures covering all stages of the process, from production through to consumption, the central and local governments in Japan are working together to establish the necessary regulations, to evaluate the extent of obedience to the regulations, to develop more effective methods of hygiene control, and to encourage continued food hygiene by companies and consumers.

Advances in science and technology have generated new food products, such as genetically modified food products and dietary supplements. Consequently, interest in the safety of these products has dramatically increased. Proper consideration to ensure the safety of these products and their rational consumption should be based on the latest scientific opinions. Japan is making efforts to establish arrangements to this end.

It is essential that the general public correctly understand how a nation administers its policies on food products. In Japan, the government uses various means of information disclosure and exchanges with the public. In addition to the information disseminated by the companies themselves, the government provides broad and timely information on food product administration to local governments and consumers and ensures that all concerned - consumers, companies, and the governments – mutually share and understand scientifically based information. Japan is also attempting to improve the labelling on food products so as to further both food safety and consumer choice.

As Japan imports many of its food products, the government is making efforts to implement regulations that conform to international standards and is actively participating in the formulation of these standards. Moreover, Japan extends support, such as technical co-operation, to developing countries to help ensure their supply of safe and good quality food products. The government believes that Japan has a responsibility to extend such international co-operation.

II. Overview of Food Safety in OECD Member Countries

Ensuring Food Safety

To ensure the supply of safe and good quality food to the nation, Japan enforces comprehensive regulations based on the Food Sanitation Law at each stage of the production, processing, import, and distribution of food products. These regulations include (i) the prohibition of the sale of harmful food products; (ii) the establishment of standards and specifications for food products, additives, equipment, containers, and wrapping; (iii) the establishment of labelling standards; (iv) the setting of standards for business facilities related to food products; and (v) the approval of businesses related to food products. In addition, the government implements measures to ensure safety at the production stage, such as the Agricultural Chemicals Regulation Law. Measures to improve the quality of processed food products are based on the Japanese Agricultural Standard (JAS). Measures against disease and harmful insect, such as animal and plant quarantine, are taken in order to contribute to domestic agricultural production.

When establishing new regulations, related ministries and agencies create advisory committee consisting, among others, of informed individuals, representatives from consumer groups, and related business representatives. Ministry responses are then based on the bodies' reports. Such reports stem from a consensus among the advisory committee members and are formulated as recommendations to the government. In principle, the discussions of the advisory committee are made public and the contents widely publicised through the Internet.

In order to promote countermeasures against food poisoning, taking into due account the results of investigations into the causes of food poisonings; the government endeavours to thoroughly enforce hygiene control in cooking facilities and to strengthen its surveillance and guidance in food-related businesses. Furthermore, to prevent food poisoning, the government publicises preventive measures. For example it has issued a manual for household use and is making efforts to widely disseminate it.

Regarding livestock and poultry meat, through the Abattoir Law and the Poultry Slaughtering Business Control and Poultry Inspection Law, meat inspectors and poultry inspectors are attempting to eliminate diseased or abnormal meat, improve facilities, and, on the basis of hygiene control standards, prevent the microbe contamination of meat and poultry products.

According to the Food Sanitation Law, at the end of 1999 residual standards were stipulated for 199 agricultural chemicals remaining in agricultural crops and 15 animal medical drugs remaining in livestock and marine food products. After setting the acceptable daily intake (ADI), these residual standards are determined in light of international standards, etc., in such a way that they do not exceed the ADI in the normal Japanese food intake. To promote the rational use of veterinary drugs, the government has established usage criteria, etc. on the basis of the Pharmaceutical Affairs Law. In the Veterinary License Law, an examination by a veterinarian is obligatory when injecting or prescribing antibiotics, synthetic chemotherapeutics, vaccines, hormone drugs, etc.

Regarding agricultural chemicals, according to the Agricultural Chemicals regulation Law, the government protects human health and the living environment by enforcing a registration system and imposing regulations on the sale and use of agricultural chemicals. The government also stipulates standards for the safe and proper use of agricultural chemicals.

Regarding fertiliser, in order to ensure the good quality of fertilisers and to guarantee the production of safe and high quality food products, official standards for ordinary fertilisers are stipulated using a scientific approach through the Fertiliser Control Law. Only fertilisers that conform to these standards are registered.

Regarding feed, to prevent the production of harmful livestock products and impediments to the production of livestock products through damage to livestock, specification, production standards, use standards, labelling standards, etc. for feed and feed additives are stipulated on the basis of the Law Concerning Safety Assurance and Quality Improvement of Feed. The production and sale of feed and feed additives that do not conform to these standards and regulations are prohibited. In particular, prior national assay is necessary for such feed additives as antibiotic substances, for which special safety consideration should be given.

Concerning imported food products; food sanitation inspectors from the Ministry of Health and Welfare at quarantine stations located at major air and seaports around the country undertake surveillance on the basis of the Food Sanitation Law. Under this law, import businesses are obliged to submit import notifications. When such a notification is submitted to a quarantine station, monitoring and other tests are carried out as necessary to check for violations.

To prevent entry into Japan of diseases and pests, the Ministry of Agriculture, Forestry, and Fisheries conducts import quarantine on the basis of the Animal Infectious Diseases Control Law, the Plant Protection Law and the Fishery Resources Conservation Law. Furthermore, for imported rice, wheat and barley, import businesses are obliged to conduct safety tests at the place of loading and safety tests on samples taken at the time of shipment.

In order to confirm the quality content of imported food products, consumer groups investigate the extent to which labelling standards are obeyed, publicise and disseminate the labelling system among import businesses, through the purchase of imported goods, the confirmation of labelling items, analysis of additives, etc. undertaken by assay organisations.

As for new methods of hygiene control, Japan is making efforts to upgrade hygiene control at each stage, such as the production and processing of food products, through the diffusion of the Hazard Analysis Critical Control Point (HACCP) method, the introduction of which is being internationally promoted. Japan has also systematised approval of the Comprehensive Sanitation-Controlled Manufacturing Process, which embodies the HACCP method, and is promoting individual approval for milk and dairy products, meat products, etc. In addition, in order to support facility improvement by food product manufacturing businesses that are attempting to upgrade their management of the manufacturing process on the basis of the HACCP method, Japan in July 1998 put into effect the Temporary Law on the Advancement of Management of Production Process of Foods.

Development of Food Health Administration in Response to the Diversification of Food

The Ministry of Health and Welfare is conducting a comprehensive review of the information necessary for food product hygiene through labelling. A report by an advisory body recommends mandatory labelling for specific materials in order to prevent health hazards through allergens, etc. It also recommends the examination of means other than labelling to supply information to consumers, as in many cases the space available for labelling is limited.

Japan has formulated safety assessment guidelines relating to GM products, food additives, feed, etc. on the basis of its own research as well as reports by international organisations, and confirms that safety has been assessed in line with these guidelines. In view of concern still being voiced among consumers about safety and in order to supply information concerning safety assessment, Japan discloses the content of discussions of advisory bodies, makes application forms relating to safety assessment available to the general public, etc.

The growing interest in health matters by the general public, coupled with its greater knowledge and opinions based on wider food experience, has resulted in vitamins and other such items – which until

now have been used as pharmaceuticals – being distributed as food products. The same phenomenon is occurring with so-called dietary supplements, whose main purpose is to supplement nutrients. Therefore, the Ministry of Health and Welfare is studying their names, definitions, and forms of labelling to ensure an appropriate intake of such products.

Regarding JAS products that have been graded by JAS standards, the Ministry of Agriculture, Forestry, and Fisheries is implementing purchase tests of distributed products to check their quality and labelling. Criteria relating to quality control have also been introduced in the criteria for certification of JAS certified plants, and the Ministry surveys and gives guidance concerning these plants.

Chemical Substance Countermeasures

The public is becoming increasingly concerned about the health effects of dioxin emitted from waste incinerators and other facilities. Japan is making efforts to investigate the health effects, including through fact-finding surveys on food product contamination and research on the health effects on the human body (including the health effects on infants from breast milk). Regarding the actual state of dioxin contamination of food products, Japan has been implementing surveys on individual food products since 1992 and surveys on the average daily intake of dioxin from food since 1996. As for dioxin TDI (tolerable daily intake), following a reappraisal of the health effects of dioxin by an expert group of the World Health Organisation in May 1998, Japan revised the level from 10 pg to 4 pg in 1999.

Since April 1998, a group of experts has been studying the effects of endocrine disrupters on human health. Japan will further promote such research in co-operation with the international community.

III. Efforts Made in Recent Years

1. Developing National Food Safety Frameworks

Japan's food health administration today consists of a target-specific sectional organisation. In other words, while a general section has been established with jurisdiction over the general implementation of standards and surveillance, independent sections have been set up to deal with specific areas, such as dairy product hygiene administration and food additive administration.

Japan is scheduled to reorganise its government ministries and agencies from January 2001. Following this reorganisation, there will be a Food Safety Department within the newly formed Ministry of Health, Welfare and Labour. In order to respond to the increasingly complex and higher level of food health administration, this department will be organised into functional-specific sections dealing with planning and co-ordination, standards, and surveillance and guidance.

Furthermore, in food sanitation administration, in order to speed up the work being implemented by the government and make it more efficient, eight regional health offices will be established around the country to take over such government work as (i) screening relating to the Comprehensive Sanitation-Controlled Manufacturing Process; (ii) surveillance and guidance of designated testing organisations under the Food Sanitation Law and Poultry Inspection Law, including Good Laboratory Practice (GLP) inspection; (iii) guidance and co-ordination for wide-spread food poisoning, etc.; and (iv) guidance and direction for facilities involved in the export of food products.

2. Regulation of Modern Biotechnology

In connection with the commercialisation of GM products, Japan ensures safety through (i) "guidelines for recombinant DNA experiments" for research at the laboratory level for the development of GMO; (ii) "guidelines application of recombinant DNA organisms in Agriculture, forestry, fisheries, the food industry and other related industries." to control the environmental impact in the case of the cultivation of GM crops in open fields; and (iii) "guidelines for safety assessment on foods and food additives produced by recombinant DNA techniques" to control the impact on human health of food products and food additives using such techniques. Regarding imported agricultural products; Japan screens safety for the environment and for human health under these guidelines.

Using these guidelines, risk assessment on the environmental and human health effects prior to commercialisation is implemented on the basis of scientific background, with reference to the concepts of "substantial equivalence" and "familiarity" as specified by the OECD.

At present, screening as a safety check of GM food products with respect to human health is not legally binding, as developers apply it on a voluntary basis. As the development and practical use of GM food products is expected to make further advances, Japan is preparing to make such screening legally obligatory from April 2001.

From April 2001 the manufacture, sale, import, etc. of GM food products that do not conform to the standards (have not been screened for safety) will be prohibited. If GM food products that do not conform to the standards are distributed in the market, administrative penalties may be applied, such as a scrap order, a retrieval order, or an order for the return of the imported item to the exporting country. Violations of the standards will also be subject to criminal punishment. As a result, the government considers that safety will be even more thoroughly ensured and that consumers' trust in safety will increase.

Regarding GM food products for, which safety has been confirmed, in order to provide product choice to consumers and to protect their interests, the government is scheduled to set new labelling standards and to make labelling mandatory from April 2001.

3. Precautionary Approaches and Principles

Japan undertakes assessments on risks related to the environment and human health, based on the latest scientific findings. If, after the assessment the scientific evidence proves to be insufficient and there are reasonable arguments for anticipating any environmental or health hazard, the Government may take appropriate measures accordingly.

However, as there has been no mutual understanding in the international community up to now on the "precautionary principle" or "precautionary approaches", there is neither mutual understanding in Japan on the "precautionary principle" in the food safety area, including its relations with the SPS agreement or other administrative measures in Japan.

4. Regulatory Enforcement and Compliance

Japan implements the necessary regulations, such as the establishment of standards and specifications for food products, additives, etc. as well as the formulation of hygiene standards. In order to raise the effectiveness of these regulations, Japan deploys nearly 8,000 food sanitation inspectors in local administrative organisations and enforces licensing, surveillance, and guidance for domestic food-related businesses, which number 4.2 million establishments. Japan also has a register system for

agricultural chemicals and feed and attempts to prevent health hazards from residual agricultural chemicals from the production stage.

As a country that imports a diverse range of food products, Japan has the Animal Quarantine Services and the Plant Protection Stations at major air and seaports around the country. In addition, to ensure the safety of these food products, Japan has stationed food sanitation inspectors at the quarantine stations and has set up surveillance arrangements at the time of import. To guarantee the safety of food products from the manufacturing stage, for those food products that have been manufactured and processed in foreign facilities and that conform to Japan's standards and specifications, Japan has introduced a Pre-certification System for Imported Foods. This system simplifies food inspection procedures at the time of import for food products, provided that the products have been previously registered.

In order to prevent health hazards caused by food products and to respond appropriately in case of incident, it is important to gather high-level information in a timely manner, analyse it, and provide feedback. To this end, Japan has established co-operative relations among prefectural sanitation research institutes, public health offices, inspection organisations, etc. and is making efforts to create a framework by which to provide continuous and appropriate management, to ensure the reliability of tests, and to upgrade testing technology.

5. Addressing Socio-Economic Concerns

The Law Concerning Standardisation and Proper Labelling of Agricultural and Forestry Products (the JAS Law) has as objective to improve the quality of agricultural and forestry products, rationalise their production, simplify and ensure fairness their business transactions, rationalise their use and consumption and contribute to the choice of general consumers through appropriate labelling.

Against the background of the growing consumer interest in the quality and safety of food products, the JAS Law has been revised in 1999. Among the amendments, the scope of the quality labelling standards, which manufactures and distributors should follow, was expanded to cover all food and beverage products for general consumers. New quality labelling standards consist of labelling standards concerning the name and the origin for fresh foods, the name, ingredients, etc. for processed foods, and those related to GM products.

Regarding organic agricultural products, since inappropriate labelling and the disparity of production standards are particularly conspicuous, the revised law stipulates that, regarding the production and manufacturing methods, only products that have received grading under the Japanese agricultural and forestry standards by a third party and carry the JAS mark can be distributed to general consumers with an attached "organic" label.

6. Communication and Consultation

In order to respond to the public's growing interest in the safety of food products, the Ministry of Health and Welfare, through an external organisation, actively undertakes to supply various information relating to food sanitation, accepts over-the-counter consultations, etc. The ministry is also attempting to provide related information through its Internet home page.

In particular, the Japan Food Hygiene Association (an external organisation of the Ministry of Health and Welfare) provides over-the-counter consultation service relating to food sanitation, through which it introduces related literature, supplies hygiene control know-how for households, and responds to various inquiries. Several times a year the association also holds explanatory meetings for the general

public, including both consumers and food-related businesses, to explain the present food safety administration and to engage in a question and answer exchange.

With a view to supplying safe and high quality food products, the Ministry of Agriculture, Forestry, and Fisheries conducts regular surveys relating to food consumption, via food consumption monitors (more than 1,000 people) appointed in major cities throughout Japan. It also solicits their opinions on food-related problems and holds exchange meetings between monitors in central and regional districts. The Ministry is in the process of establishing an information system so as to further promote dialogue and exchange among consumers, the administration, the food industry, and producer organisations, and among consumers themselves.

In light of the recent increasing confusion of dietary patterns, the Ministry has established the Forum for Promoting Better Dietary Habits, composed of representatives of organisations and companies related to food and informed individuals, whose aim is to raise consumer consciousness and encourage consumers to voluntarily improve their eating habits. This Council promotes the maintenance and development of the most notable aspects of Japan's food culture, the rationalisation of food consumption, and the stable supply of safe and high quality food.

The government continues to make efforts to ensure the transparency of procedures, in principle, making the discussions in related advisory bodies open to the public, and disclosing the results of these discussions through the Internet. It also solicits wide public opinions through "public comments procedure". In particular, regarding GM foods, the government in principle allows the free access to materials submitted to advisory bodies by developers.

The Ministry of Agriculture Forestry and Fisheries also holds study groups, offering lectures, practical training, and practical work related to biotechnology for students, teachers, general consumers and implements open surveys and research. It solicits contributions from outside in order to respond in a flexible manner to requests and proposals from consumers.

KOREA

I. Synthesis

In order to contribute to the improvement of national health by preventing sanitary dangers and harm caused by food and improving the quality of food nutrition, the Food Sanitation Act was established in 1962. There have been many amendments to reflect mainly to ensure food safety. During the period, the public interests changed from the quantity to the quality of the foods. As increasing public interests on food safety, food safety policy should be considered across all steps of the food chain from farm to consumer tables to ensure food safety. Meanwhile, the food trade in the global market increases dramatically since the World Trade Organisation (WTO) was established. This increment of food trade may spread the local food safety issues into the world market.

These factors among others economical situation of food industry in Korea, public perception, legitimate factors and new emerging biotechnology products push the government food regulators to work on these issues to ensure food safety. A new government agency, the Korea Food and Drug Administration (KFDA), which is in charge of regulating food, drugs, cosmetics and medical devices, was established in 1998 to cope with these situations. The responsibilities of KFDA are, among others, food safety policy, promulgation of standards and regulations, risk assessment, analytical method research and audits. The essential principles of making decision on food policy in Korea are as follows:

- Food regulations (include standards and specifications) based on sound scientific evidence.
- Reflection of consumer's demands for the higher level of food safety.
- Transparent procedures in developing the regulations.
- International harmonisation on food safety control.
- Encouragement of food industry development.
- National institutional structure.

In order to strengthen the food safety control, KFDA is operating Honourable Food Safety Inspector system and Hotline to report illegal activities on food safety and widening the application of HACCP system to all food products. Regarding products from the modern biotechnology, KFDA will focus the efforts to the follows:

- Make the performance of safety assessment from voluntary to compulsory.
- Label the genetically modified foods from second half of 2001.
- Make the consumer groups to actively participate on decision making processes.

– Strengthen education and information conveyance about food safety and nutritional information to public.

II. Overview of Food Safety Systems in Republic of Korea

In Korea, the Food Sanitation Act and Processing of Livestock Products Act are the two major acts to control safety of foods. Korea recently established a council, so called National Food Safety Council, under the Office of Prime Minister to co-ordinate to the food safety control systems divided into several agencies. The council consists of the Assistant Ministers of related agencies, such as Ministries of Health and Welfare (MOHW), Agriculture and Forestry (MAF), Maritime Affairs and Fisheries (MOMAF), Environment (MOE), Government Administration and Home Affairs (MOGAHA), Finance and Economy (MOFE), Korea Food and Drug Administration (KFDA) and Korea Consumer Protection Board (KCPB). The responsibilities and relations for these institutes are in Figure 1.

Since the World Trade Organisation (WTO) was launched in 1995 to facilitate trade, Korea took various efforts in enforcement of facilitate trade while keeping the level of protection against the risks from foods. The decision making and adoption process are generally started with petition from interesting parties, such as public and industrial needs. When a petition is accepted, a risk assessment and consideration of the relevant international standards and other national requirements, if available, are carefully conducted to prepare a draft. The draft is notified through an official gazette for increase transparency with comment periods, during the comment periods, internationally notified through WTO notification system. After the comment period is over, the experts are carefully consider the collected comments and, if necessary, series of meeting will called with stakeholders. As the results, the final draft will be submitted to food safety council, which consists with representatives of public, private industries, research and academia. The council finalises the draft to adopt. The Minister or Commissioner adopts the draft as technical regulations and notifies through the official gazette. After appropriate extension of periods and training of the new contents in the regulation to relative personnel, the regulation will be enforced.

Mainly the KFDA and its subsidiary institute, National Institute of Toxicological Research, conduct risk assessments with the experts from the academia, private industry and public institutes. The information form stakeholder is carefully examined as much as possible. When decide the draft for regulations, guidelines or recommendations, not only the results of risk assessment but also other factors, such as public perception, national legislative structure, international standard and other regulations of other countries. Except the evidence is scientifically clear, the decision making process is majority after full discussion. The form of implementation is decided in the regulation promulgated. The inspector or related personnel will have the training on the issue prior to enforcement of the new regulation. Stakeholder can submit their comments any time during the entire periods. KFDA, local governments and related agencies endeavour to communicate with public through many ways, such as official gazette, consumer reports, magazines, public hearings, national and international meetings.

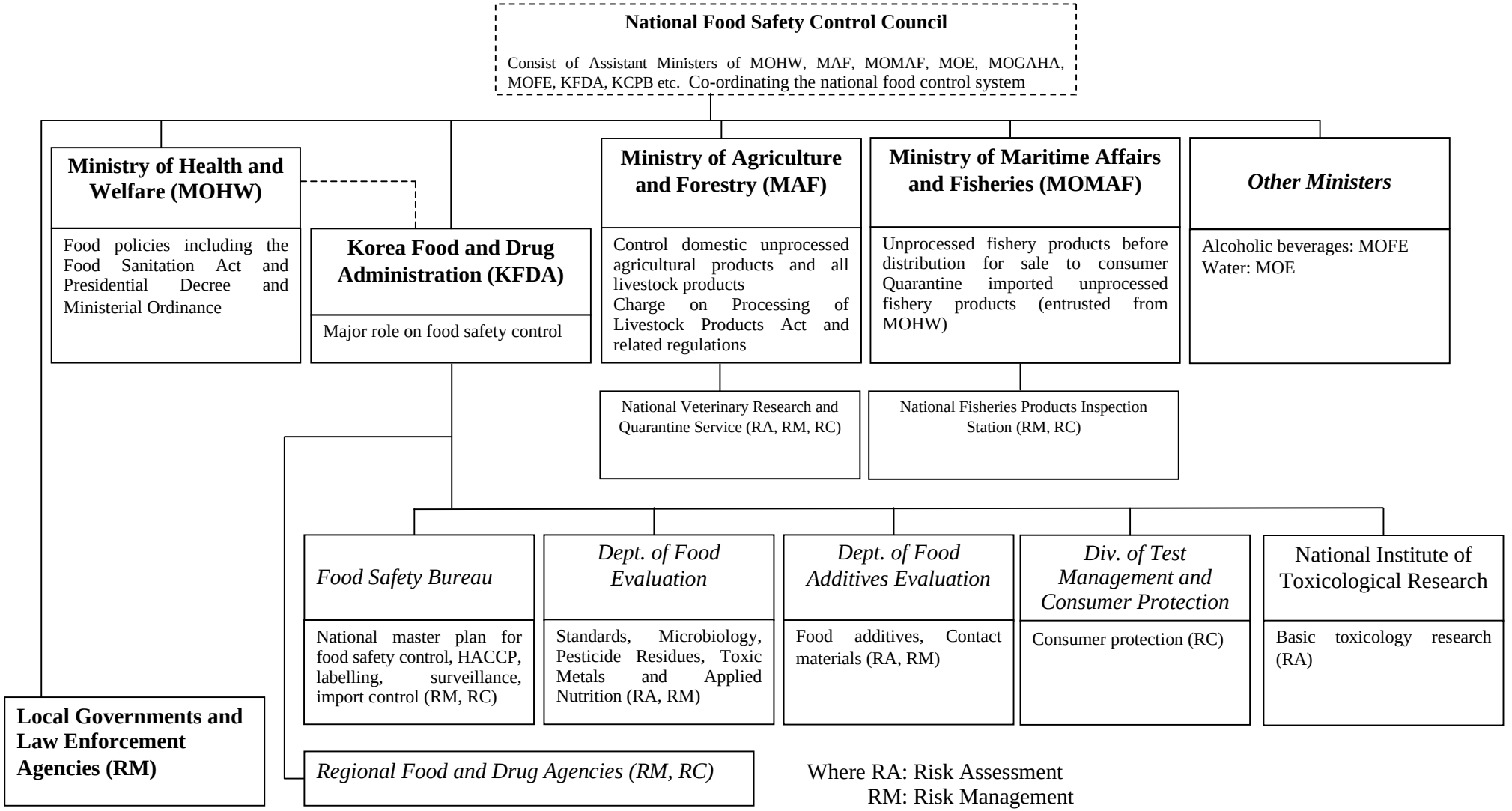


Fig. 1 Schematic Diagram for Food Safety Control

III. Activities of Republic of Korea in Addressing Food Safety Issues

Developing National Food Safety Frameworks

In order to ensure food safety, the Korea recently reformed the national food safety control structure as described in the previous session. The objectives of the regulatory structure reforming are, among others, to increase food safety, regulatory cost/benefit and to meet public needs. The reforming was conducted through public hearing as well as the National Assembly. The performance of the reformed structure is reviewing periodically as well as whenever needs are raised.

Regulation of Modern Biotechnology

While the public interest in Korea on modern biotechnology including the ethics of gene manipulation has been growing, “The Biotechnology Promotion Act” was promulgated in 1983. Based on the Act, “Guideline for DNA Recombinant Operations” was issued in 1997 as a biosafety regulatory framework for contained use of genetically modified organisms (GMO). Currently, genetically modified foods issues are handled by the Ministries of Science and Technology, Health and Welfare, Agriculture and Forestry, and KFDA. The related acts and guidelines are Biotechnology Support Act, Food Sanitation Act, Agricultural and Fishery Products Quality Management Act, and Guidelines regarding Review of Safety Assessment Data for Genetically Modified Foods and Food Additives.

Governmental institutions directly related to the issues of biotechnology are the KFDA undertaking the safety management of foods and pharmaceuticals, and the National Institute of Health (NIH) taking charge of communicable disease control and gene therapy protocols, etc. Consequently, KFDA is assessing the safety of GMO derived products, such as foods and food ingredients. NIH recently prepared the first draft of “Gene Therapy Guidelines” and initiated the revision of related regulations for risk assessment of GMO.

Guidelines regarding Review of Safety Assessment Data for Genetically Modified Foods and Food Additives is promulgated systematically to evaluate safety of genetically modified foods. The objectives of these guidelines are to ensure safety of genetically modified foods and food additives. Any manufacturers or producers encourage to be approved by the Commissioner of KFDA prior to sell in the market. Currently, these voluntary guidelines are considered making mandatory by KFDA. The guidelines contain the list of required documents to be submitted to application of approval.

The Food Sanitation Act was amended to provide legal bases for labelling the genetically modified foods. A mandatory labelling system for genetically modified processed foods will be introduced in July of 2001 as the country's parliament passed the revised bill of the Food Sanitation Act. Recently, KFDA was proposed the related labelling guidelines.

According to Agricultural and Fishery Products Quality Management Act, the Ministry of Agriculture and Forestry requires labelling genetically modified farm products such as soybean, corn and soybean sprout. This requirement will be enforced in March 2001. Importers, retailers and wholesalers must label the targeted products as "GM soybeans or corns", "soybean sprout cultivated with GM products" and "this food contains corns or beans that have been genetically modified".

Korea has a plan to suggest a comprehensive national framework this year for protection of public health by developing policies and improving the related regulations on biotechnology. These efforts will be able to contribute to the promotion of R&D in biotechnology and life science industries within the social and political acceptance.

Precautionary Approaches and Principles

Korea recognises the importance of precautionary approaches and principles. Currently, Korea is under careful considering the precautionary approaches and principles to reflect in regulatory frame. Since the precautionary approaches and principles can be used arbitrary and unjustifiable, KFDA is under evaluation about the concept and application of the precautionary approaches and principles.

Regulatory Enforcement and Compliance

Recently several consumer groups protested importing genetically modified soybean. Since public supported the protest, the National Assembly decided to amend the Food Sanitation Act to introduce the labelling of the foods and food additives derived from biotechnology.

In addition, KFDA recently launched a GM Food labelling research council consisting of 25 representatives from GMO experts including top scientist, representatives of consumers, industries, and government agencies. The council will recommend to KFDA on the labelling of the GM foods. The main topics to discuss in the council are, among others, labelling guidelines and implementation schedule *etc.*

Addressing Socio-Economic Concerns

The Korean Academy of Science and Technology held a symposium on the Safety Assurance in Biotechnology on 1999 and suggested the improvements of the related legislation, systems and transparency to promote the public acceptance on this matter. The Korean National Commission for UNESCO also had a forum called “Citizen Panel for the Acceptance of Biotechnology” on 1999. As the outcome of the forum, the government was asked to prepare national biosafety guidelines against the biotechnology concerning ethical and technical uncertainty and unanswered potential hazards.

The government is considering their recommendations and communicating with them. Education and training on the issue are also conducted.

Communication and Consultation

KFDA, local governments and related agencies endeavour to communicate with public through many ways, such as official gazette, consumer reports, magazines, leaflets, public hearings, national and international meetings. KFDA and some of the related institutes are operating a hot line for food safety issues.

When the food safety issues are raised, government can call the public hearing, food safety council. Not only these efforts, the government experts are involving related societies, research groups and related meetings, whenever possible.

MEXICO

I. Synthesis

The food policy implemented by the Government of Mexico has as a goal not only to guarantee a timely and sufficient supply of food, but also to accomplish sanitary and safety standards that ensure consumers health.

In order to accomplish this goal, an integral policy has been designed and implemented throughout the food production chain, in which different economic agents participate, represented by raw material suppliers, agricultural producers, processors, agribusiness firms, related industries, traders, non-governmental organisations, consumers, researchers and academics.

The participants within this process are committed to assume responsibilities within the food chain.

In fact, designing, implementing and operating such policy has faced difficulties arising from new areas that have not been traditionally covered by existing infrastructure and knowledge.

Regulations and standards established in Mexico in order to accomplish food safety are founded on scientifically based evidence, which allow the reduction of biological, chemical and physical risk factors. A transparent and scientifically based process supports them. Furthermore, control and inspection systems that improve food safety in a continuous basis have been in place for several years. Nevertheless, the application of the risk analysis is a learning process and the lack of data on foodborne illnesses, associated with contaminated food and related factors needs to be solved in order to fully support stakeholders to better allocate resources.

Likewise, the food safety policy is supplemented on a daily basis through integrating inspection, control, surveillance, research and risk analysis in decision-making processes related to food safety matters. In addition, officially recognised third party inspection and certification bodies are an alternative that is currently being developed in order to supplement government infrastructure of food import and export inspection and certification system.

Finally, the Government of Mexico, through its different agencies, organisations and institutions, is committed to develop a wide-ranging team in order to assure consumers, both domestic and abroad, that consumption of agricultural products and foodstuffs can be considered healthy, nutritious, and of high quality.

II. Overview of the Food Safety System

The Government of Mexico has endeavoured significantly to offer national and international consumers foods that in addition to having excellent quality are safe for the health of humans as well as for plant and animal health and, do not pose a negative impact on the environment. In order to diminish the physical, chemical and biological risk factors in the production–consumption chain, it has been necessary to develop joint efforts and actions among different sectors, Federal and State government, consumers, private sector and academia.

In particular, the Government of Mexico has taken further steps to co-ordinate and implement the food safety policy with concurrence of several government institutions holding specific responsibilities in the food chain continuum, among them, the Secretariats of Agriculture, Livestock and Rural Development; Health; Commerce and Industrial Promotion; Environment, Natural Resources and Fisheries; Social Development; Work and Social Prevision; Communications and Transport; Public Education, as well as the National Council for Science and Technology and the Water Commission.

Each of these institutions holds specific responsibilities related to the risk assessment, management and communication.

2.1 Risk Assessment.

The risk assessment process developed for different institutions of the Mexican Government, is accomplished in accordance with the international methodology established by the World Health Organisation, Codex Alimentarius, Sanitary and Phytosanitary Agreement, International Plant Protection Convention and the Office International des Epizooties.

Especially with respect to health risk assessment the next steps are followed: hazard identification, hazard characterisation, exposure evaluation and risk characterisation.

With regard to animal and plant health risks, the Secretariat of Agriculture has established in its Federal Animal and Plant Health Laws a risk analysis procedure, which includes risk assessment, management and communication.

In case of biological risk factors related to plant and animal health, the Government of Mexico has the National Phytosanitary Advisory Council, as well as the National Animal Health Advisory Council, which is integrated of various specialist committees from the country. These Councils are responsible for formulating technical recommendations concerning the plant and animal health of agricultural products and their possible implications to human health. In order to develop such sanitary risk assessment, the Secretariat of Agriculture, Livestock and Rural Development has a number of research and academic institutions, such as the National Institute for Research on Agricultural, Forestry and Livestock, the Post Graduated in Agronomical Sciences College, The “Antonio Narro” Agronomical Autonomous University, as well as the Autonomous University of Chapingo.

Likewise, the Secretariat of Health is responsible of promoting and co-ordinating epidemiological surveillance, as well as prevention and control actions for diseases of the country. Particularly, a system has been developed to report a number of cases of illness that can be utilised to identify health risk factors through the systematisation of information. Furthermore, the Secretariat of Health has research institutions regarding nutrition, a national network of disease control laboratories and food safety control laboratories.

Additionally, the National Council of Science and Technology, through its research centres all over the country, has developed research projects focused on diminishing the biological, chemical and physical risk factors in food products. Researchers from the National Council of Science and Technology are selected through the National Researchers System, which classifies them according to their specialisation areas.

There are several universities in the country, such as the National Autonomous University of Mexico and the Centre for Research and Advanced Studies from the National Polytechnic Institute, which develop research on several topics related to risk evaluation, such as the potential risk of genetically modified organisms.

The researchers take decisions in an autonomous and independent manner, but there exists communication among researchers, institutions and officers which are responsible for risk management in such a way that there is a continuous, timely and beneficial collaboration.

2.2 Risk Management

Design of policy alternatives takes into account existing infrastructure and relations with involved producers, industries, consumers and academia. The Mexican Government has considered two main control points; one is the implementation of regulatory measures through mandatory standards and the other by means of voluntary standards.

The Mexican Official Standards are currently in force and are mandatory technical regulations. They contain the terminology, classification, characteristics, meteorological qualities, specifications, sampling and testing methods, which satisfy the processes, products and services, with the aim of minimising the risks for human, plant and animal health, as well as the impact on the environment.

There also exist the Mexican Standards, which are voluntary technical instruments, elaborated by a National Normalisation Organisation, or in certain cases, by the Secretariat of Commerce and Industrial Promotion. These voluntary Standards establish certain reference specifications in order to increase the quality of products and services.

There are several offices in charge of the animal and plant health inspection services. These offices are located at ports, airports, and borders of entry in the national territory. All agricultural products and their shipping documents are physically inspected, for their introduction, transportation and trade into the national territory. Within the country, there are several inspection sites (internal verification points) which are strategically located in order to control transportation of controlled agricultural products. In these inspection sites, government officials verify compliance with the Standards.

Besides inspection officers working at the Secretariats involved in this process, there are several advisors and laboratories approved by the Government, which can be hired by producers, packers, processors, traders and transporters to have the Standards application verified. The Secretariats involved have issued several regulations in order to train these professionals and laboratories in the Standards verification process, especially for those Standards of mandatory compliance.

Mexican Official Standards, which are published by the Secretariat of Agriculture, are applied exclusively to issues related to plant health and animal health, and in certain cases, co-ordinated with the Secretariat of Health, it is required to attend issues related to the possible implications to human health.

Additionally, the Secretariat of Agriculture has taken actions to promote voluntary programs which allow agricultural producers and processors to adopt Good Agricultural Practices as well as Good Manufacturing Practices respectively, with the aim of minimising biological, chemical and physical risk factors at the primary production stages.

The risk management is delegated in different areas in accordance with the nature of each risk and with the nature of agricultural and agrifood products. Particularly, in the case of meat products, there are the Federal Inspection Type Plants, which are slaughter houses and meat processing industries regulated and inspected directly by the Secretariat of Agriculture, in order to certify that animal diseases do not represent a risk to human health.

The standardisation and verification processes are managed in two different areas, which are independent from each other. In this sense, a clear differentiation between the regulatory areas and those related to the inspection and/or verification of tasks is established. In another instance, the Secretariat of

Agriculture has a central laboratory that analyses and diagnoses the sanitary condition of agricultural and agrifood products. All of the certified laboratories, which were transferred to the private sector in order to be operated, continue to depend on this central laboratory.

The Secretariat of Health is responsible for domestic food inspection and control as well as the food import control and export certification system. The system has been designed and it is being operated to ensure that food, alcoholic and non-alcoholic beverages, food additives, cosmetics, tobacco and cleansing products, and their raw materials are in compliance with Mexican regulation. The Secretariat of Health is empowered by law to conduct, educate, take samples, verify and, if required, take regulatory actions to enforce security measures and penalties. Also, the Secretariat of Health shall carry out this task along with the producers, traders, and consumer's participation. For such purpose, it takes into account every activity involved in products processing, such as, obtaining, elaborating, manufacturing, preparing, conserving, mixing, canning, handling, transporting, distributing, storing and sales, or supplying to the public.

The system is based on a problem-solving scheme focused in risk. It is based on the premise that the more accurate, scientific and technical information gathered and fed into the system, the more effective will be the actions taken by competent authorities, industry and commerce in preventing and solving public health problems borne from product consumption. The system is applied to domestic products as well as imported ones.

Sanitary regulation has established responsibilities and rights for producers, industry, traders, importers, and service suppliers. Its scope is the human habitat, establishments, process, activities, products and labels, equipment, vehicles and persons, who might represent a risk to human health. Sanitary regulation simultaneously intends to promote preventive self-inspection measures through co-responsibility of producers, manufacturers, traders and consumers in order to reduce or eliminate hazards. The model's target is the improvement of raw material, processes, and product safety, through the prevention or elimination of risk, through regular random verification of establishments and sampling and analysis of products.

The Secretariat of Health co-ordinates its activities with other federal and state government agencies, through different means, such as co-ordination agreements, in order to support international trade.

Verification of compliance of process, products and labels includes: inspection of establishments, sanitary conditions, implementation of good sanitation practices and good manufacturing practices, in fish processing industries, implementation of HACCP. Random sampling of products and analysis at official government laboratories or officially certified laboratories. Sampling of labels and verification of all the information required by regulation, and that the product meets all the features that are stated in the label.

In such context, there has been official assessment and accreditation of several government and private laboratories to perform specific analytical determinations. These laboratories serve as auxiliary in sanitary regulation. The certified verification units issue approval certificates to those products that comply with the guidelines established in the regulation, as it is the case concerning the labelling of products.

In regard to chemical risk management, such as: additives, hormones, veterinary products, pesticides and fertilisers, among others, the responsibility is from the Inter-Secretariat Commission for the Control of Processing and Use of Pesticides, Fertilisers and Toxic Substances. This Commission is conformed by the following Secretariats: Agriculture, Commerce, Health, and Environment.

In a similar way, the Inter-Secretariat Commission for Biological Safety and Genetically Modified Organisms, integrated by six Secretariats, is responsible for co-ordinate the Mexican government policy relative to the biological safety and the production, importation, exportation, mobilisation, propagation, clearance, consumption and in general the use of Genetically Modified Organisms, as well as its products and sub-products.

In addition, microbiological risk management is carried out in an independent manner by each of the following Secretariats:

SECRETARIAT	MICROBIOLOGICAL RISK FACTORS
Health	Sewage, sanitary infrastructure, field pollution, processing and transport.
Environment, Natural Resources and Fisheries	Water quality and sewage.
Social Development	Agricultural workers and sanitary infrastructure.
Labour and Social Prevision	Agricultural workers.
Communication and Transport	Transport.

The physical risk factors management for food products (such as pebbles, nails, hair and other foreign matter) is regulated by the sanitary Standards from the Secretariat of Health and by the quality standards from the Secretariat of Commerce and Industrial Promotion.

2.3 Risk Communication

The Government of Mexico develops the risk communication process through the interactive information and opinion exchange among different economic agents, participating in the agrifood production chain, consumers, academics, researchers, risk assessors, risk managers and other interested parties.

The Federal Metrology and Normalisation Law establish the rulemaking process. It stipulates that the Mexican Official Standards elaboration corresponds to the Federal government institutions, but they must be submitted to the National Normalisation Advisory Committees for evaluation and approval. These Committees are integrated by regulatory areas comprised of government agencies, consumer and producer organisations, and universities, institutes, and research centres. The main purpose is to maintain continuous communication among all the interested parties. This allows incorporating all decisions, opinions and information for efficient risk management.

The Committees approve the draft proposal of a Mexican Official Standard, which is then published in the Official Federation Newsletter for public comment. Once these comments have been incorporated, it becomes a Mexican Official Standard, which is officially announced through its publication in the Official Federation Newsletter for its national application. The above-mentioned procedures of issuing a Mexican Official Standard are developed by each one of the government agencies.

Operation of the inspection and control system for domestic and imported food by Secretariat of Health considers the report of all regulatory actions in a continuous basis to domestic companies and importers that have been subject to inspection and testing. The system also considers regular communication of general industry and commerce performance with corresponding representatives.

III. Food Safety Activities

Following, we present the main activities related to food safety issues, that the Mexican Government has pursued:

3.1 Consult and Communication

Mexico has approached food safety and quality issues in such an inclusive manner that participation of different actors in the food chain is indispensable, including Federal, State and local governments, producers, exporters, certification and private standards organisations, consumers, researchers and academics.

In this sense, a presidential program to decentralise most of the operating functions of the Secretariat of Health to State Governments went into effect since 1996, granting such functions, including regulatory authority to State Public Health Services. Such decentralisation is intended to increase coverage and speed up communication to improve performance in the solution of public health problems. Subsequent specific co-ordination agreements were signed. And a learning process has been taking place in every state, to further implement inspection and control of the food processing industry.

Furthermore, there exist 32 Food Safety Technical Working Groups, working in a National Strategy in all the States within the country. With the purpose of continuing and reinforcing this Strategy, in 1998 the Mexican Secretariats of Agriculture and Health, signed with their U.S. counterparts the “Food Safety Joint Statement” which establishes the interest of both governments in working together to achieve food safety. In addition a Memorandum of Understanding was signed in 1999 with the Canadian Government, in order to reinforce such strategy. Also, several meetings as well as national and international seminars have been organised by these technical working groups in order to unify criteria concerning the government strategy.

3.2 Developing a Food Safety Framework

As a result of the work developed by these technical-working groups, short and medium term goals were established. In this sense, during 1999, a short-term strategy was designed and the technological development for the food quality integral program was established. This program provided basic and specialised training, regarding food safety principles, as well as technical assistance for adopting Good Agricultural Practices, Good Manufacturing Practices and Hazard Analysis Control Critical Points Systems.

During 2000, the technical working groups are working to develop activities in a co-ordinated manner with the public and private sectors. In order to reinforce and give continuity to the basic and specialised training, as well as technical assistance programs. Also, these groups will be implementing around the country the adoption of Good Agricultural Practices, Good Manufacturing Practices, and Hazard Analysis Control Critical Points, as well as research and agricultural workers assistance programs.

Also, there exists a proposal in order to review and, if necessary, to propose modifications to the legal framework regarding food safety and quality issues.

3.3 Biotechnology

The issues related to production, importation, possible environmental impact, trade of seeds, and interstate transit of genetically modified organisms are regulated by the Secretariat of Agriculture through the Federal Law for Plant Health, the Federal Law for Animal Health (when genetically modified

organisms are used in production of animal feed), as well as the Law for Seeds Production, Certification and Trade.

Genetically engineered food for human consumption is regulated by the Secretariat of Health through the General Health Law.

Currently, Mexico is in the process of restructuring its operative framework, pursuant to a November 1999 Presidential Order, which established the Inter-Secretarial Commission for Biological Safety and Genetically Modified Organisms. This Commission is integrated by the Secretaries of Agriculture; Environment; Health; Treasury; Commerce; Public Education, and the National Council of Science and Technology.

The main functions of the Commission, among others, are to:

1. Elaborate and submit to the President of the Republic the national policies regarding these issues.

2. Design proposals for updating and improving the legal framework.

3. Submit to the Normalisation Commission draft proposals concerning Mexican Official Standards in this subject.

4. Determine criteria in order to harmonise and simplify the procedures and requirements for the issuance of authorisations, licenses and permits.

5. Promote the establishment of a registry for genetically modified organisms, as well as its permanent updating.

6. Propose inspection and verification visits to ensure the purpose and effect of the regulations.

7. Recommend research projects on genetically modified organisms.

With the purpose to accomplish the functions above mentioned, the Commission will consult and analyse the opinions submitted by the Biological Safety Advisory Committee, which is composed of renowned researchers with ample experience in this area, whom will be selected through a public meeting handled by National Council for Science and Technology.

Finally, with regard to biotechnology and the application of the precautionary principle, Mexico wishes to express that in the case of insufficient scientific basis, the measures or regulations imposed on biotechnological-developed products must be applied in a similar way to those applied on other products with regard to scientific uncertainty.

3.4 Precautionary Principles in Food Safety Issues.

The Government of Mexico considers that it is a fundamental obligation for every country to protect the life and health of its consumers. Nonetheless, the Government of Mexico also considers that commerce among nations must be fair and equitable, by which there must not exist barriers and obstacles to trade.

With respect to the precautionary principle, Mexico adheres to the language of Article 5.7 of the Sanitary and Phytosanitary Measures Agreement of the World Trade Organisation. Mexico considers that it must be applied within the process for risk analysis when there are insufficient scientifically based criteria, and should not be applied in an independent way as an isolated procedure.

3.5 Socio-Economic Aspects

The Government of Mexico considers that issues related to quality, availability, animal welfare, biodiversity, as well as those related to ethical issues, must be regulated in a different manner from those related to the health and safety of consumers, and that such measures must not be used as a disguised protectionist measure that seeks to eliminate the comparative and competitive advantages of a foreign product in relation to a domestic product.

The foregoing is due to the fact that if these kinds of measures are used to maintain a certain level of protection, distortions in the world market will continue, as well as the damage to the efficiency of agricultural producers. Likewise, such measures will endanger the benefits for agricultural commerce given that they will be contrary to the principles of free trade.

NEW ZEALAND

I. Synthesis

Food safety assurance is essential to New Zealand's well being, in terms of achieving both our health and economic objectives. While New Zealand's food regulation needs to ensure a safe food supply for the domestic population, as a country where food accounts for around half of all export earnings, the need to provide credible assurance of food safety to our trading partners is also vital.

Food Regulatory Environment

Regulators are facing new challenges as the environment in which they operate changes, particularly in terms of stakeholders' demands:

- *Consumers* are increasingly paying attention to 'non-science' concerns and have a heightened awareness of food safety issues (due, in part, to recent food safety crises overseas). Social changes, such as increasing variety in diet and access to more diversified food imports, also complicate the regulatory environment.

- *Producers* are seeking flexibility in regulation to allow innovation, both in terms of foods produced and production processes.

- *Internationally* New Zealand's regulators have been exposed to a broad range of regulatory systems and stake-holder demands through their experience of exporting to a large number of countries with varying requirements.

These circumstances add to the complexity of developing and implementing workable food control measures, while keeping compliance costs and food prices reasonable.

Key Concepts

New Zealand's food regulatory system relies on several key concepts:

- The developing disciplines of risk analysis.

- 'Hazard Analysis and Critical Control Point' principles.

- Use of outcome-based standards instead of a prescriptive approach.

- A seamless food safety system facilitated by harmonisation of the practices of food regulatory agencies.

- The adoption of a single, optimal regulatory model to apply across primary processing, secondary processing, domestic food sales and exports, with industry responsibility for food safety underpinned by effective governmental regulation and monitoring.

- Consultation with industry and consumers.

II. Overview of the Food Safety System in New Zealand

The basis for New Zealand's food safety system is a scientifically derived, risk-based approach which also reflects the practical needs of the food industry. The majority of food produced in New Zealand is intended for export, which means the regulatory framework must be able to comply with overseas as well as domestic requirements.

Institutional Structure and Regulatory Framework

Delivery of regulatory safety functions in the food sector is centred on the Food Assurance Authority in the Ministry of Agriculture and Forestry (MAF Food) and the Food Safety Group in the Ministry of Health (MoH). Broadly speaking, food entering the domestic New Zealand market is regulated by MoH, while primary production and processing of meat, seafood, plant and dairy products, and MAF Food regulates export of these items. The interests of other agencies in developments in the food sector are accommodated through an Officials' Committee on Food Administration, chaired by the Department of Prime Minister and Cabinet, which meets regularly to co-ordinate regulatory approaches.

Under the Optimal Regulatory Model, on-site audit or verification that the law and standards are being properly implemented is performed by:

- Third party auditors approved by the Ministry of Health under a 1996 amendment to the Food Act.

- A Verification Agency established since 1 November 1998 in the Ministry of Agriculture and Forestry, separate from MAF Food as regulator.

Because adoption of the Optimum Regulatory Model is voluntary under the Food Act, and much of the supporting documentation is still being developed, most domestic food businesses are still regulated under prescriptive food hygiene regulations by territorial local authorities (City and District Councils - local government bodies). Regional public health units under the Ministry of Health enforce Food Act requirements relating to the safety, composition and labelling of food. The Animal Products Act 1999 also provides for the verification of animal products' compliance with the new law - at the primary processing stage and for export - to be performed by independent agencies, properly accredited, once risk management programmes are established under the law, and foreign competent authorities accept the extension away from MAF.

Current legislative requirements for food safety in New Zealand are covered by four pieces of legislation:

- The Food Act 1981, administered by the Ministry of Health.

- The Meat Act 1981, administered by the Animal Products Group, MAF Food.

- The Animal Products Act 1999, administered by the Animal Products Group, MAF Food.

- The Dairy Industry Act 1952, administered by the Dairy and Plant Products Group, MAF Food.

Because this legislation has differing approaches to food safety, work is under way to more closely align provisions of the different laws by minimising variations in the application of 'Hazard Analysis and Critical Control Point' principles. Harmonisation of legislation on paper is being

complemented by harmonisation of the practices employed by the central regulatory agencies and by auditors and others performing verification in the field. This will ensure a unity of approach in the New Zealand food industry and help to achieve consistency in the safety of food, exported to overseas markets and in the domestic market.

Risk Assessment: Hazard Analysis and Critical Control Point (HACCP)

New Zealand is prominent in international discussions to develop and implement risk analysis procedures. The Hazard Analysis and Critical Control Point (HACCP) system is a major tool employed in New Zealand for ensuring that risk analysis is appropriately applied in food safety measures. HACCP focuses on identification, evaluation and control of those hazards that have a significant impact on food safety, and includes many of the science-based principles of risk assessment and risk management. Elaboration of sanitary measures includes a requirement to apply HACCP principles in conjunction with risk analysis, and to identify the appropriate level of protection in terms of required food safety objectives. New Zealand regulators employ a working definition of food safety objectives (FSOs) for hazards in a food product: "a statement based on a risk analysis process which includes an expression of the level of a hazard in a food that is tolerable in relation to an appropriate level of consumer protection; when justified by the risk assessment, the FSO should include expression of the level of the hazard as a maximum tolerable concentration and/or frequency."

New Zealand has increasingly focussed on the inclusion of HACCP principles in its food legislation, establishing HACCP as the foremost means of underpinning risk-based management plans. Recent changes have included HACCP principles – the seven spelt out by the Codex Alimentarius Commission - as the basis of the risk-based management and food safety control programmes, increasingly replacing older legislation based on more traditional prescriptive measures. New Zealand has also worked closely with the Codex Alimentarius Commission on developing guidelines and other work on HACCP principles, risk analysis and equivalence, which ensures consistency with international understanding and standards in this area.

The increasing awareness of HACCP principles and their application by food businesses in New Zealand is resulting in new approaches and important trends such as use of prerequisite programmes, food safety objectives, validation, and the concept of equivalence.

Risk Management: Optimal Regulatory Model

A central feature of harmonisation of the food safety system has been agreement on one regulatory model for the food sector (regarded as "optimal" for New Zealand conditions). The Optimal Regulatory Model relies on Government acting as the regulator, setting appropriate sanitary measures (in consultation with stakeholders). Industry takes full responsibility for producing food and food-related products that are 'fit for purpose' (meaning that it is fit for human consumption, as defined by Codex) using risk-based management plans. Independent verification is carried out to ensure industry compliance. A graduated response is available to back up the plans, in the event of non-compliance, with increasing severity of intervention recommended or instituted by verifier or regulator, depending on the severity of the incident. A description is attached as Figure 1, titled "Optimal Regulatory Model".

By applying this regulatory model consistently, industry need only contend with one set of regulatory intervention, and the regulator can ensure that no food is marketed which does not meet New Zealand's sanitary measures. This helps ensure better compliance in itself, through increased consistency in application, and better opportunities to profit from food sector-wide experience at each of the levels of the regulatory model - regulator, verifier/auditor and industry. The model maximises industry involvement in the safety of their products through the use of HACCP-based risk management techniques to identify hazards in the food production process, and control them when they occur, rather than waiting for inspection or tests to reveal a problem.

The rigidly prescriptive standards of times past are being progressively replaced by a new generation of standards that are outcomes-based, identifying clear food safety objectives for instance. Industry thus takes more initial responsibility for producing safe food and gains more flexibility for processing innovation.

Risk Communication

Development of food safety standards in New Zealand is carried out in consultative councils, involving specialist representatives from government regulatory agencies, the industry being regulated and - a more recent innovation - representative input from consumer interests. This approach reflects that the first responsibility for safe food lies with the producer. But it also acknowledges that the government has an essential role to play in ensuring that requirements are complied with, and in providing assurances to consumers, whether in New Zealand or in overseas markets. Increasingly, primary food legislation (Acts), secondary legislation (Regulations) and the working level tertiary codes of practice, standards and manuals of procedures are available to industry and the public through the Internet.

For further information see the following web-sites:

http://www.moh.govt.nz and

http://www.maf.govt.nz (in particular under "MAF Food", "Animal Products" or "Standards").

III. Activities of New Zealand in Addressing Food Safety Issues

3.1 Developing National Food Safety Frameworks

Two regulatory authorities currently administer New Zealand's food safety environment, with other agencies also regulating activities with an impact on the food sector. However the New Zealand Government has set an objective of establishing an integrated food regulatory regime. Since mid-1998 officials have been evaluating a range of structural options for an integrated food regulatory regime. As an interim measure, the Ministry of Health (MoH) and the Ministry of Agriculture and Forestry (MAF) are working to harmonise their regulatory systems to the maximum extent possible. The objectives of reform are a credible, consistent and seamless food and food safety regime for New Zealand. Forces for change include:

- Overlapping and prescriptive requirements.
- Uneven enforcement levels.
- The changing nature and scale of food-borne diseases.

- Closer alignment with Australia on standards.

- The globalisation of trade.

MAF and MoH agree that a strategic generic approach is required to introduce and implement risk-based management plans to all food enterprises. Three over-arching areas of the programme are communications and consultation; the risk management framework and the development of policy. More specific elements identified for work include approvals and accreditation's; international standards and co-ordination; monitoring and review; emergency response; compliance and trials. Key components of these work programmes include:

- A communications strategy using a range of mechanisms including seminars and web-site consultation. Ongoing consultation will continue as the system is redeveloped.

- Alignment of terminology and concepts between risk management plans in the animal products, dairy and other food areas this is nearing completion.

- Analysis on an equitable and sustainable cost recovery regime.

- A trial risk management programme currently under way as a result of harmonisation steps taken to date by MoH, MAF and a diversified food company. The project explores the practical options of applying risk management programme requirements, with one regulatory intervention (under two separate pieces of food legislation in the interim). Results will be evaluated in early 2001.

3.2 Communication and Consultation

As part of the work programme undertaken by MoH and MAF developing a generic risk-based approach for all food produced and sold in New Zealand, it is necessary to ensure that these food safety activities are understood and supported by the industry and consumers who will be affected by them. Work of the two Ministries is still being defined in relation to communication and consultation programmes, but is likely to be directed to:

- Ensure that those affected are consulted and have adequate opportunities to engage in dialogue on issues.

- Develop adequate consultative mechanisms.

- Foster within the two agencies an understanding and appreciation of risk communication principles and of the importance of communication and consultation throughout development of the programme.

- Identify the communication needs of the programme and of those affected, and to provide support and assistance to meet these.

- Provide support for the work of the agencies through education and other programmes designed to manage risks to food safety.

A particular example of recent public consultation, which is still on-going, is the process of developing and gaining awareness and acceptance of a new standard for genetically modified foods (GMFs) and their labels. Discussion of further extension of the labelling regime to foods which are not inherently different from their "conventional" counterparts is under way in 2000.

3.3 Regulatory Compliance and Enforcement

Compliance can take two main forms: one is imposed by regulatory agencies, and the other is self-generated by the regulated food producer or retailer. The regulatory model in New Zealand relies on the first steps towards compliance being undertaken by the food industry themselves. This means that industry has less opportunity of avoiding the responsibility for producing safe food, and leaves regulators with a less intrusive, but possibly more effective ability to stand outside the production cycles and to monitor the outcomes.

Effective regulatory enforcement is of particular importance in New Zealand. The repercussions should any unsafe food produced in New Zealand enter the market would be immense, affecting not just the producer, but also the reputation of New Zealand as a reliable supplier of safe food. Effective enforcement is attained through the application of food law, particularly in ensuring that appropriate standards and procedures are in place and being implemented. This is achieved through appropriate investigative and legal powers to pursue and prosecute those who operate outside the law. Recent law changes have dramatically increased penalties for infringements, strengthening their deterrent impact and increasing the likelihood of compliance.

The Optimal Regulatory Model provides the framework in which effective regulatory compliance and enforcement is delivered. Industry takes full responsibility for producing food and food-related products that are safe and 'fit for purpose'. Producers develop and implement risk-based management plans, with independent verification ensuring plans are abided by. In turn independent verifiers are monitored through an auditor approval programme. This approach relies upon the Government acting as the regulator, setting appropriate sanitary measures and ensuring that the measures are implemented consistently, achieving the results intended. It strengthens Government accountability by making clear the lines of responsibility, and achieves transparency in the system by being based on industry quality assurance systems, with documented steps at all levels, and on a nation-wide basis.

This shift from a command and control regime to a risk-based management approach will enable a seamless switch of food and food-related products from one regime to the other, regardless of which primary law covers the process. Industry takes the initial and essential responsibility for developing and complying with risk-based management plans. These in turn are subject to independent audit, with accountability pathways and clearly defined responsibilities through to the over-all regulator in central government agencies.

3.4 Regulation of Modern Biotechnology

The two key facets to the current framework for regulation of modern biotechnology in New Zealand are the Environmental Risk Management Authority (ERMA) on introducing new organisms, and the Agreement Between the Government of New Zealand and the Government of Australia Establishing a System for the Development of Joint Food Standards, including a standard on genetically modified foods (GMFs).

Genetically Modified Foods: New Zealand has a joint food standards system with Australia. Joint standards for food, including those which have been genetically modified, are developed by the Australia New Zealand Food Authority (ANZFA), consulted on widely throughout both countries, and agreed on by an over-arching bi-national Ministerial Council. The current standard for GMFs, which came into effect on 13 May 1999, requires a pre-market safety assessment to be carried out by ANZFA before the food can be sold. The current standard also requires labelling of GMFs which are substantially different from their conventional counterparts. Recently Australia and New Zealand Health Ministers agreed that the labelling requirements should be extended to all GMFs, for consumer information purposes. Work is being carried out at present on the detail of this extension to the standard. A draft

standard, and a draft protocol intended to provide guidance on the practical implications of the new proposed labelling requirements, has both been released for public comment. Compliance cost study is nearing completion, and Ministers expect to finalise the details of the extension to the standard in May 2000.

Genetically Modified Organisms The Environmental Risk Management Authority's (ERMA's) principal function is to decide on applications for the development/ manufacture, import, or release of hazardous substances and new organisms in New Zealand. ERMA applies the decision-making principles and operates within a framework developed by the Hazardous Substances and New Organisms (HSNO) Act 1996. The HSNO Act reflects the most advanced regulatory thinking on addressing research, field tests and release of GMOs. ERMA deals individually with applications in a manner that is consistent with accepted risk principles. When assessing applications ERMA takes into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects. Risk management decisions are made on the basis of scientific evidence and take account of environmental, health, social, economic and international legal concerns.

In combination, the joint Australia New Zealand GMF standard and ERMA's role with regard to GMOs provide a regulatory framework that manages risks from genetically modified foods and organisms to New Zealand consumers and to the environment. In addition the Government will establish a Royal Commission of Inquiry into genetic modification (the highest possible level of independent review), which will give consideration to the broad range of issues arising out of the new technology as well as evaluating different strategic options for New Zealand.

Precaution

New Zealand is committed to risk assessment and sound science as the basis for the elaboration of sanitary measures for hazards in foods. There are a number of precautionary assumptions and approaches built into risk assessment that provide appropriate conservatism in generating risk estimates and associated uncertainty values. Further, risk managers can use risk assessment policy decisions to strengthen precautionary assumptions and approaches if they deem this appropriate in specific cases.

Precaution can be included in a number of ways in risk management decision-making, either on an institutional (i.e. legislative) or ad hoc basis. In situations where there is insufficient or conflicting scientific information on risks to human health, precaution is used in the elaboration and implementation of sanitary measures as a normal part of risk management in New Zealand. There is as yet, no internationally accepted understanding of what the 'precautionary approach' means when applied to food safety measures, whereas in the environmental field the precautionary approach is well established - Principle 15 of the Rio Declaration on Environment and Development refers. By contrast the application of a particular precautionary approach in the food safety context was rightly shown to be in breach of World Trade Organisation obligations in the Beef Hormones case; the Appellate Body, nevertheless, recognising that the precautionary principle finds reflection in Article 5(7) of the Agreement on the Application of Sanitary and Phytosanitary Measures. Effective risk communication can help mitigate perceived risks arising, for example, out of non-scientific concerns.

Addressing 'Non-Scientific' Concerns

The principal concern of New Zealand's food regulators is to provide credible food safety assurances that are based on science to consumers nationally and internationally. Non-scientific concerns, such as the need for information to facilitate choice, are also of importance. These non-scientific concerns are most appropriately addressed through the development of alternative mechanisms that in no way impinge upon the delivery of assurances about the safety of food. For example, in the New Zealand food

regulatory model, "quality" aspects of food production are generally left outside the scope of government intervention, recognising that elements such as size, appearance, colour and taste are largely judged in subjective terms, and they have no immediate impact on public health. Market forces therefore most appropriately regulate decisions on 'quality' aspects of food products (as opposed to safety).

It is particularly important that all World Trade Organisation Members continue to uphold the principles contained in the Agreement on the Application of Sanitary and Phytosanitary Measures. Trade restrictive measures intended to protect the health of consumers should be based upon scientific principles and evidence, not on non-scientific concerns. This helps mitigate the use of non-tariff barriers for trade protectionist purposes (such as restricting imports to assist local production).

International Food Trade

Given the scale of New Zealand's exports of food and other primary products (well over 50% of export earnings) it is inevitable that international food trade issues are of prime interest to New Zealand. This is reflected through a strong focus on the work of international standard-setting organisations, like the Codex Alimentarius Commission, and the work of the World Trade Organisation on sanitary measures in the SPS Committee.

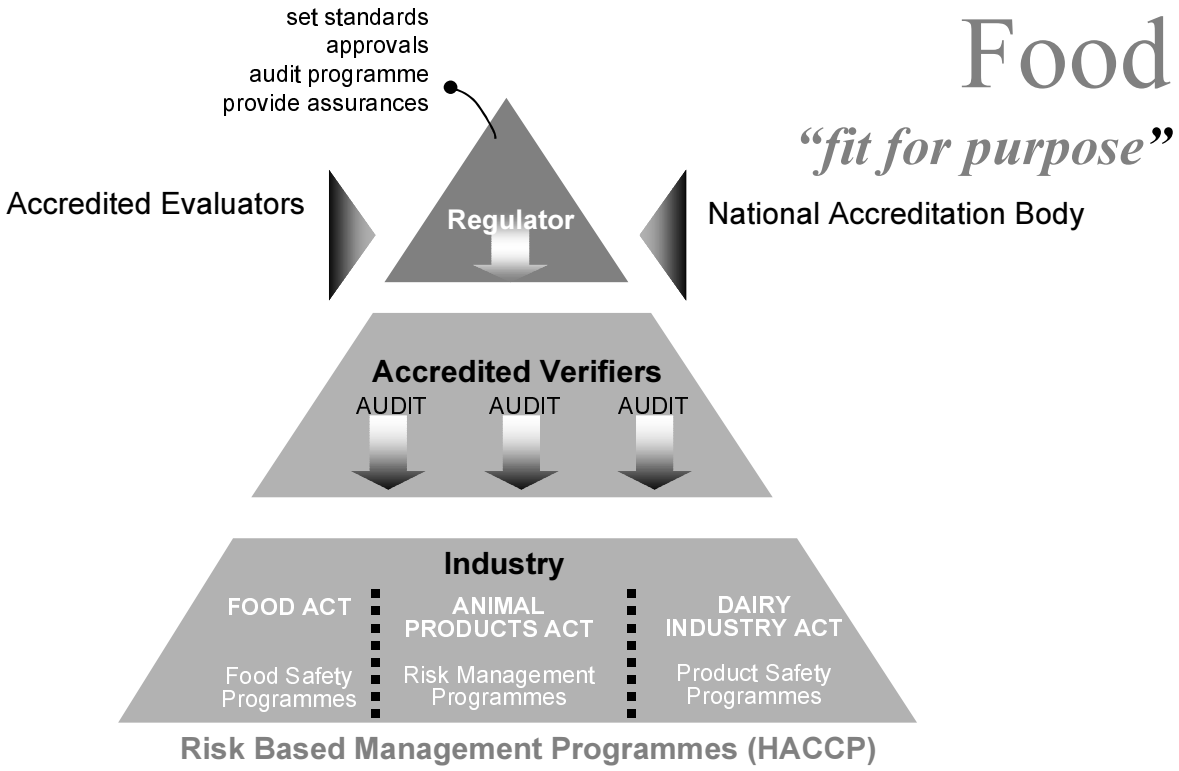
New Zealand seeks to ensure that international food trade is conducted on the basis of sound scientific principles, with clearly identified food safety objectives, where this is possible. As the concepts have developed, New Zealand has been active in discussions on the development and application of HACCP principles to food regulation, and on the definition and application of risk analysis and its related disciplines. Recent work has also contributed to a firmer understanding of the application of the concept of equivalence to the outcomes of regulatory interventions. This has multiple benefits, including:

- Ensuring that food is produced as safely as possible - with governments at either end of the food supply chain interested in the food being traded, industry heightens its attention to compliance.

- A means of reducing the need for duplicate testing, inspection and other regulatory interventions - on export and at the point of entry to a final destination.

- Appropriate regulatory intervention by a government at the production stage - where the best controls can be applied and enforced, especially when detailed knowledge of the processes may not necessarily be available to the importing government.

ANNEX



Optimal food regulatory model for New Zealand *figure 1*

NORWAY

I. Synthesis

A. Description of the Administrative System.

In Norway, the legal base is that the entire food chain must be safe - from fiord/stable to table. Food safety legislation is laid down by the Ministry of Health and Social Affairs, the Ministry of Agriculture, and the Ministry of Fisheries. Administration of the Gene Technology Act rests with the Ministry of Environment. The Norwegian Food Control Authority (SNT) is the national directorate responsible for overseeing food safety legislation. All practical enforcement of food control legislation is carried out at the local level. There is an on-going process in developing a simpler and less complex system.

B. Biotechnology

Norway has developed national GM regulations and is pursuing a rather restrictive GM food policy.

GM foods are regulated under two main laws. Firstly, the *Norwegian Gene Technology Act* which is to ensure that the production and use of genetically modified organisms takes place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and the environment. The Act applies to the production and use of genetically modified organisms and requires that each product should be evaluated on a case by case basis and after a step by step procedure.

Secondly, the *Norwegian Food Act* includes regulations on labelling and approval of GM foods. The purpose of the labelling is to meet consumers wish to know if the product has been derived from genetically modified organisms, thus enabling them to make an informed choice. An approval requirement for GM foods and other novel foods entered into force in January 1999. Prior to an approval, a risk assessment has to be conducted according to the Norwegian guidelines, mainly based on the EU guidelines for the health assessment of novel food. A Norwegian regulation is also being developed for the purpose of banning the production, import and sale of GM foods containing genes coding for resistance to antibiotics.

The Government recently established a scientific committee for the purpose of evaluating potential health risk posed by GM foods and clarifying the term «precautionary principle» in that context.

No GM food has yet been approved for marketing in Norway, although several processed products and plants are under consideration.

C. Risk Assessment and Risk Management

Health risk assessments are performed in independent scientific institutions and in SNTs Scientific Committee. The committee is an independent body whose mandate is to give scientific advice in matters of food safety. Specific health risks are assessed, and the Committee also gives its opinion on strategies and priorities important to food safety, especially in relation to monitoring, surveillance and research.

Risk management options in Norway are primarily related to the end product, production and distribution included legislative measures, control activities, monitoring programmes, labelling, consumer information or dietary recommendations. SNT‘s Advisory Council, assembling stakeholder representatives, is consulted in matters of principle and strategies. Risk management decisions are based on assessing political and socio-economic factors as well as consumer perception etc. Major decisions are based on responsibility of the relevant ministry; otherwise the responsibility lies with SNT, or the local control authority.

D. The Precautionary Approaches and Principles

Norwegian authorities apply the precautionary principle when scientific uncertainty or lack of data/knowledge makes a comprehensive risk assessment impossible. The basis is a preliminary risk assessment indicating a possibility of adverse health effects in the population in general or in certain groups. There is a legal basis in the existing rules for restrictions on foodstuffs when such adverse health effects are suspected.

Based on the national health and consumer policy, food authorities in Norway may take action to ensure safe food without awaiting results of scientific research or documentation of adverse health effects in the population. Such measures are subject to review in light of new data.

II. Overview of Food Safety Systems in Norway - Factual Description

A. Description of the Administrative System

In Norway, the legal base is that the entire food chain must be safe - from fiord/stable to table. There are five acts covering the end products of the food chain. The other links of the food chain are covered by legislation comprising plant, animal and fish health, and feed production.

The production of foods through modern biotechnology and their marketing will be addressed separately in Part 3 litra B.

Ministries: Food safety legislation is laid down by the Ministry of Health and Social Affairs, the Ministry of Agriculture, and the Ministry of Fisheries. They administrate the following acts: *the Food Control Act, the Act on the Co-ordination of Food Control, the Meat Production Act, the Quality Control Act on Fish and Fishery Products.* Also, the Ministry of Agriculture administrates *the Act on Quality Control of Agricultural Products* - an act not regarded as food safety legislation in itself, and therefore not mentioned in this paper. Administration of *the Gene Technology Act* rests with the Ministry of Environment.

The Ministry of Agriculture is financially and administratively responsible for the Food Control Authority (SNT), other responsibilities bearing on SNT's activities are being shared among the Ministry of Health and Social Affairs, the Ministry of Fisheries, and the Ministry of Agriculture.

The Ministry of Fisheries is professionally, financially and administratively responsible for the Directorate of Fisheries.

The Ministry of Agriculture is professionally, financially and administratively responsible for the Norwegian Agricultural Inspection Service and the Norwegian Animal Health Authority, which primarily supervise plant and livestock production, respectively.

Directorates: In general, the Norwegian Food Control Authority (SNT) is the national directorate responsible for overseeing food safety legislation. However, dependent on whether fish and fishery products are destined for the domestic or the international market, surveillance of fish and fishery products is carried out by the Directorate of Fisheries or SNT, as appropriate.

In addition to co-ordinating all public food control activities, SNT is authorised to make specific decisions and, to some extent, issue supplementary rules. Although practical enforcement of food legislation is primarily carried out at the local level, SNT is responsible for ensuring that food control activities are co-ordinated and uniformly conducted. In cases requiring special expertise, SNT may directly implement control measures.

SNT's objectives are to establish systems, which ensure that foods are safe, meet consumer demands and are fairly marketed.

SNT's Food Advisory Council acts in an advisory capacity on matters pertaining to SNT's objectives, regulations and enforcement efforts. SNT's Scientific Committee furnishes SNT with scientific advice on health matters involving foodstuffs and nutrition. The Advisory Council and Scientific Committee will be described more thoroughly in part 2 litra B.

The Animal Health Authority is responsible for prevention, monitoring, control and surveillance of animal and fish diseases, supervision of animal welfare, and the use of pharmaceutical products on animals. It is also charged with conducting a number of surveillance programs on animal diseases. Monitoring infectious agents capable of being transferred from animals to humans, including salmonella, is one area of priority. Under acts covering animal welfare at slaughtering and animal health, the Authority is answerable in matters of livestock control.

The Agricultural Inspection Service is, besides supervising feedstuffs, fertilisers, seed products and pesticides, responsible for early-warning prevention, monitoring, control and surveillance of plant pests.

The Directorate for Nature Management under the Ministry of Environment is charged with overall control of the release of genetically modified plants, animals and micro-organisms into the environment. A control system is being elaborated, involving the Agricultural Inspection Service and SNT.

The local food control authorities: All practical enforcement of food control legislation is carried out at the local level. The local food control authorities conduct all inspections and represent the first point of contact for consumers and foodstuffs manufacturers. T*he Act on the Co-ordination of Food Control*, stipulates that all municipalities must carry out food control activities. Today, there are 82 municipal and intermunicipal food control authorities in Norway. The local food control authority or appropriate municipal body is responsible for local decisions. Any appeal may be directed to SNT, the municipal executive board or the office of the county governor.

The local food control authorities supervise the production, imports, sale and marketing of foods and the monitoring of foreign substances in food. The Quality Control Service of the Directorate of Fisheries is responsible for the control of fish and fishery products intended for export. Control of products for the domestic market, however, is the responsibility of the local food control authorities.

The funding of the local food control authorities, largely determined in Fiscal Budget appropriations, is set out in separate legislation.

B. The Process of Ensuring Food Safety in Norway

A holistic food and nutrition policy plays a key role in the efforts of the Norwegian government to promote public health and prevent health risks. With respect to food safety this integrated food policy is enforced by the Norwegian Food Control Authority (SNT). The authority is responsible for establishing systems, which ensure that foods are safe, fairly marketed and meet consumer demands. SNT is responsible for taking immediate action towards products with potentially adverse health effects**.**

Strategies and priorities: Norwegian strategies, priorities and long term plans related to food safety are based on advice from Snit's Scientific Committee, national food, health and consumer policies as well as obligations following from international agreements.

Information gathering and knowledge: High priority is given to collecting documentation and data on food composition, food components, risk factors, health effects, as well as dietary data for the public in general and risks groups. There are extensive monitoring and control programmes with a view to survey food safety, food and diet in Norway, provide data needed in risk assessment, and detect potential health problems at an early stage. The programmes also serve to monitor the efficiency of risk reducing measures. Prioritising is risk based.

Projects may comprise the whole production chain, involving co-operation with authorities responsible for animal health, plant and feed production and environment.

All ministries responsible for foods, also finance research on food, food science and technology. Scientific data is needed in risk assessment. The Norwegian Food Control Authority has resources especially reserved for research. Research in political science and sociology is also funded by the Authority; means in order to get a scientific basis for evaluating risk management and communication.

Risk Assessment[1]: Health risk assessments are performed in independent scientific institutions and in SNTs Scientific Committee. The Committee is an independent body whose mandate is to give scientific advice in matters of food safety. Specific health risks are assessed, and the Committee also gives its opinions on strategies and priorities important to food safety, especially in relation to monitoring, surveillance and research. The committee members are selected according to their scientific qualifications in fields relevant to food safety. Care is taken to ensure compliance with the strict rules in Norwegian law

1 . In this document Codex Alimentarius' definitions are used:**RISK-** A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. **RISK ANALYSIS:** A process consisting of three components: risk assessment, risk management and risk communication. **RISK ASSESSMENT:** A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization. **RISK MANAGEMENT:** The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options. **RISK COMMUNICATION:** The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

regulating potential conflicts of interest. The process is open and opinions of the scientific committee are communicated to the public.

B.2 Risk Management

Option assessment: Food legislation in Norway is primarily related to the end product, production and distribution included. In this connection, risk management options are legislative measures (e.g. hygienic provisions, prohibition of sale, maximum limits etc), control activities, monitoring programmes, labelling, consumer information or dietary recommendations. Norwegian authorities aim at taking safety measures as early as possible in the production chain, emphasising cross-sector co-operation. Such measures are related to legislation covering primary production, environment etc, and comprise regulation concerning production methods, storage conditions, use of fertilisers, feed or pesticides, reducing industrial pollution etc.

Selection of appropriate measures is based on assessing political and socio-economic factors as well as consumer perception etc. These issues are further described in part 3. Major risk management decisions are the responsibility of the relevant ministry otherwise the responsibility lies with the Norwegian Food Control Authority or the local control units.

The Advisory Council, assembling stakeholder representatives, is consulted in matters of principle and strategies. The Council has established working groups for commenting on specific issues. Stakeholders views are also asked for on a case by case basis.

Legislation: In accordance with the EEA agreement, Norwegian legislation is harmonised with EU law. Health implications resulting from Norwegian dietary pattern or other specific national conditions are assessed prior to implementation. Amendments considered necessary from a health point of view may be negotiated within the framework of the EEA agreement.

Norwegian legislation requires food producers and distributors to establish in-house control systems, ensuring compliance with food legislation, thus, underlining that the responsibility for safe food products lies with producers and traders.

Control: Complying with food regulations is the responsibility of each individual establishment. To ensure regulatory compliance, the requirements of in-house control systems have to be met.

Work is going on aimed at fostering a domestic food control system that is better-focused, more integrated and effective, ensuring risk based priorities.

Acute health risks and management of crisis: Contingency plans and routines are in place for coping with situations where products detrimental to health are discovered.

Management options aim at preventing marketing of products hazardous to health. Risk analysis procedures are followed, adjusted to severity of the potential adverse health effects and the need for immediate action.

B.3 Information and Risk Communication.

The Norwegian government has a policy of openness and transparency and is giving information in a proactive way. Staff involved in food safety is trained in risk communication. There are formal procedures for informing about legal decisions.

Information is in itself a risk management option. Norwegian authorities have issued dietary recommendations in several cases on food safety. Most often such advice is given for food gathered, fished or hunted by consumers, examples being environmental contaminants in fish and shellfish or radioactive contamination after the Tjernobyl accident.

Norwegian risk communication activities are further described in part 3, litra E, on page 243.

III. Emerging Issues

A. Developing National Food Safety Frameworks

Because the foodstuff area in Norway today is professionally managed by three Ministries, with different surveillance authorities, there is an on-going process on developing a simpler and less complex system.

In 1994 a committee was established to consider the possibilities for simplifying food laws, and how to achieve a more effective organisation of food control. In the paper «I NOU 1996: 10 Effektiv matsikkerhet Èn lov- ett departement- ett statlig tilsyn» (Effective food safety- one law - one ministry - one governmental food control authority) the following was proposed:

- Grouping the five laws into one law.
- Establishing a common food control authority covering all foodstuffs.
- Transferring to central government all food control, including local food control at present the responsibility of municipal authorities.
- Gathering all responsibilities in one Ministry.

The Committee suggested that these responsibilities should be placed in the Ministry of Health and Social Affairs, whereas the formal consultation process disclosed that opinions differed on the placing of responsibilities.

White Paper No 40 (1996-97) «Matkvalitet og forbrukertrygghet» (Food quality and consumer safety) underlines the importance of food control being considered in a fiord/stable to table perspective.

A later report drawn up by Department of Administrate Affairs, has stressed the importance of separating health and industrial interests. A discussion is still taking place as to which considerations shall be emphasised when creating a new legal basis for the field of foodstuffs. No final decision has been made.

B. Regulation of Modern Biotechnology

B.1 Norwegian Policy, Legislation and Experience on GM Foods and Feeds Per 1.03.2000

Norway has developed national GM regulations and is pursuing a rather restrictive GM food policy. Public opinion in Norway is very sceptical to GM foods; some 20 NGOs want a moratorium on the marketing of all GM foods (both processed products and genetically modified organisms). In 1995 and 1997 the Storting (our national assembly) decided that labelling of GM foods should be mandatory and in 1997 the Storting asked the Government to forbid the use of GM foods with inserted genes coding for antibiotic resistance. Our Government recently established a scientific committee for the purpose of evaluating potential health risks posed by GM foods and clarifying the term «precautionary principle» in that context. The committee is to deliver its recommendations to the Government 1st October 2000.

B.2 Norwegian Regulatory Development on GM Foods and Feeds

The Norwegian Gene Technology Act came into force on the 2 of April 1993. The purpose of the Act is to ensure that the production and use of genetically modified organisms takes place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and the environment.

The Act applies to the production and use of genetically modified organisms. The provisions of the Act relating to genetically modified organisms also apply to substances and products that consist of or contain living modified organisms.

The Gene Technology Act requires that each product should be evaluated on a case- by-case basis and after a step-by-step procedure. This implies that each product will be evaluated individually. Five genetically modified organisms are prohibited in Norway due to the fact that they contain genes conferring resistance towards various antibiotics; two of them not classified as food.

As part of the EEA-agreement (European Economic Area) between Norway and the EU, Norway has implemented the Directive 90/220/(EEC on the deliberate release into the environment of genetically modified organisms).

A regulation on transport and import of GMO's came into force from the 1st of January 1999. The provisions lay down simplified procedures for permission to transport and import GMO's that have been notified for contained use or approved of either for contained use or deliberate release.

The Norwegian Food Law includes regulations on labelling and approval of GM foods. The Norwegian labelling requirements[2] entered into force October 1997, applying to all GM foods including genetically modified organisms and food derived from genetically modified organisms, whether their properties or characteristics be different from those of comparable conventional food or not. The purpose of the labelling is to meet consumers' wish to know if the product has been derived from genetically modified organisms, thus enabling them to make an informed choice. The labelling requirements are considered to be satisfied if products containing genetically modified ingredients are labelled as such if the

2 . The labelling requirements are set out in «Circular regarding the Norwegian regulations relating to the labelling of foodstuffs interim guidelines on the labelling of genetically modified foodstuffs and food ingredients», The Norwegian Food Control Authority 04.07.97.

genetically modified component constitutes more than 2% of the ingredient. Norwegian labelling requirements on GM feeds [3] entered into force in 1999.

Our approval requirements for GM foods and other novel foods[4] entered into force 1 January 1999. Concerning GM foods, the requirements cover all GM foods that have been derived from genetically modified organisms. Prior to an approval, a risk assessment has to be conducted according to the Norwegian guidelines for the health risk assessment of novel food. The guidelines are mainly based on the EU guidelines (Commission Recommendation, July 1997) designed for the administration of the EU Novel Foods Regulation (Parliament and Council Regulation, May 1997). A key concept in the initial assessment of GM foods is «substantial equivalence», a concept developed by FAO, WHO and OECD. We may add that the interpretation of the concept is continually being reviewed in Norway, with particular focus on including a broader analysis of possible unintended effects caused by the genetic modification.

Moreover, a Norwegian regulation is being developed for the purpose of banning the production, import and sale of GM foods containing genes coding for resistance to antibiotics when such genes have been introduced by means of genetically modification. Similar regulation for GM feedstuffs is also under development.

No GM food has as yet been approved for marketing in Norway, although several processed products and plants are under consideration. Since autumn 1997, three GM edible plants have been banned from being marketed because of the presence of antibiotic resistance genes used as marker genes[5].

The risk assessment performed relative to GM foods will, in principle, not differ from general decision-making on other products.

B.3 Presence of GM foods in Norway

Since 1998 the Norwegian Food Control Authority has analysed food products on the domestic market for the presence of GM foods. Though the 1998 results showed that several food products contained DNA coming from genetically modified maize and soya, most of the products contained only very small amounts, except for some vegetarian food products made from soya. In general, Norwegian food industry, trade and agriculture sectors are at present avoiding use of GM foods.

C. Precautionary Approaches and Principles

The precautionary principle (PP) was originally developed within environmental policy as a response to situations where choices have to be made even when uncertainties exist with regard to the environmental implications of these choices. Several definitions exist, but a common understanding of the PP is that lack of scientific certainty should not be a reason to postpone measures intended to prevent possibly serious or irreversible effects to the environment. In the recently finalised Carthagena Protocol on Biosafety (under the Convention on Biological Diversity) the PP has been operationalised by a

3 . The labelling requirements are laid down in «Regulations of feedstuff for fish», Norwegian Ministry of Fisheries 18.03.99 and in «Regulations on feedingstuffs», Norwegian Ministry of Agriculture 15.10.99.

4 . «Regulation of 18 June 1998 amending the general regulations of 8 July 1983 No. 1252 on the production and sale etc. of foodstuffs», Norwegian Ministry of Health and Social Affairs

5 . Norway has decided to prohibit deliberate releases of the following three genetically modified plants approved for marketing in the EU: Genetically modified maize (Zea mays), notification C/F/94/11-03, Commission decision 96 (206) EEC, Genetically modified chicory (Cichorium Intibus), notification C/NL/94/25, Commission decision 96 (424) EEC, Genetically modified oilseed rape (Brassica napus), notification C/UK/94/M1/1, Commission decision 96 (158) EEC.

provision (art. 10.6) saying that «lack of scientific certainty due to insufficient relevant scientific information and knowledge» shall not prevent a party from taking a decision on a certain GMO.

In the food area the meaning is essentially the same although practical applications may be slightly different. The principle has an important role in risk management and should not be seen as a component of the scientific risk assessment.

Norwegian food safety authorities apply the precautionary principle when scientific uncertainty or lack of data/knowledge makes a comprehensive risk assessment impossible. The basis is, however, a preliminary risk assessment indicating a possibility of adverse health effects in the population in general or in certain groups. When such adverse health effects are suspected, there is a legal basis in the existing rules for restrictions on foodstuffs (see part II).

Norway agrees with the Codex Alimentarius definition of risk as being the function of the probability of an adverse health effect and the severity of that effect, consequential to hazards in food[6] If the consequences are severe the risk is high even if the probability is considered low. Consequently Norwegian authorities focus not only on the probability of adverse health effects, but also on evaluating the consequences of these effects. The degree, to which scientific uncertainty (as regards probability) can be accepted in decision-making, will depend upon the severity of the potential consequences.

Frequently situations are rather complex. As shown by recent history, it is not always possible to have a clear view of which kind of possible effects should be assessed – in real life, sometimes the unexpected will happen, as for example in the case of BSE.

Food consists of a vast number of components, which have effects individually, as well as in complex interactions. Even if there are comprehensive scientific data on many substances, there is little knowledge of a large number of others. Even less is know about synergistic and antagonistic effects.

Due to the general lack of knowledge about many food components and dietary effects of them Norwegian authorities consider it important to be cautious even if the exact nature and extent of the effects cannot be described in detail, for example in cases where there are scientifically based indications of serious consequences, where vulnerable systems are at risk or where the possible effects may be irreversible.

Based on the national health and consumer policy, food authorities in Norway may take action to ensure safe food without awaiting results of scientific research or documentation of adverse health effects in the population. Such measures are subject to review in light of new data. Efforts are made to obtain sufficient data to perform a full risk assessment. It is important that measures are proportionate to the risk and the level of protection, consistent with actions taken in other cases and discussed with involved parties.

Norwegian authorities apply the precautionary principle when having a restrictive policy for fortification of foods as there is limited knowledge concerning upper limits and interactions between different vitamins and minerals. The principle also form the basis for dietary recommendations for foods containing environmental contaminants, even if the toxicological effects or the content analysed in all organisms from all potentially effected locations, are not fully assessed.

Antibiotic resistance genes represent another illustrating example of how the precautionary principle has been applied in Norwegian policy in a broad context taking environmental, food safety and other aspects into account. The scientific knowledge about horizontal gene transfer and the stability of

6 . Codex Alimentarius Commission - Procedural Manual

nucleic acids in the intestinal tract and in nature is limited. At the same time the potential harmful effects – the increased inactivation of life saving therapeuticals – are considerable. Consequently, Norway's policy is very restrictive, with the intention of prohibiting genetically modified foods and feeds containing antibiotic resistance markergenes.

Several concerns are relevant when managing modern biotechnology. According to the Carthagena Protocol on Biosafety countries should be able to apply the precautionary principle in a way - consistent with the «from farm to table» – approach – that is credible both from a human health and an environmental perspective."

D. Addressing Socio-Economic Concerns

It should be acknowledged that «socio-economic concerns» as defined in the programme of work for the Ad hoc Group on Food Safety cover a wide range of issues.

In Norway, as in other countries and in Codex Alimentarius, the primary purpose of risk analysis of food is protection of public health. In accordance with Codex definitions and FAO/WHO guidelines for risk analysis available risk management options and other factors of importance, e.g. economic costs, technical feasibility, risk perceptions etc.[7], and are considered in the process of selecting appropriate measures.

Choosing suitable measures needs consideration of several factors. Some are associated with the Norwegian governmental food and nutrition policy, e.g. the nutritional value or other risks or beneficial properties of the food in question, food availability and security etc. Norwegian authorities also evaluate the consequences for society in general in terms of economy of all stakeholders, social and cultural conditions for the affected population groups, considerations related to regional policy, employment policy effects on the environment etc.

Other important factors concern consumer preferences and perceptions. Public confidence in food is considered of vital importance. This is not only related to food safety, but a prerequisite for implementing nutritional goals and make consumer choice of healthy food possible.

Openness, transparency and proactive communication are very important in this respect, but sometimes not sufficient. Many consumers have a holistic view of food and food production. Many people require food produced in a sustainable and ethical way, and are concerned about environment, biodiversity, animal welfare, human rights etc.

Adequate information enabling consumers to make choices in accordance with their concerns is regarded as necessary even if this means broadening the basis for food labelling. The Norwegian rules demanding comprehensive labelling of genetically modified food from 1997 are based on the view that reliable labelling is a prerequisite to ensure confidence in these products.

There is, however, a growing tendency to demand other efforts than information to restrict methods considered as unacceptable among the consumers. Norwegian authorities are of the opinion that actions based on other factors than scientific health risk assessments sometimes might be necessary to maintain consumer confidence, thus going beyond product characteristics as the traditional basis for food legislation. Production methods having adverse or unknown effects on the environment or regarded as unethical are relevant concerns in this regard.

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7. Risk management and Food Safety, Report of a Joint FAO/WHO Consultation 1997

Some concerns are based on legally binding multilateral agreements, cf. biodiversity issues, where the Convention on Biological Diversity (CBD) provides a legal framework, which will be further operationalised when its new protocol on biosafety enters into force. Countries not only have the right to but are also obliged to take such concerns into consideration when developing national policies and strategies for relevant sectors including biotechnology.

E. Communication and Consultation

Confidence in food production will be a vital concern in the time ahead. Developments suggest that consumers will increasingly be looking for documentation of production, origins, animal welfare and ethics. Norway has introduced comprehensive regulations on labelling. This might be the most important vehicle for conveying information to consumers.

The public consultations on new regulations have become more extensive, involving organisations representing all stakeholders. Transparency is also achieved by making public scientific findings and inspection reports available.

A lot of information exist on hazards, risks and nutritional factors through surveillance and control programs, various reports from the control authorities, research institutions and others. However, the existing systems have been developed independently from each other. Because of inadequate co-ordination and organisation, a large amount of the available information is not fully exploited. This is, however, planned so that the information will be made more accessible to the public. Work is in progress to improve the access and presentation of this information by the use of Internet.

Openness and communication of the risk aspects of food are fundamental to mutual confidence between consumers, the authorities and the industry. In the Norwegian Food Safety Communication Program, a model has been developed for co-operation and joint action in the area of food safety involving the administration, the research sector, and the various links in the food chain and consumer organisations. It provides consumers with more information and knowledge and is an important tool in the increased focus on consumers. Where nutrition is concerned, the National Council on Nutrition and Physical Activity is a major player. The Government will sharpen the focus on consumers in food production. A plan of action will be drawn up for gearing farming and food production more closely to consumer interests. The plan will include several aspects, also food safety.

A plan of action has been drawn up which is intended to counteract the development of resistance to antibiotics where GM foods and feeds with antibiotic resistance genes are included. The plan has undergone comprehensive consultations, including industry and NGO's.

The Ministries have regular meetings with the food industry to discuss issues of mutual interest. The creation of a similar forum with consumer groups is under consideration.

A food policy forum was created in 1996. However, it has not worked well, because the forum was too big. Consequently, dialogue between stakeholders was poor. The forum is now under revision.

POLAND

I. Synthesis

The food safety system in Poland is based on:

- Statements in the Constitution of the Republic of Poland.
- Legal regulations at the level of laws and implementing decrees of lower level, a part of which has already been made fully compatible with the corresponding requirements of the European Union.
- Codex Alimentarius requirements.
- Introduction of the set of standards-EN, ISO, Polish standards and other rules set down by normalisation organisations.
- Introduction in practical activities of risk analysis and popularisation of the HACCP system, which has been already, made obligatory in manufacturing of dietetic food products.
- Introduction of the precaution principle according to the relevant recommendations of the European Commission.
- Restructured system of official food control services subordinated to the Ministry of Health, Ministry of Agriculture and Rural Development, and Office for Competition and Consumer Protection. The Ministry of Environmental Protection, especially in the case of genetically modified organisms plays an important role in this system.

Development at representative samples at country level of monitoring systems of:

- Quality of food of animal and plant origin.
- Quality of daily diets.
- Health status of the population with particular reference to diseases and health abnormalities related to inadequate food quality and to improper nutrition as an important elements of the system of early warning of the appearance of health risk factors at population level.
- The system of scientific counselling with the participation of institutions of high scientific prestige at national and international level supported financially from state budget as well as groups of independent experts.
- Openness of the food safety assurance system to co-operation with consumer movements and non-governmental organisations.

Poland's co-operation with the OECD community of countries extends significantly the chance that the food safety system in the country will be more complete, more effective and will help in strengthening in the population of the conviction of its full reliability.

The idea of ensuring food safety 'from field to table" has been known in Poland since decades. Its full realisation in practice meets with numerous difficulties, which are due, among other factors, to

fragmented structure of our agriculture, insufficient modernisation of food production and processing plants in certain branches of agricultural and food industry, as well as to not fully satisfactory education level of a part of our agricultural and food producers and also to under investment of agriculture, especially at individual farms level, and agricultural and food industry.

II. Overview of Food Safety System

A. Fundamental Legal Regulations

One of the tasks given priority in state policy is assurance of health safety of food for reduction of the incidence of many diseases and health disorders related to poor health quality of food and effective improvement of public health status in the country. The Constitution of the Republic of Poland states that:

- Everybody has the right to health protection (Article 68 1).

- Public authorities protect consumers, users and tenants against the actions endangering their health, privacy and safety and against dishonest market practices.

The main legal document in Poland regulating problems of food and nutrition is the act of 25 November 1970 with later amendments on the health conditions of food and nutrition which sets down the conditions of production of food products and stimulants, and of the turnover of these commodities in the range indispensable for public health protection.

It regulates also in the range indispensable for public heath protection the requirements concerning production equipment, machines, instruments, packing and other materials which are in contact with food products and stimulants in production and in distribution.

The act contains also general regulations, supervision and penalties. In the light of this act the supervision of the health quality of food and stimulants and maintenance of proper sanitary conditions in the production and distribution of these commodities is the responsibility of the authorities of Sanitary Inspection subordinated to the minister responsible for health and the veterinary service organs supervised by the minister for agriculture and rural development.

Presently the work is continued on the project of an act changing the act on health conditions of food and nutrition. This new act will delegate to the relevant ministers the right to issue pertinent implementing decrees harmonised with EU requirements and with its directives.

Annex 1 contains a list of the basic legal acts in Poland concerning food safety. It does not include implementing legal decrees issued by the Cabinet and ministers on the basis of delegations in the acts, which regulate in detail the questions concerning the health conditions of food and nutrition.

B. Supervision Systems

The supervision of food production, processing and distribution in Poland and especially of food quality is based on two main control systems, that is:

- The system of inner control conducted in the production plant, depending on the producer. In many plants this system in based on the Good Manufacturing Practice (GMP) and presently in an ever increasing degree, on the system of quality assurance in accordance with ISO series 9000 standards and the Hazard Analysis and Critical Control Points System (HACCP).

- The system of external control independent of the producer who is carried out by specialised state control services.

Presently, the project of the regulation of the Minister of Health is being prepared which obliges the producer to carry out inner control based on risk evaluation and on HACCP system in food production. The obligation to use the HACCP system has been in force in Poland for the production of dietetic food, in accordance with a relevant regulation issued on August 22 1996, concerning the details of the production and marketing of dietetic food products, stimulants intended for dietetic purposes and special food (Dz. U. Nr 108, paragraph 520 with later amendments). In the developing system of market-oriented economy, the producer is responsible for the quality of the produced food and he is most interested in its proper quality and compliance with declarations on product label.

The statutory supervision of the health quality of food in Poland is conducted by the following organs:

- Sanitary Inspection
- Veterinary Inspection.

Food quality control is carried out also by:

- Inspection of Agricultural Procurement and Processing
- Inspection of Plant Protection
- Trade Inspection
- Central Standardisation Inspectorate.

A short description of the activities of supervising institutions is shown in Annex 2. The problems connected with the safety of modified genetically food belong to the competence of the Ministry of Environmental Protection and inspection organs subordinated to that Ministry.

The actual competence in conduction of the control of food for its **health quality** in Poland lies, in the first place, with the Sanitary Inspection and the Veterinary Inspection. The Minister of Health supervises also the compliance with the regulations of the act on the health conditions of food and nutrition.

The organs supervising the health quality of food and nutrition, that is the Sanitary Inspection and Veterinary Inspection, finding that a food product, stimulant or additive fail to comply with the binding health quality requirements can forbid the production or introducing into the market that article, depending on the disclosed faults, can permit its use for another purposes but only after adequate adaptation and with keeping of definite conditions, or can permit its use but not for consumption. They can order destroying it as well.

C. Risk Analysis

The problems of risk analysis, particularly those connected with risk assessment in relation to food safety, are the subject of studies of many scientific research centres and advisory organs to the ministries. The Sanitary-Epidemiological Council, which is the advisory and opinion-presenting organ to the General Sanitary Inspector, works out opinions and analyses concerning, among other, food safety. In

the case of details of the problems related to health risks special scientific conferences are organised for presentation of the results of meta-analyses in these areas and country's situation assessment and practical proposals addressed to pertinent authorities. Long-term Government Programmes are prepared also, for which many experts and centres are engaged for solving of important problems concerning food safety and for elimination of health risks. The problems of risk assessment and conduction of scientific studies in this field by centres recognised at national and international levels are independent and are paid from state budget. Such studies are conducted using methods approved in the EU countries. The elaborated expertise and results are reviewed by independent, widely recognised experts, besides that, the results are published and presented for public discussion.

The problems of food safety can be found also in the education system at secondary, specialist and university levels. Postgraduate education is conducted also in the area of food safety for qualified industry workers and official food control services by scientific-research institutes of various ministries and by universities. The National Food and Nutrition Institute, the State Veterinary Institute and the State Institute of Hygiene play an important role among scientific institutes of national importance in this area.

The area of risk management in food safety lies in the responsibility of the government but also in that of industry and trade. The Polish Standardisation Committee is responsible for working out, acceptance, setting down and publication of standards (Annex 3). The standards set down are based on introduction of EN and ISO standards and also those of other standardisation institutions. In working out of Polish standards participate representatives of industry and the pertinent ministries and official food control as well as scientists. Presently, in Poland the pertinent ministers introduce through regulations the obligation of using selected Polish standards, including those from health care area and food labelling.

In the area of communication of food safety risks to the population the transmission of information is provided by special agencies, consumer associations, the Office for Competition and Consumer Protection and speakers of various ministries. Their task is to inform the population through mass media. The data on risks appearing in the country are published in materials systematically prepared by the Epidemiology Division of the State Institute of Hygiene, the Central Statistical Office and certain other institutions. The results of health risk analysis related to food of inadequate quality are the basis for evolving of directions for actions, preventive decisions and development of strategy and policy of health protection in that area.

Risk analysis is performed also in developing HACCP systems for a given plant. In Poland the HACCP system is obligatory for plants producing dietetic food products. Nevertheless, in many other industry branches this system has been voluntarily introduced for assurance of the safety and adequate health quality of the products. The HACCP implementation was particularly extensive in plants of meat industry, dairy industry and fruit and vegetables processing plants. The plants with the participation of foreign capital belonging to foreign concerns had mostly that system introduced already.

Food production in Poland is conducted according to Polish standards or own standards introducing documents, as well as regulations of food law, including the standards of the Codex Alimentarius of FAO/WHO, and according to the requirements set down in the pertinent European Union directives.

The control of food for its safety is performed in Poland by the organs of the sanitary and veterinary inspections and by agricultural universities (Bromatology Divisions) and also by scientific research institutes, the National Food and Nutrition Institute in the first place, the State Veterinary Institute, the State Institute of Hygiene, the Plant Protection Institute, the Marine Fishery Institute, the Meat and Fat Industry Institute, and the Biotechnology Institute of Agricultural and Food Industry.

The problems of food safety are in the area of interest mainly of three ministries: Ministry of Health, Ministry of Agriculture and Rural Development, and Ministry of Environmental Protection.

Since 1995 periodical monitoring has been conducted of the quality of soil, plants, agricultural and food products for detection of certain chemical contamination. This monitoring is subordinated to the Ministry of Agriculture and Rural Development.

Generally speaking the results of that monitoring show that acute or chronic health risk due to the presence of harmful heavy metals, pesticides, nitrates, nitrites, polychlorinated biphenols is so low that no acute or chronic poisonings on epidemiological scale are to be expected.

The recent monitoring results show that raw materials of animal or plant origin are of good quality and in a great majority they meet the criteria concerning the permissible content of chemical contaminants, as defined by the Polish legislation. In this area the situation in Poland is probably not differing from that in most European countries.

However, we feel in Poland a deficiency of systematic studies of the health quality of actually consumed diets. The results of such studies would permit us to estimate the real health risk derived from food. Fragmentary studies of this problem have been conducted in various scientific-research institutions. They deal with selected problems of food safety and were performed only on selected population groups. Generally it can be stated that the diets contain only low amounts of contaminants in relation to FAO/WHO requirements. However, the safety margin of food quality is narrower in the case of diets for children. High values of standard deviations indicate a high grade of variations in the intake of various contaminants.

Systematic investigations of the concentrations of substances derived from food contaminants have not yet been conducted in the general population. The results of fragmentary studies, however, do not suggest any public health risk occurring on population scale as a result of excessive contamination of food products and diets.

A new and poorly known as yet, problem in Poland is the production and distribution of food produced with the use of genetically modified organisms. The problems connected with the production and distribution of GMO are the subject of projects of legal regulations, more complete than those in force at present which would include the principles of conduction of field experiments using GMOs as well as the principles of safety assessment of GMOs or products obtained from GMOs intended for human consumption.

In the analysis of the potential health risk related to food the whole aspect of food production should be considered, from the health risk at the step of raw material obtaining, then technological processing, storage and transport. This requires usually long lasting monitoring for observing the dynamics of risk factor changes, and for drawing conclusions on the methods for preventing or eliminating risks in the phase of raw material processing. This direction of studies has been evolved in Poland by the Council of Monitoring of Soil, Plants, Agricultural and Food Products, and it takes into account the state of regions in the whole country accepting the principle of representative character of samples obtained in the smallest administration units (about 300 points or communes for the whole country). This direction can be modified depending on the direction of monitoring studies accepted in EU countries, although in these countries these studies have not yet been completely co-ordinated. Food quality, its health-promoting character achieved through ecological cleanliness, should in the future become an international indicator for health quality of life. Difficulties met in the introduction of a homogeneous model of food and diet quality assessment are caused also by differences in dietary habits.

In the assessment of potential intake of dangerous substances criteria established by the Codex Alimentarius FAO/WHO are accepted which specify their highest permissible levels (NOEL „No Observed Effect Level", ADI - Acceptable Daily Intake" or PTM - „Provisional Tolerable Weekly Intake").

Particularly thorough control should be applied to the conditions of agricultural production, that is the phase on which the initial quality of raw material depends. In the analysis of health risk and foreseeing of risk magnitude particular attention is paid to soil contamination monitoring. The content of heavy metals such as cadmium, lead, arsenic, nickel and mercury and soil acidity are considered to be fundamental parameters in the analysis (similarly as in the case of raw materials of animal or plant origin). In food control in respect of the content of nitrates and nitrites, the residues of organochlorine and organophosphate pesticides, polychlorinated biphenols, polycyclic aromatic hydrocarbons, mycotoxins (mainly ochratoxin and patulin) and radionuclides, the soil serves as a reference background.

Additional requirements are to be met by products of animal origin with respect to the content of inhibitory substances, especially the residues of antibiotics, hormones and other drugs used in veterinary medicine.

It is worth stressing that, besides continuous monitoring of the quality of raw materials and food products according to the criteria accepted by the Council of Monitoring of Soil, Plants, Agricultural and Food Products, more extensive regulation is required by the control system of risk factors which can develop suddenly. An example of such sudden risk, which could catch us by surprise, was the potential danger of mad cows', disease occurrence (BSE), or the appearance of food contaminated with dioxins. Immediate reaction to the appearing dangers, evolving and application of analogous analytical methods making possible the detection of products being potential risks or mutual and possibly rapid information exchange on the possibility of occurrence of health risk connected with food contamination are the ways to reduction of human health risk. For the estimation of risk magnitude a correct assessment of the potential rate of spread of infections caused by bacteria (Yersinia, Salmonella, Campylobacter, Escherichia, Listeria) is very important especially since these micro-organisms acquire resistance to the antibiotics (used in cattle breeding) and because of growing food allergies (for example, gluten intolerance).

Since the customs barriers are lifted according to WTO free trade is possible within the European Union, which is going to expand in a short time, the Compendium of Food Safety System should cover all the known, more important, food safety risks, contain acceptable levels of substances regarded as creating health hazards with recommended methods of their identification. Since not all events can be foreseen (the Chernobyl disaster, potassium cyanide contamination of Danube) it seems indispensable to work out the management procedure in emergencies. These problems exceed the problem of food safety.

III. Activities in Addressing Food Safety Issues

A. *The Development of Polish Organisational Structures Ensuring Food Safety.*

In Poland, as a result of significant changes of the organisational structure of state administration, in the recent three years a rather evident reorganisation has taken place in the system of official food control, although this is only the first step of activities in that area.

Through legislative changes control organs have been isolated from three ministries (Ministry of Health, Ministry of Economy, Ministry of Agriculture and Rural Development). They are still subordinated to these ministries but are separate central agencies of state administration. They are:

- Central Sanitary Inspectorate headed by the General Inspector (from the Ministry of Health).
- Central Veterinary Inspectorate headed by the General Veterinary Medicine Specialist (from the Ministry of Agriculture and Rural Development), the Central Inspectorate of Agricultural Procurement and Processing.
- Standardisation Inspectorate.
- Central Plant Protection Inspectorate, headed by General Inspectors.
- Ministry of Economy the Office for Competition and Consumer Protection was been separated headed by its President. The office carries out its control functions through the General Inspector of Trade Inspection.

The effectiveness of the activities of Sanitary Inspection and Veterinary Inspection organs observed since many years, their competence and the co-operation between these food safety control organs have rendered particular services in the consistent protection of Poland's borders against the inflow of food products with potential health risk. This seems to indicate that the Minister of Health should still play the main role as leader and co-ordinator in this area, in close co-operation with the Minister of Agriculture and Rural Development.

In solving of the problems of food safety improvement in legislative and organisational aspects for protection of public health in Poland advantage is taken of analogous proposals evolved in various economically developed countries, and expert opinions provided by Polish and foreign specialists.

One of the examples of such proposals is the programme „Strengthening Food Control System in Poland" supported financially by the FAO and realised in co-operation with the National Food and Nutrition Institute on the initiative of the Ministry of Health and the inspiration of the National Food and Nutrition Institute. The results of the programme made possible the formulation of numerous suggestions for restructurisation of the organs of official food control in Poland aiming at their integration in the aspect of their functions.

Solving of the problems of food safety improvement in legislative and organisational aspects is realised in Poland by professional governmental institutions, in the first place by the Sanitary Inspection and Veterinary Inspection. Both these bodies are potentially best prepared for the execution of official food control and supervision of food safety. They have the greatest number of specialists in public health (physicians, pharmaceutists, veterinary surgeons, biologists, and specialists in food technology, dieticians, specialists in nutrition technology, specialists in risk estimation and management analysis connected with the consumption of food of inadequate safety). The number of experts in the analysis of risk connected with inadequate food quality is small in Poland but shows an increasing tendency.

The policy and strategy of food safety improvement in public health aspect is realised in Poland by the Minister of Health in co-operation with the Minister of Agriculture and Rural Development, and with other ministers, if necessary.

It is worth stressing that the organs of Sanitary and Veterinary Inspections have at their disposal sufficient administrative and legal means for bearing full responsibility for the organisation and functioning of the Rapex System in Poland in the area of food safety and can professionally co-operate in that area with the European Union agencies.

At the National Food and Nutrition Institute the National Information Centre ″Food, Nutrition and Health″ has been organised for establishing contact with the population in the area of food safety and HACCP system.

The facilities and the staff of the Institute are potentially prepared for tasks connected with the participation in the Rapex System in food safety maintenance.

B. Regulations Concerning the Modern Biotechnology

We have presently in Poland the Inter-ministerial Consultation Group for GMO, whose task is to provide opinions on the proposals of GMO introduction into the environment and to consult the technical recommendations connected with biological safety. The Group includes representatives of the Biotechnology Committee, Ministry of Agriculture and Rural Development, Ministry of Health, Ministry of Environmental Protection and State Committee of Scientific Research.

In Poland the act of 31 Jan 1980 on protection and shaping of the environment regulate the problem of genetically modified organisms. The integral text was published in the Dz. U. of 1994, No 49 point 196 with later amendments. The act regulates the principles of GMO use, their introduction into the environment and marketing, and protection of workers exposed to GMO.

On the basis of article 37 paragraph 8 of the above act the Minister of Environmental Protection, Natural Resources and Forestry defined through regulation of 8 October 1999 on the genetically modified organisms (Dz. U. N 86, point 962) the requirements concerning:

- The applications for permission to release genetically modified organisms into the environment for experimental purposes or to introduce into the market products containing these organisms.

- Evaluation of environmental and human health risks which must be enclosed with that application for permission.

- Labelling and packaging of products in the market containing genetically modified organisms or composed of such organisms or their parts.

These regulations show that attempts are undertaken at adjustment of the Polish legislation to that in the European Union, in particular to three EU directives: 90/219, 90/220 and 91/414. Moreover, the act indicates the state organ, which must be established for GMO problems, according to the directives.

C. Precautionary Principle

In Poland, similarly as in the European Union the precautionary principle has been accepted in the area of food safety. This principle means that actions for public health and environment protection should be undertaken early even in the situation when there is no sufficiently reliable scientific evidence confirming the harmfulness of a given product or service but a justified suspicion of its harmfulness exists.

Such justified suspicion can be the reason for undertaking early preventive measures proportional to the risk.

The introduction in the food law of the precautionary principle also in Poland has raised doubts among certain experts and workers of state food control, especially in the context of reduction the already existing barriers and non-creation of new barriers in free trade of food. Difficulties can appear, ever not fully justified, e.g. in the introduction of genetically modified organisms into the natural environment or in marketing of raw materials and food products produced from such organisms. Restrictions can appear as well as difficulties in the production and marketing of food products as a result of hypotheses on health risks connected with products from GMO.

This shows that in Poland also the question of working out of possible changes in the principles of introduction of food modified by genetic engineering methods is important.

The precaution principle related to food safety has been applied in Poland since a long time.

In the introduction of the precaution principle in Poland, similarly as in other countries the basic rules are applied:

- The proportionality rule which states that the actions undertaken on the basis of the precaution principle should be proportional to the existing risk.
- The non-discrimination rule according to which similar situations should be treated identically.
- The compatibility rule which states that preventive measures should be compatible with the measures accepted in similar situations.
- Advantages and costs should be considered which result from undertaking or not undertaking of actions (negative and positive results of undertaking and not undertaking of actions in safety risk situations).

Many experts have expressed the view that if the precaution principle is to be included into risk analysis, then only as a component of risk management but not as an element in risk evaluation.

The public authorities using definite preventive measures must demonstrate that the scientific opinions on risk are not certain, and that the measures used are sufficient for that risk prevention. The precaution principle even if based on scientific hypotheses not completely confirmed by the results of reliable studies forces the authorities to react to potential dangers. If they fail to ensure sufficient safety for the consumers they can be responsible for the occurring losses.

Thus although the precaution principle is right there is the possibility that risk to the population could be overestimated. For that reason in Poland also this principle is widely discussed.

D. The Introduction of Legal Regulations

In the preparation of projects of legal regulations of food safety in Poland the situation in our country, the international legislation and own studies are considered. The projects of legal regulations are undergoing consultations in and between ministries and many of them are published before their acceptance in relevant professional periodicals. For a general discussion the projects are presented at scientific conferences. The acts are worked out by the Government and passed through the parliament and senate and after signing by the President they are published in official gazettes of laws. The introduced legal regulations in this area take into account the present *vacatio legis* period.

E. The Problem of Socio-Economic Concerns

The signals evidencing the concern of the population about food safety as expressed by non-governmental mainly consumers' agencies are addressed to state organs responsible for food safety (Ministry of Health, Ministry of Agriculture and Rural Development, Office for Competition and Consumer Protection and to scientific institutes).

These organs undertake adequate actions including information, education and organisation measures for elimination of such concerns.

F. Communication and Consultations

In the communication and consultations in the area of food safety a significant role is played by scientific-research institutes (mainly the National Food and Nutrition Institute, the State Veterinary Institute, the State Institute of Hygiene). They participate in working out of projects of legal acts and the final decision is made at the highest levels of state administration (government).

In the area of communication and consultations of food safety the major role could be played by the National Information Point „Food, Nutrition and Health", established at the National Food and Nutrition Institute.

The centre responsible for the certification of food products is the Polish Centre for Testing and Certification (Annex 3). It grants the safety sign and compatibility sign. Its tasks include accreditation of research laboratories and certifying units.

IV. Summary

Over the recent years the system of food safety has been developing in the right direction owing to systemic changes in Poland, introduction of market -oriented economy, producer's responsibility for product quality, adaptation of legal regulations to the requirements of the European Union, beginning of restructurisation changes in food safety assurance systems, wider use of risk analysis, better education of the population, freedom of mass media and development of non-governmental organisations. This development of food safety system is visible when the improvement of public health in the country is considered as well as the increased conviction of the population that the food available to the consumer is safe and the risk of the appearance of products connected with health risk is ever less probable.

ANNEX

I. The Main Legal Acts Connected with Food Safety Assurance in Poland:

1. The act of November 25 1970 on the health conditions of food and nutrition (Dz.U. No 29 point 245 with later amendments).

2. The act of March 14 1985 on Sanitary Inspection (integral text Dz. U. of 1998, No 90, point 575 with later amendments).

3. The act of April 24 1997 on control of infectious diseases, examination of slaughtered animals and meat, and on Veterinary Inspection (integral text Dz. U. of 1999, No 66, point 752).

4. The act of February 25 1958 on Trade Inspection (Dz. U. of 1969, No 26, point 206 with later amendments).

5. The act of June 30 1970 on Inspection of Procurement and Processing of Agricultural Articles (Dz. U. No 16, point 137 with later amendments).

6. The ordinance of the Cabinet of December 13 1991 on the extension of the activities of the Inspection of Procurement and Processing of Agricultural Articles (Dz. U. No 119, point 520, and of 1997, No 157, point 1031).

7. The act of July 12 1995 on the protection of cultivated plants (integral text Dz. U. of 1999, No 66, point 751).

8. The act of September 12 1998 on state standardisation supervision of agricultural products for consumption in trade with foreign countries (Dz.U. No 124 point 584).

9. The act of April 3 1999 on examinations and certification (Dz.U. No 55 point 250 with later amendments).

10. The act of April 3 1993 on standardisation (Dz.U. No 55 point 251 with later amendments).

11. The act of December 18 1998 on civil service (Dz.U. of May 31 1999, No 49, point 483, and of 1999, No 70, point 778).

12. The act of September 4 1997 on divisions of government administration (Dz.U. No 141 point 943 with later amendments).

13. The ordinance of the Minister of Health of December 30 1999 on granting of statute to the Central Sanitary Inspectorate (Dz.U. No 111 point 1315).

14. The ordinance of the Minister of Agriculture and Food Economy of December 28 1998 on granting of statute to the Central Veterinary Inspectorate (Dz.U. No 162 point 1154).

15. The act of June 5 1998 on province local government (Dz.U. No 91 point 576 with later amendments).

16. The act of June 5 1998 on governmental administration in the provinces (Dz.U. No 91, point 577, and of 1999, No 70, point 778).

Besides that, in the problems of GMO the following is in force:

17. The act of January 31 1980 on protection and restructurisation of environment (Dz.U. of 1994, No 49, point 196 with later amendments).

18. The ordinance of the Minister of Protection of Environment, Natural Resources and Forestry of October 8 1999 on genetically modified organisms (Dz.U. No 86 point 962).

19. The ordinance of the Minister of Agriculture and Food Economy of July 15 1994 on labelling of food products, stimulants and permitted additives intended for turnover (Dz.U. 94.86.402 with later amendments).

The main legal act in the Polish food legislation is the act of November 25 1970 on health conditions of food and nutrition (presently amended). It is the basis for prevention of production and marketing and use for consumption of products failing to meet the requirements of health quality. On the basis of the delegations in the main act implementing legal acts have been issued regulating in detail the problems concerning the health conditions of food and food safety, e.g. the permitted additives, labelling of food products, on the highest acceptable residues of chemical substances in food products. Presently several scores of such implementing decisions are in force.

II. The Statutory Supervision of the Health Quality of Food in Poland is Performed by the Following Governmental Administration Organs:

- Sanitary Inspection
- Veterinary Inspection.

The control of food quality is carried out also by:

- Inspection of Agricultural Procurement and Processing
- Inspection of Plant Protection
- Central Standardisation Inspectorate
- Trade Inspection.

Sanitary Inspection. The Inspection is headed by the General Sanitary Inspector as a central organ of governmental administration. The General Sanitary Inspector is appointed and dismissed by the Prime Minister at the proposal of the Minister of Health. The General Sanitary Inspector performs his duties with the aid of the Central Sanitary Inspectorate. The supervision of the Central Sanitary Inspectorate is the responsibility of the Minister of Health. The tasks, the range of activities, organisation and rights of Sanitary Inspections organs are defined in the act on Sanitary Inspection dated March 14 1985 with later changes and in the ordinance of the Minister of Health of Dec 30 1999 on granting statute to the Central Sanitary Inspectorate.

The task of the Central Sanitary Inspection is the supervision, among other, of:

- The health quality of food products and stimulants Polish as well as imported, and keeping of adequate sanitary conditions in the production and distribution of these articles (with the exception of food products of animal origin).

- State of food and nutrition hygiene.

- State of environmental hygiene.

- Working place conditions.

For the realisation of these statutory duties the organs of the Sanitary Inspection have:

- Specialised staff prepared for public health protection.

- Highly sophisticated equipment for investigations.

- Well developed network of 346 Sanitary-Epidemiological Stations including 16 at province level, 309 at county level, 5 in ports and 16 in railway health service.

- Two scientific-research centres of unquestionable specialisation in the problems of food safety and rational nutrition: the National Food and Nutrition Institute and the State Institute of Hygiene in which there are centres for co-operation with foreign organisations such as FAO/WHO, World Trade Organisation (WTO) and other.

These institutes conduct current active co-operation with the experts of the EU countries, Codex Alimentarius Commission on all problems of public health protection in the aspect of food health quality and rational nutrition.

Veterinary Inspection is headed by the General Veterinary Inspectorate. The General Veterinary Officer is the central organ of governmental administration and as such he is appointed and dismissed by the Prime Minister at the motion of the minister responsible for agriculture.

The legal foundation for its functioning is the act of April 24 1997 on the control of infectious diseases of animals, examination of animals intended for slaughtering and meat, and on Veterinary Inspection (integral text published in the Gazette of Law and Regulations of 1999, No 26, point 206).

The statute of the Central Veterinary Inspectorate is defined in the Ordinance of the Minister of Agriculture and Food Economy of December 28 1998.

The tasks of the Veterinary Inspection include the control of infectious diseases of animals, examination of animals before slaughtering and meat, and performing of other tasks resulting from pertinent regulations, among them the supervision of:

- The health quality of food products of animal origin, including the supervision of sanitary conditions of their obtaining, production and storage.

- The health quality of certain products from animals.

- The turnover of pharmaceuticals and medical materials intended only for animals.

- The health of animals intended for reproduction purposes and the quality of biological material.

Besides that, in the area of food safety an important role is played by the State Veterinary Institute in Pulawy. According to the act on control of infectious diseases of animals, examination of animals before slaughtering and meat and on Veterinary Inspection the State Veterinary Institute supervises the quality of investigations in the laboratories of veterinary hygiene and other laboratories of that Inspection, and acts as a reference laboratory for the remaining laboratories.

Inspection of Agricultural Procurement and Processing or generally the Central Inspectorate of the IPPAR is the central organ of governmental administration subordinate to the minister responsible for agriculture.

The legal foundation of the activities of the IPPAR is the act of June 20 1970 on the Inspection of Agricultural Procurement and Processing (Dz. U. No 16, point 137 with later amendments).

- The ordinance of the Cabinet of December 13 1991 on activities extension of the IPPAR (Dz. U. No 119, point 520 and of 1997: No 157, point 1031).

IPPAR is controlling a large area of food economy for the compatibility with Polish standards and other quality indicators.

The tasks of the Inspection of Agricultural Procurement and Processing include:

1. Control of the obligatory standards and regulations in the area of procurement of all raw materials and agricultural articles for consumption (with the exception of fish and herbs), their sales, transport, processing and storage.

2. Control of the obligatory standards and regulations and expertise of quality, with the exception of the health quality of:

   - Raw materials for products for consumption.

   - Food articles and their concentrates.

   - Fodder, additions to fodder and premixes, and raw materials for their production.

   - Equipment for agricultural and food production, mineral fertilisers and plant protection preparations.

3. Collecting of information and carrying out analyses of market situations in agricultural and food area, providing opinions on these situation for agricultural policy and gathering of data on prices of non-processed agricultural plant articles as well as articles of animal origin and technical production means.

4. Attesting storehouses with respect to storing of rapeseed and cereal grains purchased from Polish producers for the use by Polish food producers or pharmaceutical firms, and for supplying the Polish market.

5. Works within the framework of the governmental programme: Monitoring of the Quality of Soil, Plants, Agricultural and Food Products.

Inspection of Plant Protection is subordinate to the minister responsible for agriculture. The General Inspector of Plant Protection is the central organ of governmental administration performing his tasks through the Central Inspectorate of Plant Protection.

The foundation of its work is the act of July 12 1995 on the protection of cultivated plants (integral text published in the Dz. U. of 1999, No 66, point 751).

Its task is a comprehensive supervision of cultivated plant protection, among it:

– Phytosanitary supervision of cultivated plants and phytosanitary control of plants and means for their transport at state border checkpoints and places of custom clearance within the country.

In case of food export the province IPP inspectors give phytosanitary certificates (certificate form is compatible with the pattern accepted by FAO and standards of the International Convention of Plant Protection). These certificates are recognised by all states in the world.

The border points of province plant protection inspectors decide about further management of imported goods, that is send them for custom clearance or return them back across the border.

Central Standardisation Inspectorate - CSI is subordinated to the minister responsible for agriculture.

The legal basis for CSI functioning is the act of September 12 1996 on state standardisation supervision of agricultural and food articles in foreign trade (Dz. U. No 124, point 584). On its basis the Minister of Agriculture and Food Economy issued the ordinance on July 28 1999 concerning the list of agricultural and food articles brought from abroad and their minimal amounts subject to state standardisation supervision (Dz. U. No 65, point 745). The entity trading with the foreign country is obliged to submit the articles for assessment of their trade quality.

The Central Standardisation Inspectorate is responsible for the control of the quality of agricultural and food articles in international trading, particularly with respect to their compatibility with contract conditions. The control includes explaining whether the article in international trading complies with the standards, regulations establishing the requirements to be met in the country of its destination. Through co-operation with the EU and OECD the Central Standardisation Inspectorate works according to the rules of the international food control system. It is an obligatory control, of official character, serving as a form of supervision and promotion of export and import rationalisation. The list of goods covered by standardisation supervision is an annex to the ordinance of the Minister of Agriculture and Food Economy of July 28 1999 setting down minimal amounts of these goods. The list has been published in Dz. U. No 65, point 745.

The goods meeting the requirements of the contract receive quality certificates.

In case of justified suspicion that the goods do not meet the health conditions the CSI inspector informs the organ which can decide in such matters, that is the Sanitary Inspection or Veterinary Inspection.

Trade Inspection – It is the implementing organ of the President of the Office for Competition and Consumer Protection subordinate to the President and, to a certain extent, to province heads. Its function is based on the act of Feb 25 1958 on Trade Inspection and the ordinance (integral text published in DZ. u. of 1969, No 26, point 205 with later amendments).

The main task of Trade Inspection is protection of the interests of consumers in a wide meaning. The supervision of food quality is a part of its activities.

Trade Inspection supervises among other:

- The quality of goods in trading.
- Trading units, gastronomy and service institutions.
- Observation of rules obligatory in trading within the country.

The act of July 24 1998 on the change of certain acts defining the competence of public administration organs in connection with the reform of state system the tasks of the Trade Inspection were extended to include:

- The control of the quality and safety of goods and services, in particular those endangering the life or health of consumers (article 1 paragraph 2 point 2).

In case of disclosing offences against food safety or failure to keep to sanitary regulations the inspectors of Trade Inspection are obliged to inform the pertinent organs of official food control, that is the Sanitary Inspection or the Veterinary Inspection.

III. Organs Dealing with Normalisation and Certification

Polish Centre for Testing and Certification is subordinate to the minister responsible for economy. Its function is based on the act of April 3 1993 on testing and certification (Dz.U. No 55, point 250 with later changes).

The tasks of the centre include:

- Organisation and supervision of the system of investigations and certification.
- Accreditation of investigating laboratories and certification units.
- Certification of quality systems of the suppliers.
- Certification of auditors and leading auditors.
- Organisation of training and skill upgrading courses for staff for the needs of investigations and certification.

Polish Standardisation Committee has as its basis the act of April 3 1993 on standardisation (Dz.U. No 55, point 251 with later changes). The range of duties of the Committee includes organisation and carrying out of standardisation activities as needed in our country, in particular:

- Outlining of the conditions and directions of the development of standardisation activities.
- Establishing of Polish Norms and exclusive designation with the PN symbol, organisation of publication and supervision of PN dissemination.

- Representation of state interests in international and regional standardisation organisations, speaking abroad on problems connected with standardisation.

- Studies of the bases and methods of standardisation activities.

- Organisation and management of training, and information on promotion of standards in the country and abroad. A project of the new act is prepared.

SWITZERLAND

I. Overview

1.1. General Principles

The principle of consumer protection is enshrined in Switzerland's Federal Constitution. The Federal Food and Consumer Safety Act sets out the legal foundations. With regard to food, the aim is to protect consumers against health hazards and from being misled. It covers the entire food chain, from the farm to the consumer's plate, ingredients and imports.

1.2 Risk Assessment

Under Swiss food legislation, substances that pose a potential health hazard such as components, foreign substances, additives or micro-organisms, may be present in food only in quantities that are technically unavoidable and that pose no danger to humans. The assessment of the risk attaching to such substances is based on scientific data. The principles of risk assessment in Switzerland are based on international standards (FAO/WHO, the Codex Alimentarius, OECD and EU). Risk assessment is carried out by the scientific experts of the Federal Public Health Office (ODSP), who can upon independent experts (academics) when necessary. On the basis of these assessments, the maximum admissible concentrations in food of substances that pose a potential health hazard are specified in the Ordinance on foreign substances and food components. This Ordinance is regularly updated and serves as the basis for the enforcement of food legislation by the cantons. Legally binding microbiological criteria are set for micro-organisms. These criteria are divided into two distinct categories. The first comprises limit values for pathogenic and toxic organisms, with to view to protecting health. The second comprises tolerance levels for pathogenic organisms, which are indicative of or cause deterioration in food.

1.3 Risk Management

The basic principles are set out in the Constitution and the Food Act. The protection of the consumer against health hazards and from being misled takes account of the principle of proportionality and the precautionary principle. The basis is the current state of scientific knowledge. Under the division of powers between the federal government and the cantons, the scientific and legal aspects are handled at national level, as is also the co-ordination of tasks of national interest. The relevant specialised services are attached to the Federal Public Health Office, which is attached in turn to the Federal Department of Home Affairs. Draft legislation is drawn up by the competent federal services. The services responsible for food safety, including animal diseases transmissible to humans, are the Federal Public Health Office and the Federal Veterinary Office. In order to obtain the necessary knowledge on a subject, the office concerned may call on outside experts or hold hearings of experts. Consultation procedures between the office and the parties concerned (consumer organisations, trade associations, industry) are then organised. International recommendations must be taken into account. Once a law has been adopted, it is published in the official gazette and comes into force. The implementation of the provisions of the law is largely a

matter for the cantons. The Confederation applies the provisions the Food Act to the import, transit and export of foodstuffs, and ensures that the relevant controls are carried out. Whereas meat and meat products are controlled at the border by veterinary officers, other foodstuffs are controlled by the customs. Inside the country, food inspections are carried out by cantonal chemists and veterinary officers (livestock production and slaughter).

The new food legislation (1995) made self-inspection obligatory. Each actor in the Swiss food sector must have a system for assessing risk -- Hazard Analysis and Critical Control Points (HACCP) attesting that it meets legal requirements. The cantons are responsible for overseeing self-inspection.

1.4 Risk Communication

The office has several advisory bodies comprising representatives of industry, consumer organisations, cantonal monitoring bodies, and scientists. These are closely involved in the process of preparing and drafting legislation via the consultation procedure. The office has several means of communicating information about food safety risks, such as specialised publications, recommendations regarding the evaluation and analysis of foods, information forums and the Internet, each medium having a specific target public.

II. Switzerland's Food Safety Systems

2.1 Legal Basis and Powers

The principle of consumer protection is enshrined in Switzerland's Federal Constitution. The Federal Food and Consumer Safety Act set outs the legal foundations. With regard to food, the aim it is to protect consumers against health hazards and from being misled. The Act covers the entire food chain, from the farm to the consumer's plate, ingredients and exports.

The basic principles are set out in the Constitution and the Food Act. The protection of the consumer against health hazards and fraud takes account of the principle of proportionality and the precautionary principle. The basis is the current state of scientific knowledge. Under the division of powers between the federal government and the cantons, the scientific and legal aspects are handled at national level, as is also the co-ordination of tasks of national interest. The relevant specialised services are attached to the Federal Public Health Office, which is attached in turn to the Federal Department of Home Affairs. The implementation of the provisions of the law is largely a matter for the cantons. The inspection of foodstuffs before they reach the final consumer is thus under the responsible of a single authority, and the personnel are trained specifically for the task in line with federal requirements. This inspection is subsidiary to self-inspection, which requires the owners of goods to guarantee, in traceable fashion, that the food complies with legal requirements and to check such compliance in traceable fashion in the course of self-inspections.

Food legislation is grounded in positive law; accordingly, only foods explicitly defined in an ordinance or authorised by the office can put on sale. Additives, foreign substances and food components, hygiene and reporting requirements, as well as the training of the authorities' representatives are specified in the relevant ordinances. The Swiss Food Manual contains instructions for evaluating and analysing foods. Other information is disseminated regularly in specialised publications and on the Internet.

The office has several advisory bodies comprising representatives of industry, consumer organisations, cantonal monitoring bodies, and scientists. These are closely involved in the process of preparing and drafting legislation via the consultation procedure.

Several federal offices are responsible for enforcing the law. Food monitoring is co-ordinated at federal level by the Federal Public Health Office and carried out by the competent cantonal authorities. Food safety is monitored by twenty cantonal chemists backed by inspectors and local laboratories. Regular meetings of the representatives of federal and cantonal services are held to co-ordinate work. The laboratories collaborate at regional level and co-ordinate their analysis.

Meat imports and production are monitored by the veterinary authorities, from the border to the slaughterhouse. The Federal Veterinary Office is responsible for monitoring meat production (including poultry, rabbits, game and fish), meat products, milk and dairy products, and other foods for export, in so far as the country to which they are being exported requires monitoring and certification by an official veterinary officer.

2.2 Risk Assessment

Risk assessment of substances that are potentially hazardous for health such as components, pollutants, residues and additives contained in food.

Switzerland has a long tradition in the area of food safety systems. The legislation goes back to the beginning of the twentieth century and has structurally modified only in the past ten years. Substances that pose a potential health hazard can thus be present in food only in technically unavoidable quantities and that presents no danger for humans. The assessment of the risks attaching to such substances is based on scientific data regarding their toxicity, technically unavoidable concentrations in foods, the assimilation of the substances in the course of consumption of the corresponding foods, and the cumulative effects of the substances on the same biological systems of the human organism.

The principles of risk assessment in Switzerland are based on international standards (FAO/WHO, the Codex Alimentarius, OECD and EU). Risk assessment is carried out by the scientific experts of the Federal Public Health Office (OFSP), who can call on independent experts (academics) when necessary. The crucial toxicological characteristics (toxic potential, evolution of effects) are determined using multi-stage procedures based on toxicological tests carried out on animals. The reference doses that are risk-free for human health are extrapolated on the basis of the corresponding factors of uncertainty (acceptable daily intake (ADI), provisional tolerable weekly intake (PTWI), acute reference dose, etc.). During the next phase, possible individual exposures are assessed, again using a multi-stage procedure based on a worst-case scenario (all the food is contaminated at the scheduled maximum concentration) so as to arrive, by successive refinements, at the most realistic possible assessment of the exposure (taking into account the average residues as measured by on-the-spot analysis, good manufacturing practice, the influence of processing and storage, the “market shares” of the substances in question, and actual quantities as measured in studies of consumption.

On the basis of these assessments, the maximum admissible concentrations in foods of substances that pose a potential health hazard are specified in the Ordinance of 26 June 1995 on foreign substances and food components (OSEC, RS 817.021.23)

In the case of substances that have to be authorised (for example, pesticides, veterinary medicines, additives, packing materials), producers must register and supply documentation. They are legally bound to supply the OFSP with all the documentation (the “dossier:”) needed to evaluate the substance. This information is usually considered to be confidential and at present may be divulged only between the authorities at national level. A maximum concentration must be set for these substances. Since the last update of the Ordinance of 23 June 1999 on the approval of phytosanitary products (RS 916.161), the OECD 1998 guidelines on the “dossier” and “monographs are explicitly included among the basic requirements for registration of phytosanitary products (pesticides).

Risk Assessment in Microbiology

Risk assessment in microbiology is based on Article 10 of the Federal Food and Consumer Safety Act of 9 October 1992 (RS 817.0), which stipulates that micro-organisms may be present in food only in quantities that pose no danger to human health. By micro-organisms is meant bacteria, yeast, mould, protozoal parasites and viruses. The same article stipulates that the Federal Council may, on the basis of epidemiological studies, set legally binding microbiological criteria. A number of these criteria are embodied in the Ordinance on Hygiene (RS 817.051). These criteria are divided into two distinct categories. The first comprises limit values for pathogenic and toxic organisms, with a view to protecting human health. The second comprises tolerance levels for pathogenic organisms, indicative of or causing deterioration in food.

The tolerance values are designed to guarantee hygienic handling and processing of food. As the results of microbiological analysis depend to a large degree on the methods used the methods of analysis with regard to limit and tolerance values must be carried out in accordance with official reference methods. The official methods in the Swiss Food Manual also state the key aspects of sampling and preparation. The tolerance values given in the Ordinance on hygiene were calculated on the basis of large-scale fundamental studies. In these studies, a statistically significant number of samples are taken under the GMP conditions that are usual for the sector. The tolerance value is set so that 10 per cent of the samples analysed exceed it, and thus do not comply. The tolerance values indicate flaws in good manufacturing practice (GMP).

The limit values specified in the Ordinance on hygiene are well within international standards (for example, *Salmonella enterica* must be non-detectable in 25 g of a product that is ready to consume). Limit values for new organisms are specified in the Ordinance only if the organisms are an effective epidemiological factor, this being ascertained by specific studies. When setting a new value, reference is usually made to the most recent specialised literature, directives of international organisations like the WHO, the Codex Alimentarius or the International Commission on Microbiological Specifications for Foods (ICMSF). The data available are finally evaluated using a risk assessment procedure in accordance with the Codex Alimentarius. In most cases, a qualitative procedure should be sufficient. Quantitative risk assessments, which are required in certain cases, are not within the capabilities of our specialised authorities due to their complexity and extremely high cost. Such projects should be carried out within the framework of international co-operation or by groups of experts of international organisations (CODEX), which would also ensure international acceptance of the findings.

2.3 Risk Management

Structure of Federal Legislation

In Switzerland, legislation is made by Parliament (federal laws, parliamentary ordinances, federal decrees), the Federal Council (ordinances of the Federal Council), government departments (departmental ordinances) and, when the law provides for it, by offices or other services subordinate to government departments (ordinances). Federal laws set out the basic provisions regulating a given area. The ordinances of the Federal Council elaborate on federal laws but also contain provisions of a fundamental nature. However, they may not regulate areas, which are not covered by laws. Departmental ordinances flesh out Federal Council ordinances, as do also ordinances issued by offices, these containing technical and administrative provisions of an essentially secondary nature. Ordinances issued by departments and offices may not go beyond the scope of the laws from which they derive.

The federal government also issues recommendations but they do not constitute legislation and are not binding. It can issue recommendations only in areas in which legislation empowers it to do so. If the recommendations give rise to physical or material injury, the Confederation can be held liable for compensation.

Federal Legislative Procedures

The legislative procedure varies according to the body that is doing the drafting, i.e. Parliament, the Federal Council, government departments or services subordinate to them. By way of example, we shall describe the procedure for drafting and adopting an ordinance of the Federal Council.

The details, as well as the procedures for adopting other types of legislative instruments, can be consulted in the Guide for drafting federal legislation, which can also be downloaded from the Internet site http:www.bj.admin.ch/themen/gesmeth/intro-f.htm.

Draft ordinances of the Federal Council are prepared by the competent federal service, which may call on outside experts or organise hearings of experts in order to obtain the necessary specialised knowledge on a subject.

The Federal Act of 6 October 1995 on technical impediments to trade (RS 946.51) stipulates that technical standards must not be formulated in such a way as to constitute impediments to trade. Accordingly, they must be harmonised with the technical standards of Switzerland's main trading partners. In addition, several sectoral laws require the Federal Council to take account of international recommendations and external trade relations when formulating technical requirements (Article 38 (1) of the Food and Consumer Safety Act of 9 October 1992, RS 817.0).

Once the drafting of a bill is completed, the competent service in the federal administration circulates it internally to the relevant offices. Which offices are invited to comment on the draft depends on the nature of the legislation and the interests involved. The federal chancellery and the federal justice office must always be consulted. The federal finance ministry must be consulted when the bill has financial implications.

When a bill is very important, a consultation procedure is launched after the offices have been consulted. Once the consultation procedure has been completed, the offices are consulted again.

On the basis of the outcome of the consultation with the offices, the bill is revised by the competent office and then forwarded to the government department for the co-reporting procedure under which the department submits a proposal to the Federal Council. This proposal is transmitted to the federal chancellery, which submits the documents to other departments for consideration. The departments concerned comment on the draft within a fixed period (usually three weeks). If a department disagrees with the bill, it can write a co-report. The department responsible for the bill can respond by issuing a position on the base of the co-reports. It can maintain the initial draft, adopt the proposals sent with the co-reports or propose a draft amended in the light of these proposals. Departments that accept the initial draft can also take a position on the co-reports of the other departments.

The bill is then sent to the Federal Council for adoption. A new law must be published in the official gazette at least five days before it comes into force. The two official organs of federal law are the *Recueil officiel des lois fédérales* http://www.admin.ch/ch/f/as/index.html and the *Recueil systématique du droit fédéral* http://www.admin.ch/ch/f/rs/rs.html, both of which can be accessed free-of-charge on the Internet.

Consultation Procedure

Consultations must be organised prior to the adoption of legislation with a major political, economic, financial or cultural importance, or of provisions that will be applied to a large extent outside the federal administration. The circles concerned can express their views on a specific piece of draft legislation (Ordinance of 17 June 1991 on the consultation procedure, RS 172.062). The procedure may either be written or conducted entirely or partially in the form of discussions. The parties, which are usually consulted, are the cantons, the political parties in the Federal Assembly, national organisations in

the sector concerned such as consumer organisations, trade associations, etc. Organisations and individuals that have not been formally invited to express their position on the legislation can receive the dossier on request, and can adopt a position on it.

Once the consultation procedure has been completed, the department responsible gathers together the findings of the consultation and recapitulates the demands, suggestions and opinions. It weights the results of the consultation and submits to the Federal Council its proposal concerning the next steps or takes decisions in areas in which it is competent to do so (departmental ordinances). The results of the consultation are published.

Implementation of Food Legislation

Depending on the subject, food legislation is implemented by the federal authorities or the cantons. The federal authorities implement it at the level of imports, transit and exports of foodstuffs and ensure that the necessary controls are carried out. Whereas meat and meat products are inspected at the border by the veterinary services, other foodstuffs are controlled by the customs. Inside the country, food inspections are carried out by cantonal chemists and veterinary officers (livestock production and slaughter).

Some foodstuffs such as food supplements or genetically modified foods may not be marketed until they have been cleared by the Federal Public Health Office. The cantonal executive authorities are responsible for ensuring that products available on the Swiss market have been duly authorised.

2.4. Risk Communication

Official Organs of Federal Law

The two official organs in which legally binding federal instruments are published in the three official languages -- French, German and Italian --- are the *Recueil officiel des lois fédérales* (in chronological order) and the *Recueil systématique du droit fédéral* (see paragraph *2.2).*

Means of Communication of the Various Federal Offices

The Federal Public Health Office uses various means of communication, each targeted at a specific public. Recommendations concerning food safety evaluations and food analysis are published in the Swiss Food Manual, which is regularly updated. Scientific articles on food analysis are published in the "*Travaux de chimie alimentaire et d'hygiène,* the official organ of the Swiss Food and Environmental Chemistry Society, and of the Swiss Food Hygiene Society. This publication comes out six times a year and is aimed at a specialised public. It publishes original scientific findings in the field of food science, and the results of food inspections carried out by the cantons. It is published by the Federal Public Health Office. The bulletin of the Federal Public Health Office is a weekly in German and French that also contains articles on topical food safety issues. This bulletin reaches a very wide audience, since it is distributed free-of-charge to all doctors, pharmacists and food specialists, and its findings are also reported by the press.

The Federal Veterinary Office publishes a news-sheet every fortnight in German and French, and partly in Italian, which is distributed to veterinary officers, importers and exporters, and a wide agricultural public and other interested readers.

Internet site of the Federal Public Health Office (OFSP) and the Federal Veterinary Office (OVF)

The Internet site www.admin.ch_contains links to all the federal authorities and to federal legislation.

The Federal Public Health Office has its own Internet site, which also covers consumer protection and food safety. The address is www.admin.ch/bag. Most of the texts on food (hygiene, genetically modified foods, resistance to antibiotics, etc) are also available on the Internet site under the heading “Consumer protection”.

When serious events involving food safety occur, it is necessary to inform the public rapidly about the risks and dangers. The information service of the Federal Public Health Office has a coherent, transparent policy, and in so far as possible tries to weigh properly the real dangers posed by the food concerned (see also II). As the cantons are responsible for enforcing food safety measures, they also can inform the public, in conjunction with the federal authorities.

The Federal Veterinary Office publishes all the requirements regarding animal health, the safety of food falling within its remit, animal protection and the conservation of species, on its Internet site “INFOVET”, www.admin.ch/bvet). Information about epidemics and outbreaks of diseases transmissible from animals to man, as well as other information, is also published on the site.

III. Switzerland’s Food Safety Activities

3.1 Development of the Food Safety System in Switzerland

In 1995, Switzerland introduced new food legislation whose main objectives are to ensure the safety of food and to protect the consumer against health hazards and fraud. A few fundamental principles were enshrined in this legislation, which covers the whole food chain, from agricultural production to the final consumer.

Law making is separated from enforcement. Ordinances are framed at federal level, as are the scientific evaluations underpinning legislation. Enforcement is the responsibility of the food monitoring bodies in the cantons, which have the status and powers of a judicial police. As in most cantons, federal bodies responsible for food safety are subordinate to the health authorities.

Food inspections are standardised, and encompass all foods of animal or plant origin. The veterinary authorities are responsible for inspecting meat up to and including slaughter, as well as imports. After meat has been inspected and approved it is inspected by the food safety authorities.

The food safety system is evolving: consideration is being given to ways in which the interfaces between the veterinary and health authorities could be made even more effective. Harmonisation is also under way in the grey area between foodstuffs and therapeutic products, as part of the overhaul of federal legislation on medicines and medical apparatus.

The detailed provisions are currently set out in 34 federal ordinances and decrees. It is planned to revise this legislation completely and to redefine the respective responsibilities of government departments and the Federal Public Health Office. In line with the guidelines on the organisation of the administration, responsibilities must be devolved to the lowest possible level, in accordance with the principle of subsidiarity. At the same time, food legislation is being harmonised with the Codex Alimentarius and the main EU Regulations. Furthermore, it is planned to revise the Swiss Food Manual (a compendium of methods for analysing food, for use by the authorities and other interested parties), and to add to it guidelines for making detailed assessments. With a view to promoting greater transparency, all the legislation is accessible on the Internet and partially available on CD-ROM (in French and German).

3.2 Regulations Pertaining to Genetically Modified Organisms

General Principles

The safety of products derived from genetically modified organisms (GMOs) must be proved on the basis of the current state of knowledge before they can be made available to the consumer. Such proof must be provided for all products -- foodstuffs, additives or processing aids. Proofs are examined on a case-by-case basis, by the Federal Public Health Office, and other offices such as the Federal Agricultural Office (OFAG), the Federal Veterinary Office (OVF), the Federal Environment, Forestry and Countryside Office (OFEFP) and the Federal Commission of Experts for biological safety (CFSB) are also consulted. When a GMO is a living organism, the decision is taken in conjunction with the OFEFP and if necessary with the OFAG and OVBF.

Legal Basis

The Federal Food and Consumer Safety Act of 9 October 1992 (RS 817.0) stipulates that the Federal Council can restrict or ban food-manufacturing processes when, on the basis of the current state of knowledge, a danger for human health cannot be ruled out. This provision also applies to genetic engineering. The 1995 Ordinance on Foods defines GMOs and states that all GM products must be authorised. The Ordinance of 19 November 196 concerning the authorisation procedure for GM products (RS 817.021.35) sets out the details of the authorisation procedure proper and stipulates the information that the applicant must produce, among which information guaranteeing that the product is safe.

Risk Assessment and Management

The applicant submits an application to the OFSP. The application must contain information requested in a questionnaire. The information requested consist essentially of general information about the GM products and the applicant, the characteristics of the donor and host organisms, the characteristics and detection of the vectors used the genetically modified organism, and a guarantee of the product's safety.

The genetic modification must be characterised at the molecular level. The toxicological and allergological aspects in particular must be evaluated. The substantial equivalence of the GM product must also be evaluated. The safety of the product must be guaranteed by a system of quality control encompassing aspects such as the horizontal genetic transfer to human gut flora, the presence of genes which are resistant to antibiotics, modifications in the substantial composition, and the environmental impact.

In principle, products are licensed for five years. During this period, the GM product must be monitored, and the licence-holder must submit a quality assurance report each year. The licence is withdrawn if there is a warranted presumption that the product poses a danger to human health or the environment.

The monitoring also applies to equipment and methods of analysis, which have must be made available to the competent authorities. In particular, the methods of analysis must allow the authorities to verify that the general labelling obligation that exists since 1995 is complied with.

3.3 The Precautionary Principle and Food

The precautionary principle is set out explicitly in the Environment Act, the aim of which is to protect man and the environment from the harmful effects of pollution. In line with this principle, the Act requires that potentially harmful pollution must be minimised preventively. This principle is not explicitly stated in food legislation. Several provisions of Swiss food legislation do however endorse the principle.

Food legislation seeks to protect human health. Basically, foods must not pose a danger to human health when they are used in accordance with their intended purpose. The owner of the goods is responsible for ensuring compliance with this requirement, by carrying out self-inspections. If there is a warranted presumption that the legal requirements have not been complied with, the authorities can seize the goods in question. The Federal Council can restrict or ban substances or processes when, in the current state of knowledge, all risk to human health cannot be ruled out. This concerns in particular, agricultural additives, veterinary medicines and farming methods, as well as physical, chemical, microbiological or genetic processes used for manufacturing or processing food.

The authorities draw on a risk assessment when carrying out the scientific evaluation. The Federal Council can intervene in two situations: when the risks are considered too great or when there is not enough data available to allow the risks to be evaluated properly.

Regarding the measures to be applied, they must comply with several legal principles. Article 5 of the Federal Constitution (RS 101) stipulates that measures taken by the authorities must be proportionate, in other words that any binding measures implemented must not be excessive in relation to the circumstances. Public and private interests must be weighed against one another. Regarding bans, restrictions can take the form of limited authorisations, possibly combined with a monitoring programme; authorisations issued only for a limited time or for a limited quantity, prohibitions or specific reporting requirements.

3.4 Food Inspection and Enforcement

In the Federal Public Health Office, a staff of about 70 work in the area of food sciences and the enforcement of food law, including at the level of international co-operation. There is close co-operation with research institutes and universities in Switzerland and abroad on specific research projects. The Office has several advisory bodies with representatives of industry, consumer organisations, cantonal monitoring authorities, and the world of science. These are closely involved, via the consultation procedure, in the various stages of drafting legislation. Since the Food Act of 9 October 1992 (RS 817.0) came into force, food inspection has been based on the principle of self-inspection. This means that anybody who manufactures, processes, transfers, imports or exports food or items for consumption, must ensure that they meet legal requirements.

The enforcement of food legislation and, in consequence, the principle of self-inspection, is carried out by 20 cantonal laboratories. Food inspections are carried out by 70 full-time food inspectors plus some 700 inspectors operating on a part-time basis. The federal authorities are responsible for overseeing and co-ordinating food inspection at cantonal level.

The priorities are as follows:

- Co-ordination and harmonisation measures, principally in the area of food inspection.
- Implementing targeted programmes.
- Implementing comparative tests by standardising and harmonising methods of analysis.
- Improving the flow of information between the centre and the cantons with a view to increasing the speed of response in the event of a crisis.
- Implementing concrete measures in the event of an emergency.

In the Federal Public Health Office, about 40 people from the central administration work full or part-time on diseases which can be transmitted to humans from animals (zoonoses) and the safety of foods of animal origin.

Imports of meat and meat products are inspected at the border by more than 70 veterinary officers (on a full or part-time basis) from the Federal Public Health Office. Meat intended for export is inspected by about 90 veterinary officers in firms authorised to export. There are 26 cantonal veterinary offices. In addition, the inspection and advisory service for the dairy sector, which is directed and partially funded by the federal government, employs about 70 people in ten regional centres.

3.5. Socio-economic Aspects

The socio-economic aspects of food safety are addressed only indirectly insofar as the primary aim of food safety legislation is to protect the health of consumers and to ensure that they are not misled. They are however taken into account in the legislative process at federal level (risk assessment, management and communication), when public and private interests (freedom of trade) are weighed against one another. They may also be taken into account when measures are examined in the light of the principle of proportionality i.e. the extent to which they are necessary, adequate and proportionate.

The impact on, trade policy, and especially on compliance with Switzerland's international obligations in the WTO and the OECD are also taken into account. As a general principle, technical requirements must not be framed in such a way as to constitute technical impediments to trade.

3.6 Informing and Consulting the Public

The interests of the consumer are represented by private organisations. The Food and Consumer Safety Unit is in permanent contact with these organisations, and their views and demands are taken into account during the legislative process, for example by organising hearings (see section II). Information about food and diet is provided by a large number of organisations, including organisations in the production and distribution sectors. For 2000, the Federal Public Health Office has set itself the objective of co-ordinating information and making good any shortcomings. Public forums are also organised to allow the public to discuss controversial scientific issues with experts. In 1999, the Federal Public Health Office (OFSP) participated in a forum on genetic engineering. Recommendations regarding food safety and diet are published by the Federal Food Commission (CFA), which brings together representatives of consumer protection organisations, cantonal food inspection authorities, science and business.

In addition to the periodicals mentioned in section II, the Federal Public Health Office also publishes brochures on specific themes with a bearing on food safety, which are aimed at the general public (for example, genetically modified foods; Swiss labelling rules, 1999). They are usually distributed free-of-charge and can also be downloaded on the Internet. As the Swiss media sector is relatively small, the information service has personal contacts with journalists, and via them, with the public.

TURKEY

I. Synthesis

Food production and consumption trends have drastically changed since the beginning of the 20th century in relation to the increase in the world population and differentiated life styles and consumer trends which led to a rapid development in the production of various kinds of foods.

The introduction of new technologies has made consumers less familiar and more confused about the food they consume as the types and variability of products are increased. Due to the recent developments, some countries have increased their national efforts in maintaining high quality standards and ensuring the safety of food supply for both domestic consumption and export. At the international level, various international settings are working towards achieving global regulations.

In parallel with the developments in food science and technologies, domestic consumers become more sensitive about human health, food safety and environment aspects and they also show an increasing interest on potential hazards of this issue. In Turkey, analytical tools that are used in risk assessments are main factors giving directions to public policies under the Decree of 560 concerning Production, Consumption and Inspection of Foodstuffs. Quality control systems such as ISO 9000, HACCP, GMP are also put in place for the food industry as a means to ensure an effective food quality system.

II. Overview of Food Safety Systems

A. Institutional Structure and Regulatory Framework

A.1 Governmental Agencies Involved in Food Control System

The Ministry of Agriculture and Rural Affairs (MARA), an executive branch of the Government, inspects all food products for domestic production purpose and import/export. The MARA is responsible for the enforcement of Turkish Food Codex (TFC) and relevant regulations issued for the implementation of the Decree of 560, Force of Law, “Concerning Production, Consumption and Inspection of Foodstuffs” which regulates every stage of the food chain.

According to the Decree, production, processing, preservation, storage, packaging, marketing and import and export stages of food chain are put under control. The registration of food corporations, technical and hygienic inspections for granting work permits, inspection of foods at the retail points and all controls of domestically produced spring and mineral waters are under the jurisdiction of the Ministry of Health (MH).

Official food control services are given by the laboratories of the MARA and the MH. The General Directorate of Protection and Control of the MARA prepares legal arrangements, policies and applications related to food production, consumption, inspection and control regulations in collaboration

with other bodies of the MARA, the MH, private sector, academicians, scientific experts and producers union.

This legal framework aims to protect consumers from unhealthy and unsafe food products and to regulate the food industry in order to prevent unfair competition practices in the market. To this end, the MARA, is charged with enforcing the TFC which is prepared in harmony with the EU Directives as well as Codex Alimentarius Commission (CAC) norms which cover technical and hygienic principals of food processing, food additives, residues, sampling, labelling, transportation and storage.

There is a high capacity of scientific and technological knowledge accumulated in research organisations and universities in Turkey. All these organisations and institutions act in co-ordination on food safety issues, development of food processing technologies, new food formulations and national surveys.

The Supreme Council for Science and Technology (SCST) and the TUBITAK (Scientific and Technical Research Council of Turkey) act as the general secretariat to the Council, co-ordinate the R&D, performed under the aegis of different ministries with R&D operations.

TUBITAK, which has high standing in the government hierarchy, is the unique organisation for the advancement of S&T and the enhancement of R&D. TUBITAK also acts with its research establishments. The Marmara Research Centre (MRC) with its research institutes, the Food Science and Technology Research Institute and Research Institute of Genetic Engineering and Biotechnology, performs applied R&D studies on biotechnology. TUBITAK-MRC Food Analysis Laboratories are under preparation for accreditation.

A.2 Legal Base

In recent years, Turkey has increasingly focused on enacting a contemporary food regulation in order to make its food control system effective. These studies have targeted an efficient allocation of power and responsibilities among related agencies in line with the developments in food safety issues and the requirements of the GATT, Sanitary and Phytosanitary measures of Uruguay Round Agreement and the Custom Union with the EU. Consequently, Food Regulation Decree of 560 “Concerning the Production, Consumption and Inspection of Foodstuffs” was enacted in 1995. This framework document was followed by other regulations such as the Turkish Food Codex, Food Control Regulation and Product Directives.

This regulation aims:

- To ensure technical and hygienic standards in production, processing, preservation, storage and marketing of foodstuffs.
- To meet adequate nutritional requirements of public.
- To determine the specifications of every kind of raw and aiding materials, processed and semi-processed foodstuffs and by-products.
- To determine the minimum hygienic and technical requirements of companies producing foodstuffs and to check and inspect of foodstuffs.
- To identify the principles and procedures relating to services of foodstuffs.

1) **The Regulation Concerning the Production, Consumption and Inspection of Foodstuffs**, enforced by the MARA.

The regulation covers registration of food firms, granting production permission, responsibilities of technical managers and staff employed in plants, the right of appeal against the decision of officials, commercials and advertisements.

2) **The Regulation of Turkish Food Codex,** enforced by the MARA.

The Decree of 560 prohibits the manufacture, processing and trading of foods that are not in compliance with the Turkish Food Codex (TFC). The regulation covers specific provisions on food quality, food hygiene, food additives, food contaminants, labelling, packaging and packaging materials, storage and distribution of food products.

There exist some other regulations in order to improve Turkey's present food control system, which are prepared in parallel with recent developments. The Turkish food system encourages the food companies to be pro-active in food safety issues through requiring the implementation of Quality Assurance (QA) programs such as HACCP and GMP. This concept is included in regulatory practices by the MARA in order to urge food corporations to implement internationally accepted QA programs, HACCP in particular.

B. Risk Analysis

For many years, Turkey has been implementing food inspection and control programs in order to protect its public from food borne hazards, by regulating food industry and trade. To meet up the recent developments in food technology, it has also initiated studies for the improvement of the present system. As an initial step, the HACCP system was incorporated in food regulations.

Turkey is in the process of setting up a food control system that is based on risk analysis. Risk analysis is considered as an integral element in designing food control policies.

B.1 Risk Assessment

Hazard identification originates generally from authorities responsible for food law enforcement or from international authorities. There are residue monitoring programmes on some specific food types such as milk, honey, meat and fishery products. The laboratories of the MARA continue these studies according to the EU Directive No: 96/23 EEC. For instance, Bacterial substances, chloramphenico, benzimdazoles, phenylbutazone and aflatoxin M1 are the compounds that are examined in raw milk. Domestically produced and imported food products are regularly controlled in compliance with the legal requirements. These products are also analysed for microbiological elements and chemicals (pesticide residue, veterinary drug residues, heavy metal contamination and additives) that are related to food safety.

B.2 Risk Management

Results of risk assessment are taken into account in decision-making. The Codex Standards, EU Directives and risk management regulations in other countries are also considered.

B.3 Risk Communication

Seminars, panels, training courses and symposiums are organised in order to address the issues related to the food safety. Consumer Associations (CA) and media are important tools for risk communication. There are panels organised by CA on biotechnology to inform consumers and highlight the issues.

III. Activities of Food Safety Issues

A. Regulation of Modern Biotechnology

Turkey is in the process of reforming its regulatory framework for the products of modern biotechnology. In preparation of new regulations, domestic circumstances, regulations in other countries, science based approaches and approaches adopted by the EU and Codex Alimentarius Commission are all duly taken into account.

National studies on these products still continue. The risk assessment on human health and environmental risks of food produced by the use of genetically modified organisms are handled separately with a view that as risks related to human health are universal, environmental risks can vary according to regional and domestic conditions.

Everyone agrees that more transparency and openness is needed in risk assessment, there are practical problems about how to put it into practice. Even though no adverse effects of GM foods on human health are reported up to now, long term uncertainties and risks still remain for effects of GM foods to human health and the environment.

Concerning the biosafety regulations in Turkey, SCST appointed TUBITAK to set up a working group for preparing the regulations for biotechnology and genetic engineering. The working group decided to form different sub groups to prepare regulations for biotechnology research on humans, plants, animals and micro-organisms. It is also decided to establish a national biosafety council to handle biosafety issues.

B. Developing National Food Safety Framework

An action plan related to the food safety system has been put in place in 2000. This Action Plan aims at improving present food control systems, putting all food control services in a network system and to actively follow international developments.

C. Precautionary Approaches and Principles

The issues related to GM foods are still under discussion in Turkey. Presently, several organisations and agencies are conducting surveys on this subject.

Internationally, despite several studies and activities going on under different settings, there is no agreement on the necessity to improve risk assessment system on GM foods. The EU Countries and NGOs have been insisting on the necessity of reassessment of these foods, as the discussions on identification of risks and methods of analysis are still underway.

In Turkey, presently there exist neither a published GMO survey result nor any GMO product. Domestic production and import of GM foods and ingredients are not allowed in Turkey. The notification requirements of the WTO, under the Sanitary and Phytosanitary Agreement are strictly observed.

D. Communication and Consultation

The Turkish Food Codex is implemented through Product Directives that are issued on the basis of a consensus reached among the MARA, the MH, universities, private sector, related organisations, producers union and civil society organisations.

UNITED STATES

I. Synthesis

The United States Constitution prescribes the responsibilities of the government's three branches: executive, legislative and judicial, which all have roles that underpin the nation's food safety system. Congress, the legislative branch, enacts statutes designed to ensure the safety of the food supply. Congress also authorises executive branch agencies to implement statutes, and they may do so by developing and enforcing regulations. When enforcement actions, regulations, or policies lead to disputes, the judicial branch is charged to render impartial decisions. General U.S. laws and statutes and Presidential Executive Orders establish procedures to ensure that regulations are developed in a transparent and interactive manner with the public. Characteristics of the U.S. food safety system include the separation of powers among these three branches and transparent, science-based decision-making, and public participation.

The U.S. food safety system is based on strong, flexible, and science-based federal and state laws and industry's legal responsibility to produce safe foods. Federal, state, and local authorities have complementary and interdependent food safety roles in regulating food and food processing facilities. The system is guided by the following principles: (1) only safe and wholesome foods may be marketed; (2) regulatory decision-making in food safety is science-based; (3) the government has enforcement responsibility; (4) manufacturers, distributors, importers and others are expected to comply and are liable if they do not; and (5) the regulatory process is transparent and accessible to the public. As a result, the U.S. system has high levels of public confidence.

Precaution and science-based risk analyses are long-standing and important traditions of U.S. food safety policy and decision-making. U.S. food safety statutes, regulations, and policies are risk-based and have precautionary approaches embedded in them.

The agencies' well-qualified science and public health experts work co-operatively to ensure the safety of U.S. food. Scientists from outside government are regularly consulted to provide additional recommendations regarding technical and scientific methods, processes, and analyses used by regulators. The cutting-edge science that informs U.S. regulators is routinely shared internationally through interactions with organisations like the Codex Alimentarius Commission, World Health Organisation, the Food and Agriculture Organisation and the International Office for Epizootics.

The U.S. routinely and effectively deals with technological advances, emerging problems, and food safety incidents. It is enhancing early warning systems about pathogens in food. The legislation granting authorities to agencies generally enables them to revise regulations and guidance consistent with advances in technology, knowledge, and need to protect consumers.

U.S. food agencies are accountable to the President, to the Congress which has oversight authority, to the courts which review regulations and enforcement actions, and to the public, which regularly exercises its right to participate in the development of statutes and regulations by communicating with legislators, commenting on proposed regulations, and speaking out publicly on food safety issues.

II. United States Food Safety System

Introduction

The U.S. food safety system is based on strong, flexible, science-based laws and industry's legal responsibility to produce safe foods. Co-ordinated interactions among federal authorities having complementary and interdependent food safety missions, in partnership with their state and local government counterparts, provide a comprehensive and effective system. The implementation of the statutes and the food safety system over many years has resulted in very high levels of public confidence in the safety of food in the U.S.

Principal federal regulatory organisations responsible for providing consumer protection are the Department of Health and Human Services' (DHHS) Food and Drug Administration (FDA), the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) and Animal and Plant Health Inspection Service (APHIS), and the Environmental Protection Agency (EPA). The Department of Treasury's Customs Service assists the regulatory authorities by checking and occasionally detaining imports based on guidance provided. Many agencies and offices have food safety missions within their research, education, prevention, surveillance, standard-setting, and/or outbreak response activities, including DHHS's Centres for Disease Control and Prevention (CDC) and National Institutes of Health (NIH); USDA's Agricultural Research Service (ARS); Co-operative State Research, Education, and Extension Service (CSREES); Agricultural Marketing Service (AMS); Economic Research Service (ERS); Grain Inspection, Packers and Stockyard Administration (GIPSA); and the U.S. Codex office; and the Department of Commerce's National Marine Fisheries Service (NMFS).

The FDA is charged with protecting consumers against impure, unsafe, and fraudulently labelled food other than in areas regulated by FSIS. FSIS has the responsibility for ensuring that meat, poultry, and egg products are safe, wholesome, and accurately labelled. EPA's mission includes protecting public health and the environment from risks posed by pesticides and promoting safer means of pest management. No food or feed item may be marketed legally in the U.S. if it contains a food additive or drug residue not permitted by FDA or a pesticide residue without an EPA tolerance or if the residue is in excess of an established tolerance. APHIS' primary role in the U.S. food safety network of agencies is to protect against plant and animal pests and diseases. FDA, APHIS, FSIS, and EPA also use existing food safety and environmental laws to regulate plants, animals, and foods that are the results of biotechnology.

A. Laws and Implementing Regulations

The three branches of U.S. government -- legislative, executive, and judicial -- all have roles to ensure the safety of the U.S. food supply. Congress enacts statutes designed to ensure the safety of the food supply and that establishes the nation's level of protection. The executive branch departments and agencies are responsible for implementation, and may do so by promulgating regulations, which the U.S. publishes in the *Federal Register* and which are also electronically available. Characteristics of the U.S. food safety system are the separation of powers and science-based decision-making. Agency decisions under U.S. food safety laws can be appealed to the courts, which are empowered to settle such disputes.

Food safety statutes enacted by Congress provide regulatory agencies with broad authority but also set limits on regulatory actions. The statutes are drafted to achieve specific objectives. Food safety agencies then develop regulations that give specific direction and establish specific measures. When new technologies, products, or health risks must be addressed, agencies have the flexibility to revise or amend regulations generally without need for new legislation. Agencies are able to maintain their state-of-the-art scientific methods and analyses because changes of this type can be made at the administrative/technical level.

Major U.S. food safety authorising statutes include the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), the Egg Products Inspection Act (EPIA), Food Quality Protection Act (FQPA), and Public Health Service Act.

Procedural statutes, which regulatory agencies must follow, include the Administrative Procedure Act (APA), the Federal Advisory Committee Act (FACA), and the Freedom of Information Act (FOIA). The APA specifies requirements for rulemaking (i.e., the process by which federal agencies formulate, amend, or repeal a regulation and the process permitting any interested party to petition for the issuance, amendment, or repeal of a regulation). Substantive regulations promulgated by an agency under the APA have the force and effect of law. FACA requires that certain kinds of groups whose advice is relied upon by the government be chartered as advisory committees, that they be constituted to provide balance, to avoid a conflict of interest, and to hold committee meetings in public with an opportunity for comment from those outside the committee. The FOIA provides the public with a statutory right to access federal agency information.

U.S. food safety programs are risk-based to ensure the public is protected from health risks of unsafe foods. Decisions within these programs are inherently science-based and involve risk analyses. Risk assessment is useful in understanding the magnitude of the problem faced, and it assists the agency in determining an appropriate risk management response.

The regulatory development process is conducted in an open and transparent manner. Regulations are developed and revised in a public process that not only allows, but also encourages, participation by the regulated industry, consumers, and other stakeholders throughout the development and promulgation of a regulation. In developing new regulations and revising existing regulations, the agencies often provide the public a preliminary discussion and opportunity for comment by publishing an Advance Notice of Proposed Rulemaking (ANPR). It lays out the issues, presents the agency's suggested resolution, and solicits alternative solutions. The information received from the public is used by the agency to decide whether and how to pursue rulemaking further. All significant public comments must be addressed in the final regulation. The next steps are publication of a proposed regulation and publication of a final regulation, which is enforceable, with opportunities for public comment. The APA requires that the final regulation be justified by policy rationale, scientific bases, and legal authority.

When confronted by a particularly complex issue where advice is needed from experts, who are not part of the agency, the regulatory agency may choose to hold a public meeting or convene an advisory committee meeting. Open, public meetings, structured according to the agency's needs, bring together experts and stakeholders via an informal process. These meetings are used to receive the public's input on a specific subject area or on the agency's future programs. An advisory committee meeting is structured more formally. Public meetings and advisory committee meetings are announced in the *Federal Register* and the meetings are held in public unless an exempt issue, such as trade secrets, confidential commercial information, or personal medical information, is being discussed.

If a person or organisation wishes to challenge an agency decision, the complainant may take the agency to court. Thus, even after an agency issues a final regulation, which responds to all comments, received, an individual or organisation may still challenge the agency decision. This legal action involves the third branch of the federal government, the judicial branch. The judiciary (the federal court system) plays a critical role in the regulatory process in that it reviews an agency's action in light of the substantive law and procedural requirements. An independent judge or panel examines the whole agency record of activity detailing what the agency did and why. If the court finds that the agency did not follow its statutory mandates, fulfil the procedural requirements, or have a rational basis for its action, the judicial system can overturn the agency's action. The judicial system also serves as a forum for agency-initiated enforcement actions.

Just as it is the responsibility of the food industry to sell only safe food, it is likewise its responsibility to obey applicable laws and regulations.

B. Risk Analysis and the U.S.'s Precautionary Approach

1. Risk Analysis

Science and risk analysis is fundamental to U.S. food safety policymaking. In recent years, the federal government has focused more intently on risks associated with microbial pathogens and on reducing those risks through a comprehensive, farm-to-table approach to food safety. This policy emphasis was based on the conclusion that the risks associated with microbial pathogens are unacceptable and, to a large extent, avoidable; and that multiple interventions would be required throughout the farm-to-table chain to make real progress in reducing foodborne pathogens and the incidence of foodborne disease. This effort followed many years of concentration on managing chemical hazards from the food supply by regulation of additives, drugs, pesticides, and other chemical and physical hazards considered potentially dangerous to human health. It reflects the recognition that the approaches to analyses and review of biological hazards and safety concerns differ from those presented by chemicals.

The President's Food Safety Initiative, announced in 1997, recognised the importance of risk assessment in achieving food safety goals. The Initiative called for all federal agencies with risk management responsibilities for food safety to establish the Interagency Risk Assessment Consortium. The Consortium is charged with advancing the science of microbial risk assessment by encouraging research to develop predictive models and other tools.

The U.S. government has completed a risk analysis on *Salmonella enteritidis* in eggs and egg products, which included the first farm-to-table quantitative microbial risk assessment. It is also conducting a risk analysis for *E. coli* 0157:H7 in ground beef and has entered into a co-operative agreement with Harvard University for a risk assessment of the transmission of Bovine Spongiform Encephalopathy by foods. The U.S. is also carrying out a risk analysis for *Listeria monocytogenes* in a variety of ready-to-eat foods.

Regulatory agencies also have made progress in implementing various risk management strategies. An example can be found in Hazard Analysis Critical Control Point (HACCP) regulations. Instead of including in the text of the regulation those specific steps industry must take under a HACCP system, food safety agencies provide general requirements and direct those being regulated to apply the guidelines and develop specific steps to achieve an effective HACCP program. HACCP systems are a risk management tool because they enable the user to identify hazards reasonably likely to occur and to develop a comprehensive and effective plan to prevent or control those hazards.

Performance standards for pathogen reduction and control represent another risk management tool. For example, the U.S. has in place pathogen reduction performance standards for *Salmonella* that slaughter plants and raw ground product must meet and it also tests product to ensure that these standards are met. In the future, the government may establish performance standards for other pathogens of public health concern and define what food establishments that produce, process, or handle food must achieve.

Fair and objective regulatory decisions regarding food safety standards and requirements rely on risk analysis performed by competent authorities, qualified to make scientifically sound decisions. Risk analysis consists of risk assessment, risk management, and risk communication, which are interdependent.

Risk Assessment

Risk assessments are conducted in an objective manner. However, since data and scientific knowledge on any issue are never totally complete, an assessment of absolute risk is impossible. By

explicitly considering uncertainties in the data and analyses, decisions can be made regarding the amount of uncertainty that is acceptable. U.S. policy decisions on procedures used for risk assessment can also ensure that risks are unlikely to be underestimated.

The first component of risk assessment, hazard identification, requires decisions on the effort expended to identify hazards. In the U.S., these are established by law and experience. Laws regarding the use of new food ingredients or pesticides require a prescribed effort to uncover any hazards before introduction into the food supply. For products already on the market, hazards may be identified by experience (e.g., emerging pathogens) that require efforts to control risk.

The second component, hazard characterisation, considers data regarding the potential hazard at different exposure levels and modes, including which data are most relevant for characterising the hazard. While human data are always most relevant, animal data are usually used to characterise a hazard. The U.S. generally relies on data from the most sensitive species to characterise the risk. Where a safety threshold cannot be assumed, the U.S. may rely on linear mathematical models that are not likely to underestimate a risk. It is important to use the most realistic data and models consistent with current scientifically sound knowledge. When information is not available that can identify which is most realistic; data or models that can be shown not to underestimate hazards are used.

The third component, exposure assessment, must differentiate between short-term exposure for acute hazards and long term exposure for chronic hazards. For acute hazards, such as pathogens, data on levels of pathogens causing illness in vulnerable population groups are important. For chronic hazards, such as chemicals that may cause cumulative damage, a lifetime-averaged exposure is relevant.

Risk Management

Risk management is exercised by highly qualified regulatory authorities with the sole objective to provide high levels of protection to the U.S. consumer. Management of risk is necessary when much, some, little, or no data are available thus requiring knowledgeable experienced experts capable of making scientifically defensible decisions in the interest of public health. Risk management principles are set by law or by the risk manager's expert judgement to reduce risk to the lowest practical, or achievable, level.

U.S. laws require that the safe use of a food additive, an animal drug, and a pesticide be established before marketing; therefore risk management decisions are based on very substantial scientific evidence. For hazardous substances that are inherent components of foods (e.g., low levels of natural toxicants produced in potatoes) or unavoidable contaminants of food (e.g., mercury in fish, aflatoxin in grains), government intervention occurs when presence of a substance reaches a level known to present significant risk. The quantity and quality of scientific evidence may vary with the type of risk management decision.

As an example of risk management, every year the U.S. federal food agencies work together to develop a comprehensive, risk-based, annual sampling plan to detect drug and chemical residues in U.S. food. Violative residue information is used as the basis for standard setting and for enforcement and other follow-up activities.

Risk Communication

Routine risk communication is inherent in the transparent regulatory process, which is more fully described in Part D entitled, "Transparency." Transparent standards are employed to ensure fairness to all members of the food industry while protecting public health. U.S. law requires the government to allow and consider comment on the factual basis for a decision when it establishes regulations. Anyone can comment, including persons outside the U.S. There must be a substantial basis in law and fact for every rule. Information relied on by the government is made available for anyone to review. Government scientists use public communication media to explain to the public the science behind regulations.

When there is a need for emergency risk communication, alerts are conveyed through a nation-wide telecommunication system linking all levels of the food safety system with the nation-wide media so all citizens are made aware of the risk, and through global information sharing mechanisms by which international organisations (WHO, FAO, Office of International Epizootics and the World Trade Organisation, if appropriate), regions such as EU, and individual countries are informed immediately.

Risk communication is critical during the risk assessment and management stages. The U.S. is committed to openness and transparency of its work to protect the public from food-related health risks. For example, regulatory agencies provide public notification of recalls of food products. Information about recalls is also provided on the agency's website, as are frequent reports of regulatory and enforcement actions taken against regulated food establishments. EPA's pesticides website contains the full risk analysis for specific pesticides, and risk analyses procedures have been made available to the public for comment. Where appropriate, risk analyses processes have been modified in response to these comments.

Another example of risk management is U.S. federal agency activities on the emerging issue of resistance from the use of antimicrobials in animals. Antimicrobial risk management includes establishment of monitoring and resistance thresholds before a drug can be approved; continuous monitoring of resistance in enteric bacteria from humans and food animals; obtaining information on factors responsible for promoting resistance; and taking regulatory actions as needed, including restrictions on a drug or removing it from the market.

2. Precautionary Approach

(This approach is described in detail in the annex on Precaution in U.S. Food Safety Decision Making.)

The genesis of many health, safety, and environmental laws is associated with the prevention of undesirable events and the protection of public health and the environment. Specific prevention and protection measures reflect differing provisions of law, regulation, and circumstances. However, they all are risk-based. The precautionary approach is exercised in a variety of ways.

An example of the U.S. precautionary approach to risk is the control system for ingredients in food and feed, such as the feeding prohibition of certain animal proteins to ruminants to prevent the introduction of BSE in this country. In implementing this prohibition through a regulation, the government followed existing APA procedures to explain in the *Federal Register* why it is proposed to take the action, including a description of the risk, and to evaluate the comments received from industry, academia, private citizens, and government agencies before publishing its final regulation.

Another illustrative example of the precautionary approach is the pre-market approval requirements established by law for food additives, animal drugs, and pesticides. The products are not allowed on the market unless, and until, they are shown by producers to be safe to the satisfaction of the

regulatory authorities. When the petition is reviewed, data are evaluated to determine exposure to the additive, including exposure to all likely impurities in the additive. The degree of testing considered necessary depends on the class of chemical and exposure. The data or the lack of data drives a decision for approval. The evaluation of all is documented. The final decision explaining the basis for all significant conclusions is published in the *Federal Register*. Persons disagreeing with the decision may file an objection with the reasons for disagreeing and request a hearing. After administrative remedies for appeal are exhausted, the government may be challenged in court on its approval or denial of a petition.

C. Dealing with New Technologies, Products, and Responding to Problems

In achieving the nation's farm-to-table food safety objective, the federal government is only one part of the equation. Federal agencies collaborate with state and local agencies and other stakeholders to encourage food safety practices and to offer assistance to industry and consumers on practices that promote food safety.

The U.S. recognises the regulated industry as a stakeholder and as the party principally responsible for food safety. Establishments are responsible for producing food products that meet regulatory requirements for safety. The government's role is to set appropriate standards and do what is necessary to verify that the industry is meeting those standards and other food safety requirements. Consistent with modernisation of inspection systems and the farm-to-table initiatives, federal agencies use their resources as efficiently and effectively as possible to protect the public from foodborne illness. As an extension of HACCP, the U.S. is testing new meat and poultry inspection models to determine whether or not additional protections can be provided consumers through redeployment of some in-plant resources to the distribution segment of the farm-to-table chain, which includes transportation, storage, and retail sale of products.

Federal food safety agencies regularly enter into partnerships with states and others such as grower organisations and public interest groups to encourage improved production practices, to develop and foster food safety measures that can be taken on the farm and in marketing channels to decrease public health hazards in food, to develop and implement safer pest management practices, and to develop good agricultural practices to minimise pesticide residues and microbial risks.

The country's emergency response capability is sound and being enhanced continually. For example, U.S. food safety regulatory agencies participate in FoodNet, a network whose objectives are to determine the frequency and severity of foodborne diseases and the proportion of common foodborne diseases that result from eating specific foods and describe the epidemiology of new and emerging bacterial, parasitic, and viral foodborne pathogens.

Information on possible foodborne disease outbreaks from FoodNet and reports to state and local health departments are followed up by those health departments in co-operation with federal food agency authorities to determine the course and nature of the outbreak. Appropriate public advisories are issued and enforcement actions taken about the products involved as soon as possible.

In addition, a new technique has been developed using pulsed-field gel electrophoresis (PGE), which permits CDC to match distinctive patterns of pathogenic materials that cause foodborne illness. Using these "fingerprinting" techniques, the single casual factor of a foodborne illness outbreak can be traced using epidemiological investigation and PGE. This has led to intervention and, in at least one recent case, cessation of a serious foodborne illness outbreak. Both FoodNet and PulseNet are basic building blocks for the U.S. system of foodborne illness prevention.

D. Transparency

Various U.S. statutes and executive orders establish procedures to ensure that regulations are developed in an open, transparent, and interactive manner and that, as appropriate, the regulatory process is similarly open to the public. Regulations and their implementation must lead to fulfilment of objectives for the public good such as protecting health, safety, and environment.

The APA specifies requirements for rulemaking (i.e., the process by which federal agencies formulate, amend, or repeal a regulation and the process permitting any interested party to petition for the issuance, amendment, or repeal of a regulation). Substantive regulations promulgated by an agency under the APA have the force and effect of law. Under the APA, a notice of proposed rulemaking must be published in the *Federal Register*, an official daily publication that is available through subscription and through the Internet at no cost. All regulations and legal notices issued by federal agencies and the President are published in the *Federal Register*. In addition, though the Internet is not an official publication, U.S. government agencies make extensive use of it to provide information on regulatory activities and enhance the transparency of their processes.

The President issued an Executive Order to strengthen agencies' processes for promulgating regulations. Also, several states require analysis of the impacts of regulations: there are requirements to analyse the impact of the regulation on small business (the Regulatory Flexibility Act); the impact of the regulation on the environment (the National Environmental Policy Act); and the impact of any information collection requirements contained in the regulation (the Paperwork Reduction Act).

FACA requires that certain kinds of groups whose advice is relied upon by the government for establishing regulations be chartered as an advisory committee, be constituted to provide balance and to avoid conflicts of interest, and to hold its advisory meetings in public with an opportunity for comment from those outside the committee.

FOIA's purpose is to expand the areas of public access to information beyond those originally set forth in the APA. Any person residing in the United States has a right of access to a wealth of government information and records subject only to certain limited exemptions.

To ensure the broadest possible participation by the public, agencies publish their proposals on Internet sites and call attention to the proposed or final rule through press releases. The U.S. news media and interest groups follow the *Federal Register* and agency Internet sites closely and publish information about proposed and final regulations. In addition, U.S. agencies may hold public meetings to solicit input from interested persons. Meetings often include media coverage. For example, numerous public meetings were held to solicit input on the Food Safety Strategic Plan being developed by the President's Council on Food Safety; on the draft Guide to Minimise Microbial Food Safety Hazards for Fresh Fruits and Vegetables; as part of the process to develop the Food Safety Initiative; and on bioengineered foods, among other topics.

Regulatory agencies often offer guidance on ways to achieve compliance with regulatory requirements. Such guidance may describe situations where a food could become adulterated or misbranded or may describe data that would be needed to establish safety. Although such guidance does not have the effect of law (one need not follow it to demonstrate that a food is safe and lawful, provided that all statutory and regulatory requirements are met), such advice is helpful to the food industry and to the consumer.

The Codex Alimentarius Commission (Codex) is the major international body for promoting the health and economic interests of consumers while encouraging fair international trade in food. Within the United States, Codex activities are co-ordinated by officials from USDA, HHS, and EPA. The U.S.

Codex Office provides information via the *Federal Register* and the Internet concerning the Codex and its activities internationally and in the U.S.

E. System Accountability

U.S. food agencies are highly accountable to government's three branches and to the people:

1. U.S. food agencies are accountable to the President – the chief executive – who has constitutional responsibility to assure that laws are faithfully executed; who appoints senior officials, and whose Office of Management and Budget clears significant regulations.

2. U.S. food agencies are accountable to the Congress, the legislative branch of the U.S. government, which provides the food agencies their authority and budget; whole committees hold frequent oversight hearings; and the Senate must confirm the nomination of cabinet officers and senior officials.

3. U.S. food agencies are accountable to the courts, the judicial branch of the U.S. government, which review food agency regulations and enforcement actions.

Most importantly, U.S. food agencies are accountable directly to members of the public, who regularly exercise their right to participate in the development of laws and regulations, such as commenting on proposed regulations; whose guidance is sought in frequent public meetings; and who provide strong support for food safety regulation, the nutrition label, and other regulatory initiatives.

ANNEX I

Section 1.01
References for the United States Food Safety System

Introduction

1. Food Safety Gateway	http://www.foodsafety.gov/
2. National Food Safety Information Network	http://vm.cfsan.fda.gov/~dms/fs-toc.html
3. Public/Private Partnership for Food Safety Education	http://www.fightbac.org/
4. Department of Health and Human Services (DHHS)	http://www.dhhs.gov/
Food and Drug Administration (FDA)	http://www.fda.gov/
Centers for Disease Control and Prevention (CDC)	http://www.cdc.gov/
5. U.S. Department of Agriculture (USDA)	http://www.usda.gov/
Food Safety and Inspection Service (FSIS)	http://www.fsis.usda.gov/
Animal and Plant Health Inspection Service (APHIS)	http://www.aphis.usda.gov/
6. Environmental Protection Agency (EPA)	http://www.epa.gov/
7. U.S. Codex	http://www.fsis.usda.gov/OA/codex/index.htm
8. Links to All 50 State Departments of Public Health and Agriculture	http://www.fsis.usda.gov/OPHS/stategov.htm http://www.fda.gov/ora/fed_state/default.htm
9. Links to Food Safety Agencies and Universities	http://foodsafe.ucdavis.edu/fshttplinks2.html
10. Examples of National Consumer Organizations:	
American Council on Science and Health	http://www.acsh.org/
Center for Science in the Public Interest	http://www.cspinet.org/
Consumer Federation of America	http://www.consumerfed.org/
Consumers Union	http://www.consumer.org/
11. Examples of Industry Organizations:	
American Meat Institute	http://www.meatami.org/
Biotechnology Industry Organization	http://www.bio.org/
Grocery Manufacturers of America	http://www.gmabrands.com/
National Food Processors Organization	http://www.nfpa-food.org/

A. Laws and Implementing Regulations

12. The Constitution of the United States	http://lcweb.loc.gov/global/judiciary.html
13. Legislative Branch	http://www.house.gov/ http://www.senate.gov/ http://lcweb.loc.gov/global/legislative/congress.html
14. Executive Branch	http://www.whitehouse.gov/ http://lcweb.loc.gov/global/executive/fed.html
15. Judicial Branch	http://www.uscourts.gov/ http://lcweb.loc.gov/global/judiciary.html
16. Federal Food, Drug, and Cosmetic Act (FFDCA)	http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm
17. Federal Meat Inspection Act (FMIA)	http://www.fda.gov/opacom/laws/meat.htm
18. Poultry Products Inspection Act (PPIA)	http://www.fda.gov/opacom/laws/pltryact.htm
19. Egg Products Inspection Act (EPIA)	http://www.fda.gov/opacom/laws/eggact.htm
20. Food Quality Protection Act (FQPA)	http://www.fda.gov/opacom/laws/foodqual/fqpatoc.htm
21. Public Health Services Act (PHSA)	http://www.fda.gov/opacom/laws/phsvcact/phsvcact.htm
22. Administrative Procedures Act (APA)	http://www.fda.gov/opacom/laws/adminpro.htm

23. Federal Advisory Committee Act (FACA) http://www.fda.gov/opacom/laws/fedadvca.htm
24. Freedom of Information Act (FOIA), The Clean Water Act , The National Environmental Protection Act, The Safe Drinking Water Act, Federal Insecticide and Rodenticide Act (FIFRA): http://www.epa.gov/epahome/laws.htm

B. Risk Analysis and the United States Precautionary Approach

25. National Food Safety Initiative Report, 1997 http://www.foodsafety.gov/~dms/fsreport.html
Hazard Analysis Critical Control Point (HACCP) http://vm.cfsan.fda.gov/~lrd/haccp.html
26. USDA/FDA HACCP Training Programs and Resources Database http://www.nal.usda.gov/fnic/foodborne/fbindex/009.htm
27. Risk Assessment Site http://www.foodsafety.gov/~fsg/fsgrisk.html
28. Center for Veterinary Medicine, FDA http://www.fda.gov/cvm/fda/mappgs/fsiintro.html
29. Campylobacter in Poultry Risk Assessment http://www.fda.gov/cvm/fda/mappgs/ra/risk.html
30. *National Academy of Sciences http://www.nationalacademies.org/nas/nas/nashome.nsf
31."The Use of Drugs in Food Animals: Benefits and Risks" http://www.nap.edu/catalog/5137.html
32."Ensuring Safe Food : From Production to Consumption" http://www.nap.edu/catalog/6163.html
33. "Enhancing the Regulatory Decision-Making Approval Process for Direct Food Ingredient Technologies, Food Forum, Institute of Medicine" http://www.nap.edu/catalog/9453.html
34. "Understanding Risk: Informing Decisions in a Democratic Society" http://books.nap.edu/books/030905396X/html/index.html
35. World Health Organization (WHO) http://www.who.org/
36. Food and Agriculture Organization (FAO) http://www.fao.org/
37. Office of International Epizootics (OIE) http://www.oie.int/
38. Annex "Precaution in U.S. Food Safety Decision Making" http://www.foodsafety.gov/~fsg/fssystem.html
http://vm.cfsan.fda.gov/~dms/fs-toc.html

C. Dealing with New Technologies, Products, and Responding to Problems

39. Emerging Infections Program (EIP) http://www.cdc.gov/ncidod/dbmd/programs.htm
40. Antimicrobial Resistance http://www.fda.gov/cvm/fda/mappgs/antitoc.html
41. Foodborne Illness http://www.cdc.gov/ncidod/dbmd/foodborn.htm
http://vm.cfsan.fda.gov/~mow/foodborn.html
Foodborne Illness Education Information Center http://www.nal.usda.gov/fnic/foodborne/foodborn.htm

1 Transparency

Access to the Code of Federal Regulations	http://www.access.gpo.gov/nara/cfr/index.html
Office of the United States Trade Representative (USTR)	http://www.ustr.gov/
World Trade Organization (WTO)	http://www.wto.org/

B. System Accountability

Presidential Oversight	http://www.whitehouse.gov/WH/html/handbook.html
House and Senate Committees Oversight	http://thomas.loc.gov/
General Accounting Office	http://www.gao.gov/
U.S. Courts	http://www.uscourts.gov/

In the interest of showing how food safety is discussed within civil society, websites of organizations other than the U.S. government are included in this Annex. The U.S. government is not responsible for and does not necessarily endorse the content of those non-U.S. government websites.

1 March 2000

ANNEX II

Precaution in the United States' Food Safety Decision Making

Table of Contents

ANNEX II

A. Introduction

In this annex, the United States shows how precaution is embedded in its food safety system. This document should be treated as an attachment to the summary of the U.S. national food safety system. At its January 24-25, 2000 meeting, the ad hoc Committee on Food Safety of the Organisation for Economic Co-operation and Development (OECD) decided that each member could elect to prepare and submit an annex showing how precaution is part of its system, along with references to relevant publications, to supplement its summary of its food safety system.

A.1 A Food Safety System with Precaution as its Foundation

U.S. regulators have been world leaders in exercising precaution in regulatory systems for food and environmental safety, since before the turn of the last century. Always seeking to improve protection of human health and the environment, the United States welcomes this opportunity to exchange experiences and information on our approach and use of precaution, which has enabled the American people to enjoy a high degree of safety and well-being.

In the more than 100 years since the country's national regulatory system for food was put in place, it has evolved into today's modern and science-based food regulatory system, with a very high level of consumer protection and consumer confidence, a high degree of transparency, and extensive involvement by stakeholders.

In this annex, the United States discusses how precaution has long been an inherent part of the U.S. food safety system. It is inherent not only in the regulatory systems of national-level Federal agencies and the complementary regulatory systems of the 50 states, but also is part of the country's bedrock system of legal responsibility system for businesses, including the food industry, from coast to coast.

A.2 Producers' Responsibility for Caution

This report focuses upon the role of the U.S. regulatory system in assuring food safety. However, the success of this system can be understood only if one first grasps the legal duty of sellers of products in the United States, a legal duty enforceable by injured consumers under contract and tort law under the law of the states, and reinforced by transparency and publicity.

The U.S. food safety system has both "top-down" regulatory controls and "bottom-up" producer responsibility. The meshing and interplay between the authority and responsibility of regulators--and the responsibility of producers—have resulted in a food supply that is second to none in safety and a regulatory system that, while not perfect, is likewise second to none. (And governments and producers cannot do their jobs alone: consumers also play a key role in preventing food safety problems, through their own food handling practices, and academia and other elements of civil society likewise play a role in promoting understanding of food safety.)

At the foundation of the U.S. food safety system is the responsibility of food processors to exercise caution in marketing their products. Food processors are allowed to offer consumers only food that is safe. They may be held "strictly liable" if they fail to carry out their duty. "Strict liability" means that a processor who sells a food that causes injury to a consumer may be legally responsible even in the

absence of actual knowledge of the product's hazard. The legal responsibility includes both the possibility of a private lawsuit by any injured consumers and the possibility of regulatory actions. Also, processors must have a reasonable basis for believing their products to be safe; they cannot simply assume this is so. Factors in the caution exercised by producers are discussed in more detail at the end of the outline, in paragraphs 201-205.

In sum, the fundamental U.S. legal system generally places upon processors a duty of care to the public. On top of this fundamental legal system is strong regulatory infrastructure, administered by scientific food safety regulatory agencies at the Federal and State level.

A.3 Regulators' Caution in Food Safety Regulation under U.S. Statutes

Turning to law enforced by public officials, in the United States a combination of statutory law and case law provides regulatory agency officials with very broad authority to take strong precautionary measures (see Reference Lists III-V, below).

First and foremost, the law simply forbids the marketing of unsafe food. Anyone who violates this provision may be held criminally liable, the food may be seized and destroyed, and the establishment can be required to cease doing business until it complies with the law. The law obliges anyone who chooses to go into business selling food to others to take steps to ensure that only safe food is sold (see paragraphs 201-05, below). The regulatory law thus provides an entire additional layer of consumer protection that reinforces the general liability system.

General food safety policies and specific requirements and policies under key Federal statutes such as the Federal Food, Drug and Cosmetic Act (FFDCA), the Public Health Service Act (PHSA), the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the animal and plant health laws--and judicial decisions under these laws--show the precautionary approach in our system. Indeed, precaution is embedded in decision-making processes to ensure acceptable levels of protection.

The precautionary approaches taken are very much driven by the statutory mandates and regulations in question. This precaution is very much an inherent part of the relevant U.S. food safety statutes and regulations, as well as risk analysis policies and processes (both risk assessment and risk management).

A.4 Caution in Risk Analysis

Risk assessment procedures include several conservative assumptions about uncertainty. Under these procedures, uncertainty factors including the following are routinely identified and incorporated:

- An uncertainty factor to account for the susceptibility of sensitive subgroups; extrapolation from animal data to human application.

- A factor to account for other considerations relevant to potentially susceptible or sensitive subgroups.

- Factors to account for variations in the human population (including effects of age and gender).

- A factor to account for the implications of use of short-term data in assessing chronic effects.

- A specific factor/algorithm for use in the extrapolation from a Lowest Observed Adverse Effect level to a No Observed Adverse Effect level

- An acknowledgement (or identification) of, and an uncertainty factor incorporated to account for, incompleteness in the data base.

- Use of consumers in the high-percentage consumption category as a conservative assumption regarding exposure levels.

A.5 Complexity of Science and Variety of Precautionary Approaches

Within the context of U.S. food agencies' food safety responsibilities, precautionary approaches take different forms and are used at several points in the risk assessment and management regime in many areas, e.g., as to control of pathogens, food additives, or pesticides. Precaution is applied, not at one single point or in one single manner, but at various points depending upon the statutory regime and the underlying science.

What is striking about a review, such as this, of the precaution inherent in one country's food safety system is the variety and complexity of the scientific issues that regulators confront. What also is obvious is the improbability that any simple principle or model could serve as a useful compass to decision making, in the face of uncertainty, for a wide variety of complex issues.

A.6 The Food Safety Initiative

National food safety policies are tied together through the Food Safety Initiative (see Reference List I, below). Furthermore, as to risk analysis, U.S. scientific institutions have prepared a number of reports that describe generally the risk analysis policies and decisions of U.S. food agencies (Reference List II). U.S. statutes incorporate precaution (Reference List III), as do U.S. regulations, guidance documents, policies, programs, and decisions implementing the statutes (Reference List IV). Court decisions interpreting and enforcing the statutes uphold their precautionary approach (Reference List V). Articles and publications are useful in understanding how the U.S. food safety system works (Reference List VI), while others explain the history leading to today's system (Reference List VII).

B. Food Safety Agencies' Caution: An Overview

B.1 Food and Drug Administration (FDA)

FDA has exercised a precautionary approach in risk analysis-- specifically in risk assessment and risk management—since its origin, more than a century ago (see Reference List VII. below). Clearly, the history of food safety regulation in this country shows the evolution to today's highly preventive approach starting in colonial days with enactment of a Massachusetts statute in 1785 that forbade sale of "diseased, corrupted, contagious or unwholesome" food or drink, to the present.

The landmark triad of laws enacted more than 40 years ago on chemicals in food--the Pesticide Amendment of 1954, the Food Additives Amendment of 1958, and the Colour Additive Amendments of 1960—authorised the national government to better ensure that producers carry out their responsibility to produce only safe food with safe ingredients. "No substance could legally be introduced into the U.S. food supply unless there has been a prior determination that it was safe. By requiring the manufacturers to do the research a problem of unmanageable size was made manageable. Preventing violations through pre-

marketing clearance procedures gave consumers immeasurably better protection than merely prosecuting the few violations that could be proved after injuries were reported." Janssen, W. 1992. The U.S. Food and Drug Law: How It Came, How it Works (see paragraph 215, below).

Under the FFDCA, the sponsor of an additive is required to make an affirmative showing of safety; if this showing falls short, there is no approval even if there is no affirmative showing of risk. Thus, a strict "default zero" approach is used to control substances intentionally added to food. The law deems "unsafe" a food containing an unapproved food or colour additive (or pesticide, as will be discussed) unless a regulation has been issued approving this use.

Also, precaution in risk analysis decision-making, for example, may be exercised when the safety information on a hazard in a food is substantial but incomplete. This may be the case in performing a risk assessment on an additive where the knowledge of the toxicological behaviour of the substance may be well-characterised in animals but not in humans and uncertainty factors are employed to compensate for this lack of knowledge. Another example is when a clear food safety concern is known to exist but where there is a substantial lack of information on the entity causing the problem. This may be the case for a newly emerging food borne microbial pathogen. Precaution in risk management may also be employed when the risk assessment indicates significant uncertainty in the probability of the risk management options to achieve an acceptable level of risk. In these latter cases, conservative risk management decisions may be taken until such time as more detailed information on the agent is known.

Two FDA program offices, the Centre for Food Safety and Applied Nutrition (CFSAN) and Centre for Veterinary Medicine (CVM) administer key precautionary programs in the food safety area. Also, the compliance and enforcement arm of FDA, the Office of Regulatory Affairs, includes the FDA district offices throughout the country, whose inspectors, laboratories, compliance officers and other officials play a substantial role in both preventing, and responding to, food hazards.

B.2 Food Safety and Inspection Service (FSIS)

FSIS also has a long history of using precaution in addressing human health. The Federal Meat Inspection Act (FMIA) was originally passed in 1906 to stop the deplorable conditions in meat packing plants graphically detailed in Upton Sinclair's *The Jungle*. The provisions of the Act were so broadly written to address food safety concerns known at that time that no major revision was made to it until 1967, which is the same time Congress passed similar legislation for poultry inspection, the Poultry Products Inspection Act (PPIA).

The Jungle included descriptions of practices that could threaten human health, but also of diseases which animals' contract that may possibly be transmitted to humans. Considering that, at that time, there was scientific knowledge about the effects of these diseases on humans, the 1906 law was an early example of precaution in a food safety statute, and as a result, for nearly a century U.S. law has barred use in food of diseased animals.

The FMIA and PPIA, as amended, retain precaution as an important consideration. They remain very broadly written and have allowed FSIS to take into account all types of emerging food safety threats without need to seek statutory changes to address them. For example, in the late 1960s into the 1970s, the biggest food safety threat from meat and poultry was in the area of chemical contaminants. Under the adulteration provisions of both Acts, FSIS was able to easily revise its policies and practices to address these potential human health risks.

To meet the human health threat from microbial contaminants, the precautionary foundation to the FMIA and PPIA has also enabled FSIS to act quickly and forcefully – without making a statutory change. In October 1994, the FSIS Administrator announced that FSIS would immediately begin testing raw ground beef for the pathogen E. coli_O157:H7 and would consider raw ground beef adulterated (i.e.,

not eligible for use as human food) if it contained the pathogen. Federal courts have upheld this declaration.

Additionally, FSIS recently implemented its Pathogen Reduction/Hazard Analysis and Critical Control Points (HACCP) regulation. This regulation has precaution and prevention of food borne illness at its core and places the burden on industry to produce safe food and on FSIS to ensure industry meets its burden. The regulation is discussed in greater detail beginning in paragraph 36.

As for future food safety threats, FSIS believes it will continue to be able to address them and fully protect public health. Again, precaution is already present in the FMIA and PPIA, and the statutes provide more than enough latitude to allow the adoption of prevention, intervention, and control strategies throughout the food chain.

B.3 Environmental Protection Agency (EPA)

The EPA administers the FIFRA (see section A.4., above) and section 408 of the FFDCA (21 USC 348a). Under these statutes, EPA regulates the registration and use of pesticides in the United States and issues maximum residue levels, "tolerances," for pesticide residues in food. The objective of these statutes, concisely stated, is to protect public health and the environment.

Under FIFRA, sale of pesticides is prohibited, unless registered by EPA, and EPA also has authority to limit distribution, sale and use of pesticides. The FFDCA (21 U.S.C. 348a (a)(1)) also provides that any pesticide residue in food "...shall be deemed unsafe..." unless a tolerance or a tolerance exemption has been issued. EPA's "default zero" approach to pesticides is based on the determination that pesticides, as a general class of chemicals, are inherently hazardous. The requirement for EPA action before any use is permitted, in order to assure EPA can determine its safety and prescribe conditions of use, could be considered a precautionary approach. Precaution is embedded in EPA decision-making processes to ensure acceptable levels of protection. FSIS enforces EPA's pesticide tolerances as to meat and poultry, while FDA enforces EPA's pesticide tolerances as to other foods.

As part of the pesticide registration process, EPA may make certain risk management decisions in response to a lack of scientific data or information. For example, in extrapolating risk information from laboratory studies to humans, the level of risk (e.g., how much risk a particular level of exposure will cause) may be revised by a factor of 10 or more to provide a margin of safety in light of uncertainties in the extrapolation process. A factor of 10 approach may also be used to compensate for variabilities present in the testing process.

As part of the pesticide registration process, EPA makes certain risk management decisions. For example, the agency may prescribe conditions of use to limit human exposures and protect the environment. For example: some pesticides may be applied only by those trained and certified to handle the pesticide; protective equipment may be required; methods of application may be limited; and buffer zones around areas of pesticide usage may be required. These risk management steps protect farm workers and minimise unwanted environmental effects, as well as ensure food safety.

B.4 Animal and Plant Health Inspection Service (APHIS)

APHIS is part of the network of federal agencies with food-safety-related responsibilities. APHIS' primary role in this network is to protect U.S. agriculture from plant and animal pests and diseases. The agency implements federal laws pertaining to animal and plant health, international sanitary and phytosanitary regulation, regulation of veterinary biologicals and vaccines, control and eradication of introduced pests and diseases, and humane treatment of animals. APHIS also conducts research and operational activities to reduce bird, rodent, and predator damage to crops and livestock. APHIS programs are implemented through co-operative activities with other federal agencies, state and foreign

governments, and producers. APHIS also plays an important role in regulating biotechnology (see paragraph 125, below).

C. Precaution in Response to Newly Emerging Food Problems

The United States has also taken progressive action in response to newly emerging food problems. The current precautionary approach to antimicrobial resistance is an example (see paragraphs 141-147, below).

Also, starting in the late 1980's, food regulatory officials world-wide became concerned about bovine spongiform encephalopathy (BSE), or "mad cow" disease, and began to take steps to prevent the spread or introduction of BSE from abroad. For example, in 1989, APHIS barred the importation of beef and beef products from BSE countries (9 CFR Part 94). Shortly thereafter, FDA warned manufacturers of biological drugs for human use to source bovine materials needed for the drugs only from nonBSE countries.

As concerns spread, FDA in 1994 advised pharmaceutical and medical device manufacturers to provide information about products containing bovine materials and to consider obtaining components from BSE-free countries (59 FR 44591, Aug. 29, 1994). In 1996, FDA strengthened its import alerts to give FDA investigators greater latitude to detain bulk shipments from five BSE countries of high-risk bovine tissue for use in dietary supplements and cosmetics. Also in 1996, as information began to link the consumption of BSE-infected beef with a previously unrecognised form of Creutzfeldt-Jakob disease, FDA developed a regulation to prohibit the use of certain animal tissues in animal feed. (See 61 FR 24253 (May 14, 1996)) (advance notice of proposed rulemaking) and 62 FR 551 (proposed regulation to prohibit the use of animal protein in ruminant feed)). FDA published the final regulation to prohibit the use of animal protein from mammalian tissue in ruminant feed in 1997 (see 62 FR 30935 (June 5, 1997)).

D. Scientific Advice in Food Safety Risk Assessments

U.S. food agencies emphasise the importance of attracting and maintaining a cadre of top-notch scientists, in-house, to perform risk assessments. They also employ a range of techniques both to augment internal expertise and to provide a thorough vetting of scientific issues. Examples are:

- Advisory committee meetings (as with U.S. advisory committees, generally, these meetings are announced and open to the public), for example:

  - The National Advisory Committee on Microbiological Criteria, a standing committee established in 1988 to advise FSIS and FDA.

  - FDA's meetings before standing advisory committee meetings that permitted preapproval discussions, in public meetings, concerning approval of bovine somatotrophin (BST) and the final evaluation of the bioengineered tomato.

  - EPA's Scientific Advisory Panel, created by statute to advise EPA on certain pesticide regulatory activities.

  - Several committees that help EPA to implement the statutes it administers, e.g., the Tolerance Reassessment Advisory Committee (TRAC), which advises EPA on tolerance reassessments including a pilot process for reviewing organophosphate pesticide tolerances.

- Public meetings, e.g., the recent public meetings on U.S. policies on regulation and labelling of foods containing genetically modified organisms.

- Public meetings or expert consultations through partnerships, e.g., the meetings convened on Salmonella Enteriditis in eggs, E. coli 0157: H7 in ground beef, transmissible spongiform encephalopathies (TSEs), and modalities for effective training on good agricultural practice for fresh produce.

- Consideration of an issue by the Interagency Risk Assessment Consortium, consisting of all U.S. food agencies, which was established by the President's 1997 Food Safety Initiative to advance the science of microbial risk assessment or by the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), a partnership between the University of Maryland and U.S. food agencies.

- Referral of an issue to the National Academy of Sciences/National Research Council, e.g., FDA referrals on cyclamates and saccharin, and USDA referrals regarding meat and poultry inspection and biotechnology.

- Referral of an issue to the National Institutes of Health consensus conference, e.g., BST.

- Contracts with outside scientific bodies, e.g., FDA's use of the Federated Associated Societies of Experimental Biology (FASEB) for assistance on a number of scientific reviews, particularly concerning whether food substances were "generally recognised as safe."

- Use of co-operative agreements, e.g., USDA's agreement with the School of Public Health of Harvard University for a risk analysis of BSE.

- Participation in scientific discourse in the broad scientific community, through meetings, peer-reviewed journals, and Federal Register notices, e.g., how FDA gathered and used the mounting evidence on the association between diet and cancer or cardiovascular disease, in changing U.S. nutrition labelling and health claims rules.

- Seeking peer review on particular substances, e.g., FDA's arranging for peer reviews of assessments of the colour additive FD&C Blue No. 2 (21 CFR 74.102).

- Use of a Public Board of Inquiry (21 CFR Part 13), a panel of three scientists used in lieu of a trial-type public hearing to consider the safety of aspartame.

- Participation in international expert consultations of the World Health Organisation and/or Food and Agriculture Organisation.

E. Economic Factors

As a general rule, U.S. law requires cost-benefit analysis of regulations (Executive Order 12866, Regulatory Flexibility Act). This general rule does not apply where cost-benefit analysis is prohibited by law. Cost-benefit analysis is not applicable to most food safety decisions. Rather, these food safety decisions are based solely upon science and risk analysis. For example, FDA is not permitted to consider economic factors in determining whether a food additive, colour additive, or animal drug is safe, and therefore allowed to be approved. In these determinations, economic factors are forbidden at the risk management step as well as, of course, the risk assessment step. Likewise, EPA is generally not permitted to consider economic factors in determining whether, with respect to human dietary risks, a pesticide is "safe."

There are some situations in which consideration of economic factors in food safety decisions is required or permitted. For example, a 1994 statute created the Office of Risk Assessment and Cost-Benefit Analysis in USDA (Pub. L.103-354). This office's primary role is to review drafts of USA's "major regulations" to provide an added assurance that they are based upon sound scientific, technical, and economic analysis. A "major rule" is one that concerns human health, safety, or the environment and that has an annual economic impact of at least $100 million. For major USDA food safety regulations, this statute requires USDA to conduct a thorough analysis that makes clear the nature of the risk, alternative ways of reducing it, the reasoning that justifies the proposed rule, and a comparison of the likely costs and benefits of reducing the risk. The consideration of costs and benefits is for the purpose of identifying efficient ways of mitigating risk. This thorough analysis should describe the uncertainty and variability inherent in these analyses along with an evaluation of how these factors affect the outcome of the analyses. (Because few food safety regulations have exceeded the $100 million threshold for treatment as a major rule, the main contribution in the food safety area of the Office of Risk Assessment and Cost-Benefit Analysis, since its creation in 1995, has been its review of the Pathogen Reduction and Hazard Analysis and Critical Control Points proposed and final regulation.)

Further discussion of consideration of economic factors is found in paragraphs 209-213.

F. Reference Lists with Analysis on Precaution in U.S. System

What follows are Reference Lists with discussions showing how precaution is part of the U.S. food safety system and citations to relevant documents. The Table of Contents at the beginning of this Annex can help the reader to find specific topics.

Reference List I. General U.S. Food Safety Policies

1. Useful U.S. internet addresses are provided in a separate annex for both U.S. agencies and for several non-governmental organisations. For example, the following information on the Food Safety Initiative is derived from the U.S. government's food safety internet gateway site, www.foodsafety.gov.

2. On January 25, 1997, the President announced his food safety initiative. He directed the Secretaries of Agriculture and Health and Human Services and the Administrator of the Environmental Protection Agency to identify ways to further improve the safety of the food supply. Those agencies held public meetings with consumers, producers, industry, states, universities, and the public, and reported back to the President. The Report, issued in May 1997, was entitled *Food Safety from Farm to Table: A National Food-Safety Initiative*. To implement the recommendations in the report, USDA and HHS submitted joint budget requests for pathogen research, surveillance, risk assessment, inspection, and education for FY 98, FY 99 and FY 2000. Through this initiative, and other activities, HHS, USDA, and EPA have laid the groundwork for a strategic planning effort. In the May 1997 report, the agencies recommended a longer-term strategic planning effort to consider how to best address important challenges and make the best use of the agencies' limited resources.

3. The President's Council on Food Safety was established in August 1998 under E.O. 13100 to strengthen and focus U.S. efforts to co-ordinate food safety policy and resources. The Council was directed to: 1) develop a comprehensive strategic Federal food safety plan; 2) advise agencies of priority areas for investment in food safety and ensure that Federal agencies annually develop co-ordinated food safety budgets for submission to the Office of Management and Budget (OMB); and 3) ensure that the Joint Institute for Food Safety Research (JIFSR) establishes mechanisms to guide Federal research efforts toward the highest priority food safety needs.

4. A co-ordinated food safety strategic planning effort is needed to build on common ground and to tackle some of the difficult public health, resource, and management questions facing Federal food safety agencies. The draft strategic plan—which was the subject of public meetings held in July 1999 and January 2000-- focuses on not just microbial contamination but on the full range of issues discussed in the paper on the Scope of the Council's Comprehensive Strategic Food Safety Plan. The goal is to develop a comprehensive strategic long-range plan addressing the steps necessary to achieve a seamless food safety system including key public health, resource, and management issues on food safety. The plan will be used to set priorities, improve co-ordination and efficiency, identify gaps in the current system and mechanisms to fill those gaps, enhance and strengthen prevention and intervention strategies, and develop performance measures to show progress. The strategic plan is due to the President in July 2000.

5. In developing the strategic plan, the Council is taking into account the 1998 recommendations of the National Academy of Sciences (NAS) in response to a Congressional request for a study of the current food safety system (NAS/NRC, August 20, 1998, Ensuring Safe Food from Production to Consumption).

6. Prevention is central to the Food Safety Initiative. For example, the 1997 recommendations in *Food Safety From Farm to Table: A National Food-Safety Initiative* "are based on the public-health principles that the public and private sectors should identify and take preventive measures to reduce risk of illness, should focus our efforts on hazards that present the greatest risk, and should make the best use of public and private resources".

7. The report also recommended a new early-warning system for food borne disease surveillance, an interstate outbreak containment and response co-ordination, strengthened risk assessments, research, improved inspections and compliance, education, and a blueprint for a better food-safety system. All of these initiatives are underway.

8. As part of the Food Safety Initiative, in 1997 FDA, USDA, and EPA established an interagency risk assessment consortium at the Joint Institute of Food Safety and Applied Nutrition at the University of Maryland. The goal of the consortium is to co-operatively advance the science of microbial risk assessment. The agencies are working to further focus critical research needs and reach consensus on the priorities of those needs based on their potential to reduce the uncertainty of risk management decisions.

Reference List II. General Risk Analysis Policies and Articles

9. The U. S. food agencies also make use of documents on risk analysis produced at the international level, as well as ones produced at a national level. An example is the World Health Organisation's 1987 document setting forth "Principles for the Safety Assessment of Food Additives and Contaminants in Food." There are many similarities between the national and international documents, which is not surprising.

10. The United States has considered it a priority for our experts to participate actively in international activities in this area by the relevant bodies, particularly the World Health Organisation (WHO), the Food and Agriculture Organisation of the United Nations (FAO), and their joint food standards program, Codex Alimentarius, the authoritative body for establishment of international standards for food. (Also, OECD has produced documents relevant to risk analysis for pesticides, toxic chemicals, and bioengineered foods.) In participating in the development of documents on risk analysis at the international level, U.S. experts have contributed information about U.S. national practices of interest to others in the international food safety community, and the result is a body of international work that is highly congruent with national approaches. In this annex to the U.S. national summary, international references are omitted, as OECD is certain to include them in the report on relevant international food safety activities.

11. National Research Council, National Academy of Sciences (NAS/NRC) has studied many aspects of food safety. See www.nap.edu/catalog/9453.html Examples of its studies are:

- 1982. Diet, Nutrition and Cancer: Directions for Research.
- 1999. Enhancing the Regulatory Decision-Making Process for Direct Food Ingredient Technologies.
- 1999. Ensuring Safe Food: From Production to Consumption.
- 1975. Principles for Evaluating Chemicals in the Environment.
- 1982. Risk and Decision-Making: Perspectives and Research.
- 1983. Risk Assessment in the Federal Government: Managing the Process.
- 1994. Science and Judgement in Risk Assessment.
- 1996. Understanding Risk: Informing Decisions in a Democratic Society.
- 1999. The Use of Drugs in Food Animals: Benefits and Risks.

12. The U.S. Office of Science and Technology Policy (OSTP) has also done studies:

- 1981. Technologies for Determining Cancer Risks from the Environment.1
- 1982. Report on Risk Assessment Principles.
- 1984. Chemical Carcinogens. 49 FR 21594, 21598 (1984).

13. Gaylor, D. and Kodell, R.1980. Linear interpretation algorithm for low dose assessment of toxic substances. J. Environ. Pathol. Toxicol. 4:305. This is a peer-reviewed, seminal work in the area of models for use in quantitative risk assessment of toxic chemicals at low exposure levels. Its "linear-at-low-dose" model has been used extensively by FDA and EPA as the default, appropriately protective approach in the absence of sufficient scientific data establishing the validity of alternative approaches.

Reference List III: Precaution Embedded in Statutes

Federal Food, Drug, and Cosmetic Act (FFDCA) and Related Statutes

14. The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) (FFDCA) prohibits distribution in the United States, or importation, of food that is adulterated or misbranded (21 U.S.C. 331).

15. A food is “adulterated” (21 U.S.C. 342) if it bears or contains any poisonous or deleterious substance that may render it injurious to health (with stricter rules for added substances than for naturally occurring substances). The word “adulterated” applies to products or materials that are unsafe, defective, filthy, or produced under insanitary conditions.

16. The FFDCA forbids distribution of any food or food ingredient required to be approved by FDA and lacking such approval. For example, it deems “adulterated,” as a matter of law, any food containing an unapproved food or colour additive (21 U.S.C. 342). Similar provisions govern departures from

requirements as to use of veterinary drugs. The law covers food for human use and food for animals (both pets and food animals). Food irradiation and indirect additives, including food packaging containing substances that may become part of food, must be approved under the food additive regulations. Food and colour additive requirements are discussed in paragraphs 99-124, below.

17. An important development, beginning in the 1970s, was FDA's use of regulations "for the efficient enforcement of the Act" (FFDCA, 21 U.S.C. 371(a)), having the force and effect of law. Regulations "for the efficient enforcement of the Act" provide a broad array of regulatory controls, discussed below (paragraphs 73-76, 206). Although FDA's statutory food safety authority has not changed significantly in 40 years, except as to infant formula, nutrition labelling and dietary supplements, the interpretation of the authority by the agency, the Congress, and the courts has evolved in response to consumer protection needs, e.g., for regulations to prevent growth of pathogens. Dozens of court decisions have interpreted the FFDCA in the consumer's interest, as is discussed in the Reference List V. below, summarising several pivotal or representative cases.

18. Regulations are issued following a notice-and-public comment process under the procedural requirements of the Administrative Procedure Act (5 U.S.C. 553). The substantive authority for the regulations derives from the statute. For example, the statute forbids distribution of adulterated food (21 U.S.C. 331, 342). Citing to these provisions and to the general provision enabling regulations for the efficient enforcement of the FFDCA (21 U.S.C. 371 (a)), FDA can issue a regulation informing manufacturers of what they need to do to avoid running afoul of the statute. Court decisions upholding this regulatory approach thus uphold FDA's view that it possesses the flexibility under the FFDCA and other laws to develop regulations requiring the industry to take preventive steps so as to assure production of safe food. See paragraphs 73-76, Reference List V.

19. In regulating food safety, FDA relies not only on the FFDCA but also upon the Public Health Service Act (42 U.S.C. 241 et seq.) (PHSA). This law provides general and flexible authority for a range of activities to protect public health. This authority underlies the nation's hugely successful milk safety program as well as its shellfish and interstate transportation sanitation program. Specific authority in the PHSA for regulations to control communicable diseases has been delegated both to FDA to carry out its enforcement responsibilities and to the Centres for Disease Control (CDC) to carry out epidemiology and surveillance work. This authority is key to both agencies' activities to combat food borne illness, which are carried out in close co-operation with FSIS, when the outbreak implicates meat, poultry, or egg products.

Federal Meat Inspection Act (FMIA) and Related Statutes

20. The Federal Meat Inspection Act (21 U.S.C. 601 et seq.) (FMIA), is one of three important food safety laws administered by FSIS. It requires FSIS to administer an inspection program to ensure that meat and meat products moving in commerce, and for export, are safe, wholesome, and correctly marked, labelled, and packaged. This inspection program, which has as its goal the prevention of shipments of contaminated meat, is mandatory as to cattle, calves, swine, goats, sheep, lambs, and horses. Similar provisions apply to poultry (i.e., chickens, turkeys, ducks, geese, and guineas) under the Poultry Products Inspection Act (PPIA) and to egg products, under the Egg Products Inspection Act. While the origin of the FMIA lies in the precautionary legal concept that animal diseases can affect humans and, therefore, diseased animals should be prevented from being used for human food, the FMIA and PPIA are also flexible and precautionary enough to address today's other food safety concerns as well.

As is discussed below in the section on regulations and policies, these inspection programs are based upon application and enforcement of Hazard Analysis and Critical Control Points (HACCP) system, a fundamentally precautionary food safety system to be applied by producers and monitored and enforced by the federal and state authorities.

21. FSIS also monitors meat and poultry products in storage, distribution, and retail channels, and takes necessary compliance actions to protect the public, including detention of products, oversight of voluntary recalls, court-ordered seizures of products, administrative withdrawal of inspection, and referral for criminal prosecution.

FIFRA and Section 408 of the FFDCA

22. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA registers pesticides for use in the United States and prescribes labelling and other regulatory requirements to prevent unreasonable adverse effects on health or the environment. Furthermore, under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 348a), EPA establishes tolerances (maximum legally permissible levels, or MRLs) for pesticide residues in food. Tolerances are enforced by FDA for most foods and by FSIS for meat, poultry, and egg products.

23. Section 2bb of FIFRA and section 408 of the FFDCA mandate a single, health-based standard for all pesticides in all foods and provide special protections for infants and children. In addition, both statutes require periodic re-evaluation of pesticide registrations and tolerances to ensure that the scientific data supporting pesticide registrations and tolerances will remain up to date in the future. Other examples include FIFRA provisions that expedite the approval of safer pesticides.

24. Details about EPA's implementation of FIFRA and the pesticide provisions of the FFDCA may be found on the EPA homepage, http://www.epa.gov. Policy and guidance documents at various stages of development are listed at paragraphs 175 and 176, below.

25. The Environmental Protection Agency (EPA) is the principal Federal agency responsible for the safety of drinking water under the Safe Drinking Water Act (42 USC 300f). This work is carried out in close co-operation with States and municipal governments. FDA regulates bottled water, in close co-operation with EPA. FDA and FSIS carefully monitor the water used in food processing plants under their jurisdictions.

Animal and Plant Health Laws

26. APHIS' Plant Protection and Quarantine (PPQ) regulates and inspects imports of plants and plant commodities to prevent the accidental introduction of plant pests and diseases such as citrus canker and exotic fruit flies and noxious weeds. PPQ regulates the planting of genetically engineered crops prevent adverse impacts upon agriculture, and facilitates the export of U.S. plants and plant products by ensuring and certifying that they comply with the requirements of the importing country. PPQ also has programs to eradicate introduced plant pests and diseases.

27. APHIS' Veterinary Services (VS) regulates the importation of animals and animal products to prevent the accidental introduction of animal diseases, thus ensuring the health, quality, and marketability of U.S. animals and animal products. VS programs are intended to prevent the introduction of foreign animal diseases such as foot-and-mouth disease, classical swine fever, rinderpest, and BSE. VS also has programs to eradicate selected animal diseases such as bovine tuberculosis, brucellosis, and pseudorabies, some of which are food-borne and potentially transmissible to humans. VS participates in and provides guidance to industry sponsored quality assurance programs such as the National Poultry Improvement Plan (NPIP), the swine industry's pork quality assurance program for trichinella certification, and the sheep industry's scrapie certification and eradication program. Veterinary Services also licenses and monitors the production of veterinary biologicals and vaccines to ensure that these products are safe and effective. Similar to PPQ, VS facilitates the export of U.S. animals and animal products by ensuring and certifying that they comply with importing countries, sanitary regulations.

Interagency Agreements and Co-operation

28. The food safety initiative, described earlier, has greatly strengthened interagency co-operation on food safety. Co-ordination of food safety activities also takes place among APHIS, EPA, FDA, FSIS, and other agencies through interagency co-operative agreements and other means. For example, FSIS and FDA have an agreement to share information about potential enforcement problems in meat and poultry plants that are primarily under FSIS inspection.

29. To avoid both duplication and gaps, the meat, poultry, and egg product laws and the FFDCA contain provisions explaining their relationship to one another. Livestock being raised for food use are "food" under the FFDCA. Anyone involved in handling, transporting, or manipulating "food," as well as the "food" itself, falls under the jurisdiction of the FFDCA. Thus, meat, poultry, and egg products are foods remain "food" under the FFDCA and therefore can be reached by FDA except to the extent of the application and scope of the FSIS-administered laws. Bell v. Goddard, 366 F. 2d 177 (7th Cir. 1966) ("The Federal Food, Drug, and Cosmetic Act and the Poultry Products Inspection Act are complementary"); United States v. Articles of Food…Buffalo Jerky, 456 F. Supp. (D. Neb. 1978) (the Federal Meat Inspection Act does not derogate from the FFDCA but creates a separate area of concern, meat and meat products, over which USDA is given additional powers in the interest of protecting public health and welfare).

30. For example, farm animals destined for food use are food under the FFDCA. Inspectors of both FSIS and FDA possess authority to detain shipments of meat, poultry, or egg products that appear to be adulterated (21 U.S.C. 672 (meat), 467(a) (poultry), 1048 (eggs)). In most situations, however, FSIS exercises this authority. FDA approves veterinary drugs (except veterinary vaccines); food and colour additives for use in all food including FSIS-regulated products, and irradiation of all food including meat and poultry. Hence, the authority of the two agencies is complementary, highly consumer-protective, and characterised by very close interagency co-operation.

Federal-State Agreements and Co-operation

31. Food safety regulation is a matter of shared responsibility under the U.S. system. Under the Constitution, Federal laws have supremacy over inconsistent State laws, and States are not allowed to have laws that burden interstate or foreign commerce. In fact, however, the vast majority of State food safety laws present no issue concerning of inconsistency with Federal laws but, rather, complement the Federal laws and add resources to their enforcement. The FFDCA contains provisions for State officials to be commissioned ("deputised") to help enforce the Federal statute, i.e., the FFDCA. Furthermore, States have their own food safety statutes. For many years an association known as the Association of Food and Drug Officials has maintained and periodically updated a Model State Food and Drug Act that has been closely followed in most States' laws.

32. Many co-operative programs are carried out with the states, e.g., those under the PHSA, discussed above. Sometimes FDA-funded contracts provide for the conduct by the States of particular categories of inspections or other activities. As is discussed in paragraph 68, FDA has issued, and is promoting state and local government adoption of, a model Food Code governing restaurants, supermarkets, and food service establishments. The states' food safety role is particularly important as to the latter classes of establishments.

33. As for the FSIS food safety programs, since 1967 there has been a federal-state co-operative program under which FSIS helps fund and oversee state-conducted meat inspection programs. State inspection programs must be "at least equal to" the federal program. A similar program of federal-state co-operation has been in effect for poultry products since 1968 and for egg products since 1970. State-inspected products are not permitted to be shipped in interstate or foreign commerce.

States are authorised to enact meat laws aimed at protecting the health and well-being of its citizenry, but those laws need to be consistent with Federal laws. Mario's Butcher Shop and Food Centre, Inc. v. Armour and Co., 574 F. Supp. 653 (N.D. Ill. 1983).

34. EPA and APHIS likewise carry out an array of co-operative activities with the States.

Reference List IV: Examples of Precaution in Application of U.S. Statutes: Regulations, Guidance Documents, Policies, Programs, and Decisions

FSIS

http://www.fsis.usda.gov

35. An example of a precautionary approach is the decision by FSIS to treat E. Coli O157:H7 as an adulterant under the FMIA, even if the beef contaminated with such bacteria would injurious to health only if improperly cooked, is an example of the precautionary approach. This decision was upheld in Texas Food Industry Association v. Espy, 870 F. Supp. 143 (W.D. Tex. 1994), prior to implementation of the Pathogen Reduction and HACCP regulation, discussed below. The court explained that, under the FMIA, the product is adulterated if it contains a substance which may render it injurious to health and with E. Coli O157:H7, unlike many other pathogens, thorough cooking is necessary to protect consumers.

36. FSIS has put in place a new regulatory system for meat and poultry safety within the meat and poultry plants it regulates that has at its core the more effective prevention of food borne illness due to pathogens and other contaminants. The new, science-based system is improving food safety and making better use of agency resources.

The Pathogen Reduction and HACCP Regulation

37. This regulation was published on July 25, 1996 (61 FR 38805) and is now fully operational. The system is based upon Hazard Analysis and Critical Control Points, or HACCP. HACCP is a way for industry to control and prevent problems and ensure safe food by controlling the production process from beginning to end, rather than detecting problems at the end of the line. HACCP is widely recognised by scientific authorities and international organisations and is used extensively in the food industry to produce products in compliance with health and safety requirements.

38. The system has four major components. First, FSIS has required the plants it regulates to implement HACCP. This includes intrastate plants as well as plants in foreign countries wishing to export products to the United States. Second, FSIS-established food safety performance standards that plants must meet and is conducting testing and other activities to ensure those standards are met. Third, FSIS has provided training for its inspectors to provide the oversight necessary to ensure that industry is meeting regulatory standards. Fourth, FSIS has reorganised to strengthen its enforcement methods for dealing with plants that do not meet regulatory standards.

39. The regulation addresses the serious problem of food borne illness in the United States associated with meat and poultry products by focusing more attention on the prevention and reduction of microbial pathogens on raw products that can cause illness. It also clarifies the respective roles of government and industry in food safety. Industry is accountable for producing safe food. Government is responsible for setting appropriate food safety standards, maintaining vigorous inspection oversight to ensure those standards are met, and maintaining a strong enforcement program to deal with plants that do not meet regulatory standards.

40. The Pathogen Reduction and HACCP regulation: (1) requires all meat and poultry plants to develop and implement a system of preventive controls, known as HACCP, to improve the safety of their products, (2) sets pathogen reduction performance standards for Salmonella that slaughter plants and plants producing raw ground products must meet, (3) requires all meat and poultry plants to develop and implement written standard operating procedures for sanitation, and (4) requires meat and poultry slaughter plants to conduct microbial testing for generic E. coli to verify the adequacy of their process controls for the prevention of faecal contamination.

41. FSIS prepared extensively for the implementation of the final regulation by providing technical assistance to small plants, training its workforce, undergoing a reorganisation, and reforming its regulations to be consistent with HACCP. These steps help to make sure that compliance will, in fact, occur.

42. FSIS moved to the new system after nearly a century of experience with the traditional inspection program, with its emphasis on organoleptic (sight, touch, and smell) methods. The traditional program has been successful in removing diseased animals from the food supply and enforcing other consumer protection standards. At the time the first major law on meat inspection was passed, animal diseases were the major concern, and science had not advanced to the stage in which invisible hazards such as pathogenic micro-organisms would attract the attention of public health authorities. Since that time, however, animals have become healthier. Changes in the meat and poultry industries have resulted in products having a wider distribution, potentially affecting large numbers of people. In addition, the growing concern with microbial pathogens, and, in particular, emerging pathogens, and the development of new technologies to control pathogens on raw products has contributed to the need for new approaches to ensuring food safety.

43. Scientific support for new approaches to ensuring food safety has existed for some time. In the 1980s, the NAS issued the reports listed in paragraph 60, which supported the need for FSIS to better address pathogenic micro-organisms and to have industry implement systems that prevent food safety problems in plants. Despite overwhelming scientific support for change, progress occurred very slowly. In late 1992 and early 1993, however, an outbreak of E. coli O157:H7, attributed to undercooked hamburgers served at a fast-food restaurant, highlighted the weaknesses in the traditional system and provided a national impetus for ground breaking change.

44. Acting quickly to address the problem, USDA began by issuing a regulation requiring safe handling labels that address storage, cooking, and holding practices for raw meat and poultry products. In 1994, USDA declared E.coli O157:H7 an adulterant in ground beef and established a monitoring program for the pathogen in ground beef. USDA also began work on its Pathogen Reduction and Hazard Analysis and Critical Control Points (HACCP) rule, with the extensive public rulemaking process completed with publication of the regulation on July 25, 1996.

45. Under HACCP, a plant analyses its processes to determine at what points hazards might exist that could affect the safety of its products. These points are called critical control points (CCPs). Examples of CCPs are chilling; the cooking process; processing procedures, such as filling and sealing cans; and certain slaughter procedures, such as removal of internal organs. The location and number of hazards will differ greatly depending on type of facility, foods prepared, processing procedures used, and many other factors. Once the CCPs are identified, the plant must establish critical limits. Critical limits are usually expressed as numbers representing such parameters as time/temperature, humidity, water activity, pH, salt concentration, and chlorine level.

46. Critical limits may be in the regulations, such as the requirement that poultry are chilled to 40 degrees F., or they may be established by the plant based on the scientific and technical literature or recommendations of experts. Next, the plant establishes monitoring requirements for each CCP and the corrective actions to be taken when monitoring indicates there is a deviation from an established critical

limit. Examples of corrective actions are adjusting the process, holding and destroying all product if it cannot be brought into compliance, and developing an alternative process. The plant must also establish record keeping procedures that document the operation of the HACCP system and verify that controls are working as intended.

47. Under the new rule, all plants must develop and implement a HACCP plan for the food safety aspects of their processes. Plants are required to validate their own HACCP plans--that is, they must ensure that the plans do what they were designed to do. FSIS will not approve HACCP plans in advance but will review them for conformance with the final regulations.

Performance Standards for Salmonella

48. FSIS believes that HACCP systems must be combined with performance standards as a means of establishing the degree of protection HACCP systems must achieve. FSIS already has in place microbiological performance standards for ready-to-eat and other processed products, but, with one exception, such standards for raw products did not previously exist. (The exception is the current "zero tolerance" for the pathogen E. coli O157:H7 in raw ground beef.) Therefore, as part of the final rule, FSIS has established performance standards for Salmonella that slaughter plants, and plants that produce ground products, must achieve. The implementation dates for the standards correspond to the implementation dates for HACCP. Salmonella was selected because it is a major pathogen of concern, it is present on virtually all classes of raw food products in numbers large enough to detect, and its presence is an indicator that other pathogens may be present. FSIS expects that reducing the percentage of carcasses with Salmonella will lead to a reduction in other pathogens as well.

49. Performance standards for Salmonella are based on the current national baseline prevalence for Salmonella for each major species and product class. FSIS intends to revise its performance standards for Salmonella periodically, as new data become available, to further reduce the risk of food borne illness. FSIS will be conducting the Salmonella testing for slaughter establishments and establishments that grind products to determine whether they are meeting the pathogen reduction performance standards. The Agency will require corrective action when establishments are not meeting the standards.

50. Salmonella testing data will be available in accordance with the requirements of the Freedom of Information Act. In all cases, FSIS will provide an explanation of the purpose of the testing and the meaning of the data when data are provided.

Sanitation Standard Operating Procedures (SSOPs)

51. A sanitary environment is a basic prerequisite for preparing safe food. As of January 27, 1997, all meat and poultry plants were required to have in place a written plan--called Sanitation Standard Operating Procedures (SSOPs)—to address sanitation. The new regulation does not impose new sanitation requirements. Instead, it institutes a process to ensure better compliance with existing Federal sanitation requirements that focus on preventing direct product adulteration. A plant’s SSOPs describe all procedures it conducts daily to ensure effective sanitation, both before and during operations. Plants are also responsible for detecting, documenting, and correcting sanitation deficiencies and using that information to strengthen their sanitation control systems to prevent similar problems in the future. Inspectors will monitor plants’ adherence to SSOPs while continuing to look for, and require the correction of, problems after they occur. In this way, FSIS will verify that the SSOPs are maintained and effective, and will take appropriate action if a plant fails to comply with SSOPs. Since January 1997, FSIS has temporarily withheld the mark of inspection from about 20 plants and has moved to withdraw inspection from one plant, based on violations of the SSOPs.

Testing for Generic E. coli

52. Since January 1997, slaughter plants have also been required to test carcasses for generic E. coli as an indicator of the adequacy of the plant's ability to control faecal contamination, a primary avenue of contamination for pathogenic micro-organisms.

53. FSIS has adopted performance criteria for E. coli for each species of animal that reflect the frequency and levels the micro-organism on carcasses according to FSIS nation-wide baseline surveys. FSIS is using the term "criteria" because they are guidelines, not regulatory standards. FSIS will not use the test results by themselves to take any regulatory action, but will consider them in conjunction with other information to evaluate whether a problem exists that require regulatory action, including plant closure. The required frequency of E. coli testing is based on production volume.

Culture Change

54. Implementation of the Pathogen Reduction and HACCP regulation has required a significant change in the roles and attitudes of both inspectors and industry. In the past, some plants have relied on FSIS inspectors to identify deficiencies before the company would take action to correct them. Implementation of HACCP clarifies the respective roles of industry and FSIS. Businesses that produce food are accountable for its safety. They need to look at all the things that could possibly go wrong, ensure their systems prevent those problems, and take immediate action if a problem arises.

55. FSIS' role is to set appropriate food safety standards, maintain vigorous and continuous inspection oversight to ensure those standards are met, and take enforcement action when standards are not met through system failures. By clarifying the respective roles of industry and government, the Pathogen Reduction and HACCP regulation sets the stage for enabling FSIS to better target inspection and oversight on the most significant food safety hazards. Under the new system, instead of focusing only on individual problems in plants, FSIS inspectors and compliance personnel will evaluate whether plant systems are working as intended to prevent and control contamination.

56. The conceptual shift embodied in HACCP, in which industry better assumes its proper responsibility for food safety, enhances the importance of an effective enforcement program. The agency's goal is to address plant problems at early stages, making it unnecessary for FSIS to intervene to withhold the marks of inspection for any extended period.

57. FSIS has established a new strategy for enforcement to complement the new regulation and to provide a high level of public confidence. Under the new system, FSIS has established a link between a plant's ability to control processes and the eligibility of products to bear the marks of inspection. In other words, FSIS will base its obligation under the law, to find that products are not adulterated, on the continuous demonstration that a plant's sanitation and process control systems are working to prevent adulteration. Under traditional inspection, the finding that product was not adulterated was based on inspectors examining products to catch evidence of contamination.

58. FSIS has integrated its compliance staff into the field regulatory staff and assigned new roles to compliance officers to create a team approach to enforcement. In the past, compliance officers were primarily responsible for products in distribution channels and generally contacted plants only when following up on violations involving products that had already been distributed in commerce. Under the HACCP system, compliance officers are assisting inspectors in documenting failures of plant control systems and helping to ensure appropriate due process when enforcement actions are needed, including such actions as suspending the use of the inspection marks and formally closing plants, i.e., withdrawing inspection.

59. FSIS is carrying out other activities to complete the new regulatory approach. For instance, to improve the inspection component even further, FSIS is exploring what changes should be made to the current system of carcass-by-carcass inspection that inspectors carry out to prevent diseased animals from being used for food. FSIS believes this function remains critically important but that in light of improvements in process control that are occurring under HACCP, changes to the tasks currently performed by FSIS inspectors can be made to improve inspection effectiveness and make the use of inspection resources more productive. One objective is to increase resources available for follow-up as to products that have left the inspected plant.

References

60. NAS/NRC 1983. Meat and Poultry Inspection--The Scientific Basis of the Nation's Program.

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Centres for Disease Control and Prevention. March 17, 2000. MMWR (FoodNet data show decline in food borne illness).

FDA's Centre for Food Safety and Applied Nutrition (CFSAN)

HACCP and Related Regulations

HACCP Regulations

61. http://vm.cfsan.fda.gov/~lrd/haccp.html

As has been discussed, HACCP is a science-based, systematic approach to the identification, assessment of risk and severity, and control of the biological, chemical and physical hazards associated with a particular food production process or practice. FDA considers HACCP as a key part of the foundation of the U.S. food safety assurance program because HACCP, although simple in its basic concepts, is a sophisticated system for ensuring food safety. HACCP appropriately affirms that the food industry has the primary responsibility for producing safe food and the government has responsibility for providing a system of regulatory oversight.

62. In 1994, FDA published an Advance Notice of Proposed Rulemaking, entitled Development of Hazard Analysis and Critical Control Points for the Industry (59 FR 39888). In this document, the agency asked over one hundred questions regarding if, when, and how it should apply HACCP to industry segments. The comments received have been used by the agency in a variety of food safety activities.

63. FDA has undertaken a HACCP pilot program with volunteer food companies to aid in the understanding and evaluation of HACCP as it applies to various industries. The program has involved cheese, frozen dough, breakfast cereals, salad dressing, fresh and pasteurised juices, bread, flour and other products. The pilot program continues to provide FDA with additional experience in both evaluating companies' food control systems and gaining experience with audit-type inspections.

64. In 1995 the FDA published the seafood HACCP regulation, entitled "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products" (21 CFR Part 123). It took effect in December 1997. FDA recognised that change to an HACCP-based system of controls could be a significant challenge for the seafood industry, as well for the FDA and state regulators. Therefore, the effective date of the regulation was preceded by a two-year phase-in period to enable seafood processors to prepare for the new program. During this period, FDA worked with the Seafood HACCP Alliance (a consortium of Federal and state regulatory agencies, educators, and industry trade associations) to develop and deliver low-cost, nationally uniform training for processors. The training was designed to provide

processors with the kind of information necessary for them to develop and operate HACCP systems that would be in compliance with the regulation.

65. FDA also assembled guidelines for processors on how to develop their HACCP systems. Processors were given the opportunity to comment and participate in the development of the guidelines, called the "Fish and Fishery Products Hazards and Controls Guide." In addition, FDA has published three editions of answers to the most frequently asked seafood HACCP questions from regulatory and industry personnel, in a document called, "HACCP Regulation for Fish and Fishery Products; Questions and Answers." These documents aid industry in taking a properly cautious approach.

66. An important factor regarding the embrace of HACCP has been that the size of the food industry and the diversity of products and processes have grown tremendously--in the amount and kinds of foods produced domestically and imported. The need for HACCP in the United States, particularly in the seafood industry, was further fuelled by the growing trend at the international level to establish benchmarks for world-wide equivalence of measures to assure the safety of food products. The Codex Alimentarius Commission's 1997 adoption of HACCP set an international standard for food safety.

67. In April 1998, FDA proposed HACCP controls for fruit and vegetable juices (63 FR 20486).

68. Also, FDA has incorporated HACCP into the Food Code, a document that gives guidance to and serves as model legislation for state and territorial agencies that license and inspect food service establishments, retail food stores, and food vending operations in the United States. See Food Code, 1999 Recommendations of the United States Public Health Service, Food and Drug Administration (National Technical Information Service Publication PB99-115925).

Low-Acid Canned Food Regulation (LACF)

69. http://vm.cfsan.fda.gov/~comm/lacf-toc.html

As a result of several outbreaks of botulism from consumption of improperly processed canned food products in the early 1970s, the National Food Processors Association (then the National Canners Association) petitioned FDA to adopt a comprehensive regulation which would describe good manufacturing practices for canned foods. The resulting regulations, currently found in 21 CFR Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers, are frequently cited as the first regulatory use of HACCP concepts in the food industry. FDA later promulgated similarly styled regulations for the production of acidified food (AF) products (21 CFR Part 114, Acidified Foods). The LACF and AF regulations may be enforced through the emergency permit control under section 404 of the FFDCA and 21 CFR Part 108, as well as through other relevant remedies under the FFDCA (seizure, criminal prosecution, etc.).

70. The purpose of 21 CFR Parts 108, 113, and 114 is to assure safety from harmful bacteria or their toxins, especially the deadly Clostridium botulinum (C. botulinum). This assurance can be accomplished only by adequate processing, controls, and appropriate processing methods, such as cooking the food at the proper temperature for sufficient times, adequately acidifying the food, or controlling water activity. Together these regulations have been very successful in helping to assure the safety of canned food products.

Good Manufacturing Practices (GMPs)

71. The establishment of regulations on current good manufacturing practices (GMPs) (21 CFR Part 110) aided in the implementation of the statutory provisions that deem adulterated food that has been held under insanitary conditions (FFDCA, 21 U.S.C. 342(a)(4)). GMPs require industry to take steps to avoid the contamination of their food. For example, firms must take steps, including GMPs, to guard against

cross-contamination of food by allergens (e.g., traces of peanuts in bakery products not labelled as containing peanut, due to failure through GMPs to control a processor's moving from production of peanut-containing cookies to non-peanut-containing cookies).

72. Susceptible individuals can die or suffer serious illness, due to anaphylactic reactions, if they consume products that contain unlabeled traces of the substances to which they are allergic. Accordingly, strict adherence to GMPs by processors, backed up by inspections, voluntary recalls, and enforcement by FDA and partner agencies at the State level, comprise a lifesaving form of precaution in the U.S. food safety system.

Legal Authority for HACCP, LACF, and GMP Regulations

73. FDA's HACCP, LACF and AF, and GMP regulations are based upon a solid body of case law interpreting the statute as authorising regulations to guard against food adulteration. Indeed, courts have not only upheld, but have encouraged, FDA's use of its authority for regulations to implement general statutory provisions such as those forbidding food adulteration.

74. Courts have actually encouraged FDA to issue detailed regulations and guidance specifying steps to be taken to assure that a reasonable degree of care and cleanliness is accorded the production of food. See e.g., United States v. Article of Food…Pasteurised Whole Eggs, 339 F.Supp. 131, 141 (N.D. Ga. 1972).

75. The FFDCA "imposes upon persons exercising authority and supervisory responsibility reposed in them by business organisation not only a positive duty to seek out and remedy violations but also, and primarily, a duty to implement measures that will insure that violations will not occur." United States v. Park, 421 U.S. 658 (1975).

76. Many of the resulting regulations incorporate precautionary approaches, e.g., United States v. Nova Scotia Food Products, 568 F.2d 240 (2d Cir.1977) (regulation specifying requirements for processors of smoked fish); National Association of Pharmaceutical Manufacturers v. FDA, 637 F.2d 877 (2d Cir.1981) (good manufacturing practices). The regulations may require that food producers use precaution in their marketing of food products, with the objectives of preventing the marketing of unsafe food and assuring preparedness for remedial actions if mishaps occur. For example, in National Confectioners Association v. Califano, 569 F.2d 690 (D.C. Cir. 1978), the court upheld an FDA regulation requiring the manufacturers of certain food products to use product coding, and maintain records, so as to facilitate product recalls in the event of a future problem with the food.

Contaminants: Tolerances, Regulatory Limits, and Action Levels

77. FDA's Total Diet Study (TDS) has provided data on dietary intake of food contaminants for almost 40 years. Since its inception in 1961 as a program to monitor radioactive contamination of foods following atmospheric nuclear testing, TDS has grown to encompass residues of pesticides, industrial chemicals, toxic and nutritional elements, vitamins, and radionuclides. In all instances, analyses have been performed on foods prepared for consumption, so that the final results provide a realistic measure of human intake. (More information on the TDS can be found at www.fda.gov, under foods.)

78. Part of the U.S. precautionary approach to food safety is FDA's use of food additive control, tolerances, binding regulatory limits, and advisory action levels to control unavoidable contaminants in food that may be poisonous or deleterious to health (21 U.S.C. 342, 346; 21 CFR 109.4). For example, FDA minimised food sources of lead through a series of restrictions. FDA has limited permissible levels of aflatoxin in a way that applies pressure upon producers of peanuts and corn to minimise their occurrence. 39 FR 42751 (1974). Other examples are the tolerances for polychlorinated biphenyls (PCBs) (21 CFR 109.15, 109.30) and for lead in ceramic ware (109.16) as well as many action levels, which are

posted on the FDA internet homepage (www.fda.gov). In 1999, USDA and FDA restricted imports of products that might be dioxin-contaminated.

79. Early cases concerning FDA's authority to regulate chemicals showed a precautionary approach inherent in the food adulteration provisions. "The statute on its face shows that the primary purpose of Congress was to prevent injury to the public health by the sale and transportation … of adulterated foods… As against adulteration, the statute was intended to protect the public health from possible injury by adding to articles of food consumption poisonous and deleterious substances which might render such articles injurious to the health of consumers." United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1914) (interpreting language appearing in both the Food and Drugs Act of 1906 and the FFDCA). "It is not required that the article of food containing added poisonous or other added deleterious ingredients must affect the public health, and it is not incumbent upon the Government in order to make out a case to establish that fact… Congress doubtless took into consideration that flour may be used in many ways, in bread, cake, gravy, broth, etc. It may be consumed, when prepared as a food by the strong and the weak, the old and the young, the well and the sick; and it is intended that if any flour, because of any added poisonous or deleterious ingredient, may possibly injure the health of any of these, it shall come within the ban of the statute."

80. This case was one of several early U.S. government cases that "helped establish, in practice and in law, a conservative regulatory policy and a cautious commercial attitude toward artificial ingredients and other chemicals added to foods," S. Junod. 1999. Bleached Flour: The Supreme Court Mandates Regulatory Science. FDLI Update. 1: 16.

Food and Colour Additives

Background

81. Beginning in 1950, a Select Committee of Congress met to consider the implications of the "chemo-gastric" revolution in food production and preparation that had occurred following World War II. Out of these hearings came three food safety laws that put the burden for insuring food safety squarely on the backs of food manufacturers and producers: a 1954 law on pesticides, a 1958 law on food additives, and a 1960 law on colour additives. All three laws apply to both substances in food for human use and substances in food for animal use.

82. These amendments exemplify application of a precautionary approach in regulating food safety but were needed, in part, to create a means of securing governmental approval of chemicals for use in food. Lab testing may have shown the chemicals to be toxic when used at high levels, and yet the chemicals, with adequate uncertainty factors, can be used safely in food. An example of the U.S. law on the eve of these amendments is Flemming v. Florida Citrus Exch., 358 U.S. 153 (1958). In this case, the Supreme Court held that FDA could not allow any colour that had been shown to be toxic in animals, a ruling that essentially disabled FDA from continuing the approval of virtually all colour additives. Thus, a chief purpose of the Colour Additive Amendments of 1960 was to restore a "safety in use" standard for the approval of colour additives (with a stricter rule retained for carcinogenic additives, as will be discussed).

83. During the nearly half century since the enactment of these three basic precautionary statutes, a vast quantity of publications have been issued to explain, or to apply, these laws. This section covers the highlights of FDA's implementation of the food and colour additive laws, with a particular emphasis upon their precautionary features.

84. Later in this document, in paragraphs 139-173, are examples of precaution in related law administered by FDA as to residues of veterinary food and drugs for food animals, followed by information in paragraphs 174-181 on the recently revised pesticide laws, administered by EPA.

85. Although the 1954 Pesticide Additive Amendment did not include an anticancer clause barring the approval of a product found to induce cancer in man or other animals, FDA very quickly encountered a decision about carcinogenic pesticides. The Pesticide Additive Amendment allowed any pesticide to be registered but gave FDA the authority and option to establish a zero tolerance for residues in crops. This authority (later transferred to EPA, in 1970) put the burden squarely on farmers to use pesticide chemicals according to the label directions to ensure that no residues remained for ingestion by consumers.

86. In 1959, this provision was tested when it was discovered that carcinogenic aminotriazole residues remained on some portion of the nation's cranberry crop. In this highly publicised episode, occurring just before the traditional U.S. Thanksgiving holiday in which cranberries are an expected dish, the Secretary of Health, Education and Welfare declared that no cranberries would be marketed that year without clearance from the nation's food safety scientists at the FDA.

87. Just one year before the cranberries episode, reflecting the uncertainty of that era (when knowledge was know to be inadequate as to the causes of cancer, the relationship between diet and cancer, and the scientific testing methodology for cancer causing agents), Congress had adopted the precautionary approach first advanced by Congressman James Delaney. Junod, S. 1994. Chemistry and Controversy: Regulating the Use of Chemicals in Food, 1883-1959.

Under both the 1958 Food Additives Amendment and the 1960 Colour Additives Amendment, the Commissioner of FDA is prohibited from approving the addition of any substance to the food supply that has been found to cause cancer. The wisdom of adopting such a strict prohibition was widely debated, its scientific grounding was often questioned, and the decisions made under the Delaney clause were challenged. The legislative history of the Food Additive Amendments shows that Congress recognised that perfect certainty and zero risk were not real possibilities. Nonetheless, many scientists, as well as consumer groups, supported the provisions. Scientific advances have deepened confidence in the methodology used to determine human risk from ingested carcinogens, but the Delaney clause has remained in place as a precautionary statement about the need to exercise caution in considering the addition of potential carcinogens to the food supply.

General Safety Standard and Delaney Clause

88. The standard for decision making under U.S. food additives law (21 U.S.C. 348) includes both a general food safety standard and a special rule for carcinogens. The general food safety standard provides that FDA shall not approve a food additive petition "if a fair evaluation of the data … fails to establish that the proposed use of the food additive, under the conditions of use in the regulation will be safe…"

89. Immediately after this language is the Delaney clause (sometimes called the Delaney proviso): "Provided, that no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labelling and reasonably certain to be followed in practice, such additive will not adversely affect the animal for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g)) in any edible portion of such animal after slaughter or in any food…"

Enactment of Additional Laws

90. In 1960, the Colour Additive Amendments became law and also included both a general safety clause and a Delaney clause, as well. The third Delaney clause was enacted in 1968, as part of the Animal Drug Amendments passed that year to streamline duplicative regulatory requirements. The purpose of the

1968 Act was to ensure that manufacturers of animal drugs for food animals could submit a single application, the new animal drug application, instead of both a new drug application and a food additive petition. The animal drug Delaney clause was thus a carry-over from the food additives law. Thus, there actually are three Delaney clauses--for food additives, animal drugs, and colour additives (21 U.S.C. 348(c)(3)(A), 360b(d)(1)(H), and 379e(b)(5)(B). They are similar, and therefore are treated as one in this document.

91. The Colour Additive Amendments "reflect a Congressional and administrative response to the need in contemporary society for a scientifically and administratively sound basis for determining the safety of artificial colour additives, widely used for colouring food… The Amendments reflect a general unwillingness to allow widespread use of such products in the absence of scientific information on the effect of these products on the human body… A colour additive would be permanently listed if those desirous of producing it had proven to the satisfaction of the Commissioner that it was safe for its intended use." Certified Colour Mfg. Ass'n v. Mathews, 543 F. 2d 284, 286-87 (D.C.Cir. 1976).

92. Over time, however, the Delaney clause as a per se risk management law presented some challenges to FDA and to regulated industry, as is discussed in the articles cited in paragraphs 122-123.

Regulations and Guidance Documents

93. The general safety standard is elaborated in 21 CFR 70.3 and 170.3: "Safe" means that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the colour or food additive. A similar definition of "safe" is used for additives in animal food and feeds. Other regulations involving a precautionary approach are found in 21 CFR 70.40, 70.50, 170.20, and 170.22.

94. FDA. 1982. Toxicological Principles for the Safety Assessment of Direct Food Additives and Colour Additives (original FDA "Red Book"). FDA announced the availability of this influential guidebook through a notice in the Federal Register on Oct. 15, 1982 (47 FR 46141). This 253-page book shows how precaution is inherent in the U.S. risk assessment process for these additives. The testing recommended satisfying the risk assessment process thus assures that decisions as to approval are both science-based and consistent with legal criteria. This book contains lists of references to publications showing the precaution of the U.S. system (pp. 62- 68, 128-29, 139-40, 152-53, 166-67, 180-81, 195, 204-06, 247). Considerations of space forbid more detailed description other than this cross-reference to those lists, along with a few quotations from the book itself to give a flavour of the agency's approach in this area.

> The last quarter century has been a period of change and progress in the fields of regulatory toxicology and analytical chemistry… Today, toxicological criteria and standards are generally more rigorous and test endpoints are more sensitively measured than 25 years ago… Today there is increased emphasis on understanding the potential of a compound to cause specific types of toxicity such as reproductive, teratological, behavioural or mutagenic effects… A growing base of experimental data now permits at least tentative predictions of toxic potential of compounds based upon knowledge of their molecular structures (pp. 7-8).

95. The Red Book also includes a detailed discussion of "Criteria for Assessment of Safety: the Concept of 'Concern':"

> The degree of effort expended in reducing uncertainty about the safety of an additive ought to relate in some concrete way to the likelihood that the substance poses a potential for health risk to the public…[known as] a 'principle of commensurate effort'… For this purpose the common word 'concern' takes on a more specialised meaning with respect to the variables such as exposure and toxicity per unit doses… For this purpose the Degree of Concern can be thought of as a relative

> measure of the degree to which the use of an additive may present a potential hazard to the public health. It must therefore simultaneously depend on, 1) the degree to which exposure exceeds the level justified on the basis of toxicological information, and 2) The nature and severity of any adverse toxic effects that are predicted to occur on the basis of the same information (pp 18- 19).

96. The document goes on to explain related concepts such as Level of Concern (p. 20), Exposure (p. 21), Structure of a compound (p. 22), types of testing for each level of concern (pp. 22-28), and guidelines for toxicological tests (pp. 28-end).

97. In 1993, FDA announced its proposed revision of the Red Book and solicited comments via the Federal Register and scientific meetings (58 FR 16536, Mar. 29, 1993); FDA later extended the comment period for an additional 100 days (see 58 FR 40151, July 27, 1993)). FDA sought comments as part of open communication with scientists to ensure that precaution is built into the agency's decision making for food and colour additives, consistent with the views of the larger scientific community, and also to avoid recommending procedures that do not add to safety. Based on the comments received, FDA is making changes in the draft revision for future publication. In the meantime, sponsors may consult both the 1982 version and the 1993 draft revision in developing data intended to show that additives are safe.

98. FDA, Guidance Document, Estimating dietary exposure to direct food additives and contaminants, http://vm.cfsan.fda.gov/list.html. This document includes an extensive discussion of uncertainty, use of default assumptions, and ways to refine estimates to reduce uncertainty and allow for use of values/assumptions other than default, where justified.

Decisions on Food and Colour Additives: Related Policies

99. FDA maintains positive lists of permitted food additives (21 CFR Parts 172-80) and colour additives. The agency also maintains lists of substances of which FDA is aware that were prior-sanctioned (21 CFR Part 181); these substances, e.g., nitrates and nitrites (21 CFR 181.33, 181.34) were allowed by FDA or USDA before the enactment of the Food Additive Amendments of 1958.

100. Also published are lists of substances found generally recognised as safe (21 CFR Parts 182-186) as well as those banned from use in food (21 CFR Part 189). These lists are not complete as to allowed or disallowed substances but are a useful starting point as to what substances are allowed in food to be distributed in the United States. See 21 CFR 170.30(d), 189.1(b).

101. Diethylpyrocarbonate. 1972 (37 FR 15426). In this final rule, FDA rescinded a previous approval for the food additive diethylpyrocarbonate, a yeast inhibitor for use in beverages. The compound decomposes to ethanol and carbon dioxide. However, in the presence of ammonium ions (not uncommon in certain beverages), urethane, a carcinogenic chemical, may also be formed, albeit in small amounts. This document also illustrates the limited range of risk management possibilities open to FDA before the development of a policy entailing the use of formal quantitative risk assessment procedures for informing decisions regarding carcinogenic contaminants or impurities in food and colour additives. (See the discussion below, in paragraph 113, of a 1988 decision on a related substance, dimethyl dicarbamate; the 1988 decision showed the enhanced sophistication of, and confidence in, quantitative risk assessment procedures in making an appropriate risk management decision in a similar situation.)

102. Sometimes the studies simply are not sufficient to determine that an additive is safe and that there is no carcinogenicity issue. Red No. 2 and Red No. 4 are examples.

103. Red No. 2. 1976 (41 FR 5823). Termination of Provisional Listing and Certification of FD&C Red No. 2. This document describes the basis for FDA's delisting (banning of the use) of FD&C Red No. 2 including referral of the data to a Toxicology Advisory Committee.

104. Red No 2. 1980 (45 FR 6252). Denial of Petition for Permanent Listing. Commissioner's Decision; Denial of Petition for Permanent Listing; Final Decision. 45 FR 6252 (Jan. 25, 1980). "The petitioner's burden to show the safety of a colour additive by adequate studies has a critical effect on the outcome of this proceeding…the petitioner has not, in my judgement, shown through adequate studies that Red No. 2 is not a carcinogen. Accordingly, the petition to list the colour additive for permanent use must be denied. This determination does not mean, however, that Red No. 2 has been found to be a carcinogen. The existing studies are not sufficient to show definitely either that it is a carcinogen or that it is not. The questions about its possible carcinogenicity are simply unresolvable on this record. In this type of situation, the petition must fail because it is insufficient at present to meet the statutory requirement that safety be affirmatively shown with reasonable certainty."45 FR 6253. The Commissioner's decision affirmed the initial decision of the Administrative Law Judge following an evidentiary hearing held in response to the petitioner's objections to the FDA decision to deny their petition. Corwin, E., and Pines, W. April 1976.Why FDA Banned Red No. 2. FDA Consumer.

105. Red No. 4. 1976 (41 FR 41853). Termination of provisional listing. As with Red No. 2, the petitioner's studies failed to show safety, and the petition was denied. 1983 (48 FR 48533). Commissioner's decision denying permanent listing.

106. Acrylonitrile. 1977 (42 FR 48528). Acrylonitrile was permitted for certain uses in the fabrication of beverage containers following the passage of the Food Additives Amendment of 1958. Subsequently, the development of improved methods for detection of migration of acrylonitrile into the contents of the containers raised questions regarding the safety of this use. In 1974, FDA placed limitations upon the use of acrylonitrile in food packaging, pending submission of toxicological data by manufacturers in support of the safety of the substance.

107. Thereafter, for five years (1979-84), FDA employed provisional measures and a precautionary approach to assuring the safety of a substance in food packaging that might migrate to food. "The Commissioner concludes that it is in the public interest to act prudently, albeit not definitively, at this time on the acrylonitrile copolymer beverage containers." 42 FR 13546. The sponsor challenged this decision, claiming that the minute quantities migrating from the acrylonitrile bottles did not constitute a health hazard. The U. S. Court of Appeals allowed the stay to remain in effect while a hearing was held and until the Commissioner could issue a final decision.

108. The agency did eventually, based on the science and the law, and following fair and transparent procedures, allow the material to be used, after concluding that it is safe.

109. As this case indicates, FDA regulates food packaging as a form of "indirect" food additive. For regulations on indirect food additives, including food packaging materials, see 21 CFR 170.39, 171.8, and 174.6.

110. FDA. 1982 (47 FR 14464). This general policy for regulating carcinogenic chemicals in food and colour additives discusses the basis for proposed regulations regarding the assessment of carcinogenic chemicals that might be present as contaminants or impurities in food and colour additives. It addresses such factors as exposure estimates, dose-response relationships, and choice of algorithm(s) for use in quantitative risk assessments and shows how precaution is an inherent part of this process.

111. FDA. 1982 (47 FR 24278). D&C Green No. 5. 1982 (47 FR 24278). Again, this approval was based upon the constituents policy.

112. A consumer opposed to this policy challenged the decision, and in Scott v. FDA, 728 F. 2d 322 (6th Cir. 1984), the court upheld FDA's decision to approve D & C Green No. 5 based upon the constituents policy. Its opinion summarised FDA's assessment of the cancer risk associated with human exposure to the trace levels of p-toluidine present in Green No. 5, and observed that the petitioner "does

not contest the validity of the tests employed by FDA in determining that [the colour] was safe…The FDA's conclusion that the risk levels ascertained after testing D&C Green No. 5 … were so low as to preclude a reasonable harm from exposure to the additive within the meaning of the General Safety Clause, is also in accordance with the law." 728 F.2d 325.

113. Dimethyl dicarbamate. 1988 (56 FR 40502). In this final rule, FDA approved the use of the food additive dimethyl dicarbamate, a yeast inhibitor for use in beverages. As in the case of diethylpyrocarbonate (above), the additive decomposes, eventually, to methanol and carbon dioxide. However, in the presence of ammonium ions (not uncommon in certain beverages) methyl carbonate, a carcinogenic chemical, may also be formed, albeit in small amounts. This document describes how FDA used formal quantitative risk assessment procedures to estimate the upper-bound limit of carcinogenic risk to humans posed by urethane generated by decomposition of the additive. The agency concluded that the potential risk was sufficiently low that the additive would be safe for the requested use.

Food Irradiation Regulated Under Food Additive Law

114. The statutory definition of food additives (21 U.S.C. 321(s)) includes use of sources of food irradiation in food processing. Therefore, irradiation may not be used on food for sale in the United States without FDA approval. See 21 CFR 179.26 for existing approvals such as use of irradiation for spices, poultry, and ground meat.

Labelling Additives to Alert Sensitive Individuals to Their Presence

115. FD&C Yellow No. 5. 1979 (44 FR 27212; 21 CFR 74.340(d)(2)). FDA required label declaration of this colour, due to mounting evidence of allergic-type reactions to FD&C Yellow No. 5. With this action, persons sensitive to the colour could avoid it. There was no justification for banning the additive, as labelling dealt with the issue.

116. Similar considerations led to a requirement for the following statement on food containing aspartame, to protect susceptible individuals against harm without denying the public a generally safe, useful substance: "Phenylketonurics: Contains phenylalanine" (21 CFR 172.804(d).

FSIS Authority over Additives and Irradiation

117. FSIS has the authority to promulgate regulations prohibiting or restricting the use of food additives in meat products. Chip Steak Co. v. Hardin, 332 F. Supp. 1084 (D.C. Cal. 1971). FSIS also carries out its own review of irradiation of meat and poultry.

118. As part of the Administration's National Performance Review, FSIS has published a new regulation on its approval processes for additives (Dec. 9, 1999). FDA and FSIS cooperate on approvals of additives and irradiation processes involving meat and poultry.

References

119. FDA. 1984. Procedures for carcinogenic risk assessment. Food Technology. This article presents an overview of scientific risk assessment techniques and their relationship to the FDA decision-making process.

120. Lipman, A. 1998. Regulation of Food Ingredients in the U.S.A. Proceedings, Global Conference on Natural Colours and Flavours. Intertech Conferences, Portland, ME. This paper describes the conservative approach mandated by law that all colour additives must be listed before they can be used and describes FDA's scientific and administrative requirements for information needed to support listings.

It references guidelines available from FDA on chemistry and toxicology requirements. Descriptions of the petition process and the strict interpretation of colour additive regulations are included.

121. Lipman, A.1995. Safety of Xanthene Dyes According to the U.S. Food and Drug Administration. American Chemical Society Symposium Series, "Light Activated Pest Control." J. R. Heitz and K. R. Downum, eds. American Chemical Society: Washington, D. C. 616: 34-53.

122. Merrill, R. 1978. Regulating Carcinogens in Food: A Legislator's Guide to the Food Safety Provisions of the Federal Food, Drug, and Cosmetic Act. Mich L. Rev. 77: 171.

123. Merrill, R. 1988. FDA's Interpretation of the Delaney Clause. Yale J. on Reg. 1:77. "FDA's standard risk assessment procedures are calibrated to avoid underestimating human risk."

124. Scheuplein, R. 1987. Risk Assessment and Food Safety: a Scientist's and Regulator's View. Food Drug Cosm. L. J. 42: 249.

Biotechnology (FDA, APHIS, and EPA)

A Thorough, Precautionary Review Process

125. The U.S. government's thorough, precautionary review process for bioengineered plants and resulting foods has been well-documented in U.S. food safety agencies' documents and also at the Edinburgh conference that is part of the OECD ad hoc food safety review. Therefore, in consideration of space limitations, this discussion can (like others in this document) be abbreviated.

Three U.S. food agencies share responsibility for regulating agricultural biotechnology. APHIS is responsible for assuring that the growth of bioengineered plants does not harm the agricultural environment. EPA is responsible for assuring the human and environmental safety of pesticidal substances engineered into plants. FDA is responsible for assuring that foods derived through bioengineering are as safe as their traditionally bred counterparts. FDA maintains a consultation process through which it has been notified of, and has reviewed, safety information on all bioengineered foods marketed in the United States. FDA is not aware of any circumstance where a food safety question remains unresolved for a product of modern biotechnology that has been marketed.

Applicability of Food Safety Law

126. FDA regulates the safety of food and feed products derived from modern biotechnology using the same standards and requirements as under U.S. food law generally. Substances added to food that do not meet the statutory definition of "generally recognised as safe," and that are not pesticides, are classified as food or colour additives and must be pre-approved before they may be marketed.

127. Manufacturers of food and colour additives are not only held responsible for the safety of their food and colour additives—as they had long been held to be, under both general law in this country on legal responsibility and general provisions of the FFDCA—but, prior to marketing these additives, such manufacturers are required to submit to FDA documentation demonstrating their safety and await approval for their use.

1992 FDA Policy

128. FDA, Statement of Policy: Foods Derived From New Plant Varieties. May 29, 1992 (57 FR 22984). In this policy, FDA described how foods from new plant varieties, including those from bioengineered plant varieties, would be regulated under the same statutes and regulations as foods from

existing plant varieties already on the market. Thus, the same adulteration, labelling, and food additive provisions apply to bioengineered foods as apply to their conventionally derived counterparts. For example, if a plant were engineered such that food from that plant contained a food additive, the additive would be subject to the same premarket approval requirements, as would a traditional food additive used in processed food.

1999 Public Meetings

129. In 1999, FDA held public hearings in Chicago, Washington, D.C., and Oakland California, to explain its policies on regulation and labeling of foods derived from bioengineered plants and to get receive public comment on those policies. Oct. 25, 1999 (64 FR 57470). On May 3, 2000, FDA announced initiatives stemming in part from input received from the public and building upon current programs. In addition to proposing a rule mandating developers of bioengineered foods and animal feeds to notify FDA, detailed specific information will be required to determine potential safety, labeling or adulteration issues. The FDA will propose that the submitted information and FDA's conclusions be made available to the public, consistent with applicable disclosure laws, by posting them on FDA's website. Labeling guidance to assist manufacturers who wish to voluntarily label foods being made with or without the use of bioengineered ingredients will be drafted by FDA with public input.

Earlier Steps

130. In 1986, the U. S. government issued the Co-ordinated Framework for the Regulation of the Products of Biotechnology (51 FR 23302). This document described how products developed through bioengineering would be regulated under the existing statutory framework by the relevant federal agencies, such as APHIS, FSIS, FDA, and EPA.

131. Starting in the 1980s and continuing through the 1990s, food safety agency scientists participated actively in OECD and Codex meetings in which nations exchanged information about their regulatory regimes for handling bioengineered products.

132. Also, FDA, APHIS and EPA have held numerous public meetings requesting input on scientific and policy questions in this area.

133. Thus, the policy development process in the United States as to foods containing genetically modified organisms has been highly transparent, with many opportunities for public comment.

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FDA's Centre for Veterinary Medicine (CVM)

139. FDA, through its Centre for Veterinary Medicine (CVM), is responsible for regulating animal food and feeds, including additives for use in these products. FDA also approves drugs for animal use and assures that any residues found in meat, milk, or eggs are safe.

140. Clear examples of the agency's precaution in the veterinary medicine include its past and current activities in the areas of antibiotic resistance, residues, and BSE. (Precaution against BSE is discussed in section C., above, in the introduction to this annex, and in paragraph 179, below.)

Veterinary Antimicrobial Resistance Issue

141. FDA has taken new regulatory steps to address antimicrobial resistance from the use of antimicrobials in animals. In November 1998, FDA issued draft guidance for industry on the subject. The guidance was followed by a document entitled "A Proposed Framework for Evaluating and Assuring the Human Food Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals," which described the agency's thinking about the regulatory approach it was considering on the issue. The draft document developed the concept of antimicrobial risk management. According to the concept, monitoring and resistance thresholds would be established before a drug could be approved. Once shifts in susceptibility to a drug crossed a pre-determined monitoring threshold, FDA would call for additional information to ascertain which factors were most responsible for promoting resistance development. If resistance rose to the predefined threshold level, certain regulatory actions would take place, up to and including restrictions on the drug or removing it from the market.

142. In December 1999, FDA issued guidance to industry relating to consideration of resistance in approvals.

143. Continuous monitoring of resistance in enteric bacteria from humans and food animals is the key to effectiveness of the concepts in the draft document. For resistance monitoring, FDA is relying on the National Antimicrobial Resistance Monitoring System—Enteric Bacteria (NARMS). NARMS is a collaborative program among FDA, CDC, and USDA. The program monitors shifts in antimicrobial susceptibilities in zoonotic enteric organisms, from both human and animal sources.

144. Risk assessments are also a key part of the program. For example, to better estimate the actual risks posed from the use of antimicrobials in food animals, FDA has conducted a risk assessment that modelled the human health impact of fluoroquinolone-resistant Camphylobacter infections associated with the consumption of chicken. Significantly, this draft risk assessment has demonstrated quantitatively that resistance development in food-producing animals does have an impact upon human health.

145. The agency has contracted for a second risk assessment to examine the indirect transfer of resistance from animals to humans. For this risk assessment, FDA will be modelling the impact of virginiamycin resistance in Enterococcus faecium in animals on the ability to treat vancomycin resistant Enterococcus faecium in humans with the recently approved human antimicrobial, Synercid.

146. Research is also important. FDA has initiated its own intramural and collaborative research efforts to investigate factors associated with development, dissemination, and persistence of bacterial antibiotic resistance in both the animal production environment and food supply. Agency microbiologists are currently conducting or are participating in projects specifically targeted to gathering data. In addition

to conducting intramural research, FDA also collaborates in extramural research grants and funds extramural research activities through co-operative agreements

147. Partnerships are essential. In addition to the intergovernmental co-operation already described, the agency endorses efforts by outside groups to help reduce the threat of antimicrobial resistance such as the Judicious Use program of the American Veterinary Medical Association (AVMA) and others. FDA is supporting educational initiatives about Judicious Use for veterinarians and livestock producers.

Program for Control of Residues in Meat and Poultry

148. This program is an excellent example of effective interagency co-operation that minimises risk to the public from residues in meat and poultry. Every year FSIS, FDA, and other federal/state agencies work together through the Surveillance Advisory Team process to develop a comprehensive, risk-based, annual sampling plan to detect drug and/or chemical residues in U.S. meat and poultry.

FSIS takes samples in meat and poultry plants across the United States, and timely information on any violative residues detected by FSIS's testing would be entered into the Residue Violation Information System, an interagency computer information system that collects information as to residue violations in domestically slaughtered livestock and poultry.

FDA's district offices throughout the country receive weekly reports of residue violations from the system and used the system to track federal/state follow-up activities. (As was explained earlier, livestock being raised for food use are "food" under the FFDCA. Anyone involved in handling, transporting, or manipulating "food," as well as the "food" itself, falls under the jurisdiction of the statute. FDA routinely exercises its authority on the farm, although more often in "for-cause" situations than in routine inspections.)

149. FDA instructs its FDA district offices to conduct on-site investigations of first-time violators when the FSIS reports a violative tissue residue of public health significance (Compliance Program 7371.006--Illegal Drug Residues in Meat and Poultry).

150. If a violative tissue residue of public health significance is found and it is an initial residue violation, the FDA district office decides what action is warranted. For first-time violators, in general the 32 states that have co-operative agreements with FDA conduct inspections of first-time violators to determine the cause of the residue and to prevent a repeat violation through education or regulatory action, or both. State participation is thus an integral element of the United States' residue reduction effort. FDA and state officials' conduct further sampling at the farm level as needed to ascertain the cause of the tissue residue violation. Feed, drug, and environmental samples are collected. Although the FDA has authority to conduct targeted live animal testing; the agency does not find it necessary to routinely include such testing in the U.S. residue control program, due to the program's regulatory strength and its emphasis on prevention. During an investigation, FDA and state investigators follow the inspection guidelines established in the compliance program described above, and they complete a standardised information that is entered into the Tissue Residue Information Management System for program evaluation and improvement purposes.

151. For repeat violators, FDA district offices are instructed to perform follow up actions in all cases and to recommend enforcement action as appropriate. A repeat violator is an individual who sells a slaughter animal whose carcass is found to contain a violative concentration of a drug, pesticide, or environmental contaminant within a 12-month period after receiving the USDA, FSIS Violation Notification Letter of a previous violation.

152. FDA works very closely with the other federal agencies involved in residue reduction efforts through monthly meetings of the Interagency Residue Control Group. National and regional meetings are

also organised for federal and state residue control officials to discuss emerging issues and develop appropriate education, prevention, and/or enforcement strategies.

Approval of Animal Drugs and Food Additives

153. FDA's regulations and guidelines on animal drug testing and approvals demonstrate a precautionary approach to testing of animal drugs, the use of exposure estimates, and the determination of appropriate withdrawal periods. See 21 CFR Part 514 and ww.fda.gov/cvm/fda/TOCs/guideline3toc.html

154. Just as bioengineered plant foods are subject to regulation as food and potentially as food additives, meat from transgenic animals is likewise regulated under these national food laws.

Precaution in Regulating Animal Drugs

155. Hormones for growth promotion in food animals. FDA's approvals of hormones for use in growth promotion in food animals are based upon a thorough review of adequate and well-controlled scientific studies. See, Guest, G. and Fitzpatrick, S. (FDA, CVM). March 1987. Safety of Meat from Animals Treated With Naturally-Occurring and Synthetic Hormones.

156. Chloramphenicol. 1985 (50 FR 27059). Chloramphenicol has never been approved for use in food animals. The safety of the residues of chloramphenicol could not be determined, as there was no animal model available. However, chloramphenicol had been approved for use in dogs. Several formulations as well as an oral solution were marketed. FDA withdrew the applications for the oral solution based on information that the oral formulations were being used in food-producing animals and that the label directions were not likely to followed in the future.

157. Dimetridazole. 1986 (51 FR 45244). In this notice of opportunity for a hearing, FDA proposed to withdraw approval of new animal drug applications for dimetridazole, an antiprotozoal agent approved for use in turkeys. The action was based on the determination that the drug was not shown to be safe for use (1) because new evidence provided a reasonable basis from which serious questions about the ultimate safety of dimetridazole and the residues that may result from its use may be inferred, (2) because new evidence shows that dimetridazole is no longer shown to be safe by adequate tests by all methods reasonably applicable, and (3) because new evidence shows that the labelled directions for use have not been followed in practice and not likely to be followed in the future. As no one had requested a hearing, FDA withdrew approval of the applications for dimetridazole.

158. Nitrofurans.1991 (56 FR 41902, 41903). This FDA Commissioner's Decision Withdrawing Approval also follows this approach as to allocation of burden of proof and found, among other things, that the risk standard to judge nitrofurans and their metabolites is 10^{-6}. Judicial review was not sought of this Commissioner's decision, and the products were withdrawn.

159. The case of bovine somatotropin, (bST) and recombinant bovine somatrotropin, (rbST), demonstrate precaution in FDA's decision making.

160. Bovine Somatotropin (rbST 1993. On November 5, 1993, FDA's Centre for Veterinary Medicine (CVM) approved a bovine somatotropin (bST) product, Posilac®, for use in lactating dairy cows to increase milk production after a thorough review characterised by precautionary approach to both human and animal health issues. bST is a proteinaceous hormone released from the anterior pituitary of cattle for normal growth and lactation. Although recombinant DNA processes are used to manufacture recombinant BST (rbST) products--similar to other new protein drug products for both humans and animals--rbST products themselves are not "genetically altered," nor are the food products derived from treated animals. In 1992, the 38th Joint Expert Committee on Food Additives (JECFA) of the WHO and FAO confirmed the human food safety of rbST products.

161. In March 1993, CVM convened its Veterinary Medicine Advisory Committee to address the question as to whether increased incidence of mastitis in dairy cows treated with Posilac® raised any concerns from the standpoint of potential risk to human health. (CVM was already satisfied as to acceptability from the standpoint of animal health.) The Committee concluded that the human health risk posed by the possible increased use of antibiotics to treat the mastitis was insignificant.

162. The sponsor agreed to conduct a post-approval monitoring program to track incidence of mastitis, animal drug use, and proportion of milk discarded due to positive drug tests. Results of the post-approval monitoring program were presented to FDA's Veterinary Medicine Advisory Committee, which met in late 1996. Each member of the Committee concluded that the labelling for Posilac® provides adequate directions for actual conditions of use. Also, the committee concluded that the post-approval monitoring program had confirmed that bST is safe and its approval had no adverse effect on the milk supply.

163. The review of rbST products and approval of Posilac® stimulated much public concern and controversy, often generated by groups opposed to rbST for socio-economic or other reasons. For example, during the 1980s and early 1990s, rbST was the subject of a number of citizen petitions, Congressional inquiries, and state legislative initiatives. FDA conducted a thorough review, and finding that the sponsor had submitted a wealth of information demonstrating the product safety and effectiveness, FDA applied the statutory criteria and approved this product, as it had been demonstrated safe and effective. Federal law does not provide for FDA to consider the social and economic impact of a new animal drug in its approval decision.

164. Upon approving the drug, the agency also decided that it did not have a legal basis under the FFDCA that would justify requiring labelling for milk products from cows treated with rbST. However, food companies could voluntarily label their products provided the information was truthful and not misleading. Also, Monsanto also agreed to conduct a post-approval monitoring program to track the incidence of mastitis, animal drug use, and proportion of milk discarded due to positive drug tests.

Precaution in Regulating Animal Foods

165. Control over composition of animal food and feeds: FDA’s control of the safety of the animal food supply mirrors that used for human food. Additives to animal feed are approved by CVM. Standards for contaminants are established, the feed supply is monitored for unsafe contaminants and ingredients, inspections are conducted of feed mills, especially those that make medicated feed, enforcement is employed to address unsafe situations, and labelling is reviewed for compliance with agency regulations.

166. For example, FDA has approved several food additives (formaldehyde and irradiation) for controlling salmonella in animal feed and feed ingredients. Also, the agency is presently developing guidance for the industry on the levels of the mycotoxin fumonisins in human food and animal feed as a precautionary measure to prevent animal and human health problems.

167. Nearly all states have active feed safety programs too, and co-operation with them is a critical element of FDA’s animal feed safety program. This co-operation occurs individually with states and through the agency’s excellent working relationship with the Association of American Feed Control Officials (AAFCO). AAFCO publishes yearly its Official Publication, which contains, among other things, working definitions of all processed ingredients used in animal feeds. FDA reviews the safety of these ingredients before AAFCO accepts them. The states do not permit an ingredient in feed unless AAFCO has adopted a definition for it. FDA recognises these definitions as the common and usual names of feed ingredients.

168. Gentian Violet. 1991 (56 FR 40502). Gentian violet had a long history of use as a mold inhibitor in poultry feed. In this final rule, FDA declared that gentian violet is not generally recognised as safe for

use in animal feed and was prohibited for use as a food additive and as an animal drug, unless FDA approved a food additive petition. The decision was based on published literature demonstrating that gentian violet has mutagenic, genotoxic and other toxic properties.

Authority to Reconsider Data

169. FDA has authority to withdraw approvals of products based upon new reconsideration of data previously approved. A longstanding case on this point that also affirms the propriety of doing so for reasons of sound precautionary public policy is Bell v. Goddard, 366 F. 2d 177 (1966): "The petitioner contends that the final approval of his application was improperly suspended because the suspension was not based upon any evidence from tests or clinical experience after the effective date of his application. …[FDA had] in fact withheld approval of his application pending further study of the same tests later used as evidence to support suspension of his application. He argues that …the suspension of his application can only be attributed to the change in policy embarked upon by the Secretary of Health, Education and Welfare which was allegedly prompted by the latter's desire to achieve improper retrospective application of the so-called 'Delaney clause' of the Food Additives Amendment of 1958."

170. The court held that the Commissioner could properly conduct "an extensive re-evaluation, which drew together clinical experience in a manner not previously attempted and which perhaps brought its full impact to the attention of the experts for the first time, provid[ing] a basis for the Commissioner's findings. An interpretation of the statute prohibiting such a new application of existing information would do violence to the paramount interest in protecting the public from unsafe drugs. The fact that the re-evaluation may have been inspired by a change in administrative policy is irrelevant."

Allocation of Burden of Proof

171. Although FDA's Center for Veterinary Medicine "must provide a basis from which serious questions about the ultimate safety of [an animal drug] and the residues that may result from its use may be inferred,"once that limited threshold burden has been satisfied, the burden passes to the sponsors to demonstrate safety. Commissioner's Decision, 44 FR 54861 (1979).

172. See Rhone-Poulenc, Inc. v. FDA, 636 F. 2d 750 (D.C.Cir.1980).

173. Also, approval of an animal drug may be withdrawn, after revocation of approval of the analytical method for detecting drug residues, if there is no other analytical method. 44 FR 54851 (1979).

Pesticides (EPA)

174. As was discussed earlier, FIFRA and section 408 of the FFDCA establish the safety standard--reasonable certainty of no harm--that must be applied to all pesticides used on foods.

175. In an October 29, 1998 Federal Register notice, EPA published a framework to describe issues involved in the implementation of the Food Quality Protection Act (FQPA) and a preliminary schedule for the release of the policy and guidance documents associated with each issue. Among these are documents on:

1. Applying the FQPA 10-Fold Safety Factor.

2. Dietary Exposure Assessment - Whether and How to Use Monte Carlo Analyses and the 99.9th Percentile Issue.

3. Exposure Assessment - Interpreting "No Residues Detected".

4. Dietary Exposure Estimates.

5. Drinking Water Exposures.

6. Assessing Residential Exposure.

7. Aggregating Exposures from All Non-Occupational Sources.

8. How to Conduct a Cumulative Risk Assessment for Organophosphate or Other Pesticides with a Common Mechanism of Toxicity.

9. Selection of Appropriate Toxicity Endpoints (or Critical Effects) for Risk Assessments of Organophosphates.

176. Other papers that have also been prepared for public comment on science and risk management policies include:

- Draft Toxicology Data Requirements for Assessing Risks of Pesticide Exposure to Children's Health.
- Draft Exposure Data Requirements for Assessing Risks of Pesticide Exposure to Children.
- Guidance for the Submission of Probabilistic Human Health Exposure Assessments to EPA.
- Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern.
- Use of the Pesticide Data Program in Acute Dietary Assessment; A Statistical Method for Incorporating Nondetected Pesticide Residues into Human Health Dietary Exposure Assessments.
- Assigning Values to Nondetected/Nonquantified Pesticide Residues in Human Health Dietary Exposure Assessments.
- Threshold of Regulation Policy--Deciding Whether a Pesticide With a Food Use Pattern Needs a Tolerance (Revised).
- Dietary Exposure Estimates: A User's Guide to Available EPA Information on Assessing Dietary (Food) Exposure to Pesticides.
- Aggregating Exposures from All Non-Occupational Sources.
- Guidance for Performing Aggregate Exposure and Risk Assessment.

- Guidance for Identifying Pesticide Chemicals and Other Substances That Have a Common Mechanism of Toxicity (Revised).

- Cumulative Risk Assessment Guidance.

- Science Policy on the Use of Data on Cholinesterase Inhibition for Risk Assessment.

- The Role of Use-Related Information in Pesticide Risk Assessment and Risk Management.

- Data for Refining Anticipated Residue Estimates Used in Dietary Risk Assessments for Organophosphate Pesticides.

- Guidelines for the Conduct of Bridging Studies for Use in Probabilistic Risk Assessment.

- Guidelines for the Conduct of Residue Decline Studies for Use in Probabilistic Risk Assessment.

- Guidance for Performing Aggregate Exposure and Risk Assessment.

177. For background, see NAS/NRC. 1987. Regulating Pesticides in Food: The Delaney Paradox; Wargo, J. 1996. Our Children's Toxic Legacy. Yale University Press: New Haven. Documents issued before the FQPA include:

- EPA. 1984 (49 FR 46294) General guidelines as to acceptable risk, including the one in a million standard.

- EPA. 1986 (51 FR 33992). Guidelines for carcinogen risk assessment.

Plant and Animal Health Regulations (APHIS)

178. APHIS exercises a so-called "precautionary approach" when it learns about a pest or disease threat, including situations where the information may be incomplete. A precautionary approach is taken when faced with an imminent hazard to animal or plant health, particularly in situations where there is a lack of sufficient time or information to complete an appropriate risk assessment. The agency, like other regulatory agencies, uses interim regulations to impose such emergency measures. These interim measures can become effective immediately where there is sufficient justification.

179. A good example of APHIS' emergency interim measures can be seen in the approach APHIS took when it banned the importation of animal products (i.e., primarily ruminants) from Europe following reports of BSE. This interim regulation, like others, can be modified eventually once the exporting countries affected by the ban provide the necessary information to APHIS and, to FDA and FSIS as well, to conduct a more complete risk assessment and to determine that less restrictive regulatory measures can be taken. This approach is consistent with Article 5.7 of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which requires members to review provisional measures within a reasonable time period and to support such measures with a more complete assessment of risk.

180. APHIS risk assessments are designed to present scientific evidence and the inferences and conclusions that can reasonably be drawn from that evidence to the agency's decision makers, stakeholders, trading partners, and the general public. APHIS believes risk assessments should neither minimise nor exaggerate the likelihood of adverse outcomes and recognises that negative consequences may result from both excessively risk averse and excessively risk taking decisions.

181. Describing uncertainty is a key part of the risk assessment process. Indeed, the fact that the world is uncertain at times is the primary reason why risk assessment is necessary and useful. To be useful, risk assessments should describe analytical uncertainty about outcomes. Risk assessments, however, should not use that uncertainty to justify risk-averse bias in assessment findings. Decision-makers, taking account of risk assessment findings, the degree of uncertainty, and public attitudes toward risk, may reasonably use precaution while in the process of determining an acceptable level of risk.

FDA Nutrition Policy: Labelling and Fortification

The Link between Diet and Disease

182. The placement of this topic at the end of this annex should not be construed as indicating unimportance. Indeed, recent evidence suggests that governmental policies to encourage healthy choices may be one of the most important factors in avoiding preventable forms of cancer and other disease.

Nutrition Labelling

183. Therefore, mandatory nutrition labelling is precautionary in that informed consumer's can, through such labelling, make choices that reduce their risk of cancer and cardiovascular diseases. Under the Nutrition Labelling and Education Act of 1990 (NLEA), food is required to bear information about serving size, number of servings per container, calories, and certain nutrients (including total fat, saturated fat, cholesterol, sodium, carbohydrates, sugars, dietary fibre, and protein.) 21 U.S.C. 343(q)(1); 21 CFR 101.9. A uniform format promotes consumer understanding and comparisons.

Nutrition Claims

184. Nutrient content claims, whether expressed or implied, are forbidden unless they are allowed specifically and follow FDA's regulations. 21 CFR 101.13 (b). This provision protects consumers, by guarding against abuses as to claims. A substance is eligible for a health claim if its decreased or increased use is associated with a disease or health-related condition for which the general U.S. population, or a subgroup, is at risk (21 CFR 101.14).

185. Claims are allowed as to:

- Calcium and osteoporosis (101.72).
- Fat and cancer (101.73).
- Sodium and hypertension (101.74).
- Saturated fat/cholesterol and heart disease (101.75).
- Fibre-containing grains/fruits/vegetables and cancer (101.76).
- Fibre-containing grains/fruits/vegetables and heart disease (101.77).
- Fruits/vegetables and cancer (101.78).
- Folic acid and neural tube defects (101.79).
- Dietary sugar alcohol and dental caries (101.80).

- Soluble fibre from certain foods—oat bran and psyllium--and risk of coronary heart disease (101.81).

186. Special rules govern the use of "reduced" (21 CFR 101.62 (c)(4)), "light" or "lite" (101.56 (b)), "free" or like expressions (101.13(e)), "low" (101.60-101.62), and other expressions in order to standardise what is meant by these terms and protect consumers against misleading uses of them.

Fortification

187. Government policy on fortification of food with vitamins and minerals also represents a precautionary approach, in two respects. First, food fortification policies, by setting minimum levels of nutrients in certain foods, can reduce incidence of deficiency diseases. Second, food fortification policy, by setting maximum levels of nutrients, can guard against adverse effects upon vulnerable populations, or consumers generally.

188. FDA's fortification policies are expressed in food standards, e.g., the standard for enriched flour (21 CFR 137.165), in general guidance on fortification (21 CFR 104.20), and in labelling. The general FDA approach has been to establish standards for enriched basic dietary staples, such as flour, through "a uniform enrichment formula that would target the major deficiency diseases of the day in a rational, well-documented fashion," S. Junod. 1999. Whose Standards Should Prevail? Quaker Oats' Battle over "Bottled Sunshine." FDLI Update. 2: 12.

189. In Federal Security Administrator v. Quaker Oats Co., 318 U.S. 218 (1943), the Supreme Court upheld FDA's use of food standards authority to regulate fortification. "The evidence of the desire of consumers to purchase vitamin-enriched foods, their general ignorance of the composition and value of the vitamin content of those foods, and their consequent inability to guard against the purchase of products of inferior or unsuitable vitamin content, sufficiently supports the Administrator's conclusions." 318 U.S. 229. In sum, the Court permitted the FDA to employ a precautionary approach to increase the likelihood that consumers, through consumption of standardised, enriched products, could avoid vitamin or mineral deficiencies.

190. Concerning a food standard on iron in bread, the Commissioner of Food and Drugs concluded, after a formal evidentiary public hearing, that there are safety concerns about raising the level of fortification of iron in bread to the level that had been proposed. "[B]ecause of a safety question, there is a greater burden on the proponents to show need and effectiveness" of the fortification level they favoured…the witnesses' opinion testimony…was backed by very little good data in the form of reliable studies that answered the questions raised." FDA, Iron Fortification of Flour and Bread; Findings of Fact, Conclusions, and Final Order, 43 FR 38575, 38577 (Aug. 29, 1978).

191. The Commissioner's decision was motivated, in part, by concern that increased iron fortification could present a danger to those at risk from increased iron. In response to the suggestion of a participant in the proceeding that such persons receive a "special precautionary treatment," presumably through a warning statement on the label, rather than to withhold a regulation that would benefit many due to the possible danger to a few, the Commissioner responded that, "[t]here is no evidence in the record as to how one could identify latent hemochromatotic individuals" and therefore "this suggestion does not sufficiently protect those at risk." Id.

Protecting the Next Generation

192. Folate and Neural Tube Defects. 1996 (44 FR 8752). FDA took several actions to assure that women of childbearing age maintain adequate folate intakes, particularly during the years before conception, to reduce the risk of a neural tube birth defect-affected pregnancy. First, FDA authorised a

health claim on this subject. Second, FDA amended the food standards for enriched grain products to require inclusion of folate. Third, FDA approved new food additive uses as need for folate fortification.

193. Special regulations govern infant formulas, recognising the extraordinary need for precaution as to foods for our vulnerable youngest group in the population (21 CFR Parts 106 and 107).

Reference List V. Court Decisions

Interpretation of Statutes

194. The FFDCA is to be liberally construed consistent with its public health purposes. United States v. Bacto-Unidisk, 394 U.S. 784 (1969).

195. The consumer protection purposes of the FMIA have been recognised in a long line of court decisions. The purpose of the FMIA is, above all, to protect the health and welfare of consumers. G.A. Portello & Co. v. Butz, 345 F. Supp. 1204 (D.C.D.C. 1972). The FMIA is intended to ensure a high level of cleanliness and safety of meat products. United States v. Mullens, 583 F. 2d 134 (5th Cir.1978).

Deference to Agencies

196. U.S. courts accord "substantial deference" to expert agencies' interpretations of their statutes. Chevron v. NRDC, 467 U.S. 837 (1984).

197. On matters of fact, agency decisions are not set aside unless they are found to be arbitrary or capricious, or not in accordance with law. See, e.g., Borden Co. v. Freeman, 256 F. Supp. 592 (D.C.N.J. 1966), affirmed 369 F. 2d 404, certiorari denied 386 U.S. 992 (upholding FSIS regulations unless their promulgation was "arbitrary, capricious, abuse of discretion, or otherwise not in accordance with law"). Even where the particular statute has prescribed a more stringent evidentiary standard, e.g., "substantial evidence," U.S. courts generally defer to agency findings as to fact.

198. Also, expert agencies possess primary jurisdiction to decide what matters are under their control. United States v. An Article of Food…Food Science Laboratories, 678 F. 2d 735 (7th Cir. 1982). "When the quality and the magnitude of hazards potentially associated with a new food product are as uncertain as they are here, the proper judicial response is aversion to the risks and strict enforcement of the regulatory framework for risk management established by the Congress." United States v. An Article of Food…Food Science Laboratories, 678 F. 2d 735 (7th Cir. 1982). The sponsor, Food Science must "shoulder the burden of proving" to FDA that the ingredient in question qualifies for an exemption from the food additive requirements, and if FDA is unpersuaded, "it would certainly be unwise for this Court to create a judicial exception…" In other words, the proponent of a food substance bears the burden of showing that a food substance is "generally recognised as safe," and therefore exempt from the definition of "food additive."

The lack of studies showing adverse effects of a substance cannot establish general recognition of safety. United States v. Articles of Food and Drugs, 518 F. 2d 743, 747 (5th Cir. 1975). An affidavit by a single expert asserting that a substance is safe does not suffice. United States v. An Article of Food…Coco Rico, Inc., 652 F. 2d 11 (1st Cir. 1985).

199. U.S. courts are particularly likely to defer to the fact finding of regulatory agencies operating on the "frontiers of science." Industrial Union Dep't v. Hodgson 499 F.2d 467 (D.C. Cir. 1974).

200. Despite the deference as to legal interpretations and facts, courts are stringent in their demands that agencies adhere to procedural requirements in the Administrative Procedure Act that ensure the

public's ability to participate meaningfully in the proceeding. United States v. Nova Scotia Food Products, 568 F.2d 240 (2d Cir. 1977).

Industry Responsibility

201. This discussion supplements section A.2 in the introduction. Factors in the caution exercised by many producers include the desire to avoid liability to injured consumers. Liability can result in court orders to pay damages to injured consumers or their survivors--and to pay damages to commercial partners in the food distribution chain due to breach of contract--and in adverse publicity. These factors combine with the overwhelming desire of most processors to sell only safe products and to protect their commercial reputations. The sum of all of these factors amounts to a powerful incentive for a cautious approach to food safety in the private sector. Therefore, U.S. experience suggests that a national food safety system not only rests upon strong regulatory laws and enforcement agencies, but also depends upon an effective private responsibility system, well-functioning courts, and a free press. (Both the threats of liability and knowledge that news media might publicise a processor's food safety mishaps encourage caution.)

The precaution of most processors strengthens the efficacy of the governmental regulatory controls. While the principal purpose of governmental food safety regulation is consumer protection, an ancillary purpose is assuring a level playing field, so that prudent processors who make an investment in testing, training, and control measures are not forced to compete with those who do not. In sum, strong governmental compliance programs for food safety laws protect the investment made by responsible processors who take a precautionary approach to food safety. Processors generally, not just those predisposed to be good commercial citizens, need to adhere to essential requirements for precaution in their production, processing and distribution of food.

The private legal system described is predominantly a matter of the common law and statutes of the 50 states, each of which has a private system of tort and contract law that creates a legal incentive for food producers to exercise caution. A very high degree of harmonisation has occurred among the states. Many court decisions on liability for personal injury refer to decisions in similar cases in other state courts as well as to treatises such as the Restatement of Torts with its authoritative discussion of liability law. Furthermore, all states (with the possible exception of Louisiana, whose basic legal system is based upon the Napoleonic Code) have enacted the Uniform Commercial Code, with its "implied warranty of fitness" of products.

It needs to be clearly understood that a private liability system, alone, is inadequate to protect consumers. A strong regulatory system is also essential because food can contain hazards, e.g., that are invisible to consumers. Also, consumers need expert food safety regulatory agencies to perform such tasks on their behalf as scientific risk analyses, approval of new products, and enforcement actions. A strong regulatory system also compensates for weaknesses in the private liability system. Not all injured consumers bring lawsuits and collect damages, and causality is sometimes difficult to prove (e.g., was illness or death was due to a danger present in food or another factor). Also, the private liability system rests to some degree upon experts employed by the litigants, rather than the rigorous and independent scientific review of innovation provided by the U.S. food safety agencies.

It should also be mentioned that there are currently some unresolved issues in the U.S. legal system about the relationship between regulatory statutes and private personal injury cases. Most cases to date have involved products other than food; some hold that the existence of a regulatory law implies that Congress must have meant to preclude private cases, which others hold that the existence of a regulatory law implies no such preclusion. The answer depends upon Congressional intent in each individual statute. Leading illustrative cases have involved tobacco products and medical devices.

202. Turning to industry responsibility in governmental enforcement actions, officials are strictly responsible for violations of the FFDCA, whether or not they had any personal awareness of the violation. In the landmark case of United States v. Dotterweich, 320 U.S. 277 (1943), the U.S. Supreme Court held that:

> "The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if is to be treated as a working instrument of government and not merely as a collection of English words...[The] legislation dispenses with the conventional requirement for criminal conduct--awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger...
>
> "Hardship there doubtless may be under a statute which thus penalises the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it [i.e., the hardship] upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless." Id. 283-86.

203. "[The] public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors." Smith v. California, 361 U.S. 147 (1959). "[T]he Act punishes 'neglect where the law requires care, or inaction where it imposes a duty.'" Morissette v. United States, 342 U.S. 246, 255 (1952). In United States v. Park, 421 U.S. 658 (1975), the Supreme Court affirmed the continued validity of Dotterweich's doctrine on corporate official strict liability and went on to elaborate upon the particular responsibilities of these officials:

> "Thus Dotterweich and the cases which have followed reveal that in providing sanctions which reach and touch the individuals who execute the corporate mission--and this is by no means necessarily confined to a single corporate agent or agent or employee--the Act imposes upon persons exercising authority and supervisory responsibility reposed in them by business organisation not only a positive duty to seek out and remedy violations but also, and primarily, a duty to implement measures that will insure that violations will not occur. The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding and perhaps onerous, but they are no more stringent that the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them. 421 U.S. 672 (emphasis added).
>
> The court noted that, "Assuming, arguendo, that it would be objectively impossible for a senior corporate agent to control fully day-to-day conditions in retail outlets it does not follow that such a corporate agent could not prevent or remedy promptly violations of elementary sanitary conditions in 16 regional warehouses." 421 U.S. 678.

204. As an additional deterrence to violations of the laws administered by FSIS, an officer of a company who is convicted of distributing adulterated products can be prevented from engaging in any business requiring federal inspection services. If FSIS finds that the company official unfit to engage in such business, it may withdraw inspection services to that company so long as the convicted individual is associated with it. Toscony Provision Co., Inc. v. Block, 538 F. Supp. 318 (D.C.N.J. 1982); Windy City Meat Co. v. U.S. Department of Agriculture, 926 F.2d 672 (7th Cir. 1991); Wyszynski Provision Co., Inc. v. Secretary of Agriculture, 538 F. Supp. 361 (E.D. Pa. 1982).

205. The requirements of U.S. food safety laws can be enforced through court actions, based directly upon the statute, or they can be implemented in regulations. "The total scheme of this Act contemplates judicial obligation to enjoin distribution of unsafe foods even in the absence of formally promulgated regulation and it is not mandatory for the administrator to promulgate regulations establishing tolerances." United States v. Goodman, 353 F. Supp. 250 (E.D.Wis.1972), affirmed 486 F. 2d 847, affirmed 502 F. 2d 715, certiorari denied 420 U.S. 945.

Regulations Having the Force and Effect of Law

206. FDA regulations for the efficient enforcement of the FFDCA under 21 U.S.C. 371(a) have the force and effect of law. "We have come to recognise that, if the administrative process is to be practically effective, specific regulations, promulgated pursuant to a general statutory delegation of authority must be treated as authorisation…especially in areas where the agency possesses expertise not shared by the courts…[W]e have learned from experience to accept a general delegation as sufficient in certain areas of expertise." National Nutritional Foods Ass'n v. Weinberger, 512 F. 2d 688, 696 (2d Cir.), certiorari denied, 423 U.S. 827 (1975). The court particularly noted the advantage of rulemaking over other decision processes, in affording the industry, and the public generally, the opportunity to participate in the process of formulating broad policies. Id. 698.

207. See, generally, National Association of Pharmaceutical Manufacturers v. FDA, 637 F.2d 877 (2d Cir. 1981).

208. Regulations promulgated under FSIS statutory authority also have the force and effect of law. United States v. Cudahy, 243 F. 443 (D.C. Conn. 1917) (case under Federal Meat Inspection Act).

Cost-Benefit Analysis Applicable Only if Statute Allows

209. This discussion supplements section E. of the introductory section of this annex. One issue to be covered in the submission to OECD is whether a country's food safety system requires or provides for cost-benefit analysis in decision making under the law. With respect to U.S. food safety law, this depends upon the particular statute. While, in general, U.S. government agencies are subject to the requirement that they analyse the potential costs or impacts of their regulations under the Regulatory Flexibility Act and Presidential Executive Order 12866 on Regulation, these requirements do not apply where a statute precludes use of cost-benefit analysis. Indeed, the U.S. Supreme Court has held that "[w]hen Congress has intended that an agency engage in cost-benefit analysis, it has clearly indicated such intent on the face of the statute…Congress uses specific language when intending that an agency engage in cost-benefit analysis." American Textile Manufacturers Inst., Inc. v. Donovan ("the cotton dust case"), 452 U.S. 490, 510-11 (1981).

210. Thus, in decisions such as those taken under FDA's food or colour additive authority where the standard for decision making is safety, EPA's pesticide tolerance authority with a similar standard, or FDA's animal drug authority where the standard is safety (and effectiveness), the absence of explicit Congressional authorisation to conduct cost-benefit analysis means that under these laws the administering agencies may not base their regulatory decisions upon the results of a cost-benefit analysis. There is no barrier to agencies' performing studies to measure and report upon the economic impact of their decisions, as a way of informing themselves and the public. However, economic impact can play no determinative role in the decision taken as to a food or colour additive, animal drug, or pesticide tolerance for food: safety is the operative criterion.

211. In 1980, the Attorney General of the United States issued an authoritative decision that neither the Secretary of Health and Human Services nor the Secretary of Agriculture has the authority to balance the benefits of a carcinogenic additive against its possible carcinogenic properties. They do, however,

have the discretion to adopt timetables and procedures to assure the orderly removal of food substances from use if determined to be carcinogenic. 43 Op. Atty. Gen., Mar. 30, 1980.

212. As to veterinary drugs, FDA's position has long been that, in its decision making, the agency is precluded from cost-benefit analysis. See FDA's 1979 decision banning DES (44 FR 54852) and FDA's 1991 regulation banning gentian violet as an additive in animal feed or as an animal drug (56 FR 40502) (citing the American Textile Manufacturers case).

213. One situation in which the statute permits consideration of whether a substance is unavoidable in food, or is required in food production, involves the authority granted FDA to issue formal tolerances for unavoidable food contaminants under the FFDCA (21 U.S.C. 346). See, for example, FDA's decision setting a formal tolerance of 2 parts per million of polychlorinated biphenyl's (PCBs) in fish and shellfish. 49 FR 21514 (May 22, 1984) (considering possible food loss due to a strict tolerance).

Reference List VI. Other Publications on Law and Science in U.S. Food Safety Regulation

214. Other articles and publications of interest include:

- Degnan, F. The Regulation of Food Safety. 1997. Fundamentals of Law and Regulation: An in-depth look at foods, veterinary medicines, and cosmetics [hereinafter, Fundamentals]. Food and Drug Law Institute. Washington, D.C. 161-204.

- Hutt, P. 1973. The Philosophy of Regulation under the Food, Drug, and Cosmetic Act. Food Drug Cosm. L.J. 28:177.

- Lambert, E. Food and Drugs for Animals Other than Man. 1997. Id. Fundamentals. 285-314.

- Olsson, P. and Johnson, D. 1997. Meat and Poultry Inspection: Wholesomeness, Integrity, and Productivity. Id., Fundamentals. 205-236.

- Hutt, P. and Merrill, R. 1991. Safety of Food Constituents, 283-377, and Regulation of Carcinogens, 863-963. Food and Drug Law: Cases and Materials—Second Edition. Foundation Press. Westbury, N.Y.

- Taylor, M. Food and Colour Additives: Recurring Issues in Safety Assessment and Regulation. 1984. Seventy-Fifth Anniversary Commemorative Volume of Food and Drug Law. Food and Drug Law Institute. Washington, D.C.

Reference List VII. Publications on History of U.S. Food Law and Its Evolution to Today's Precautionary Approach

215. Other articles and publications of interest include:

- Hutt, P. 1978. The Basis and Purpose of Government Regulation of Food. Food Drug Cosm. L.J. 33.

- Janssen, W. 1992. The U.S. Food and Drug Law: How It Came, How it Works. A reprint from FDA Consumer magazine. DHHS Publication No. (FDA) 92-1054.

- Junod, S. 1994. Chemistry and Controversy: Regulating the Use of Chemicals in Food, 1883-1959.