on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting pursuant to subsections (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(b)).

Dated: October 22, 1984.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 84-28224 Filed 10-22-84; 3:20 pm]

BILLING CODE 6714-01-M

5

FEDERAL RESERVE SYSTEM

TIME AND DATE: 11:00 a.m., Monday, October 29, 1984.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposed acquisition of real property by a Federal Reserve Bank. (This item originally announced for a closed meeting on October 17, 1984.)
2. Federal Reserve Bank and Branch director appointments.
3. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
4. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202)452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: October 19, 1984.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 28125 Filed 10-22-84; 9:02 am]

BILLING CODE 6210-01-M

6

FEDERAL TRADE COMMISSION

TIME AND DATES: 10:00 a.m., Wednesday October 24, 1984.

PLACE: Room 432, Federal Trade Commission Building, 6th Street and Pennsylvania Avenue, NW., Washington, D.C. 20580.

STATUS: Open.

MATTER TO BE CONSIDERED: Presentation by the American Association of Advertising Agencies entitled "Advertising In the Year 2000."

CONTACT PERSON FOR MORE INFORMATION: Susan B. Ticknor, Office of Public Affairs: (202) 532-1892. Recorded Message: (202) 523-3806.

Emily H. Rock,

Secretary.

[FR Doc. 84-28206 Filed 10-22-84; 1:48 pm]

BILLING CODE 6750-01-M

7

NATIONAL TRANSPORTATION SAFETY BOARD

[NM-84-32]

TIME AND DATE: 9 a.m., Tuesday, October 30, 1984.

PLACE: NTSB Board Room, 8th Floor, 800 Independence Ave., SW., Washington, D.C. 20594.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. *Highway Accident Report*—Collision of DeQueen Police Department Police Department Police Car and Terrel Trucking, Inc., Tractor-Semitrailer, Ashdown, Arkansas, July 5, 1984.
2. *Response* to Petition for Reconsideration of Probable Cause: Aircraft Accident—Western Helicopters, Inc., Bell UH-1B, N87701, Valencia, California, July 23, 1982.
3. *Marine Accident Report*—Capsizing and Sinking of the U.S. Ocean Towing Vessel M/V EAGLE in the Gulf of Alaska, October 27, 1983.
4. *Maine Accident Report*—Grounding of the U.S. Tankship SS MOBILOIL in the Columbia River, near Saint Helens, Oregon, March 19, 1984.
5. *Response* to Petition for Reconsideration of Probable Cause: Aircraft Accident—Cessna A185E, Middleton Airport, Evergreen, Alabama, January 3, 1981.

CONTACT PERSON FOR MORE INFORMATION: Sharon Flemming, (202) 382-6525.

Dated: October 19, 1984.

H. Ray Smith, Jr.,

Federal Register Liaison Officer.

[FR Doc. 84-28195 Filed 10-22-84; 1:14 pm]

BILLING CODE 7533-01-M

8

PACIFIC NORTHWEST ELECTRIC POWER AND CONSERVATION PLANNING COUNCIL

AGENCY HOLDING THE MEETING: Pacific Northwest Electric Power and Conservation Planning Council (Northwest Power Planning Council).

ACTION: Notice of meeting to be held pursuant to the Government in the Sunshine Act (5 U.S.C. 552b).

STATUS: Open.

TIME AND DATE: October 31, 1984, 9:00 a.m.

PLACE: Cooper King Inn, 4655 Harrison, Butte, Montana.

MATTERS TO BE CONSIDERED:

1. Council Decision on Surcharge Methodology (Amendment to the Northwest Power Plan, Appendix D).
2. Council Decision on Street and Area Lighting (Amendment to the Northwest Power Plan, Action Item 12.13).
3. Public Comment on Issue Paper on Possible Exemptions to Council's Model Conservation Standards.
4. Staff Report on Power Planning Decision Analysis.
5. Council Business.

Public comment will follow each item.

FOR FURTHER INFORMATION CONTACT: Ms. Bess Wong (503) 222-5161.

Edward Sheets,

Executive Director.

[FR Doc. 84-28142 Filed 10-22-84; 10:17 am]

BILLING CODE 0000-00-M

9

SECURITIES AND EXCHANGE COMMISSION

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meetings during the week of October 22, 1984, at 450 Fifth Street, NW., Washington, D.C.

Closed meetings will be held on Tuesday, October 23, 1984, at 10:00 a.m. and on Thursday, October 25, 1984, following the 2:30 p.m. open meeting.

Open meetings will be held on Thursday, October 25, 1984, at 10:00 a.m. and at 2:30 p.m.

The Commissioners, Counsel to the Commissioners, the Secretary of the Commission, and recording secretaries will attend the closed meetings. Certain staff members who are responsible for the calendared matters may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, the items to be considered at the closed meetings may be considered pursuant to one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9)(A) and (10) and 17 CFR 200.402(a) (4), (8), (9)(i) and (10).

Chairman Shad and Commissioners Treadway, Cox, Marinaccio and Peters voted to consider the items listed for the closed meetings in closed session.

The subject matter of the closed meeting scheduled for Tuesday, October 23, 1984, at 10:00 a.m., will be:

Institution of injunctive action.

Settlement of administrative proceeding of an enforcement nature.

Institution of administrative proceedings of an enforcement nature.

Formal orders of investigation.

The subject matter of the closed meeting scheduled for Thursday, October 25, 1984, following the 2:30 p.m. open meeting, will be:

Post oral argument discussion.

The subject matter of the open meeting scheduled for Thursday, October 25, 1984, at 10:00 a.m., will be:

1. Consideration of whether to adopt amendments to Securities Exchange Act Rule 15c2–11 (17 CFR 240.15c2–11), which regulates quotations for over-the-counter securities. The amendments would: (1) Extend the rule's information maintenance requirement to the publication of quotations without a specified price and quotations for certain foreign securities and ADRs; (2) create exceptions for NASDAQ securities and for quotations representing a customer's indication of interest; and (3) clarify treatment under the rule of quotations for the securities of reporting companies. For further information, please contact Nancy J. Burke at (202) 272–2848.

2. Consideration of a final rule which will delegate to the General Counsel the authority to file notices of appearance in bankruptcy reorganization cases under Section 1109(a) of the Bankruptcy Code. For further information, please contact Gordon K. Fuller at (202) 272–3087.

The subject matter of the open meeting scheduled for Thursday, October 25, 1984, at 2:30 p.m., will be:

Oral argument on an appeal by Pagel, Inc., a registered broker-dealer, Jack W. Pagel, its president and sole stockholder, and Duane A. Markus, its executive vice-president, from the decision of an administrative law judge. For further information, please contact R. Moshe Simon at (202) 272–7400.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: David Powers at (202) 272–2091.

Dated: October 19, 1984.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 84–28196 Filed 10–22–84; 1:14 pm]

BILLING CODE 8010–01–M

federal register

Wednesday
October 24, 1984

Part II

Environmental Protection Agency

40 CFR Part 158
Data Requirements for Pesticide Registration; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 158

[OPP-30063A; FRL 2591-5]

Data Requirements for Pesticide Registration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Today, EPA is promulgating a new rule, 40 CFR Part 158 which specifies the kinds of data and information that must be submitted to EPA to support the registration of each pesticide under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). EPA uses the submitted data and information to make regulatory judgments with respect to the safety of each pesticide proposed for registration or experimental use. By promulgating Part 158, EPA will provide pesticide registrants with explicit instructions concerning the data requirements and therefore will enable more efficient pesticide development and registration.

EFFECTIVE DATE: Under section 25(a)(4) of FIFRA, this rule must be referred to Congress for review before it can become effective. This rule will become final after the expiration of the statutory period provided for Congressional review. A minimum of 60 days of continuous Congressional session is allowed for this review.

The Agency will publish a notice in the **Federal Register** at the end of the review period announcing the effective date of Part 158.

FOR FURTHER INFORMATION CONTACT: By Mail: Frederick S. Betz, Hazard Evaluation Division (TS-769), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., Washington, D.C. 20460.

Office location and room telephone number: Rm. 821A, Crystal Mall No. 2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-9307).

SUPPLEMENTARY INFORMATION: EPA issued a proposed rule published in the **Federal Register** November 24, 1982 (47 FR 53191) and corrected in the **Federal Register** of January 18, 1983 (48 FR 2142), which proposed to amend Title 40, Chapter I by adding Part 158—Data Requirements for Registration.

I. Introduction

A. Purpose and Scope

Part 158 encompasses the full range of data requirements pertaining to the registration/reregistration or experimental use of each pesticide product under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Hereafter, use of the term registration will pertain to new registrations and amended registrations as well as reregistrations accomplished under section 3(g). The purpose of Part 158 is to specify the types of data and information the Agency requires to make regulatory judgments with respect to the safety of each pesticide proposed for registration or experimental use. This Part also specifies the test substance to be used in tests conducted to fulfill the data requirements.

B. Background

Under the FIFRA, all pesticides that are sold or distributed in commerce must be registered. In order to obtain registration, data must be available to EPA to allow the Agency to evaluate its risks and benefits. EPA will register a product only if the Agency has sufficient information about a pesticide product to make the statutory risk/benefit determinations. Part 158 identifies the types of data which EPA requires to make these determinations.

On July 3, 1975, the Agency promulgated final registration regulations, 40 CFR Part 162, Subpart A. These regulations established the basic requirements for registration of pesticide products.

During 1975 to 1981, EPA issued or made available several subparts of the Guidelines for Registering Pesticides in the United States which described, with more specificity, the kinds of data that must be submitted to satisfy the requirements of the registration regulations. These guidelines included sections detailing what data are required and when, the standards for conducting acceptable tests, guidance on the evaluation and reporting of data, and examples of acceptable protocols.

In October 1981, EPA decided that it was impractical and unnecessary to include in a regulation most of the detailed technical and scientific information contained in the guidelines. EPA recognized that it was inappropriate to set forth most of the guidelines material (e.g., test protocols and provisions for evaluating and reporting data) as regulations since there may be several acceptable or even preferable protocols and provisions in addition to those in the regulation. Moreover, due to the vast diversity of pesticide products subject to regulation and due to the rapidly advancing state of the art in chemical testing and evaluation, it is impractical to attempt to specify detailed testing regulations that will adequately address each situation. Finally, based on its past experience, the Agency concluded that it was unnecessary to codify all the guidelines information as regulations in order to ensure that the necessary information and data would be available to the Agency to make the regulatory decisions required by FIFRA. The Agency recognized that only a relatively small portion of the information—primarily, what and when data are required—needs to be set forth in a regulation.

Therefore, in 1981 EPA decided to reorganize the guidelines and limit the regulation to a concise presentation of the data requirements and when they must be fulfilled; thus the data requirements for pesticide registration pertaining to all former subparts of the guidelines are now specified in Part 158. Information not requiring codification as a regulation, namely the standards for conducting acceptable tests, guidance on evaluation and reporting of data, further guidance on when data are required, and examples of protocols are not specified in Part 158. This information (i.e., Pesticide Assessment Guidelines) is available as an advisory document through the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703-487-4650). Part 160, Good Laboratory Practice, was published as a final rule on November 29, 1983.

Three section titles have been changed and six new sections have been added since the proposal. The title of § 158.65 has been changed from Biorational Pesticides to Biochemical and Microbial Pesticides, § 158.100 has been changed from Overview to How to Determine Registration Data Requirements, and § 158.165 has been changed from Biorational Pesticide Data Requirements to Biochemical Pesticide Data Requirements. The new sections are § 158.101 (Required vs. Conditionally Required Data), § 158.102 (Distinguishing between what data are required and what substance is to be tested), § 158.108 (Product Identity and Composition), § 158.112 (Nominal Concentration and Analytical Enforcement Method), § 158.142 (Spray Drift Requirements) and § 158.170 (Microbial Pesticide Data Requirements).

II. Availability of Support Documents and Comments

The support documents mentioned in this preamble and all written comments received under this notice are available for public inspection in the OPP Reading Room, Room 236, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202 from 8:00 a.m. to 4:00 p.m.,

Monday through Friday, except legal holidays.

III. Organization and Philosophy of Part 158

The data requirements for registration presented in Part 158 are intended to identify the kinds of data and information necessary to permit EPA to determine the identity and composition of pesticides and to evaluate potential adverse effects and environmental fate of each pesticide.

Part 158 consists of two Subparts, A and B. Subpart A contains the general provisions and policies pertaining to the registration data requirements. Section 158.20 states the legal authority for, and purposes of the rule. Section 158.25 of Subpart A explains the applicability of the data requirements to registrants of pesticide products and § 158.30 explains the timing of the imposition of data requirements. Several policies pertaining to the flexibility of the data requirements are outlined in § 158.35 (e.g., consultation with the Agency, data waivers, formulators' exemption, and minor use policy) and detailed in §§ 158.40 through 158.60. The remaining sections of Subpart A deal with the Agency's policy on biochemical and microbial pesticides (§ 158.65), acceptable protocols (§ 158.70), requirements for additional data (§ 158.75), acceptability of data (§ 158.80), and revisions of requirements and guidelines (§ 158.85).

Subpart B contains the data requirements for registration. Sections 158.100 through 158.102 explain how to determine which of the data listed in §§ 153.120 through 158.170 are required. The purposes of the registration data requirements are briefly outlined in § 158.105. Sections 158.108, 158.110 and 158.112 set forth detailed product chemistry data requirements pertaining to product identity and composition, certified limits, and nominal concentration and analytical enforcement methods, respectively. Section 158.115 explains the organization of the Pesticide Assessment Guidelines and their relationship to the data requirement tables presented in §§ 158.120 through 158.170. Each of the data requirements tables covers a separate disciplinary area and contains a reference to the associated Pesticide Assessment Guidelines document.

Section 158.130 *Product chemistry data requirements*, contains the requirements for information on the formation, identification, and quantification of the intentionally-added ingredients and the impurities in pesticide products, and for data on chemical and physical characteristics of the products and their components.

Section 158.125 *Residue chemistry data requirements*, contains the requirements for data on pesticide residues in crops produced for human food, in meat, milk, poultry, and eggs, and in feed for domestic animals used for human food. This section also addresses data developed for residues in fish used for human food, and for pesticide residues in tobacco and certain other nonfood/nonfeed items where residues can pose harm to humans or domestic animals.

Section 158.130 *Environmental fate data requirements*, sets forth the data required to demonstrate the fate of pesticides in the environment through degradation, metabolism, mobility, dissipation, and accumulation.

Section 158.135 *Toxicology data requirements*, includes the requirements for data on pesticide effects in laboratory animals and microorganisms for assessment of potential hazards to humans and domestic animals.

Section 158.140 *Reentry protection data requirements*, contains requirements to calculate the length of time required before persons can safely enter a pesticide-treated site, and for the data needed for the calculation.

Section 158.142 *Spray drift data requirements*, contains requirements for data on pesticide spray drift to evaluate the likelihood and extent of pesticide transport from the site of application to nontarget areas by aerial drift.

Section 158.145 *Wildlife and aquatic organism data requirements*, contains requirements for data on potential adverse effects on birds, mammals, and aquatic organisms.

Section 158.150 *Plant protection data requirements*, sets forth the requirements for data to evaluate the potential for adverse effects on plants in nontarget areas and on desirable plants in target areas.

Section 158.155 *Nontarget insect data requirements*, indicates the data required to assess potential adverse effects on bees and other beneficial nontarget insects.

Section 158.160 *Efficacy data requirements*, contains the requirements for data to demonstrate that pesticide products will control the pests specified in the claims on product labels.

Section 158.165 *Biochemical pesticide data requirements, and § 158.170 Microbial pesticide data requirements*, contain the requirements for data concerning the fate and potential adverse effects of biochemical and microbial pesticides, respectively. Biochemical pesticides include products such as insect pheromones, juvenile growth hormones and natural plant regulators. Microbial pesticides include bacteria, fungi, viruses and protozoa intended for pest control purposes.

IV. Response to Comments

Comments on the proposed rule were received from twenty-eight sources and are available for public inspection at the Office of Pesticide Programs Reading Room, Rm. 236 from 8:00 am to 4:00 pm Monday through Friday except legal holidays, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

EPA has considered the comments carefully and has revised the rule accordingly. Several of the comments made only suggestions for minor changes, many of which have been incorporated into the final rule. Other comments were more substantive, however, and they are discussed below along with EPA's response to each comment. A third category of comments focused on the detailed subject matter of the Pesticide Assessment Guidelines. These comments will not be addressed in this final rule, but they will be considered when the Agency reviews and updates the Pesticide Assessment Guidelines in the future. Likewise, several commenters recommended incorporation of detailed information into the final rule which is already outlined in the Pesticide Assessment Guidelines. The Agency believes that this material is adequately discussed in the Guidelines and that incorporation of this material is, as discussed at I.B., impractical and unnecessary. Therefore, these comments are not included in the following discussion.

The following public comments and Agency responses are grouped according to subject matter, and are presented in the same general order as the subjects appear in the regulation: General Policies and Procedures, Product Chemistry, Residue Chemistry, Environmental Fate, Toxicology, Reentry, Aerial Drift Evaluation, Wildlife and Aquatic Organisms, Plant Protection, Nontarget Insects, Product Performance, and Biochemical and Microbial Pesticides.

A. General Policies and Procedures

1. *Conditional registration data requirements.* One commenter interpreted § 158.25 *Applicability of data requirements*, to exclude the conditional registration data requirements from Part 158. This is not the Agency's intent. The Agency used the term "registration" in the proposed § 158.25 to apply to both conditional and unconditional registrations. Therefore, the data requirements listed in § 158.120

through § 158.170 apply to both conditional and unconditional registrations. The timing and imposition of the data requirements to support both conditional and unconditional registrations is now fully described in § 158.30 *Timing of the imposition of data requirements.*

2. *Peer Review.* A commenter stated that the proposed rule was developed without the assistance of a peer review body such as the FIFRA Scientific Advisory Panel (SAP), and recommended that there be such a body of experts to review this rule. Although the SAP did not review the proposed rule, the SAP has, over the past 7 years, conducted numerous, extensive reviews of the corresponding pesticide assessment guidelines. In addition, the SAP reviewed the final draft of this rule in October 1983, at which time copies were made available for review, and for comment at the public meeting of the SAP. A summary of the SAP's comments and the EPA's responses is presented at VII of this preamble.

3. *Policy on flexibility.* Several commenters addressed the Agency's policies concerning flexibility of the data requirements as summarized in § 158.35 and detailed in §§ 158.40 *Consultation with the Agency,* 158.45 *Waivers,* 158.60 *Minor uses* and 158.70 *Acceptable protocols.* Commenters representing the pesticide industry responded favorably, indicating that such policies are essential in order to address responsibly the wide range of problems and circumstances that arise when regulating such a diversity of products. Other commenters, however, felt that such policies were irresponsible and indicated a greater concern for pesticide registrants than for public health and environmental concerns. The Agency disagrees with the latter viewpoint.

Commenters that disagreed with the Agency's policies on flexibility did so primarily because they view these policies as a mechanism for requiring less data to support registration of pesticide products. The Agency agrees that implementation of certain of these policies (e.g., waiver policy and policy on minor uses) can result in a reduction of data requirements for specific products. However, as it has in the past, EPA will also require additional data when necessary to properly evaluate a product. Specific provisions for requiring additional data are found at § 158.75. This section states that "if the information required under this part is not sufficient to evaluate the potential of the product to cause unreasonable adverse efforts on man or the environment, additional data requirements will be imposed." Therefore, the Agency views its policies on flexibility as a mechanism to increase as well as decrease the data requirements as necessary in specific situations in order to fulfill the purposes of this rule as stated at § 158.20(b).

The Agency has overseen the regulation of pesticides since 1970, when it assumed this responsibility from the U.S. Department of Agriculture. Since then, the Agency has strengthened its ability to assess hazards associated with the use of pesticides by expanding the kinds of data required (particularly in the area of nonhuman, nontarget species and environmental fate and to a lesser extent, toxicology and residue chemistry) and by upgrading the standards for testing as outlined in the current Pesticide Assessment Guidelines. As the Agency has increased its assessment capabilities over the years, it has always attempted to require only the data necessary to properly assess hazard and make regulatory decisions with respect to safety of the pesticide use. Rather than rigidly impose all data requirements in all situations, the Agency has developed tier testing schemes as well as various conditions and criteria for requiring (or not requiring) data. In addition, consultation with pesticide registrants and provisions for the waiver of data requirements are further manifestations of the Agency's intention to require testing on the basis of factual information and scientifically derived data. These approaches and policies have been developed and upgraded over the past eleven years, and their inclusion in the rule should not be construed as representing an altogether new or different approach. Instead, their inclusion in Part 158 serves to summrize existing policies which the Agency believes better serve both the pesticide industry and the environment, than would a rigid policy on data submittal. Some examples of the benefits of the Agency's policy on flexibility are provided in the discussion of waiver policy at IV. A. 4. of this preamble.

4. *Waiver Policy.* Numerous commenters discussed the proposed waiver provisions. Most of the industry commenters supported the proposal, while environmental groups generally opposed the granting of waivers. The environmental groups charged that the Agency lacked the legal authority to waive data requirements, and that, even if the Agency did have such authority, the proposed waiver provision was too broad, lacked meaningful standards, and provided inadequate opportunity for public participation. Moreover, they argued that the proposed waiver provisions overemphasized the interests of pesticide companies and that the proposed system would require substantial Agency resources to administer, resources which could be better devoted to evaluating the safety of currently registered pesticides. Industry comments suggested several procedural changes, including publication of notice in the **Federal Register** of all waiver decisions and a requirement that EPA respond to all waivers in writing within 30 days.

EPA's legal authority to promulgate final regulations establishing data requirements, subject to specific, case-by-case waivers, is based on well-established principles of administrative law. In fact, in several decisions, the Supreme Court has indicated that a waiver provision is an important element of any set of uniform rules implementing a general statutory requirement. Moreover, courts have ruled that federal agencies which have authority to regulate both by adjudication and by rulemaking have substantial discretion in choosing which procedure to use. It follows, therefore, that EPA may issue regulations establishing broad data requirements while also reserving the authority to require or not require particular data—either by waivers or by imposing additional requirements—for individual products.

The Agency agrees with the comments that the proposed waiver provision was too broad and has decided to limit waivers to specific products. Broad data waivers would be implemented by amending the "when required" provisions of the regulation by the rule-making process. The efficacy data waiver specified at § 158.160 is an example of a broad data waiver that has been implemented by rulemaking. This provision is set forth in the conditional registration regulations (40 CFR Part 162) and waives the requirement to submit to EPA efficacy data for all but a few broad classes of pesticide products. The Agency expects that in the future, any broad data waivers would be implemented in a manner similar to that used for the efficacy data waiver.

In addition, in order to further define and narrow the scope of the waiver provision, the Agency has deleted proposed § 158.45(a)(3) which provided for EPA to waive data on its own initiative. The rule now states at § 158.45(a)(2) that the Agency will waive data requirements on a case-by-case basis in response to specific written requests by the applicant.

After reviewing the registration standards issued from 1980–1984 and some recent reviews of new chemicals the Agency concludes that it grants very few data waivers compared to the number of requirements imposed. This review indicated that EPA has waived about 25 data requirements in connection with its comprehensive review of 70 chemicals in the registration standards process. In addition, several data waivers are still under consideration for about eight of these chemicals.

In a recent decision pertaining to a new chemical, the Agency waived the chronic feeding and oncogenicity studies for an aerial broadcast bait product that was to be applied at extremely low doses, had a non-lethal mode of action in the target insect and underwent rapid photodegradation after application. The waiver was contingent upon the receipt of subchronic and teratogenicity studies that demonstrated no significant toxicity in treated animals. On several occasions, the Agency has also waived the requirement for acute testing on each end-use product if acute tests on the technical material or manufacturing-use product demonstrate that the active ingredient has little or no mammalian toxicity (e.g., toxicity category III or IV), the inert ingredients in the end-use product are innocuous, and the active ingredient is significantly diluted in the end-use product. These are examples of the kinds of data waivers the Agency would expect to grant in the future in accordance with § 158.45.

The Agency believes that the standards set forth in the waiver policy at § 158.45(a) are meaningful and has revised the section to state the standards more clearly. In addition, the Agency has added § 158.101 (a) and (b) to clarify the role of the waiver policy and the manner in which the Agency determines whether or not a particular data requirement must be fulfilled to support the registration of a specific product. Section 158.101(a) states that data designated as "required" ("R") are needed unless the requirement has been waived for the product or unless the product is covered by a specific exception set forth in the notes that accompany §§ 158.120 through 158.170. Section 158.101(b) states that data designated as "conditionally required" ("CR") are needed if the product meets the conditions specified in the corresponding notes accompanying the data requirements table. The Agency (and applicants) must evaluate each applicable note to determine whether or not conditionally required data must be submitted.

One commenter suggested that the Agency approve a waiver only if there is "clear and convincing evidence" that the required data would not be relevant to the registration decision under section 3(c)(5). After reviewing some recent waivers, the Agency has reaffirmed its position that waiver decisions often are based on scientific judgments and regulatory policy. Therefore, the Agency has retained the standards for waiver decisions from the proposal.

The Agency recognizes that by soliciting public comment it might obtain additional information relevant to a waiver decision. Moreover, if the waiver decision could apply to other products, the potentially affected registrants and public would have an opportunity to express their views. The Agency, however, believes that the resulting delays could be significant and that there is no legal requirement to solicit public comment. Further, since waivers are to be granted only for unusual products or products with atypical use patterns, the Agency expects that waiver requests will be of interest only to a limited number of people. For these reasons, the Agency has decided that it will not solicit public comments on most waiver requests.

EPA thinks the comments of some groups improperly characterized the proposed waiver provisions as pro-industry. The Agency regards its waiver policy as having a number of important "public" benefits.

By waiving unnecessary data requirements, waivers help to reduce the cost of developing new pesticides, thereby encouraging research and development of safer and more pest-specific products. Eliminating unnecessary testing costs may also reduce the price of the retail product purchased by consumers. Finally, EPA stresses that the waiver policy is intended to eliminate only those requirements which are inappropriate while still requiring submission of those data necessary to make the statutorily required safety determinations.

One commenter opposed the waiver provision because its implementation would require too many resources. The Agency thinks that the policy reasons for granting appropriate waivers justify the resources needed to review such requests. The Agency expects that, as a practical matter, the issuance of this rule will cause little or no change in the Agency's workload, since applicants already request waivers informally. Moreover, it is not clear that eliminating the waiver provision would save Agency resources, since disputes about applying purportedly inflexible data requirements to particular applications would be likely to result in time-consuming litigation.

The Agency has also made it clear that it will respond promptly in writing to all waiver requests. Further, while the Agency does not intend to rely on the Scientific Advisory Panel to make waiver decisions, as one commenter proposed, it may selectively refer waiver requests to the Panel. This, in turn, will minimize delays in acting on routine registration applications. The Agency is currently developing a proposal to charge fees for reviewing applications for registration. Fees for reviewing waiver requests will also be considered for inclusion in this proposal.

The Agency has not set a 30-day deadline for deciding on waiver requests. Waiver requests present issues of varying complexity, and therefore will require different amounts of time to evaluate.

Finally, the Agency has decided to announce only selected waiver decisions in the **Federal Register.** The Agency believes that only those waivers which could apply to more than a small number of products should be announced in the **Federal Register.** Information pertaining to more limited waivers will be publicly available for inspection at the Agency headquarters. In addition, the Agency is revising § 162.9 of 40 CFR Part 162 (Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act) to provide a better mechanism for informing the public of what data EPA relied on in registering a product. Revised § 162.9 stipulates that within 30 days of registration, EPA would (except for cite-all applications) make available a list of all the data EPA had available at the time of registration as well as a list of any data requirements that were waived in accordance with § 158.45.

5. *Minor use policy.* Five commenters questioned the Agency's rationale for certain aspects of its minor use policy, the major elements of which are summarized in § 158.60. The Agency has developed a minor use policy in response to section 3(c)(2)(A) of FIFRA which stipulates that data requirements to support minor uses of pesticides should be commensurate with the anticipated extent of use, pattern of use, and potential exposure of man and the environment. Section 158.60 is not intended to be a comprehensive or detailed account of the Agency's policy and the underlying rationale. Instead, this information is presented in EPA's policy on minor uses published in the **Federal Register** of March 5, 1979 (44 FR 12097). It is not the Agency's intent, nor

its policy, to guarantee the availability of a pesticide product to protect every crop, without regard to the potential hazards to the public and the environment. All pesticides, including minor use products, must meet the requirements for approval of registration as outlined in sections 3(c)(5) and 3(c)(7) of FIFRA and reiterated in § 158.20(a)(1)(i) through (iii). The Agency does, however, in cooperation with USDA, support the IR–4 project, whose overall objective is to identify and develop the data necessary to support minor use pesticide registrations for which there would otherwise be insufficient commercial interest. Finally, the Agency has modified § 158.60(a) to address only those elements of the policy pertinent to this part; i.e., those elements concerning data requirements for minor uses of pesticides.

6. *Acceptable Protocols.* One commenter suggested the Agency adopt language in this rule stating that all data requirements must be fulfilled in accordance with the Pesticide Assessment Guidelines. The Agency agrees with the general thrust of this suggestion; however, we believe that the current language in § 158.70(a), which states that the purpose of the test standards specified in the pesticide assessment guidelines must be met, is preferable because it explicitly recognizes that other protocols may be acceptable, or even preferable, depending on the particular pesticide product and/or its use pattern.

Three commenters requested that EPA clarify its position on the acceptability of protocols published by the Organization for Economic Cooperation and Development (OECD) and requested a specific reference stating that OECD protocols are acceptable.

The Agency agrees that it would be useful to reiterate in this rule EPA's position with respect to the acceptability of OECD protocols. Therefore, while the Agency's general policy on acceptable protocols [§ 158.70(a)] remains unchanged, a paragraph has been added at § 158.70(b) to state the Agency's policy on acceptability of OECD protocols as follows:

> Tests conducted in accordance with the requirements and recommendations of the applicable OECD protocols can be used to develop those data necessary to meet the requirements specified in this part. Readers should note, however, that certain of the OECD recommended test standards, such as test duration and selection of test species, are less restrictive than those recommended by EPA. Therefore, when using the OECD protocols, care should be taken to observe the test standards in a manner such that the data generated by the study will satisfy the requirements of this part.

7. *Policy on test substance.* Nine commenters expressed viewpoints on the Agency's policy on test substance [§ 158.75(b)] which states that the Agency will generally accept tests performed using a technical grade chemical which is substantially similar to the technical grade used in the product for which registration is sought. Most of the commenters (six) stated that they supported this approach. However, two commenters asked the Agency to define the term "substantially similar," and one suggested that decisions should be made based on substantially similar products only when the "production material" is unavailable, and then, only if the surrogate substance contains more active ingredient than the product in question. Finally, one commenter suggested that the Agency require an applicant seeking registration of a "similar or identical" technical material to obtain and analyze a sample of the already registered technical material. The commenter suggested that this would ensure that the applicant has appropriate analytical methodology, and would lessen the reliance the Agency must place on a comparison of trade secret composition statements.

Several considerations are involved when the Agency makes a determination as to whether one technical grade substance is substantially similar to another. First, the composition of almost every technical grade active ingredient varies from one production batch to the next, as well as from one manufacturer to the next. Variability in composition may exist in either the percent active ingredient, or the percent impurities, or both. Therefore there is, in most cases, no set standard (i.e., single set of percentages for the active ingredient and impurities) against which a comparison for the purpose of determining similarity can be made. Instead, this determination must be made by comparing the averages and ranges of actives and impurities in/among technical grade substances.

With these considerations in mind, the Agency bases its determination of substantial similarity on a comparison of the substances. In order for two or more substances to be substantially similar, their active ingredients must be identical and any quantitative differences between active ingredients or qualitative and quantitative differences between impurities must be determined by the Agency to be of no toxicological significance. Finally, the Agency agrees that it would be useful for applicants seeking to register a "similar or identical" technical material to obtain and analyze a sample of the already registered substance.

The Agency believes that its policy on test substance allows EPA to avoid requiring unnecessary and duplicative testing of substantially similar active ingredients. As a result, testing facilities and Agency resources are conserved and can be directed towards untested products and products warranting additional testing and evaluation. An additional benefit of the policy is that since the total number of tests that must be conducted with a particular active ingredient is reduced, fewer test animals (e.g., rats, hamsters, mice, dogs) are required for testing purposes.

It is not the intent of this policy to specify what data would be required to support the registration of a product containing an active ingredient which the Agency has determined is not substantially similar to, for example, the technical grade of the active ingredient (TGAI) in an already registered product. An applicant would have several choices of how to proceed in this situation. The applicant could: (1) Alter the composition of his technical grade chemical to be substantially similar to that in the already registered product, (2) conduct all the required testing using his own TGAI as the test substance, or (3) he could develop the appropriate additional testing on the active ingredient and/or the impurities to attempt to demonstrate why or to what extent the test(s) on the TGAI in the already registered product should be used to support registration of his product.

8. *Acceptability of data.* In reference to § 158.80(a), "Acceptability of Data, General Policy" one commenter asked what the Agency's criteria are for determining that results are reproducible. The Agency has no set criteria, but instead believes that such determinations must be made using good scientific judgment and be based on the specific test in question, the protocol used, the specific end point, and the variability reported among the replicate test groups if replicates were used.

9. *Required vs. conditionally required data.* One commenter cited an apparent lack of distinction between required data (R) and conditionally required data (CR) as discussed in § 158.100(c), and suggested that this could be corrected by clarifying the role of waiver requests with respect to data that are required and conditionally required. The Agency agrees that such a clarification would be useful and has amended § 158.100(c)

(now § 158.101) to indicate that required data must be submitted unless the data requirement does not apply to the product for reasons specified in the note(s) accompanying the data requirement, or unless the Agency has, upon request of the registrant, granted a waiver of the data requirement. For example, § 158.135(b)(1) is a note which accompanies the requirement for acute oral LD_{50} data (§ 158.135(a)), and indicates that such data are "not required if test material is a gas or highly volatile." On the other hand, conditionally required data must be submitted as specified if the conditions or criteria established by the note(s) accompanying the data requirement apply to the product in question. Therefore, it is the Agency's intention that the need to submit conditionally required data will be determined on the basis of the applicable conditions expressed in the notes. Waiver requests for conditionally required data are only necessary if, for example, an applicant disagrees with the Agency's decision that certain conditionally required data apply.

The procedures for waiver requests are discussed in this preamble under unit IV.A.4.

10. *Use pattern index—Appendix A.* One commenter made several suggestions pertaining to the Use Pattern Index (Appendix A) and the corresponding general use pattern categories used in § 158.120 through § 158.165. This commenter felt that the Use Pattern Index did not adequately identify nonagricultural uses. The commenter urged the Agency to include a wide variety of uses (e.g., domestic ornamentals, lawn, turf, non-commercial outdoor termite control) under the "Domestic Outdoor" use pattern category and to eliminate all domestic consumer uses from the "Terrestrial Non-food Crop" category. The commenter further suggested that swimming pool disinfectants should not be classified as aquatic non-food products since many of the "required" tests (unspecified by the commenter but presumably the environmental fate and fish and wildlife tests) would not be useful for evaluating applications for registration.

The Agency has taken several steps to address these comments and improve the Use Pattern Index. First, the Agency reduced the number of use site groups in the index from 33 to 13 by combining several of the groups under the broader headings of "Commercial and Industrial Uses," and "Domestic and Human Use." Second, the Agency agrees that the uses classified as "Domestic Outdoor" require revisions. Therefore, use site group number seven ("Household") now includes all household uses and further, includes a subgroup titled "Outdoor Areas (non-commercial, homeowner use)." Most of these outdoor area uses (e.g., domestic ornamentals, lawn, turf) are now classified as "Domestic Outdoor." Because home garden and orchard uses may involve treatment of food crops, they are now classified as "Domestic Outdoor or Terrestrial Food Crop." Finally, the Agency has decided to retain the "Aquatic non-food" category for the swimming pool disinfectants because the Agency believes that information on environmental fate and nontarget organisms other than humans are necessary to evaluate the potential for adverse effects resulting from the discharge of swimming pool water into the environment. Of course, should certain requirements be demonstrated to be inapplicable for a specific product, the Agency would consider a waiver of these requirements.

11. *Experimental use permits.* In the tables presented in §§ 158.120 through 158.165, the data required or conditionally required to support an experimental use permit (EUP) are designated by [R] and [CR], respectively; the brackets being the designation for EUP. Due to a typographical error, the proposed rule published in the Federal Register of November 24, 1982 (47 FR 53193) incorrectly specified several data requirements as being necessary to support an EUP. These errors were corrected in a subsequent Federal Register notice published January 18, 1983 (48 FR 2142). After further review of §§ 158.120 through 158.165, the Agency has identified certain data requirements that are normally needed to support an EUP but were not so designated in the proposal. Therefore, in order to bring these sections into conformity with Agency practice, all product chemistry requirements (§ 158.120) and the primary eye irritation, primary dermal irritation, dermal sensitization and acute delayed neurotoxicity requirements for forestry use (§ 158.135) are now designated as required or conditionally required to support an EUP. All other changes with respect to the data needed to support an EUP were made in response to specific public comments and are discussed elsewhere in this preamble.

12. *Animal rights.* Although the Agency did not receive written comments on the issue of animal rights, EPA is aware that there is considerable concern on the part of individuals and public interest groups regarding the use of animals in laboratory testing. Because this rule requires tests that use a wide variety and a potentially large number of test animals, the Agency believes it is appropriate to address the issue in this preamble.

Both this rule and the Pesticide Assessment Guidelines address the animal rights issue in a way that will minimize the number of animals used for pesticide testing while still assuring that adequate numbers and kinds of testing are required in order to make available the information EPA needs to make regulatory judgments about the risks and benefits of pesticide products. First, the Pesticide Assessment Guidelines, which contain recommended test standards and examples of protocols, also incorporate numerous recommendations that help minimize the number of animals that must be tested. For example, the acute toxicology tests (e.g., rat acute oral toxicity) include provisions for conducting these tests using only one group of test animals dosed at a maximum level. If this test produces no compound-related mortality, then the full study using several groups of test animals (to establish a dose response) is normally not required. Also, due to their predictable corrosive properties, strongly acidic or alkaline test substances need not be tested for primary eye and primary dermal irritation. For regulatory purposes, the Agency assumes these substances are corrosive.

Second, the Agency's policies on flexibility (as summarized in § 158.35) are intended to ensure that only the necessary data are required, therefore reducing the potential for unnecessary animal testing. Third, as indicated previously in this preamble under unit IV.A.7, the Agency's policy on test substance also serves to eliminate unnecessary and duplicative testing of substantially similar technical materials.

Finally, EPA is continuing to evaluate alternative methods for obtaining data on acute toxicity in order to reduce the use of laboratory animals. However, for the purpose of risk assessment and for extrapolation of results to humans, EPA must be certain that the alternative methods have been verified and will provide the necessary data and information to regulate pesticides.

13. *Pesticide inert ingredients.* One commenter stated that it is not sufficient to test only the technical grade of the active ingredient, because the pesticidally inert ingredients in manufacturing-use products or end-use products produced by integrated formulation systems may be neither

non-toxic nor biologically or chemically inert. This commenter also noted that inerts may react with other ingredients in a formulation to produce impurities which may be of concern; and that the minimal acute toxicity testing currently required of formulations is not sufficient to detect this potential for hazard. Other commenters have asked the Agency to clarify its intention (as noted in the proposal of Part 158) to waive certified limits requirements for innocuous inert ingredients.

The Agency recognizes the need for a comprehensive plan for dealing with intentionally added inert ingredients and impurities and a systematic approach to screen them for safety. The various regulatory initiatives on inerts will be phased in, and full implementation of the comprehensive plan will require several years. To this end, the Agency is currently developing a tiered, interdisciplinary scheme of tests for evaluating inerts. The testing scheme will emphasize mammalian toxicology and will include residue analysis for inert ingredients in products requiring a tolerance. Testing will progress to other disciplines as indicated by the use pattern and the results of the basic (Tier I) tests. These data requirements will be used for systematic screening of new and existing inert ingredients although the pesticide program will continue to devote the major part of its regulatory resources to review of the safety of pesticidally active ingredients.

In order to provide guidance to applicants in the certification of limits, the Agency will also identify and list those inerts and impurities of toxicological concern for which analytical methods will be required for enforcement purposes (see unit B.6. Analytical Methods for Enforcement Purposes and § 158.112). For this purpose, the Agency will screen its files to identify toxic inerts so that the Agency can then require registrants to back their certified limits for these inerts with analytical methods. Section 3(c)(2)(B) of FIFRA will be used to call in residue data and other information for hazard evaluation of inerts of toxicological concern. As noted in the proposal, EPA is also planning to identify innocuous inerts (by use) which will be exempt from any data requirement other than the identification of product composition. The Agency is also concerned about problems of potential synergism of inerts with actives and other ingredients in formulations. Although we plan to focus new data requirements on individual inerts, we are prepared to require toxicology testing of inerts in combination with actives to determine acceptable levels if we have reason to believe that synergism may occur.

The Agency will publish the list of inerts for deregulation at a later time as part of a comprehensive plan for inerts. We anticipate that this set of innocuous inerts will include some of the chemicals listed in 40 CFR 180.1001. The public will be given an opportunity to comment on elements of this plan and the data requirements for inerts before they are implemented.

14. *Formulator's exemption.* As written, the formulator's exemption (§ 158.50) applies only to end-use products. EPA plans to issue a policy statement in the near future that will expand the scope of the formulator's exemption to apply to any product that has been registered and purchased, including pesticide intermediate products. Pesticide intermediates consist of manufacturing-use products that have been diluted and repackaged for sale to formulators for use in making end-use products.

EPA will be issuing a proposed rule reflecting this policy notice and will amend this Part accordingly when the proposal becomes final.

B. Product Chemistry

1. *Need for additional regulation.* EPA solicited comments on whether or not the product chemistry requirements in Part 158 provided sufficient detail and whether a separate regulation for product chemistry as a detailed Supplement to Part 158 would be preferable. Public comments responding to this question indicate that it is appropriate to promulgate rules requiring information on pesticide composition. Only representatives of the pesticide industry commented on this issue, and all opposed using rulemaking to establish the requirements for information on pesticide composition. Nonetheless, most of the same commenters also submitted extensive suggestions for revisions of the provisions of the Pesticide Assessment Guidelines that specified the information needed on the composition of a pesticide. Not only did comments show some confusion about the extent to which the Guidelines were advisory or mandatory, but they also reflected a keen interest in the nature of the requirements for pesticide composition information. Because there is no single, generally accepted understanding about the kinds of information needed on the composition of a pesticide, the Agency determined, therefore, that it would be appropriate to clarify through rulemaking exactly what types of information EPA would require to evalute a product and to give all interested parties a further opportunity to express their concerns about these requirements. Therefore, the Agency will, in the future, issue a proposed rule specifying the kinds of information needed on pesticide product composition.

The Agency has incorporated two additions involving product chemistry requirements into Part 158. First, the Agency has included a more detailed product identity and composition requirement which clarifies and specifies the information needed in the Confidential Statement of Formula. This can be found in the regulation at § 158.108. Second, in response to a commenter who did not understand the terminology used in §§ 158.110, 158.112, and 158.120, the Agency has defined several key terms, at § 158.108.

2. *Manufacturing process requirements.* The Agency received many comments from the pesticide industry to the effect that the detailed information set forth in Subdivision D, Product Chemistry Guidelines, regarding the manufacturing process is excessive and that this information is not needed, nor can it be used to assess product composition. In addition, industry objected to divulging processing details because of their confidential nature.

The Agency requires a basic manufacturing flow chart including chemical reactions and, in some cases, manufacturing parameters. This information can be used by the manufacturer and the Agency to make some reasonable estimates as to the identity of impurities in the products. If the basic information submitted indicates that the manufacturing process may lead to the formation of highly toxic impurities (such as "dioxins" or nitrosamines), the Agency will ask for more details. The Agency believes this information will be useful to identify the potential for formation of impurities that may be toxicologically significant. In addition, the required information and data on the manufacturing process are expected to be consistent with and to support reported data on composition.

3. *Identification of impurities.* The Agency received many comments on its requirements for identification of all impurities present in quantities equal to or greater than 0.1 percent of the technical chemical. Some commenters wanted the level set at 0.01 percent, citing human and environmental concerns as their basis. Others approved of the 0.1 percent level but claimed it would be impossible to quantify all impurities to that level and

recommended that such composition data be accepted by the Agency on a "best effort" basis.

The Agency is aware that applicants will be unable to quantify all of the impurities present in some products down to the 0.1 percent level. Accordingly, the Agency does not intend to require 100 percent accountability in the analysis of the technical chemical with no allowances for what is technically feasible. Rather, it requests that the degree of accountability or closure actually achieved be indicated (typically > ca 98 percent). Furthermore, (as noted in unit B.2 above) when an examination of the manufacturing process indicates the likelihood that an impurity of toxicological concern might form, the Agency will require composition data to lower levels (i.e., <0.1 percent) to ensure that such impurities are at an acceptably low level.

4. *Deletion of microbial assays.* EPA received many comments about the proposed deletion of the battery of *in vitro* microbial assays for screening products for genotoxic contaminants. Generally, the pesticide industry applauded the Agency for dropping these requirements while the environmental groups opposed this action. The Agency has determined that deletion of these requirements is appropriate. As stated in the proposal, the Agency continues to be concerned about the overall validation of this battery of tests and its ability to reliably and accurately identify low levels of genotoxic components. Therefore, the Agency is requiring the identification of all impurities occurring at 0.1 percent or greater concentrations in the technical grade of the active ingredient. In addition to information about composition and identity of ingredients, the Agency will also use the information about the manufacturing process (discussion of formation of ingredients) to assess whether or not highly toxic impurities are likely to be present at much lower levels (See unit B.2., Manufacturing Process Requirements and unit B.3., Identification of Impurities).

The Agency is still interested in the potential of short term tests to identify the presence of toxic impurities at very low levels. Therefore, we will continue to monitor the effectiveness of microbial assays and any other short term test method for their sensitivity and reliability.

5. *Certification of limits.* Some commenters expressed concern about procedures for setting limits for inert ingredients, since starting materials, solvents and other inert ingredients vary in composition. In addition, numerous commenters objected to the proposed requirement that applicants establish certified limits for each intentionally added inert ingredient in their product.

While the Agency believes that in many cases these ingredients pose little risk to humans or to the environment, the Agency has decided, for a variety of reasons, to require a certified upper and lower limit for these ingredients.

Differences in the amount of an inert ingredient may affect the toxicity and efficacy of the product, the residue of the active ingredient left on food, and the behavior of the active ingredient in the environment. Under this regulation, a certified limit is a promise that the composition of the product will never contain more than the upper certified limit or less than the lower certified limit. Conversely, the limits are a statement, in effect, that the product could contain as much as the upper or as little as the lower certified limits.

Moreover, the certified limits, collectively, constitute a promise that the product will contain no intentionally added inert ingredients other than ones reviewed and approved by EPA. In the absence of such promises, EPA cannot be sure that the products distributed and used after registration will have the same composition as the product which the Agency initially approved. Thus, even though the inert ingredients in a product may not be toxicologically significant, the Agency believes it is necessary and appropriate to require the applicant to establish certified limits for these ingredients.

In opposing limits for intentionally added inert ingredients, some commenters claimed that they would impose substantial additional costs for development and validation of assays for each ingredient.

This regulation would not routinely require an applicant to perform the research described above. Under the final rule, the Agency only requires analytical methods for enforcement on a case-by-case basis for intentionally added inerts determined to be toxicologically significant. In most cases, however, the Agency expects that comparatively little work would be required to establish certified limits for intentionally added inert ingredients. To develop a certified limit for an intentionally added inert ingredient that does not react chemically with other components of the product, an applicant would normally calculate the percentage in the final product based on the amount added during formulation based on normal procedures. Thus, the Agency believes that the costs associated with establishing certified limits for intentionally added inert ingredients would not be excessive.

6. *Analytical methods for enforcement of certified limits.* As discussed previously, some commenters assumed that an applicant would need to develop analytical enforcement methods for all product components for which limits were certified. Because the cost of developing enforcement methods is substantial, these commenters requested that the requirement for limits apply only to toxicologically significant ingredients and impurities.

EPA recognizes that significant costs would be associated with a requirement to develop an analytical enforcement method for every intentionally added inert ingredient and every impurity requiring a certified limit. The Agency agrees with the thrust of the public comments that such costs generally are not justified except when the ingredient is toxicologically significant. Accordingly, under the final rule, analytical methodology suitable for enforcement purposes will be routinely required only for active ingredients. This requirement will be extended to intentionally added inert ingredients and impurities on a case-by-case basis when EPA determines that the ingredient is toxicologically significant. For clarity, the Agency has added, at §158.112, a tabular summary specifying the requirements pertaining to nominal concentration, certified limits, and analytical methods for enforcement of certified limits.

7. *Corrosion characteristics.* One commenter objected to the extensive data requirements regarding corrosion characteristics and other data related to containers and closures. It was claimed that packaging requirements and shipment of contained pesticides has been effectively controlled by the Department of Transportation for years and therefore regulation by EPA is unnecessary.

EPA disagrees with this comment. First, the Agency has the authority and responsibility under the FIFRA to require applicants to provide data on both the container and the packaging of pesticide chemicals. Moreover, flammability, corrosiveness, and other physical/chemical characteristics of the formulation are needed to determine the acceptability of the proposed container and packaging. While such data are considered in evaluating the safety of a product during transportation and shipment, they are also used to determine what precautionary statements and other labeling would be necessary to assure public safety after

the product has left the channels of trade and is in use.

C. Residue Chemistry

One commenter indicated that disinfectants and sanitizers used in food or feed handling establishments should be exempted from EPA's residue data requirements because these residues are regulated by FDA. The Agency agrees that FDA regulates the residues of many of these products as specified at 21 CFR 178.1010, and has modified § 158.125(b)(10) to note this exemption.

Another commenter stated that data on residues in potable water should be required for all pesticides that might enter drinking water or ground water, and not just for pesticides that are applied directly to water. The Agency agrees in principle, however, the appearance of pesticides residue in either ground or surface water at times and places remote from the original application is much less certain and much less controllable than residues arising from direct water application. Environmental transport processes are strongly affected by factors such as soil type, cover crop, slope, and rainfall. The data requirements of §158.130 are designed to elucidate the behavior of pesticides in the environment and thus to identify likely paths of transport. Because of many chemical and environmental variables involved, the Agency commonly uses environmental simulation models as predictive tools to combine these variables to predict the likelihood of a pesticide to reach either ground water or surface water. It is not feasible to require actual test data in remote water bodies as a premarket test requirement. The Agency can, however, require monitoring in water bodies once conditional registration has been granted.

The proposed rule states at § 158.125(b)(4) that exemptions from the requirement of a tolerance will usually require an analytical method. One commenter indicated that all exemptions should, without exception, require an analytical method. Analytical methods are needed in cases where accidental or illegal use of a pesticide may result in excessive residues which could raise a public health concern. However, in other cases, even if gross contamination occurs, there would be no public health concern because of the non-toxic nature of the chemical. Examples of this latter case are acetic acid, corn cobs and certain other naturally occurring chemicals. Therefore, the Agency believes it is appropriate to retain the requirement for a method as a conditional requirement depending on the nature of the chemical for which an exemption is requested.

The Agency has also clarified the status of analytical methods used to enforce tolerances. In the past, these methods have been claimed as confidential business information and thus were not released to the FDA, USDA or state agencies responsible for monitoring pesticide residues. To resolve this problem, the final rule stipulates at § 158.135(b)(4) that analytical methods used to enforce residue limits for emergency exemptions, temporary tolerances and permanent tolerances must be available for use by enforcement agencies and thus may not be claimed as confidential business information. In addition, the Agency has added a provision for food use pesticides at § 158.125(b)(15) requiring applicants to provide data on whether the FDA/USDA multiresidue methodology would detect and quantify food use pesticides.

A commenter stated that the Agency should always require data on the reduction of residues in order to decrease the amount of pesticide chemicals to which humans are involuntarily exposed. The calculation of the exposure of the general population to residues in food is done by assuming first that humans consume foods containing residues equal to the tolerance level. If this conservative assumption yields a calculated level of exposure which would be unacceptably high, then the Agency requires data on the exposure that actually occurs. Routinely requiring these data, would in many cases, result in an unnecessary expense with no beneficial effect on public health. However, in order to provide the data to develop more realistic exposure estimates, the Agency has modified § 158.125(b)(11) to recommend that data to establish tolerances include not only the data on the commodity as it travels in interstate commerce, but also data on those portions of the commodity as actually consumed.

The Agency agrees with the comment that reasonable grounds in support of a petition (sections E and G) are not actual data requirements. However, since the Federal Food, Drug and Cosmetics Act specifies that a petition for tolerance should include these sections, they are referenced in § 158.125 along with the residue chemistry data requirements in support of petitions for tolerances.

Two commenters requested that the terms "residue" or "residue of concern" be defined in the final rule. The term "total toxic residues" is defined, along with other key terms, in Subdivision O of the Pesticide Assessment Guidelines. "Total toxic residues" is synonymous with residue of concern and is similar to the commenters' proposed definition of residue. Therefore, the Agency has made no change in response to these comments. Also, the term residue as used in this rule includes both toxic and non-toxic components of the residue, and therefore the commenters proposed definition of "residue" is not appropriate because it pertains only to components "considered to be of toxicological significance."

Finally, two commenters suggested that the discussion in § 158.105(c) of the residue chemistry data requirements should not claim that EPA can "estimate the exposure" to pesticide residues. Rather, the discussion should state that EPA will "estimate the maximum exposure" or "estimate the maximum potential exposure." The Agency does not believe this change would be appropriate. As explained above, § 158.125(b)(11) provides that data on "residues in food as consumed" would be required if the theoretical exposure is unacceptably high and therefore, EPA will obtain data on "actual exposure" in addition to "maximum exposure."

D. Environmental Fate

Three commenters indicated that if volatility studies indicate the tendency for a pesticide to dissipate in air, then the Agency should require a study of the photodegradation in air, rather than decide whether to require such a study on a case-by-case basis. The Agency believes that volatility, alone, does not provide a complete basis for requiring a study of photodegradation in air. Instead, the Agency will require these data when it determines there is potential for significant inhalation exposure based on an evaluation of the pesticide's volatility, in addition to its other pertinent chemical/physical characteristics, its use pattern, its use site characteristics and its inhalation toxicity.

Two commenters suggested that testing for photodegradation in soil be required for non-food terrestrial, greenhouse and domestic outdoor use in addition to the food crop and forestry uses. The Agency has attempted to limit the requirements for these data to situations where use volume is large and to those products for which photodegradation is likely to be a significant mechanism of decomposition. The Agency believes that the proposed rule met these objectives and therefore no change has been made in the final

rule concerning the requirement for testing photodegradation on soil.

Several commenters were concerned that the Agency would not require dissipation studies for combination products and tank mix uses. As indicated at § 158.130 and discussed in the preamble to the proposed rule at V.D., these data will be required on a case-by-case basis when there is a likelihood that the presence of one pesticide would influence the environmental fate of another pesticide.

One commenter suggested that, considering the concern over contamination of ground water, the leaching and adsorption/desorption study should be required to support an experimental use permit. The Agency agrees that data on leaching and adsorption/desorption are important information to have available in order to evaluate the potential for ground water contamination resulting from the experimental use of pesticide products. In the past, the Agency has required the leaching and adsorption/desorption data, when necessary, to support an experimental use permit. Therefore, § 158.130 has been revised to indicate that these data are required to support an experimental use permit (now designated as [R]) involving terrestrial and forestry use patterns.

EPA is aware that there is great concern on the part of industry and public interest groups regarding the occurrence of pesticides in ground water. Because of this concern, the Agency believes it is important to discuss, in this preamble, how the requirements in Part 158 relate to the Agency's evaluation of pesticides with respect to the potential for ground water contamination.

The Agency believes it is preferable to prevent the contamination of ground water rather than to remove pollutants from it. Therefore, as part of the assessment of a pesticide, the Agency evaluates potential for ground water contamination based on data developed from the environmental fate requirements contained in § 158.130. The data requirements of this section that pertain to ground water contamination potential include hydrolysis, photodegradation, soil metabolism, adsorption/desorption, and dissipation under field conditions. In addition, data on vapor pressure and solubility in water are required in § 158.120 (product chemistry). These data, along with pesticide use pattern and other pertinent information, are used in conjunction with various predictive models to determine the likelihood of contamination resulting from pesticide use.

The Agency has several regulatory options available to minimize pesticide contamination of ground water depending on the degree of risk posed by a particular product. Most pesticides do not have the potential to contaminate ground water and no special regulatory action is necessary. However, some pesticides demonstrate a level of risk that warrants certain restrictions on use. For example, product labeling may be used to prohibit the use of a product with significant leaching potential in regions where the aquifer is particularly vulnerable. Restrictions on use rate, frequency of application and formulation type may also be imposed through labeling in order to diminish the likelihood of ground water contamination. In other situations, where the benefits and risks are more uncertain, the Agency may require the applicant to conduct ground water monitoring as a condition of registration. Based on the results of these studies the Agency may then further restrict use of the product, if necessary.

In some cases the Agency may determine that the risks of pesticide use outweigh the potential benefits and therefore deny a new registration or cancel or suspend an existing registration. Finally, EPA may set health advisory levels when pesticides are found, or thought likely to be present, in ground water as a result of existing pesticide use.

Another commenter asked EPA to clarify when it would require the long-term dissipation (in soil) field studies. The general circumstances under which these data are required are presented in § 158.130(b)(4): "required if pesticide residues do not readily dissipate in soil." As indicated in § 158.115(a), the Pesticide Assessment Guidelines provide further guidance on when data are required. In this case, the guidelines state that these data are required by Part 158 if the pesticide product:

(i) Contains an active ingredient with residues that do not reach 50 percent dissipation in soil prior to recommended subsequent application of that same active ingredient to the same sites utilized for the field dissipation studies for terrestrial and aquatic uses; or

(ii) If in the aerobic soil metabolism study for field and vegetable crop uses pesticide (excluding bound) residues in soil are greater than fifty percent of the amount of pesticide initially applied at the time when a subsequent application would occur.

One commenter requested further explanation of the term "significant pesticide residues" as used in § 158.130(b) (6) and (8). Additional guidance on the Agency's interpretation of this term is provided in the Pesticide Assessment Guidelines Subdivision N (Chemistry: Environmental Fate). In the case of confined accumulation studies on rotational crops, significant residues includes parent compound, closely-related degradates, metabolites and/or their conjugates in the crop, but do not include C^{14} activity in the crop associated with that being incorporated into the carbon pool and ultimately into natural plant constituents. With reference to accumulation studies in non-target aquatic organisms, the significance of residues depends on whether residues reach water, persistence of the residues in water, and potential for accumulation in fish as indicated by its octanol/water partition coefficient. Further, extractable residues present in test organisms at 0.05 ppm or greater should be identified.

A commenter noted that registrants have the option to request a tolerance for pesticide residues resulting from crop rotation practices rather than having to place a crop rotation restriction of the pesticide product label. The commenter further suggested that this may not be a good policy because it would not discourage the use of persistent pesticides and may allow more residues in crops than necessary. The Agency recognizes that soil pesticide residues may not fully dissipate during the time of cultivation of the treated crop, and may still be present in measurable quantities when a subsequent crop is planted. The establishment of rotational crop label restrictions to prevent uptake into the crops that follow has resulted, in some cases, in severe restrictions which preclude normal agricultural practices with no concurrent and demonstrable protection of public health because the residues were not of toxicological concern. Therefore, the Agency has decided to use rotational crop label restrictions when such restrictions are appropriate. However, when some measurable quantity of pesticide residues in the crop is toxicologically acceptable, the Agency will use its statutory authority to set tolerances for rotational crops as specified in 40 CFR 180.29(a) and to take them into account in exposure assessments rather than ignoring them.

One commenter indicated that the anaerobic and aerobic aquatic metabolism studies, the leaching and adsorption/desorption study, and the aquatic (sediment) dissipation study should be "conditionally required," rather than "required," for products used in aquatic non-food sites, such as products used in swimming pools and

cooling towers. The Agency has not adopted this suggestion because it believes that most products used in aquatic non-food sites would reach natural soils or water in significant quantities, and therefore such testing is required for most products. However, a registrant may wish to demonstrate that this is not true for his particular aquatic non-food use product, in which case the registrant may request a waiver of the data requirement as provided for in § 158.45 of the rule.

The same commenter suggested that the aerobic metabolism, leaching, and soil dissipation studies should be required for domestic outdoor products only if the product is applied to soil or expected to reach soil in significant quantities. The Agency generally agrees with this observation, and further, believes that domestic outdoor uses generally result in application of significant quantities of product to soil Therefore no change is necessary.

One commenter indicated that accumulation studies in fish should be required rather than conditionally required because such studies are almost always required for the typical terrestrial food-use products, regardless of the specific use pattern. Although these studies may be required for many terrestrial food-use products, the Agency believes that the criteria presented at § 158.130(b)(8) and further detailed in section 165–4 of Subdivision N of the Pesticide Assessment Guidelines (Chemistry: Environmental Fate), provide the necessary guidance to determine whether or not the data are required for a specific product. The Agency further believes that use of these criteria is preferable to requiring these studies under all circumstances to support products intended for terrestrial food uses.

A commenter agreed with Agency's decision to combine the adsorption/desorption studies with the leaching studies as explained in V.D. of the preamble of the proposal, and assumed that the requirement for a water dispersal study had been dropped. The water dispersal study has not been dropped, but instead would be carried out as part of the aquatic (sediment) dissipation studies.

E. Toxicology

1. *General.* One commenter discussed the criteria for requiring each of the subchronic and chronic studies. In most situations the commenter felt that the criteria were too vague, and that generally each test should be required for every pesticide, regardless of the use or potential for exposure. The commenter expressed particular concern for worker exposure (e.g., pesticide applicators, mixers, and farmworkers). The Agency's position on requiring all tests in all situations is discussed under unit IV.A.3. of this preamble and in several of the individual responses to comments on the specific toxicology tests. Briefly, the Agency believes that, considering the different degrees of exposure resulting from pesticide use, requiring all tests for every product is to subject pesticides to more extensive testing on the basis of their toxicological properties as determined by short term testing and on the basis of potential exposure resulting from their use as determined by an evaluation of the pesticide use pattern, environmental fate characteristics (e.g., persistence, mobility) and chemical/physical properties. With respect to exposure of different groups of individuals, the Agency takes a more conservative approach towards those that may be exposed involuntarily (i.e., through the diet) than it does towards those that subject themselves to exposure on a more voluntary basis (e.g., pesticide applicators). As a result, the full range of toxicology tests is normally required for food use pesticides and the requirements for non-food use pesticides are less stringent where workers are the group most likely to be exposed and they can voluntarily take measures to prevent excessive exposure (e.g., protective clothing). However, acute toxicity and mutagenicity testing is required to assess risks to applicators. In addition, 21-day dermal, subchronic oral and/or inhalation studies, are also required as indicated by the proposed pattern of use. Longer term studies may also be required for applicators.

2. *Acute inhalation.* Section 158.135 indicates that acute inhalation toxicity data in the rat are required to support the registration of products for all general use patterns except forestry and to support indoor use products on a case-by-case basis. Two commenters noted that past Agency practice has been to require the LC_{50} for every chemical that is expected to be inhaled, and therefore should be required for the forest use. The Agency agrees and § 158.135 (a) and (b)(16) have been modified to be consistent with the Agency's practice.

3. *Dermal sensitization.* The requirement for dermal sensitization testing is based on a determination that use of the product results in "repeated contact with human skin." One commenter wondered how the Agency defines this qualification and was concerned that the Agency's interpretation would be too narrow, and would not require the study for a product to which farm and other workers are routinely exposed. Two considerations are involved in determining when dermal sensitization testing is required. First, use of the product must result in the potential for contact with human skin. This is primarily a function of the formulation type and method of application. For example, liquid products to be mixed with other products or to be diluted and applied as a spray could obviously result in exposure of human skin, while products contained in traps or baits would not result in such exposure. Second, if use results in potential exposure of human skin, then there must also be potential for repeated exposure in order to warrant the dermal sensitization test. Potential for repeated exposure is a function of the label directions (i.e., whether repeated applications are required), and the user (e.g., professional pesticide applicators may apply the same product repeatedly in different locations). Products to which farmworkers and other applicators are routinely exposed obviously meet the criterion for requiring the dermal sensitization and it is the Agency's policy to require this test for such products.

4. *Neurotoxicity.* One commenter recommended that the Agency require both the acute and subchronic (90-day) delayed neurotoxicity studies for all pesticides and include tests for other neurotoxicity effects. The Agency believes that neither past experience nor the available data support the need for specific neurotoxicity testing for all compounds. Instead, neurological damage other than delayed neurotoxicity should be detected by the other required testing (i.e., acute and subchronic oral, dermal and inhalation toxicity studies). Whenever potential for persistent or permanent neuropathy is observed in any of these tests the appropriate additional testing will then be required [refer to § 158.135(b) (7) and (8)]. The neurotoxicity data requirements are intended specifically for the assessment of delayed neurotoxicity (i.e., prolonged, delayed-onset locomotor ataxia) and they apply specifically to the organic phosphate pesticides and pesticides that are structurally related to substances that cause delayed neurotoxicity. Use of acetyl cholinesterase depression as one of the criteria for requiring the acute delayed neurotoxicity study should not be interpreted as an implicit assumption by the Agency that significant central nervous system effects are limited to acetyl cholinesterase depression. Based on past experience, the Agency has

determined that, of the pesticides that caused acetyl cholinesterase depression, only the organic phosphates have been shown to cause delayed neurotoxicity in the hen. Therefore, it is appropriate to limit this data requirement to those pesticides as specified in § 158.137(b)(4). The hen is specified as the species to be tested for screening the organic phosphate compounds because it has been shown (for these compounds) to react similarly to humans.

5. *Subchronic tests.* Two commenters noted that the proposed rule did not require the 90-day feeding study to support nonfood uses of pesticides. They recommended that this study be required to support such uses because, as one commenter put it, "it is a cornerstone in toxicological evaluation." The Agency agrees with this evaluation of the importance of the 90-day rat feeding study. However, most nonfood use pesticide products are used in such a way that human exposure is not of a magnitude, duration or frequency to justify a subchronic study. Therefore, the Agency has modified § 158.135 to conditionally require this study to support nonfood uses when, as specified in § 158.135(b)(17), expected exposure is oral, is over at least a limited portion of the human life span and is significant in terms of the frequency of exposure, magnitude of exposure, or the duration of exposure.

Another commenter fully supported the testing of food crops for contamination with pesticides to protect the public but noted that pesticides applied to nonfood items also contaminate our environment and expose the general population to pesticides. The Agency agrees with the commenter that pesticide usage in nonfood areas may contaminate the environment. Therefore a conditional requirement (CR) for a 90-day feeding study, rodent and nonrodent, and requirements for data on spray drift (refer to unit IV.G of this preamble) have been added in order to strengthen the evaluation of nonfood crop pesticides.

Two commenters indicated that the requirement for the oral subchronic test was unclear and they were not sure whether one oral subchronic test using either a rodent or a nonrodent is required or whether both rodents and nonrodents must be tested. The Agency requires two 90-day feeding studies: one study performed using a rodent (usually the rat) and the second study performed using a nonrodent (usually the dog). Section 158.135 has been modified to state this more clearly.

One commenter requested that the Agency define the terms "limited portion of the human life span" and "significant exposure" as used in § 158.135(b)(17) to describe when the subchronic (90-day feeding) studies are required. The Agency's interpretation of these terms is illustrated in § 158.135(b)(17) by the cited examples, namely situations such as temporary tolerances, and emergency exemptions which result in pesticide uses of a limited amount, location and period of time. Although there may be a significant exposure to the applicator or consumer of the treated food due to, for example, use of a pesticide under a temporary tolerance, this exposure would constitute only a small portion of a human's life. For these types of exposures, the Agency believes that subchronic studies provide the correct indices of toxicity to compare to this potential exposure of one year or less.

Concerning the 21-day dermal toxicity test, a commenter questioned whether 21 days is an adequate duration to determine potential hazards to "workers." The commenter recommended that the 21-day test be deleted and the 90-day test be required for all pesticides in all use patterns. The Agency disagrees. The 21-day dermal study has traditionally been used to evaluate the potential dermal hazard to applicators when dermal exposure is estimated to be of limited frequency and duration. The commenter offers no justification to change to a longer, more costly study to evaluate this degree of exposure. The Agency will continue to reserve the 90-day dermal study for pesticidal uses in which skin contact is purposeful and/or prolonged.

A commenter expressed concern that there are no subchronic testing requirements for experimental use permits other than the 90-day feeding studies for food uses. The commenter stated that experimental use permits can last a year or longer during which time workers are exposed to the substances. While it is true that an experimental permit can last for a year or longer, each permit is granted for testing a specific product to control a specific pest(s) at specified sites. As a result, pesticide applications under an experimental use permit involve limited pesticide usage, usually over a limited period of time during the year when the pest is present and/or vulnerable to control. Although the Agency believes that under these limited conditions of use, the currently required battery of acute toxicity studies provides adequate data to assess the potential hazards associated with the potential exposure to pesticide applicators, the Agency may require additional testing based on the anticipated exposure, results of previous testing, and/or the pesticide's chemical structures and chemical/physical properties. In addition, pesticides used in experimental programs must be labeled and carry all the appropriate precautionary information, including requirements for protective clothing. Moveover, many if not most experimental use permits are granted to allow further study on already registered active ingredients, and in these cases more extensive data would have already been developed to support the registered product.

6. *Mutagenicity.* Many commenters commended the Agency on its flexible approach to mutagenicity testing. Several comments on the mutagenicity data requirements were directed to specifying the number and selection of tests within each category of end points (gene mutation; structural chromosome aberrations; and tests for other genotoxic effects such as DNA damage and repair, numerical chromosome aberrations, mammalian cell transformation and target organ/cell analysis). One commenter recommended the following battery of tests to address the three end points:

a. Gene mutation—bacteria (Ames *Salmonella)* and mammalian cells (mouse lymphoma, L51788);

b. Chromosomal aberration—*in vivo* rat cytogenic test (bone marrow); and

c. DNA Damage—Human cell WI–38 (unscheduled DNA synthesis) and Bacteria *E.* Coli:polA+/polA- (unscheduled DNA synthesis).

The Agency has the following objectives for the selection of a battery of tests for mutagenicity assessment: (1) To detect, with sensitive assay methods, the capacity of a chemical to alter genetic material in cells, (2) to determine the relevance of these mutagenic changes to mammals, and (3) when mutagenic potential is demonstrated, to incorporate these findings in the assessment of heritable effects, oncogenicity, and possibly, other health effects. To this end, a battery of tests is required to assess the end points of concern to the Agency. The battery will be designed with the nature of the test substance in mind, and the selection of tests within the battery be justified. A representative set of tests of each end point is listed in the Pesticide Assessment Guidelines—Subdivision F.

The Agency believes that the battery of tests mentioned by the commenter above is appropriate for some test substances. However, the Agency has intentionally refrained from spelling out the number of mutagenicity tests required within each category of endpoints because a different number of tests may be appropriate for different pesticide chemicals. For example, a

minimum number of tests might be adequate for a test substance with close structural similarities to non-mutagens, low exposure, negative long term oncogenicity studies, and well-documented mammalian metabolism; while additional testing might be required for a substance that does not exhibit these characteristics. Furthermore, the use of a less validated test may warrant requiring additional testing within a category. As the Agency continues to receive and analyze additional data, we find that with some classes of test substances, certain test are less relisble than others. For example, the use of one gene mutation test (bacterial) for sensitivity and another one (mouse lymphoma cells in culture) to relate to mammalian systems is an excellent combination. However, the most appropriate test in the third category ("other mechanisms") may not be DNA damage tests. For example, an assessment of numerical chromosome aberrations may be useful if a test substance is suspected of interfering with the spindle apparatus.

Other comments on mutagenicity were concerned with the acceptability of specific tests and put forth the recommendation that highly specific methodology is needed. Because of rapid improvements in the field, the Agency has not at this time published detailed recommended protocols for mutagenicity testing under FIFRA. References to current standards for test protocols, conduct of studies and presentation of data, are found in the Pesticide Assessment Guidelines—Subdivision F which are available from the National Technical Information Service. These guidelines include publications from the Gene-Tox Program of the EPA Office of Toxic Substances and the EPA/SRI International Project. See also A.6 of this preamble for a general discussion on acceptable protocols. Applicants should use the procedure which is most suitable for evaluation of the particular product. We expect that proper scientific methodology will be used and that the testing will be designed with sufficient sensitivity. The Agency encourage registrants to submit protocols and battery selection prior to testing for our review and comment.

Two commenters recommended that mutagenicity testing should be required for all pesticide active ingredients for all uses, and particularly in situations where chronic feeding studies are not required. One of the commenters further stated that these tests are relatively inexpensive, simple and quick, and provide useful information. The Agency basically agrees and has revised § 158.135(a) to indicate that mutagenicity testing on the technical grade of each active ingredient in a product will be required to support the registration of pesticide products for all use patterns. Therefore the conditional requirement (CR) has been changed to required (R) for all nonfood, forestry, domestic outdoor and indoor uses. However, as noted at § 158.135(b)(22)(i), mutagenicity studies will not be required if it can be demonstrated that use of the pesticide product precludes human exposure.

7. *Chronic feeding and oncogenicity testing.* Two commenters stated that the Agency should require the chronic feeding and oncogenicity studies to support registration of all pesticides for all use patterns. In support of this position, these commenters stated (1) that repeated human exposure to pesticides occurs by many routes in addition to exposure from food and household products, (2) that many people live in or may visit less densely populated areas where pesticides are also applied, (3) that there is not a threshold of exposure below which carcinogenesis can be discounted, and (4) that Congress explicitly required (in FIFRA) protection of public health from the adverse effects of pesticides. As discussed in general terms under IV.A.3 of this preamble, the Agency does not believe it is in the public interest to rigidly impose all the data requirements for all pesticides, regardless of the use pattern. Instead, the Agency attempts to provide assurance of public safety within the limits of resources, facilities and toxicological skills available for conducting term effects and within the limits of the hazard evaluation science. While the Agency generally agrees with most of the commenters' points, the Agency's and industry's resources must, nevertheless, be focused on those situations where experience shows that exposure to chemicals is most likely to pose a significant hazard.

As stated in the *Principles for Evaluating Chemicals in the Environment* [1] by the National Academy of Sciences, "to study every chemical to the same extent would be an unjustifiable expenditure of very limited and valuable resources. To do so would be to assign equal importance to problems (chemicals) of unequal risks." Therefore, the Agency, due to these limitations, has of necessity had to prioritize requirements for testing, whereby pesticides with use patterns and environmental fate characteristics which result in significant long term exposures have data requirements which correspond to that type of exposure (i.e., chronic feeding, oncogenicity and reproduction studies). As a practical matter, however, the results of chronic feeding and oncogenicity studies are often available on the active ingredients of many end-use pesticide products for which the Agency would not normally require such testing. This situation arises because any one active ingredient often has a wide variety of uses and is formulated into different products, one or more of which will require the chronic feeding and oncogenicity testing. Finally, as discussed previously, the Agency has modified § 158.135 to require mutagenicity testing for all use patterns and, as specified in § 158.135 (21)(i)(B), positive mutagenicity test results are one of the criteria for requiring oncogenicity testing. Therefore, a mechanism now exists for screening all active ingredients for potential mutagenic effects and for requiring oncogenicity testing, as warranted, based on the pesticide use pattern, potential for human exposure and results of mutagenicity testing.

The Agency received numerous comments pertaining to the duration of the chronic feeding and oncogenicity studies. Some commenters felt that test durations were too long, others felt that they should be lengthened, and finally some commenters were confused about the test durations as they were specified in the proposal.

First, to clarify the requirements concerning test duration for chronic feeding and oncogenicity studies, § 158.135(b)(9)(ii) has been revised to read: "Minimum acceptable test durations for chronic feeding and oncogenicity studies are as follows: (A) Chronic rodent feeding study (food use pesticides)—24 months; (B) Chronic rodent feeding study (non-food pesticides)—12 months is usually sufficient; (C) Chronic nonrodent (i.e. dog) feeding study—12 months; (D) Mouse oncogenicity study—18 months; (E) Rat oncogenicity study—24 months."

A commenter interpreted § 158.135(b)(9) as stating that the Agency would accept a 12-month rodent study to meet one of the chronic feeding and one of the oncogenicity testing requirements for nonfood uses. This is not the Agency's intent, nor is it the Agency's current practice. As stated above, and in the preamble of the proposed rule at V.E., the Agency requires two chronic feeding studies and will accept 12-month studies in both

[1] *Principles for Evaluating Chemicals in the Environment*, National Academy of Sciences, P. 111. 1975.

rodents and non-rodents for nonfood uses in order to assess chronic non-oncogenic effects. The Agency believes that this policy harmonizes its policy with that of other federal governmental agencies and international groups (OECD) and that such data will provide a scientifically sound basis on which to assess the chronic effects of a pesticide. When oncogenicity testing is required for either food use or nonfood use pesticides, two "lifetime" studies are required.

One commenter argued that a 90-day or 6-month dog study is adequate for the assessment of chronic toxicity in a second species. Another commenter, however, questioned the Agency's requirement that in the chronic feeding studies the rodent would be tested for 24 months, its approximate life span, while the nonrodent would only be tested for 12 months of its life span (for example, dogs, the recommended test species, usually live 10–12 years). The Agency believes that the 12-month duration for a dog study is adequate to allow the development of most, if not all, non-oncogenic chronic effects. Therefore the information obtained from a study of longer duration would not justify the substantial increase in cost for such a study. In addition to providing scientifically defensible data to assess the non-oncogenic chronic effects of a pesticide, the Agency also believes that its recommended time periods will satisfactorily harmonize its requirements with those published by other governmental agencies and international groups.

One commenter did not agree with the Agency that a 1 year interim report on a chronic feeding study should be required to support a temporary tolerance petition if the theoretical maximum residue contribution (TMRC) would exceed 50 percent of the maximum permitted intake (MPI). The commenter felt the Agency was extremely conservative and proposed "that only the 90-day subacute study (utilizing a safety factor appropriate for the toxicological response) be required to support a temporary tolerance even if 50 percent of the MPI is exceeded." Another commenter expressed the opposite viewpoint and wanted the one year interim data to be required regardless of what percent of the MPI is used by the TMRC. The Agency has historically required interim data on ongoing chronic studies when a petition for a temporary tolerance has been requested, in addition to the required acute and subchronic data. Using the TMRC and MPI, the Agency estimates potential risk to man based on residue levels of the pesticide in or on raw agricultural commodities and based on the toxicologic potency of the pesticide. The Agency believes this is a useful screening mechanism and a realistic approach to estimating risk which considers the independent nature of both of these variables and the relative relationship between them. Therefore the Agency will continue to require this information under these circumstances and has made no changes in the rule in response to these comments.

Two commenters submitted recommendations concerning combined chronic feeding and oncogenicity testing.

One of the commenters suggested that rats and mice should be stated as the preferred species for the chronic feeding studies instead of rodent and nonrodent so that those studies could be combined with the two oncology studies. The second commenter expressed concern about the provision at § 158.135(b)(a) that would allow the chronic feeding study and oncogenicity study to be conducted simultaneously as a single study. The commenter did not think this was common scientific practice and thought that results of chronic studies are used to set dose levels in the oncogenicity tests.

The Agency has made no changes in response to either commenter. Regarding the first commenter, EPA believes that use of the rodent (rat) and nonrodent species (dog) in the chronic studies allows a better evaluation of non-oncogenic chronic effects than if only rodents were tested. The nonrodent, usually the dog, may metabolize chemicals differently than the rodent, so that taken together, these two species give a broader understanding of the toxic effects than if only rodents were used. On the other hand, the oncogenic studies do require the use of the rat and the mouse because the purpose of these studies is to detect increased occurrences of tumors and preneoplastic and preneoplastic lesions in a lifetime exposure study. Animals must be observed for long periods of time very close to the natural life span because of the long latency period of tumors. The mouse and the rat are suitable species because their life spans usually are 18 months and 2 years, respectively.

Concerning the second commenter, the Agency believes that a combined test is acceptable if, as stated in § 158.135(b)(9), the study is designed to simultaneously meet the requirements of both studies. Therefore, the combined study must incorporate various features of each individual study. For example, the design and conduct of the combined study must allow for the detection of neoplastic effects and a determination of oncogenic potential as well as general toxicity, including neurological, physiological, biochemical, and hematological effects and exposure-related morphological (pathology) effects. The Agency believes that this approach is generally accepted by the scientific community. The Agency's Scientific Advisory Panel has reviewed and endorsed this approach, it is used or accepted by other federal agencies, and it is recommended by the Organization for Economic Cooperation and Development (OECD) in their guidelines. Therefore, the Agency has retained the provision in § 158.135(b)(9) to allow for combined chronic feeding and oncogenicity testing.

8. *Teratogenicity and reproduction.* One commenter characterized the Agency's teratogenicity data requirements as limited to an evaluation of potential effects that may arise from exposure to females. The commenter points out the potential for male exposure as a cause of birth defects and questions the Agency's apparent disregard for such a possibility. The commenter is correct that the teratogenicity study is limited to an evaluation of potential effects arising from exposure of females. The protocol recommended by the Agency involves dosing pregnant test animals, therefore this test is not designed to evaluate potential effects from exposure of males. However, the Agency also evaluates results of acute, subchronic, chronic and reproduction toxicity studies as well as the mutagenic potential of a chemical in order to determine possible reproductive toxicity in the male. Reproduction, chronic feeding and mutagenicity studies are generally required along with teratogenicity studies, and therefore the Agency believes that any reproductive toxicity possibly arising from exposure of males is evaluated by the most practical methods currently available. Therefore, while the Agency agrees with the concern expressed (i.e., potential for male exposure as a cause of birth defects) it believes that no changes in the teratogenicity data requirements are necessary in response to this comment.

A commenter recommended that the Agency use tests which observe neonates for a period after birth which is sufficient to evaluate potential effects on neurological development (e.g., poor coordination, behavior abnormalities). The Agency is concerned about the potential effects of chemicals on neurological development. However,

there are several considerations that complicate the study of behavioral effects of teratogens. Many of these effects are compatible with survival, and are more subtle than effects which can be observed in a standard teratology study. Most of the tests for specific developmental behavioral "landmarks" in rodents are insensitive. Some investigators attribute this insensitivity to the capacity of the rodent to adapt to neurological functional deficits. In addition, the meaning of the effects with respect to the animal's life is not easily determined, and the value of the observed effects for extrapolations to man for hazard evaluation is uncertain as well. All of these factors indicate that behavioral teratology is a new area in which validated standard testing procedures have not been developed. Therefore the Agency believes that testing requirements in that area would be premature. However, the Agency remains concerned about the potential of pesticides to induce behavioral defects and will continue to investigate the need for post natal teratology studies.

With respect to the teratogenicity and reproduction requirements, several commenters questioned the Agency's use of phrases such as "significant numbers of women", ". . . may reasonably be expected to result in significant exposure . . . to human females", and "acute exposures." Another commenter asked how the Agency would identify the populations potentially at risk with respect to teratogenicity and how "significant exposures" would be determined. The Agency believes that the use of the terms described as vague by commenters is necessary since each determination as to whether these data are required is based on an evaluation of the specific pattern of use (e.g., use site, formulation type, and application rate, frequency and method), the potential for exposure based on the available environmental fate data, and the physical and chemical properties of the product. Moreover, because each pesticide and its use pattern is somewhat different, it would be impractical if not impossible to develop specific, detailed criteria for requiring these studies that would adequately address each individual situation. Therefore, based on its past experience, the Agency believes the best approach is to set forth, in general terms, the criteria for when these data are required, and to impose the requirements based on a case-by-case analysis.

The Agency is concerned about both acute and long-term exposures in terms of determining the need for teratogenicity studies. Acute exposures are considered just as critical in teratology as long-term exposures because birth defects arise from initial events occurring at precise times during gestation. The Agency requires the teratogenicity studies when there is significant exposure from any use whether in or around the home, in agricultural fields, or elsewhere.

One commenter suggested that the Agency return to recommending a 100-day treatment of male and female animals prior to mating in order to increase the sensitivity of the study. The pesticide assessment guidelines recommend minimum standards. The protocol described in section 83–4 of Subdivision F (Hazard Evaluation: Human and domestic animals) is a recommended guideline for investigators to follow when evaluating potential reproduction effects. The Agency will certainly accept studies that employ a 100-day treatment of animals prior to mating. We believe the multigeneration protocol in section 83–4 is adequate to evaluate the potential reproductive effects of pesticides and that the 100-day treatment is longer than necessary.

9. *Dermal penetration.* The need for dermal penetration data and the circumstances under which EPA would request such data are discussed in Subdivision F of the Pesticide Assessment Guidelines, but the recommended test standards and applicable protocols have been held in reserve for this study. Nevertheless, the Agency does require these data in certain circumstances and discusses appropriate protocols with applicants prior to testing. Therefore, the Agency believes it is appropriate to include the requirement in this rule and had done so at § 158.135(a). This data is conditionally required ("CR") as specified in § 158.135(b)(24) which states that "Dermal absorption studies are required for compounds having a serious toxic effect as identified by oral or inhalation studies, for which a significant route of human exposure is dermal and for which the assumption of 100 percent absorption does not produce an adequate margin of safety. Registrants should work closely with the Agency in developing an acceptable protocol and performing dermal absorption studies."

F. Reentry

One commenter suggested that § 158.140(6)(3), concerning use of the allowable exposure method for proposal of a reentry interval, be modified to direct the reader to Subdivision K of the Pesticide Assessment Guidelines for additional information. The Agency agrees and has modified § 158.140(b)(3) accordingly.

The same commenter further suggested that rigid data requirements should not be set in place, but that reentry data should be developed as needed on a case-by-case basis. The Agency believes that the data requirements are not rigid requirements because they are conditionally required based on the criteria specified in § 158.140(b)(1) through (4). Furthermore the Agency's approach to waiver of data requirements as specified at § 158.45 allows for added (and necessary) flexibility in imposing these requirements. In addition sections 130–3(a)(2), (b) and (c) of Subdivision K of the pesticide assessment guidelines provide further details on the Agency's flexibility in imposing these requirements.

Three commenters recommended that the scope of the current requirements should be broadened to include reentry protection data for indoor uses on a case-by-case basis. The Agency agrees in principle; however, as explained in unit V.F of the preamble to the proposed rule, requirements to address indoor uses have been withdrawn as recommended by the FIFRA Scientific Advisory Panel. The Panel expressed concern that different routes and mechanisms of exposure are likely in interior settings, and the conceptual model proposed to set field reentry levels and intervals would not be applicable for these settings. Therefore, the scope of the current requirements is limited to use patterns associated with growing crops. The Agency will develop other requirements that address interior use patterns using the applicable conceptual models.

Another commenter stated that reentry data to develop reentry intervals to protect field workers from deleterious eye effects, dermal irritation or skin sensitization effects are not warranted; these data should be required on a case-by-case basis depending on a combination of factors including physical/chemical and toxicological properties of the pesticide.

Although dermal irritation and/or dermal sensitization has often been reported to occur during reentry to treated fields, the Agency has, for several reasons, decided against including these effects in the criteria for requiring reentry intervals and supporting data. The Agency's approach to establishing a reentry interval employs a dose/response relationship to

determine an allowable exposure level. Therefore, the use of effects which are dose dependent (e.g., acute oral toxicity) is implicit in the establishment of meaningful reentry intervals. However, the dermal sensitization response is not, for all practical purposes, a dose dependent effect. Furthermore, the data generated by the eye and dermal irritation tests yields no information concerning the relationship between pesticide dose and the resulting response (i.e., irritation). Instead, using the commonly accepted protocols (including those recommended by EPA) a single dose is applied and irritation effects are graded according to a standard scale. Finally, EPA is unaware of any means to measure the extent of ocular exposure resulting from worker reentry into treated fields. Therefore, the Agency does not believe it is feasible to establish meaningful reentry intervals based on the available irritation and sensitization data. Nor, does the Agency believe that the establishment of reentry intervals, using the concept of a dose/response relationship to determine an allowable exposure level, is an effective way to deal with health effects which may be manifested at very low exposure levels in certain sensitive individuals. Therefore, rather than attempting to use results of the irritation and sensitization tests to establish an allowable exposure level, the Agency intends that in some cases reentry intervals will be established using the criteria of § 158.140(b)(1)(i)(E) which allows reentry intervals to be established on the basis of field experience with adverse effects such as dermal irritation or sensitization.

One commenter stated that acute inhalation and acute oral toxicity results should not be used as triggers for requiring reentry studies because reentry poisonings are almost exclusively caused by dermal exposure. EPA does not agree. If human dermal toxicity data existed for each pesticide, then the Agency would agree that use of these data as triggers would not be warranted. However, dermal toxicity data are derived almost exclusively from animals which are at best only rough models for estimating human dermal toxicity. The Agency believes it would be unwise to rely solely on these data. Experience indicates that the large majority of reentry-type fieldworker poisonings have been caused by toxicity Category I pesticides. Therefore, as specified in § 158.140(b)(1), the Agency has adopted the criteria for Toxicity Category I pesticides as the criteria for defining when reentry data must be submitted. The Agency believes that this approach provides greater assurance that potential reentry problems are identified and avoided. The Agency agrees with the commenter that results from the acute oral and acute inhalation studies are not relevant to the procedures used to estimate reentry intervals, but as stated previously, believes the results can be used as criteria for defining when reentry data must be submitted.

Another commenter stated that the Agency's use of discretionary language—such as "reasonably foreseen" human exposure—in determining the need for reentry data is unacceptable. Based on the Agency's considerable experience with reentry exposure episodes occurring over the past 30 years, we believe that exposure can be reasonably foreseen in most cases. The data requirements are written in a flexible manner, as discussed earlier, so that judgment may be exercised to either expand or narrow the scope of requirements for any particular circumstances, depending on past experience or specific conditions.

The same commenter also expressed concern that potential health effects other than acute oral, dermal and inhalation toxicity are not considered when determining the need for reentry data. The Agency disagrees with this assertion. Section 158.140(b)(1)(i) (D) and (E) explicitly include subchronic, chronic, reproductive and other effects as well as epidemiological evidence in the criteria for determining the need for reentry intervals.

Finally, one commenter noted that studies of dermal and inhalation exposure would only be required if "appropriate surrogate data are not available" and "the applicant chooses to use the allowable exposure level method for proposal of a reentry level." This commenter wondered what surrogate data the Agency considers appropriate. The Agency has addressed this question in Subdivision K of the Pesticide Assessment Guidelines, and has indicated that surrogate data such as that of Popendorf [2] is acceptable for use in establishing reentry intervals by the allowable exposure level method.

G. Pesticide Aerial Drift Evaluation

Several commenters have stated that the Agency has not given the matter of spray drift adequate attention and noted that pertinent requirements necessary to evaluate spray drift were not included in Part 158.

The data requirements for aerial drift assessment of pesticides are now included as § 158.142. The requirements found in § 158.142 are a restatement of the Agency's current policy. The Agency issued its original policy to request spray drift data in 1976 and from the 1976 policy and its accompanying protocol for field evaluation came the data requirements and protocols as presented in the proposed Subpart J published in the **Federal Register** of November 3, 1980 (45 FR 72948). Comments were received in response to this proposal and were subsequently incorporated into the protocols and data reporting procedures. Comments were also received in response to public presentations on the requirements and guidelines made during meetings of several scientific societies.

The Agency requires data for spray drift assessment based on an assessment of a pesticide's toxicological properties along with a consideration of those situations where people, animals, or plants may be readily exposed through aerial transport of the pesticide spray. These situations could include highly toxic pesticides that are likely to evaporate quickly and cases where the proposed labeling would allow use of equipment and operating conditions that produce fine droplets and meteorological conditions that could allow the spray to drift for significant distances. The studies will be requested when concerns about risks to humans, wildlife or nontarget plants coupled with estimated exposures, dictate a need for more precise exposure assessments.

The required studies may consist of either of the following, or a combination thereof: (1) A reevaluation of existing published or unpublished data when chemical properties, use patterns, and general geographic/meteorological situations are similar to the proposed product, (2) An undertaking of the studies required in § 158.142.

The use of surrogate data is discussed further in Subdivision R of the Pesticide Assessment Guidelines at section 200–1(d). The evaluation may include modeling efforts based on previous work in the area of spray drift. In time, the evaluation of spray drift will depend more on available information and modeling than on the performance of field studies on a particular pesticide.

Many registrants have tested for potential effects caused by their products that are applied by either ground or aerial application equipment. The Agency has received and evaluated data on spray drift for more than five

[2] Popendorf, W.J., 1980. *Exploring Citrus Harvesters' Exposure to Pesticide Contaminated Foliar Dust.* J. Am. Ind. Hyg. Assoc. (41): 652–659. and Popendorf, W. J. and T. T. Leffingwell, 1982. *Regulating OP Pesticide Residues for Farmworker Protection.* Residue Reviews (82): 125–201.

years and we are aware of several ongoing studies, the results of which will be submitted to the Agency for evaluation. These studies have been performed by various applicants to determine the most efficacious method of application while minimizing spray drift. Some studies have been performed and submitted on a voluntary basis, while others have been requested by the Agency in order to better understand the drift potential and possible harmful effects of various products.

Finally, many researchers are also studying problems associated with spray drift and the impacts of the drifting pesticide on humans, animals, and plants. The Agency is in frequent contact with these researchers in order to learn about potential problems that may arise concerning various pesticides, changes in application equipment, and techniques.

H. Wildlife and Aquatic Organisms

One commenter suggested that the requirement for avian reproduction data be changed from conditionally required (CR) to required (R) for all uses; alternatively, it was suggested that § 158.145(b)(3), which specifies the conditions under which the avian reproduction study is required, be changed to a routine waiver of the test unless the pesticide is extremely toxic to birds and/or was at least moderately persistent. The same commenter also suggested that the fish early life stage data requirement and the aquatic invertebrate lifecycle data requirement should be changed from CR to R for all aquatic uses.

The Agency estimates that the § 158.145(a) Tier 2 data (i.e., fish early-life stage, aquatic invertebrate life-cycle and avian reproduction data) have been requested for approximately 50 percent of the 1,500 or so registered pesticide active ingredients. While the percentage is higher for insecticides and fungicides than for herbicides and disinfectants, there is no clear relationship between the Use Pattern Index in Appendix A, Part 158, and the Tier 2 requirements. The notes provided in § 158.145(b) provide the Agency an opportunity to consider relevant factors such as toxicity, persistence, use site characteristics and exposure before deciding if the data are needed. By considering these factors, the test is required only when the data are pertinent to assessing a potential risk. The Agency recognizes that Tier 2 data are more likely to be required for specific use patterns under a use site group, i.e., "rice" under "aquatic food crop." However, the use pattern alone does not dictate whether or not the data are required. As previously mentioned, many other factors are considered. If the Agency were to designate these data requirements as "Required," an unnecessary burden would be placed on the applicant to submit waiver requests when such studies are not applicable and this would be inconsistent with our stated policy on flexibility in imposing the data requirements (§ 158.135). Therefore, the Tier 2 data requirements will continue to be designated CR.

Several commenters indicated that § 158.145(a) and the accompanying notes [§ 158.145(b)] need modification for the sake of clarity and completeness. Specifically, commenters wondered how many different species must be tested to meet the avian acute oral, avian dietary and acute fish toxicity studies, requested further clarification regarding the data requirements on aquatic species as related to registration of fish toxicants for fish population control, and requested further guidance on § 158.145(b)(1) as to when data are required to support registration of indoor-use products.

The Agency agrees and has modified these sections accordingly. The number of tests required and recommended species are now included in § 158.145(a). Section 158.145(b)(5) now advises applicants seeking to register fish toxicants to consult with the Agency before conducting extensive tests on aquatic species. Finally § 158.145(b)(1) has been modified to indicate more explicitly what data are required to support registration of products to be used indoors.

A commenter stated that the possibility of many products getting into water is underestimated. He questioned the use of some of the criteria in § 158.145(b)(5), i.e., "product is applied directly to water or expected to be transported to water" and "the pesticide is persistent in water, e.g., half-life greater than 4 days," and described them as being too optimistic in their description of the duration of the pesticide in the environment. In addition, the commenter said that the criteria imply that only continuous exposure will be a problem.

In 1976, the Agency commissioned the American Institute of Biological Sciences (AIBS) to convene an expert panel to develop criteria and rationales for the use of basic test data already required (acute toxicity and environmental fate data), and to determine the need for additional testing (life cycle, early life-stage, accumulation, simulated and actual field studies) see Cairns *et al.*, 1978. The criteria set forth in § 158.145(b) represent a consensus of this AIBS Panel.

The Table in § 158.145 indicates that only acute aquatic toxicity data are "Required." The Agency uses these data and the "Required" environmental fate data, § 158.130, (1) to compare the toxicity value(s) with the estimated or measured concentrations of the pesticides in the acquatic environment, and (2) to determine the potential of the pesticides to accumulate and persist in the environment. In other words, the Agency estimates the potential of the pesticide to cause both acute and chronic effects. If the potential is high, then additional data beyond the basic test data are required to further characterize the effects. These data are described as "Conditionally Required."

The Agency recognizes that pesticides applied to extensive acreage in agricultural areas are very likely to contaminate the aquatic environment. However, the more important question for the protection of nontarget aquatic organisms is whether the pesticide application will result in concentrations in the water that are acutely or chronically toxic. The Agency believes that the current criteria provide the mechanism to request sufficient data to address this question. Research and data analyses are continuing in order to improve the criteria and their use in pesticide risk assessment.

A commenter suggested that tests on fish that show potentially lethal behavioral effects should be required in addition to the fish acute toxicity tests. Section 158.145(a) currently requires tests in which behavioral observations are recommended. Effects such as behavioral changes are reported in the fish early life-stage tests and the fish life-cycle protocols recommended in Subdivision E of the Pesticide Assessment Guidelines and "Conditionally Required" in § 158.145. Since the Agency currently receives behavioral effects data as part of the fish toxicity study, we believe that no additional testing to evaluate behavioral changes in fish are necessary.

A commenter pointed out that there are no data requirements for reptiles and amphibians in § 158.145. Without including specific references, the commenter stated that some of these organisms have shown particular sensitivity to pesticides, while others store residues of pesticides and pose a secondary toxicity hazard to predators. The Agency has responded to this comment previously in the discussion section of Subdivision E of the Pesticide Assessment Guidelines. It is appropriate to reiterate this response here:

Subdivision E currently does not provide testing guidelines to address the effects of pesticides on nontarget amphibians and reptiles. At the present time, the Agency assesses hazards to these nontarget organisms from the use of pesticides on a case-by-case basis, using all available and appropriate data. The Agency is currently gathering literature on the effects of pesticides on amphibians and reptiles, and on the appropriate test methods needed to measure these effects. After a review of the available literature, the Agency—That the data required by CFR Part 158.145 and developed according to Subdivision E of the guidelines are sufficient to determine hazards to nontarget amphibians and reptiles; or—That additional data are needed in order to determine hazards to these nontarget organisims.

One commenter, after reviewing both the data requirements in § 158.145 and the test protocols in Subdivisions E and F of the Pesticide Assessment Guidelines, concluded that (1) data requirements for wildlife were limited to acute and reproductive effects data, and (2) there was no concern for other chronic effects, e.g., cancer, birth defects, or fetotoxicity, unless such a concern arose for humans. The commenter thought that the Agency was being delinquent in its mandated charge to protect the whole environment, by not considering other chronic effects on wildlife such as cancer, birth defects, fetotoxicity and by assuming that chronic data required in § 158.135 are generally sufficient to predict chronic effects on wild mammals.

The Agency believes that the comprehensive chronic mammalian toxicity data required in § 158.135 , i.e., chronic feeding, oncogenicity, reproduction iand teratology, are adequate to predict chronic effects for wild mammals as well as for humans. These data are normally available to the Agency for the review of pesticide products whose use would result in widespread exposure of wildlife. Therefore, to require these studies to be duplicated on wild mammals would be expensive and time consuming, and the Agency has no indication that such studies would provide significantly better information than those already required in § 158.135. At present, the Agency is concerned with these other chronic effects only as they result in mortality or reproductive impairment as observed in the required reproduction studies and or field tests.

Furthermore, the Agency considers direct (actute) mortality and reproductive impairment to be the most important pesticidal effects on wildlife populations. The Agency has a growing data base to support this prioritization. Data on direct field mortality associated with the use of pesticides are currently being compiled by the Agency as part of an overall plan to update and improve its environmental risk assessment procedures. Therefore, the Agency believes that it is, at the present time, requesting and using the most pertinent chronic data needed to assess the effects of pesticides on wildlife; no changes have been made in response to this comment.

A commenter stated that the standards and criteria which guide the Agency in determining when the data in Tiers 2, 3, and 4 are required are vague and lack specificity, definition and explanation. For example, many of the criteria refer to the estimated environmental concentration (EEC) yet the Agency does not explain in the rule how the EEC is derived. The commenter requested specific clarification of all the criteria for determining when "Conditionally Required" data are required.

Under EPA Contract No. 68-01-2457, The American Institute of Biological Sciences (AIBS) provided the Agency with recommendations concerning acceptable test protocols and criteria to determine the need for testing beyond Tier 1. The following two reports contained most of the criteria now found in the § 158.145 footnotes ["Criteria and Rationale for Decision Making in Aquatic Hazard Evaluation," AIBS Aquatic Hazards of Pesticides Task Group, 1978; "Analysis of Specialized Pesticide Problems, Volume VI, Wildlife Toxicology Study," AIBS Wildlife Toxicology Task Group, 1974]. Many of these criteria lacked the specificity and clarity that the Agency would have desired. However, the data needed to support increased specificity and greater clarity were not available. The Agency has recently taken three steps to improve these criteria. First, the Agency has initiated an analysis of pertinent inhouse and published acute and chronic toxicity data. This analysis is based on the relationships between dose/concentration of the pesticide and the response of the test organisms. Second, the Agency has begun an intensive retrospective review of inhouse and published data concerning actual pesticide field effects. The data will be used to verify the criteria, and to determine the causal factors that result in field effects or lack of effects. Finally, the EPA Office of Research and Development (ORD) is conducting three field studies that have been designed to field validate the "when to test" decision criteria. Through these efforts, it is hoped that clearer, better supported, and more specific standards and decision criteria will be provided for future inclusion in § 158.145.

While it is rare that measured concentrations in water or on wildlife food items are available, the Agency normally obtains sufficient information from studies conducted to meet the environmental fate requirements for registration. If measures concentrations are avilable they are used in the decision criteria. Normally, the Agency estimates the amount of aquatic and terrestrial exposure (pesticide residues) to nontarget organisms based on the numerous factors that can determine exposure including pesticide use pattern, and use site characteristics. The result is the "estimated environmental concentration" (EEC). In general the following equation and references form the basis for the Agency's current EEC determinations:

Equation

$$\text{EEC for Direct Application to Water (ppb)} = \frac{\text{Pesticide loading to the body of water}}{\text{weight of the water}}$$

References

(1) Wauschope, R.D. "The Pesticide Content of Surface Water Draining fron Agricultural Fields—A Review." *J. Environ, Qual.* 7(4):459–472. 1978.

(2) Burns, L.A., D.M. Cline, and R.R. Lassiter. "Exposure Analysis Modeling System (EXAMS): User Manual and System Documentation." EPA–600/3–82–023, EPA, ERL, ORD, Athens, Georgia 30613. 1982.

(3) Kenaga, E.E., "Factors to be Considered in the Evaluation of the Toxicity of Pesticides to Birds in their Environment." *In* Environmental Quality and Safety; Global Aspects of Chemistry, Toxicology and Technology as Applied to the Environment, Vol II; *Eds*, F. Coulston and F. Korte; Georg Thieme Publishers, Stuttgart and Academic Press, Inc., New York, NY. Pp. 166–181. 1973

(4) Hoerger, F. and E.E. Kenaga. "Pesticide Residues on Plants: Correlation of Representative Data as a Basis for Estimation of Their Magnitude in the Environment." *In* Environmental Quality and Safety, Chemistry, Toxicology and Technology, Vol I: Global Aspects of Chemistry, Toxicology and Technology as Applied to the Environment; Eds, F. Coulston and F. Korte; George Thieme Publishers, Stuttgart and Academic Press, Inc., New York, NY. Pp. 9–27. 1975.

At present, all of the estimation methods need field validation. The Agency hopes that its field validation research efforts will begin to satisfy this need.

I. Plant Protection

One commenter recommended that in the interest of sound scientific procedure, the data requirements for

plant protection should be held in reserve. The Agency believes that adequate methods are available to develop the kinds of data EPA requires for plant protection and therefore we do not agree with this commenter. At present, the Agency's major concern with respect to phytotoxicity is with unintentional damage to natural plant populations, particularly the forests and natural grasslands which possess strongly diversified populations and have reached a "balance of nature." If pesticides are used in these locations to control large insect or fungal infestations or to restore the area to its natural condition, the potential effects of these pesticides would warrant close examination to ensure that natural plant systems will be maintained. This does not mean that the Agency is not concerned about crops, home gardens and ornamentals. In these cases, pesticides are primarily used to maintain these atypical or unnatural monocultures or other specific systems. Therefore, the plant protection data requirements will not be held in reserve but will be imposed as specified in § 158.150(b)(2) for the specific use patterns noted above where knowledge of a pesticide's phytotoxic nature is needed.

Forest site preparation and site maintenance involves the maintenance of a monoculture of trees, and therefore would preclude the need for submission of data on effects on nontarget terrestrial plants. However, streams that run through reforested areas contain diversified and stable plant populations and therefore data on aquatic plant effects would be required.

Data on plant protection following protocols found in Subdivision J of the Pesticide Assessment Guidelines, have been developed and used by several applicants to evaluate the phytoxicity of their pesticides. In fact, most applicants, especially those of herbicides, fungicides, and insecticides, conduct studies similar to those found in Subdivision J. Therefore, requesting the data on a limited basis will not place an unreasonable or extra burden on the applicants.

One commenter expressed great concern over the phytotoxic effect exhibited by non-herbicidal pesticides. Through a survey of the labels of 410 non-herbicidal pesticides, this commenter found that 95 of the pesticides may be injurious to certain plants. The Agency appreciates receiving this indepth review. However, the Agency would not preclude the use of a certain pesticide solely on the basis that it may cause damage to nontarget plants. Instead, the Agency would more likely require the precaution statements as are normally found on these labels. Such statements are provided voluntarily by the registrants based on their own evaluations. Although the Agency normally does not have the data to determine whether these label statements are sufficient or even necessary, experience indicates that "self-policing" has been acceptable in this situation. Moreover, requiring data to substantiate these label statements would require a significant investment of time on the part of both the applicant and the Agency, and the end result would most likely be to require the same label statements as those already developed by the applicant.

Another commenter stated that he did not understand the terminology of "25 percent or greater detrimental effect." This terminology is explained in Subdivision J in various places: Definitions (Section 120–2), and General evaluations and reporting requirements [Section 120–4 (c) and (d)]. A statement has been placed in Part 158 [§ 158.20(d)] directing registrants and other interested readers to the individual subdivisions concerning definitions of certain terms.

Several commenters mentioned that they were dismayed by the setting aside of the nitrogen fixation, mutagenicity, and sorption studies. Nitrogen fixation by bacteria and blue-green algae fixation is one of the major mechanisms by which "fixed" or reduced nitrogen enters the biosphere. Like many other biochemical processes within organisms, however, it can be assessed as well at the organism level as at the biochemical/enzymatic level. The question one asks when requesting data on the effects of a pesticide on nitrogen fixation is what is the mode of action of the pesticide. To answer the question correctly, a long series of biochemical/physiological/morphological tests should be conducted on such processes as photosynthesis, glycolysis, electron transport system, nitrate reduction, nitrification, storage food production, nutrient uptake by the roots, and gaseous exchange by the shoots, and anatomical and morphological changes that occur due to changes in the physiology, in addition to the nitrogen fixation process. The purpose of the studies specified in this regulation, however, is to generate the data necessary to assess the effects of a pesticide at a gross or overall organism level. If a phytotoxic effect occurs, the question then is whether the effect is sufficient to cause concern, e.g., is there reduced yield or aesthetic value, or a possible effect on the natural population.

Mutagenicity studies for plants and the implications of their results have not progressed sufficiently beyond the cause and effect level of an individual plant. The incidences that have occurred of reported tolerances by some weeds to some of the triazine herbicides could most likely be a process of natural selection. Again as with the nitrogen fixation requirements noted above, if a detrimental effect is noted at the gross morphological level, researchers within industry and academia will normally seek the cause. It is not the intent of the Agency to require basic research on every pesticide with which a problem may arise.

The intent of the sorption studies was to obtain information on a specific aquatic system. As the data requirements are currently set forth, this information can be derived from environmental fate studies specified in § 158.130(a) and therefore need not be reiterated in the plant protection requirements.

J. Non-Target Insects

Currently the Agency only requires bee exposure studies when a potential for bee exposure exists. A commenter questioned the Agency's ability to assess the potential for bee exposure and suggested that the contact acute test be routinely required. The Agency disagrees and has designated this test as conditionally required (CR) based on the criterion in § 158.155(b)(1). Use pattern information (i.e., use site, time and frequency of application, formulation type, etc.) is available for each product and is routinely considered along with the available environmental fate data and physical/chemical characteristics of the pesticide in order to assess the potential for bee exposure and to decide whether to require the honey bee acute contact toxicity study. It would be an unnecessary expense for applicants and a burden for Agency reviewers to require the data when exposure is unlikely.

One commenter addressed the Agency's proposal to conditionally require a test on wild bees that are important in alfalfa pollination. This commenter had served on the Agency's expert panel in 1979 to develop protocols for bee data requirements. He noted that the Agency must have misinterpreted the panel's recommendations because the requirement for a study on wild bees is inappropriate for several reasons. For example, only one investigator in the U.S. has the necessary facilities for

conducting such tests and adequate stocks of the alkali bee are difficult to obtain. In addition, the commenter noted that alfalfa seed growers are "quite cognizant" of the potential hazards to wild bees resulting from pesticides, and they work closely with their respective State Department of Agriculture to ensure that adequate restrictions are placed on pesticide use. Therefore, for the above reasons, and to correct an apparent misunderstanding, the Agency has deleted the requirement for testing wild bees important in alfalfa pollination from § 158.155(a).

The Agency included insect predators and parasites in the nontarget insect section of the proposal and in the discussion section of Subdivision L of the Pesticide Assessment Guidelines. However, for a variety of reasons, the Agency reserved these data requirements in the proposal. Three commenters submitted recommendations pertaining to requirements for developing data on insect predators and parasites.

One commenter stated that field testing is not a feasible Tier I data requirement because test insects are not readily available and the natural variability of insect populations (due in part to variable weather conditions) makes it very difficult to develop testing that will yield reliable results. As an alternative, the commenter recommended that the Agency consider testing insect predators and parasites in Tier I using standardized laboratory tests. Another commenter urged the Agency to amend pesticide labels to warn users of the hazards to beneficial insects. To develop these statements, the commenter recommended that EPA require testing on representative species of insect predators and parasites. Data from these studies could also be used to predict effects on other species. The third commenter stated that in order to evaluate effects of end-use products on insect predators and parasities, the Agency should require testing on each end-use product and especially on those products containing ingredients known to cause problems with beneficial insects.

Early in the development of the pesticide assessment guidelines and data requirements, the Agency considered a series of simple field tests as a possible Tier I requirement. However, this idea was discarded for the reasons cited by the first commenter, above, among others. The Agency also considered the use of label statements to warn the users of pesticide hazards to insect predators and parasites. However, there are a number of problems with this approach that must be resolved before such an approach can be taken. For example, label statements would have to be developed from data derived from testing on a few representative species. Unfortunately, EPA has little information on the predictive value of these data. A further complication is the practical value of such information on the label in terms of use restrictions. The Agency is reluctant to require precautionary labeling until we are confident that it will serve a useful purpose. This issue will be considered in the forthcoming proposal on labeling requirements (Part 156).

Finally, with respect to the third comment, the Agency believes that it is unnecessary to test every end-use product, and due to the sheer number of end-use products, such testing would be virtually impossible, as would any rational evaluation and application of the test results. Instead, the Agency believes that initial tests should be conducted on the technical chemical to determine the toxicity of the active ingredient to representative beneficial insects.

Due to the problems outlined in the above discussion, these data requirements remain reserved. However, the Agency is taking steps to resolve some of these problems. It appears that laboratory testing on a few representative species will have to serve as the basis for insect predator/parasite hazard assessment. Therefore, the Agency is looking into funding research in laboratory methods development, as well as field evaluation, to determine the validity of extrapolations from laboratory to field situations and from representative (test) species to similar (related) species.

K. Product Performance

The proposal limited the scope of the product performance data requirements to those products bearing a claim to control pest microorganisms that pose a threat to human health and whose presence cannot be readily observed by the user. The Agency received numerous public comments urging EPA to require efficacy data for products used to control additional public health pests, primarily mosquitoes and rodents. After review and analysis of the public comments, the Agency has decided to rescind the proposed efficacy data waiver with respect to vertebrate control agents intended for control of pests that directly or indirectly transmit disease to humans.

Currently, however, EPA's conditional registration regulations [40 CFR Part 162.163(b)(2)] specify that such data will only be required on a case-by-case basis. Until this regulation is amended, EPA cannot make effective the final rule to routinely require efficacy data on vertebrate control products. Accordingly, EPA has issued a proposed amendment to the conditional registration regulations rescinding the efficacy waiver for vertebrate control products [49 FR 35804, September 12, 1984]. Because efficacy data requirements for vertebrate control products cannot be made final at the same time as the final rule being published today, the Agency will issue the product performance data requirements for vertebrate control products in a separate rulemaking action which will eventually be codified in Part 158. This rulemaking action will be accompanied by a preamble discussing the public comments and explaining how and when the requirements will become effective.

L. Biochemical and Microbial Pesticides

1. *General.* Eight commenters responded to the Agency's request for comment on use of the term "biorational" to describe microbial and biochemical pesticides. None of the commenters favored use of the term "biorational," and the terms biological, biochemical/microbial, biogenic, biorigin, biosource, and biogenous were suggested as possible alternatives. After considering these alternative terms the Agency has decided to discontinue its use of the term "biorational" and to use the terms "biochemical" and "microbial" to describe these pesticides. Section 158.65 has been modified to reflect this change. In addition, the data requirements for biochemical and microbial pesticides are now specified in separate sections, §§ 158.165 and 158.170, respectively.

2. *Biochemical Pesticides.* Four commenters expressed the belief that the potential risks posed by biochemical pesticides have not been sufficiently characterized to warrant the possibility for reduced data requirements as provided in the tier testing schemes for these pesticides. One of these commenters suggested that the Tier I data requirements are "too skimpy to protect public health adequately" and that certain basic data, beyond that outlined in Tier I, should be required before any pesticide product is put into commerce. Other commenters questioned the basis for distinguishing between biochemical products and synthetic chemical products since both could share the same characteristics, such as low use volume, unique mode of action, and target species specificity. Along this line, one of these commenters

suggested that the requirements to submit residue data should be same for conventional and biochemical pesticides.

EPA agrees that the distinction between biochemical and conventional pesticides is not absolute. However, the Agency believes that the data requirements for biochemicals are appropriate because they take into consideration the general characteristics shared by most biochemicals, and because they reflect the Agency's policy concerning regulation of biochemicals.

Biochemical pesticides are usually developed from a careful study of the target pest and its habitat, life cycle, feeding habits and interaction with other organisms. This leads to an understanding of the natural chemical and/or biological mechanisms that control the target populations. As a result, biochemical pesticides are generally species specific and control their target pest by means such as growth regulation or mating disruption (e.g., pheromones, hormones, and natural insect and plant growth regulators). In contrast, conventional pesticides are generally developed because they are toxic (usually lethal) to a pest, and less attention is given to the selectivity of the pesticides for the target species.

Furthermore, most biochemicals are applied at very low rates of application, are highly volatile, or are applied in bait, trap or "encapsulated" formulations. Thus, the application of most biochemical pesticides results in less exposure to humans and the environment than most conventional pesticides. The Agency believes therefore, that because risks of exposure of biochemicals will be lower, the likelihood of adverse effects from biochemicals will also be relatively lower than for most conventional pesticides.

The Agency's approach to regulating biochemicals reflects its intent to specify data requirements for a class of products taking into account their general characteristics (i.e., species specific, non-lethal mode of action and low use rate). Although biochemicals are evaluated in a tier testing scheme, the testing regimen makes ample provisions for requiring the same degree of testing as conventional products, when necessary. Product chemistry requirements for biochemicals are not tiered and are virtually identical to those for conventional products. Similarly, the Tier I nontarget plant and insect requirements are the same as those for conventional products.

The acute toxicology tests (oral, dermal, inhalation, primary skin and eye irritation) are also the same for both classes of products. Further, based on recommendations from the FIFRA Scientific Advisory Panel and public comments, the requirement for subchronic testing and teratogenicity testing (one species) was moved from Tier II to Tier I in § 158.165(c). If human exposure is indicated based on the pesticide use site, rate of application or formulation type, then dermal sensitization, mutagenicity, subchronic feeding and teratogenicity studies may all be required in Tier I. Tier I also includes the requirement for studies to assess effects on immune response, as well as chronic feeding and oncogenicity studies. The Agency believes that the criteria for progressing to higher tiers are sufficiently sensitive to ensure that biochemicals whose use results in significant human exposure and/or elicits a toxic response in Tier I tests will be subjected to virtually the same toxicology and residue data requirements as a conventional pesticide.

As for the residue data requirements for biochemicals, the final regulation will require residue data on biochemicals if the compound is applied at a rate exceeding 0.7oz of the active ingredient/acre in a single application or if the compound is subject to Tier II toxicity testing. Unlike conventional products, none of the biochemicals reviewed to date which are applied at low rates (less than 0.7 oz of ai/acre/application) have triggered Tier II toxicity testing. In contrast, most conventional pesticides applied at such low rates are highly toxic and would be subject to further study if evaluated under the tiered testing scheme used for biochemicals. Thus, different criteria seem appropriate. EPA notes that an applicant seeking to register a conventional pesticide used at a low rate could request a waiver of the residue data requirements if the compound were not persistent and did not cause adverse effects in toxicity studies. In the past the Agency has granted such waivers in appropriate circumstances.

Finally, the Agency's data requirements for biochemicals are also influenced by a number of important policy considerations. First, the Agency believes its approach is appropriate because it eliminates much of the confusion that existed among applicants in the past when requirements for these products were determined solely on a case-by-case basis. Second, EPA expects that, as a result of the tiered data requirements, pesticide manufacturers will generally be able to satisfy these data requirements more quickly and at less cost than is needed to meet data requirements for conventional chemical pesticides. Consequently, these requirements should encourage faster development and market entry of these innovative products, whose characteristics and use history to date indicate that they are among the safest pesticides available.

3. *Microbial Pesticides.* Several commenters raised concerns about the Agency's decision to establish a separate testing scheme for microbial pesticides and questioned the adequacy of that testing scheme. Specifically, one commenter pointed out that microorganisms can produce extremely potent toxins, and two commenters expressed concern that the requirements for microbial pesticides did not appear to address the capacity of viral agents to undergo spontaneous mutation to species of different and undefined characteristics.

EPA's data requirements for microbial pesticides (bacteria, viruses, protozoa, and fungi) reflect the consensus of the scientific experts in the disciplines relevant to evaluation of the hazards of these organisms. In 1975 and again in 1978, EPA co-sponsored a working symposia of experts to evaluate the potential hazards of viral pesticides and to provide guidance on the Agency's evaluation of these products. In 1979, the American Institute for Biological Sciences, under contract to EPA, convened an expert panel which set forth the basic elements of the Agency's testing scheme for human safety. In 1982, the Agency's Office of Research and Development sponsored a workshop to critically evaluate the test protocols and testing scheme for microbial pesticides. Based on these efforts, as well as its experience with microbial products, the Agency believes that the data requirements, and particularly the separate tiered testing scheme for microbial pesticides, will be adequate to evaluate the risks that these products may pose to humans and the environment.

The Agency agrees with the commenters that microbial pesticides have characteristics which require that they be tested differently from conventional pesticides. Unlike chemical pesticides, microbial products may survive, reproduce, and infect non-target organisms. Thus, the first tier of toxicity tests for these products includes requirements directed specifically at assessing these characteristics. The products must be studied in tests using immunodepressed animals (for mammalian studies) and several routes of exposure including intraperitoneal,

intravenous or intracerebral injection. In several of those tests, the study must evaluate the ability of the microbe to infect the test species (i.e., its ability to survive and multiply) as well as evaluate its toxicity. Other tests in Tier I will evaluate irritancy and allergenicity.

The Agency also agrees with the commenters that microorganisms can produce extremely potent toxins. However, if an agent did produce a potent mammalian toxin, this would be readily identified in a Tier I study and further testing would be mandatory.

The Agency also considers that the data requirements are sufficient to allow the Agency to evaluate risks from spontaneous mutations in viruses. The product analysis requirements for microbial products include provisions to address the stability of viral agents by requiring information on the integrity and purity of microbial products. These requirements are imposed to ensure that the species and strain of a microbial organism remains the same during production.

EPA does not consider it likely that mutations in viral pesticides will increase risks to humans and the environment. Spontaneous mutations are a result of normal cellular operations or interactions with the environment. The Agency is not aware of any documented case where a virus has undergone a single spontaneous mutation to an entirely new species. Instead, viruses evolve, with their hosts, over long periods of time and new species probably evolve only very slowly.

Therefore, although spontaneous mutations may occur in a viral pesticide after it is applied, the Agency believes that they pose no more potential hazard than mutations in the same viruses which are already present in the environment. EPA sees no basis for thinking that viral pesticides are more susceptible to mutations or that the mutations will produce greater risks than viruses already present in the environment. Mutations are usually detrimental to the virus and thus most mutant viruses are not well adapted for survival in the environment.

In any event, if the Agency's product analysis and toxicology testing requirements identify a viral agent with a high mutation rate, potential hazards can be examined in more depth. It is also possible that the applicant may decide to abandon development of such an agent.

One commenter recommended that product performance (efficacy) data should be required for biochemical and microbial pesticides. As noted elsewhere in this preamble, the Agency fully expects that registrants will conduct the necessary testing to demonstrate the efficacy of their products. In addition, the requirements for product identity and disclosure of ingredients [§ 158.170(a)] include such product performance information as target species, pest host range, life cycle, and mode of action, as detailed in Section 151–20(c)(vi) of the Pesticides Assessment Guidelines (Subdivision M). Subdivision M also contains recommendations at Section 156–2(a) for submitting information on host spectrum, the time required to achieve the desired level of pest control, and the minimum effective dosage (MED) necessary to achieve the desired level of pest control, or other performance standards. Although Part 158 does not, except as specified at § 158.170(a), contain explicit requirements for this information, such information can and will be required by the Agency for individual products, if determined necessary to judge the safety of a microbial product. See § 158.75(a).

One commenter was interested in developing seed products "treated with various beneficial microorganisms" in order to allow certain plants access to otherwise unavailable soil phosphates, to protect plants from root pathogens, to control various seed and seedling pathogens and seed-attaching insects, or to stimulate growth of plants and in the absence of any recognizable pathogen or pest. In the latter instance "displacement of quasi-pathogens or toxigenic organisms . . . appears to be the mode of action." This commenter noted that optimum utilization of these organisms will probably require that strains be matched with the crop, cultivar, soil type, time of year, and/or production area. A given strain would have a very limited market potential under these conditions. Therefore, the commenter contended that requiring extensive testing of each strain would likely doom the commercial use of these organisms.

While recognizing the potential health hazards associated with the production and application of concentrated inocula, the commenter further stated, based upon the following arguments, that the extensive regulations regarding the use of these organisms on seed are not justified:

1. The pesticidal nature of these organisms is uncertain.

2. The seeds are treated with microorganisms that would already be present at lower levels in the surrounding soil.

3. An excessively strict regulatory approach will impede research into microbial ecology of plants.

Several points are relevant to the Agency's position with respect to treatment of seeds with "beneficial microorganisms." First, it is not clear from the comment whether the use of the product would be considered a pesticidal use. Only those uses which were pesticidal would be subject to the requirements specified in Part 158. Second, it is not clear whether all of the data specified in Part 158 would be required for each strain. Based on its experience in regulating different strains (isolates) of microbial pesticides, the Agency does not automatically require all testing to be performed for each different strain of microorganism. Instead, the Agency examines factors such as host spectrum and mode of action of a new strain compared to a registered strain and considers any changes in virulence or production techniques. The Agency uses this information (along with the quantitative or qualitative information used to identify, separate and characterize the strains) as guidance in determining what additional data, if any, would be required on the new strain. Third, waivers may be appropriate for some of these data requirements if a low level of exposure is likely to result from the proposed use pattern. Thus, while the standard data requirements may possibly be inappropriate for the commenter's proposed product, EPA cannot conclude that any of them would be waived without examining the product and relevant data.

One commenter requested the Agency to reduce the number of toxicology and non-target organisms data requirements necessary to support an experimental use permit (EUP) for microbial pesticides. This commenter suggested that only acute oral (mammal), acute dermal (mammal), acute oral (avian), and honeybee testing be required (using maximum challenge doses of the technical grade of the active ingredient in the mammalian studies, and technical grade of the active ingredient in the two remaining studies). The commenter recommended that the nine remaining EUP requirements specified in the proposal should be conditionally required. The commenter's primary justification for this recommendation was that the reduced set of requirements would be an adequate data base for hazard assessment, and that "unlike conventional pesticides, the nature and low use rate of biorational pesticides have built-in safety factors."

Part 158 reflects the Agency's general agreement with the commenter that the data required to support an EUP for a microbial pesticide should be less than

for conventional chemical pesticides. For example, no environmental fate, residue or long-term toxicology data are normally required to obtain an EUP for a microbial pesticide. The four data requirements recommended by the commenter are inadequate, however, because of the potential for microbial pesticides to survive, reproduce, and infect nontarget organisms, and because exposure (resulting from application as a pesticide) would probably be greater than under natural conditions, in terms of number of non-target organisms exposed, the number of different species exposed, and the degree of exposure (number of microbes per non-target organism). Thus testing beyond the four studies proposed by the commenter is normally required. The Agency has reconsidered requesting both of the avian tests for an EUP and has decided that data from either test will now be sufficient to satisfy the avian data requirement for an EUP. The additional avian data requirement would be required when the application for registration is submitted. A footnote to this effect has been added at § 158.170(d)(2)(iii).

One commenter noted that the immune response requirements as detailed in the Pesticide Assessment Guidelines are inappropriate as presented, and that the results of such tests would be extremely difficult to interpret.

The Agency believes that immune response tests can provide basic information on potential human health and ecological effects of biochemical and microbial pesticides. Results of these tests provide information needed to determine the ability of microbial agents to survive and grow in vertebrates and/or to impair the immune system. The Agency agrees that the guidance on immune response testing provided in Subdivision M needs considerable refinement. The requirement for data on immune response will be retained in this rule. However, the Agency urges registrants of biochemical and microbial pesticides to contact the Agency to discuss appropriate test methods before conducting the immune response tests.

4. *Novel Microbial Pesticides.* The Agency is considering changes in two regulations in anticipation of increasing requests to field test and register novel microbial pesticides (i.e., genetically modified or nonindigenous microbial pesticide products). These changes are intended to allow the Agency to obtain the necessary information to evaluate the safety of these new products in a timely and responsible manner.

The Agency believes that, because they are living, reproducing microorganisms which may not be subject to natural control mechanisms, novel microbial pesticides may be capable of spreading beyond the site of application, with potential adverse human and environmental effects. This would be true even when novel microorganisms are applied in small outdoor field studies. Therefore, the Agency is considering a change in 40 CFR Part 172 Experimental Use Permits to require that people notify the Agency before they conduct small scale field studies (e.g., on <10 acres) with novel microbial pesticides. A notification would include information on the identity of the microorganism; whether the microbe has been genetically altered and, if so, how; a description of the test to be conducted, including any programs for monitoring and containing the microorganism, and information on pathogenicity, infectivity and survival of the microbe in the environment (e.g., greenhouses or laboratory test data). The Agency is considering setting itself a specified period of time (e.g., 90 days) in which it must review the notice and notify the applicant of any potential problems or of the need to request an experimental use permit. An applicant would be free to perform his test any time after that period unless informed otherwise by EPA.

The Agency is also considering amendments to Part 158 to require efficacy data to support the registration of novel microbial pesticides. This change is being considered so that the Agency would routinely have data on benefits at the time of registration. The Agency would use this added information to refine its perspective of the potential risks or the uncertainty associated with the use of these products compared to the benefits of their use.

V. Regulatory Analysis

A. Paperwork Reduction

The basic functions of the Office of Pesticide Programs are the registration of new pesticide products and new uses of pesticide products, and the continuing review of previously registered products and uses to assure continuing safety. Part 158 specifies the types of data and information which the Agency ordinarily requires to evaluate the safety of a pesticide and to make decisions on its registration or reregistration. Development of the data specified in Part 158 constitutes an information collection burden.

In order to examine the size of this information collection burden (as well as to satisfy the requirements of Executive Order 12291, the Regulatory Flexibility Act, and FIFRA section 25), the Agency has developed a Regulatory Impact Analysis. This analysis is entitled, "Regulatory Impact Analysis of Data Requirements for Registering Pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act," and is available for public inspection in the OPTS reading room specified in unit II of this Preamble.

The data requirements set forth in Part 158 has evolved over the years as the state of the art of testing has developed. The Agency believes that the industry is generally in agreement with these requirements and that these testing requirements track internationally accepted standards.

The cost of developing a new chemical for use as a pesticide, including research and development, registration, plant construction, production, marketing and other expenses is typically about $50–75 million, or about $25–30 million if the cost of plant construction is excluded. The Regulatory Impact Analysis indicates that there is no incremental increase in the cost of registering a new chemical as specified in Part 158 compared to the costs of registration under the current system. The data requirements for registration specified in Part 158 account for only 3–6 percent of the typical total development cost, or 6–12 percent if the cost of plant construction is excluded.

For all applications for registration (both old and new chemicals), the annual direct and indirect costs of complying with Part 158, or in other words, of satisfying the information collection burden specified in Part 158, is about $109 million per year. The primary data development burden will result from the reregistration of older chemicals to bring their data base up to date.

The reporting or recordkeeping (information) provisions in this rule have been approved by the OMB under section 3504(h) of the Paperwork Reduction Act of 1980 U.S.C. 3501 *et seq.*, and have been assigned OMB Control Numbers.

OMB Control Number 2000–0483 covers:

1. Application for new or amended pesticide registration.
2. Confidential statement of formula.
3. Data reference list for pesticide applicant.
4. Offer to pay statements for pesticide registrants.
5. Certification statement for pesticide registrants.

OMB Control Number 200–0468 covers:

a. Registration standards/data call-in.
b. Registration standards bibliography.

B. Regulatory Flexibility

This rule has been reviewed under section 3(a) of the Regulatory Flexibility Act of 1980 (Pub. L. 96–354; 94 Stat. 1165, 5 U.S.C. 60 *et seq.*), and the Agency has determined that it will not have a significant economic impact on a substantial number of small businesses, small governments, or small organizations. This conclusion is based on the Agency's regulatory impact analysis which evaluated economic impacts on pesticide producers, formulators, governmental units and pesticide users.

The primary impact on pesticide producers results from the cost of data to support registrations, but these costs are now borne primarily by the larger pesticide-producing firms in the industry. Of the major producers (34 reporting in 1980), the smallest firms account for rather limited pesticide R&D efforts, and therefore would tend to be less affected by the data requirements than would the larger firms.

The "formulators' exemption" limits the impacts of the registration data requirements on formulators who do not produce basic active ingredients of pesticides. This exemption applies to the formulation of end-use products from other products which have registrations as specified in subsection 3(c)(2)(D) of FIFRA. Specifically, that subsection of FIFRA reads:

> No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into an end-use product shall be required to:
> (i) submit or cite data pertaining to the safety of such purchased product; or
> (ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

This means that most of the formulating firms in the industry are not required to incur data costs for the active ingredients used in products which they formulate unless they are also the basic producers of the active ingredients.

The Office of Pesticide Programs has a minor use policy that is applicable to small volume-pesticides and minor use sites. Under this policy which is outlined at § 158.60, EPA will adjust data requirements in accordance with the potential market volume and aggregate risk. By these and other steps, EPA intends to minimize the burden of data requirements pertaining to minor use registrations to as low a level as possible, while still allowing for an informed decision based on risk/benefit criteria.

No significant impacts are anticipated on small governmental units from implementing the data requirements because these units, such as those at the county, city or local level, are generally not involved in any of the pesticide registration functions under FIFRA.

Finally, the data requirements for registration would not produce a significant impact on users of pesticides in general, either due to the prices of pesticide products or loss of current products, because pesticides are a relatively small component of cost for most firms in their operations regardless of the industry or the size of firm involved, because the increases in prices attributable to data requirements will be insignificant, and because alternatives are likely to be available for cancelled products.

Accordingly, I certify that this regulation does not require a separate regulatory flexibility analysis under the Regulatory Flexibility Act.

C. Agricultural Sector Impacts

The Regulatory Impact Analysis for this proposed regulation includes an analysis of the expected impact on the agricultural sector of the U.S. economy. The general findings were that the costs which might be passed on to agricultural pesticide users would not have significant impacts on agricultural commodity production or prices. Furthermore, retail prices to the consumer and the general agricultural economy would not be noticeably affected by this proposed regulation. These factors are specifically taken into account as required by section 25 of FIFRA.

VI. Designation of the Public Record

EPA has established a public record for this rule [OPP–30063] which is available for inspection in the Office of Pesticide Programs (OPP) Reading Room from 8:00 a.m. to 4:00 p.m. Monday through Friday except legal holidays, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. This record includes basic information considered by the Agency in developing this rule. The Agency has supplemented this record with additional information as it was received. The record includes the following categories of information:

1. Minutes, summaries, or transcripts relating to public meetings held to develop or review this rule.
2. Published documents (or copies thereof) cited in any document in this record, to the extent that they would not be available through ordinary library loans.
3. Public comments received on the proposed Part 158 regulation.

VII. Statutory Review

The FIFRA Scientific Advisory Panel (SAP) reviewed the draft final Part 158 regulation in a public meeting held October 18 and 19, 1983. The panel, in general, fully endorsed the policies, procedures and data requirements for registration as set forth in Part 158, and stressed the need for flexibility and a common sense approach in the imposition of data requirements on prospective registrants. In its final written report the Panel made three specific comments pertaining to the regulation. Each of these comments is discussed below, together with the Agency's response.

1. The Panel found the term "biorational" to be highly controversial and opposed setting apart the biochemicals insofar as data requirements are concerned. The Panel stated that all pesticides in this group, except the microbial pesticides, should be subjected to the same data requirements for registration as any other pesticide. Waivers could be granted in cases where it makes little sense to require the full range of data to support registration.

EPA Response: The Agency will discontinue use of the term "biorational," and instead will refer to these products as biochemical and microbial pesticides. EPA agrees that the distinction between biochemical and conventional pesticides is not absolute. However, as discussed in unit IV.L.4 of this preamble, the Agency believes that the data requirements for biochemicals are appropriate because they take into consideration the general characteristics shared by most biochemicals, and because they reflect the Agency's policy concerning regulation of biochemicals. Nevertheless in the response to the SAP's concerns the Agency has reevaluated the toxicology data requirements and has added to Tier I a conditional requirement for a 90-day rodent study and a teratogenicity study in one species. These requirements provide additional assurance that potentially hazardous biochemicals will be detected in Tier I and subjected to further testing in subsequent tiers.

2. The Panel concluded that there is insufficient information available on the intentionally added inert ingredients of pesticide products and on how EPA regulates these substances. The Panel, therefore, recommended that EPA develop a better regulatory program than now exists for inert ingredients in pesticide products.

EPA Response: The Agency agrees with the SAP's comments on inert ingredients and expects to phase in various regulatory initiatives on inerts over the next several years. As discussed under unit IV.A.13 of this preamble, the Agency is currently developing a tiered interdisciplinary scheme of tests for evaluating inert ingredients. The data derived from these tests will then provide a basis for regulating the use of these substances in pesticide products. Also, as part of its inert ingredients plan, the Agency intends to identify and publish a list of innocuous inerts which will be exempt from most data requirements. To provide guidance to applicants in certifying limits, the Agency will also identify and list inerts and impurities of toxicological concern for which an analytical enforcement method will be required. Both the SAP and the public will be given an opportunity to review and comment on the elements of this plan and the data requirements for inert ingredients before they are implemented.

3. The Panel noted that the field of testing for mutagenic effects is evolving rapidly and urged EPA to communicate on a regular basis with the mutagenicity testing community in order that the Agency's policies and requirements reflect the most current thinking in this area.

EPA Response: EPA agrees with the Panel. Scientists in the Office of Pesticide Programs maintain close contacts with the mutagenicity testing community through direct communications, professional meetings, and through the Agency's Office of Research and Development which sponsors research in this area.

In accordance with FIFRA section 25, copies of an earlier draft of this regulation were submitted in March, 1984, to the U.S. Department of Agriculture (USDA). USDA provided written comments on the regulation in April, 1984. Each of these comments is discussed below, together with the Agency's response.

1. USDA noted that the regulation refers to the registration process as an evaluation of risks and benefits. They suggested that registration be referred to as a risk analysis process as the data requirements so indicate or, alternatively, efficacy/benefit data should be required at the time of registration.

EPA Response: EPA agrees with USDA that the focus of the regulation and the data requirements is largely on the risk analysis process. The need for efficacy/benefit data is often based on results of the risk analysis. For most pesticides, the risk criteria set forth in the Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act (40 CFR Part 162) are not met or exceeded. Therefore, rather than require efficacy data the Agency presumes that benefits exceed risks. A relatively few pesticides, however, demonstrate a risk potential that, when judged by the criteria, is of such magnitude that it is presumed they ought not be registered at all, unless an intensive evaluation of the risks and benefits of each use of the pesticide demonstrates that the benefits of such use warrant the acceptance of the risks associated with that use. Thus, as noted in this preamble at IV.K., submission of product performance data will be required for the evaluation of product benefits when product risk are determined substantial. The provision for EPA to require these data, when necessary, is set forth in § 158.160(b)(1) of this regulation.

2. USDA agreed with the public comment summarized in IV.L. of this preamble which suggested that the toxicology and non-target organisms data requirements to support an experimental use permit (EUP) for microbial pesticides should be reduced.

EPA Response: As discussed in IV.L. of this preamble, the Agency does not agree with the commenter because the limited data that were suggested would not provide an adequate basis for assessing potential hazards associated with use of a microbial product in an experimental program.

3. USDA supported the concept of "required vs. conditionally required" data as discussed in § 158.101 but suggested that the discussion be expanded, particularly with respect to the rationale for requiring only acute and mutagenic toxicological data for pesticides designated for forestry use.

EPA Response: As stated in § 158.101(6), conditionally required data must be submitted when the applicable criteria set forth in the notes accompanying each requirement are met. Therefore, it should not be assumed that only the data designated as required are needed to support registration. Rather, the complete list of data required to support registration of a product for a specific use will consist of all the required data plus all the conditionally required data. § 158.110(c) has been modified to emphasize this point more clearly. In the case of forest use pesticides, § 158.135(a) specifies that all the toxicology data (e.g., subchronic, chronic, oncogenicity, reproduction, teratogenicity) may be required, depending on the particular product and whether the criteria in the accompanying notes (§ 158.135(b)) are met. For example, depending on the extent, duration and route of pesticide exposure expected for a particular forest use pesticide, one of the three subchronic studies (oral, dermal, inhalation) normally would be required. These studies are listed as conditionally required rather than required, since all three of the subchronic studies would rarely, if ever, be required to support a single use of a product.

4. USDA suggested that the regulation outline what EPA should do with data after they have been evaluated. More specifically, USDA recommended that EPA publish, in the **Federal Register**, data evaluation summaries for each product. Such summaries would include information such as the animal tested, dosage and result.

EPA Response: EPA agrees with this comment and is working on ways to further disseminate this information to the public. The purposes of the data requirements and how the Agency uses the data in its review of pesticide products are discussed in § 158.105 of this regulation. As stated at IV.A. 4 of this preamble, the Agency is revising § 162.9 of 40 CFR (Regulations for the Enforcement of the Federal Insecticide, Fungicide and Rodenticide Act) to provide a better mechanism for informing the public of what data EPA relied on in registering a product. For products that have been reviewed in the reregistration process, the Registration Standard document and data evaluation records are available upon request. In addition, the Agency is now preparing pesticide "fact sheets" which will be available for chemicals reviewed under the reregistration program as well as for new chemicals.

5. Concerning the discussion of product performance in the preamble at IV.K, USDA felt the discussion implied that EPA had discussed with them a procedure to resolve efficacy questions for invertebrate control agents; however they are unaware of such discussions.

EPA Response: USDA is correct in stating that discussions have not taken place. It was not the Agency's intent to imply that discussions had taken place, but rather to indicate how efficacy questions may be resolved in the future.

Copies of this rule were also submitted to the Committee on Agriculture of the U.S. House of Representatives and the Committee on Agriculture, Nutrition and Forestry of the U.S. Senate.

List of Subjects in 40 CFR Part 158

Administrative practice and procedures, Pesticides and pests, Data requirements.

Dated: July 23, 1984.

Alvin L. Alm,

Acting Administrator.

40 CFR Chapter I is amended by adding Part 158 to read as follows:

PART 158—DATA REQUIREMENTS FOR REGISTRATION

Table of Contents

Subpart A—General Provisions

Subpart B—Data Requirements

Authority: Sec. 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (7 U.S.C. 136 *et seq.*).

Subpart A—General Provisions

§ 158.20 Overview.

(a) *Legal authority.* These requirements are promulgated under the authority of sections 3, 5, 12, and 25 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA) (7 U.S.C. 136–136y).

(b) *Purposes of this part.* (1) The primary purpose of this part is to specify the types and minimum amounts of data and information the Agency requires in order to make regulatory judgments about the risks and benefits of various kinds of pesticide products under the criteria set forth in FIFRA sections 3(c)(5) (C) and (D) and 3(c)(7).

(2) This part also specifies the types and minimum amounts of data and information the Agency requires to decide whether to approve applications for experimental use permits under FIFRA section 5.

(3) Finally, this part specifies the types and minimum amounts of data and information that an applicant for registration, amended registration, or reregistration must submit or cite in support of an application in order to satisfy the requirements of FIFRA section 3(c)(1)(D) and sections 3(c)(5)(B) or 3(c)(7). Use of the term "registration" in this part will pertain to new registrations and amended registrations as well as reregistration accomplished under section 3(g), unless stated otherwise.

(c) *Availability of related guidelines.* The data requirements for pesticide registration specified in this part pertain to product chemistry, residue chemistry, environmental fate, toxicology, reentry protection, aerial drift evaluation, wildlife and aquatic organisms, plant protection, nontarget insects, product performance, and biochemical and microbial pesticides. The standards for conducting acceptable tests, guidance on evaluation and reporting of data, further guidance on when data are required, definition of most terms, and examples of protocols are not specified in this part. This information is available in advisory documents (collectively referred to as Pesticide Assessment Guidelines) through the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (telephone: 703–487–4650).

§ 158.25 Applicability of data requirements.

(a) Some kinds of data and information are specified in §§ 158.120 through 158.170 as "required" ("R") for the evaluation of some or all types of products. Other kinds of data and information are specified in those sections as "conditionally required" ("CR"), that is, they are required if the product's proposed pattern of use, results of other tests, or other pertinent factors meet the criteria specified in those sections. The terms "required" and "conditionally required" are further discussed in §§ 158.100 and 158.101.

(b) The Agency recognizes that certain data requirements may not be applicable to (or should be waived for) some products, and has made provisions for such cases in this part as specified in § 158.35 *Flexibility of the data requirements,* § 158.40 *Consultation with the Agency,* § 158.45 *Waivers,* and § 158.60 *Minor uses.*

§ 158.30 Timing of the imposition of data requirements.

This part establishes requirements for the types of data which are necessary to support the unconditional registration of a pesticide product under section 3(c)(5) of the Act. While every registered pesticide product must eventually be supported by the data required by Part 158, when an applicant or registrant must initially satisfy these data requirements depends on the factors listed below in this section.

(a) *Existing Registrations.* A registrant of a currently registered pesticide product is not obligated to satisfy any data requirement in Part 158 with respect to that product until he receives a notice under section 3(c)(2)(B) of the Act that additional data are required to support the continued registration of the product, until he applies for an amendment to the registration, or until the product is subject to reregistration.

(b) *Applications.* The amount of data required by the Agency to evaluate an application for initial or amended registration depends on whether the product is being reviewed under section 3(c)(5) of the Act (unconditional registration) or section 3(c)(7) of the Act (conditional registration). Refer to 40 CFR 162.7 (d) and (e) or consult with the appropriate EPA Product Manager to determine under which section of the Act the application will be reviewed. The following paragraphs identify, for each different type of application, the minimum amount of data that must be available for EPA review to permit EPA to make the statutory risk-benefit determinations required by section

3(c)(5) or 3(c)(7) of the Act. In addition to satisfying these minimum data requirements, applicants may be required to submit or cite additional data, either to permit EPA to assess the safety or efficacy of the product (refer to § 158.75) or to comply with the statutory requirements of section 3(c)(1)(D) of the Act, or both.

(1) *Applications for unconditional registration under section 3(c)(5) of the Act.* EPA will not approve an application for unconditional registration unless all data required by this part which have not been waived are available for EPA to review.

(2) *Applications for conditional registration of a new chemical under section 3(c)(7)(C) of the Act.* EPA will not approve an application for conditional registration of a pesticide containing an active ingredient not contained in any currently registered product unless data required by this part are available for EPA to review except for:

(i) Those data for which the requirement has been waived.

(ii) Those data for which the requirement was imposed so recently that the applicant has not had sufficient time to produce the data.

(3) *Applications for conditional registration of products which are identical or substantially similar to currently registered products under section 3(c)(7)(A) of the Act.* EPA will not approve an application for conditional registration of a pecticide product which is identical or substantially similar to a currently registered pesticide unless the following data are available for EPA to review:

(i) Product chemistry data, as required by § 158.120.

(ii) Product performance data, to the extent required by § 158.160.

(4) *Applications for conditional registration of new uses of currently registered products under section 3(c)(7)(B) of the Act.* EPA will not approve an application for registration of a pesticide for a new use of a currently registered pesticide product unless the following data are available for EPA to review:

(i) Product chemistry data, as required by § 158.120.

(ii) Product performance data, to the extent required by § 158.160.

(iii) Other data pertaining solely to the new use. The applicant may generally determine which data pertain solely to the new use by comparing the data requirements for all existing uses of all currently registered products containing the same active ingredient(s) with those for all uses including the new use. Any differences are attributable to the new use and must be submitted with the application.

(Approved by the Office of Management and Budget under control numbers 2000-0483 and 2000-0468).

§ 158.35 Flexibility of the data requirements.

Several provisions of this part provide EPA flexibility in requiring (or not requiring) data and information for the purposes specified in § 158.20(b). These provisions are summarized in this section and discussed elsewhere in this part.

(a) The Agency encourages each applicant, particularly a person applying for registration for the first time, to consult with the Product Manager for his product to resolve questions relating to the protocols or the data requirements before undertaking extensive testing under § 158.40.

(b) Any applicant who believes that a data requirement is inapplicable to a specific pesticide product may request a waiver of a data requirement under § 158.45.

(c) The Agency may require an applicant to provide additional data or information beyond that specified in §§ 158.108, 158.110, 158.112 and 158.120 through 158.170 when these data are not sufficient to permit EPA to evaluate the applicant's product under § 158.75.

(d) Several policies are in effect that govern the data requirements for registration of products having minor uses. These policies reduce substantially the data requirements that need to be met on the basis of limited exposures and economic equity, and allow case-by-case decision making to determine the specific needs for each kind of use under § 158.60.

(e) The data requirements and guidelines are not static documents. Section 3(c)(2) of FIFRA states that the administrator "shall revise such guidelines from time to time." Therefore, the data requirements and guidelines will be revised periodically to reflect new scientific knowledge, new trends in pesticide development, and new Agency policies under § 158.80.

§ 158.40 Consultation with the Agency.

This Part establishes data requirements applicable to various general use patterns of pesticide products, but some unique or unanticipated aspect of a proposed product's use pattern or composition may result in the need for conferences between registration applicants and the Agency. Such conferences may be initiated by the Agency or by registration applicants. Applicants are expected to contact their respective Product Managers to arrange discussions. The Agency welcomes suggestions for changes to improve the clarity, accuracy, or some other aspect of the data requirements set forth in this Part. Specific suggestions should be forwarded to the Director of the Hazard Evaluation Division.

§ 158.45 Waivers.

(a) *Rationale and policy.* (1) The data requirements specified in this part as applicable to a category of products will not always be appropriate for every product in that category. Some products may have unusual physical, chemical, or biological properties or atypical use patterns which would make particular data requirements inappropriate, either because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks or benefits of the product. The Agency will waive data requirements it finds are inappropriate, but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards.

(2) The Agency will waive data requirements on a case-by-case basis in response to specific written requests by applicants. Because of the wide variety of types and use patterns of pesticides, it is impossible to spell out all of the circumstances which might serve as a basis for waiving data requirements. The Agency, however, will take into account, as appropriate, the factors enumerated in sections 3(c)(2)(A) and 25(a)(1) of FIFRA.

(b) *Procedure for requesting waiver.* (1) An applicant should discuss his plans to request a waiver with the EPA Product Manager responsible for his product before developing and submitting extensive support information for the request.

(2) To request a waiver, an applicant must submit a written request to the appropriate Product Manager. The request must specifically identify the data requirement for which a waiver is requested, explain why he thinks data requirement(s) should be waived, describe any unsuccessful attempts to generate the required data, furnish any other information which he believes would support the request, and when appropriate, suggest alternative means of obtaining data to address the concern which underlies the data requirement.

(c) *Notification of waiver decision.* The Agency will review each waiver request and inform the applicant in writing of its decision. In addition, for decisions that could apply to more than a specific product, the Agency may

choose to send a notice to all registrants or to publish a notice in the Federal Register announcing its decision. An Agency decision denying a written request to waive a data requirement shall constitute final Agency action for purposes of FIFRA section 16(a).

(d) *Availability of waiver decisions.* Agency decisions under this section granting waiver requests will be available to the public at the Office of Pesticide Programs Reading Room, Rm. 236, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202 from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays. Any person may obtain a copy of any waiver decision by written request in the manner set forth in 40 CFR Part 2.

§ 158.50 Formulators' exemption.

(a) FIFRA section 3(c)(2)(D) provides that an applicant for registration of an end-use pesticide product need not submit or cite any data that pertain to the safety of another registered pesticide product which is purchased by the applicant and used in the manufacture or formulation of the product for which registration is sought.

(b) This exemption applies only to data concerning safety of a product or its ingredients, not to efficacy data. Data concerning safety includes toxicity, metabolism, environmental fate, product chemistry, and residue chemistry data.

(c) This exemption does not apply to data concerning the safety of the applicant's end-use product itself, unless the composition of the applicant's product and that of the purchased product are identical, i.e., data which this part indicates must be developed by tests using the end-use product for which registration is sought as the test substance. These requirements can be identified by the notation "EP*" in the "test substance" column of the tables in §§ 158.120 through 158.170 and these are the minimum data requirements that the applicant described in paragraph (a) of this section (i.e., the "formulator") must satisfy.

(d) The data to which this exemption applies usually will concern the safety of one or more of the end-use product's active ingredients, specifically, those active ingredients which are contained in the purchased product. These data requirements normally can be identified by the notations "TGAI" (technical grade of active ingredient), "PAI" (pure active ingredients), "PAIRA" (pure active ingredient, radiolabeled), or "TEP" (typical end-use product) in the "test substance" column of the tables in §§ 158.120 through 158.170.

(e) EPA interprets FIFRA section 3(c)(2)(D) as allowing an applicant to use the formulator's exemption with respect to a data requirement concerning the safety of an ingredient of his product only if:

(1) His application indicates that the ingredient's presence in his product is attributable solely to his purchase from another person of an identified, registered product containing that ingredient and his use of the purchased product in formulating his product; and

(2) The purchased product is a registered manufacturing-use product whose label does not prohibit its use for making an end-use product with any use for which the applicant's product will be labeled; or

(3) The purchased end-use product is a registered end-use product labeled for each use for which the applicant's product will be labeled.

(f) Notwithstanding FIFRA section 3(c)(2)(D), EPA will not approve an application unless there is available to EPA for its review whatever data is necessary in order to make the required risk/benefit finding under FIFRA section 3(c)(5) or section 3(c)(7).

§ 158.55 Agricultural vs non-agricultural pesticides.

Section 25(a)(1) of FIFRA instructs the Administrator to "take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risk between agricultural and non-agricultural pesticides." This part distinguishes the various classes of pesticide use (e.g., crop *vs* non-crop) and the corresponding data necessary to support registration under FIFRA. This information is present in each data requirement table (§§ 158.120 through 158.170). In addition, the Use Pattern Index (Appendix A) is a comprehensive list of pesticide use patterns, cross-referenced to the general use patterns appearing in the tables; the index will further assist the reader in distinguishing agricultural versus non-agricultural uses of pesticides.

§ 158.60 Minor uses.

(a) *Minor use policy.* A minor use of a pesticide is a use on a "minor crop" (a crop which is planted on a small total amount of acreage) or a use which is otherwise limited such that the potential market volume of the product for that use is inherently small. EPA's policy concerning data requirements for minor uses of pesticides includes the following elements:

(1) Since the market volume for a minor use of a pesticide is intrinsically low, and the risk associated with the use often is also correspondingly low, EPA will adjust the data requirements concerning the minor use appropriately.

(2) A new data requirement pertinent to both an unregistered minor use and a registered major use will not be applied to a minor use applicant until it is applied to the major use registrations.

(3) EPA will accept extrapolations and regional data to support establishment of individual minor use tolerances.

(4) Group tolerances will be established to assist applicants for registration of products for minor uses as described in 40 CFR 180.34.

(b) *Advice on data requirements to support minor uses.* Applicants for registration are advised to contact the appropriate EPA Product Manager of the Minor Use Officer for advice on developing data to support new applications for minor uses of pesticides.

§ 158.65 Biochemical and microbial pesticides.

Biochemical and microbial pesticides are generally distinguished from conventional chemical pesticides by their unique modes of action, low use volume, target species specificity or natural occurrence. In addition, microbial pesticides are living entities capable of survival, growth reproduction and infection. Biochemical and microbial pesticides are subject to a different set of data requirements, as specified in §§ 158.165 and 158.170, respectively.

(a) *Biochemical pesticides.* Biochemical pesticides include, but are not limited to, products such as semichemicals (e.g. insect pheromones), hormones (e.g., insect juvenile growth hormones), natural plant and insect regulators, and enzymes. When necessary the Agency will evaluate products on an individual basis to determine whether they are biochemical or conventional chemical pesticides.

(b) *Microbial pesticides.* (1) Microbial pesticides include microbial entities such as bacteria, fungi, viruses, and protozoans. The data requirements apply to all microbial pesticides, including those that are naturally-occurring as well as those that are genetically modified. Each "new" variety, subspecies, or strain of an already registered microbial pest control agent must be evaluated, and may be subject to additional data requirements.

(2) Novel microbial pesticides (i.e., genetically modified or non-indigenous microbial pesticides) will be subject to additional data or information requirements on a case-by-case basis depending on the particular micro-organism, its parent microorganism, the

proposed pesticide use pattern, and the manner and extent to which the organism has been genetically modified. Additional requirements may include information on the genetic engineering techniques used, the identity of the inserted or deleted gene segment (base sequence data or enzyme restriction map of the gene), information on the control region of the gene in question, a description of the "new" traits or characteristics that are intended to be expressed, tests to evaluate genetic stability and exchange, and/or selected Tier II environmental expression and toxicology tests.

(3) Pest control organisms such as insect predators, nematodes, and macroscopic parasites are exempt from the requirements of FIFRA as authorized by section 25(b) of FIFRA and specified in 40 CFR 162.5(c).

§ 158.70 Acceptable protocols.

The Agency has published Pesticide Assessment Guidelines, as indicated in § 158.20(d), which contain suggested protocols for conducting tests to develop the data required by this Part.

(a) *General policy.* Any appropriate protocol may be used provided that it meets the purpose of the test standards specified in the guidelines and provides data of suitable quality and completeness as typified by the protocols cited in the guidelines. Applicants should use the test procedure which is most suitable for evaluation of the particular ingredient, mixture, or product. Accordingly, failure to follow a suggested protocol will not invalidate a test if another appropriate methodology is used.

(b) *Organization for Economic Cooperation and Development (OECD) Protocols.* Tests conducted in accordance with the requirements and recommendations of the applicable OECD protocols can be used to develop data necessary to meet the requirements specified in this part. Readers should note, however, that certain of the OECD recommended test standards, such as test duration and selection of test species, are less restrictive than those recommended by EPA. Therefore, when using the OECD protocols, care should be taken to observe the test standards in a manner such that the data generated by the study will satisfy the requirements of this part.

(c) *Procedures for requesting advice on protocols.* Normally, all contact between the Agency and applicants or registrants is handled by the assigned Product Manager in the Registration Division of the Office of Pesticide Programs. Accordingly, questions concerning protocols should be directed, preferably in writing, to the Product Manager responsible for the registration or application which would be affected.

§ 158.75 Requirements for additional data.

(a) *General policy.* The data routinely required by Part 158 may not be sufficient to permit EPA to evaluate every pesticide product. If the information required under this part is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed. However, EPA expects that the information required by this Part will be adequate in most cases for an assessment of the properties of pesticide.

(b) *Policy on test substance.* In general, where the technical grade of the active ingredient is specified as the substance to be tested, tests may be performed using a technical grade which is substantially similar to the technical grade used in the product for which registration is sought. In addition to or in lieu of the testing required in §§ 158.120 through 158.165 the Administrator will, on a case-by-case basis, require testing to be conducted with:

(1) An analytical pure grade of an active ingredient, with or without radioactive tagging.

(2) The technical grade of an active ingredient.

(3) The representative technical grade of an active ingredient.

(4) An intentionally added inert ingredient in a pesticide product.

(5) A contaminant or impurity of an active or inert ingredient.

(6) A plant or animal metabolite or degradation product of an active or inert ingredient.

(7) The end-use pesticide product.

(8) The end-use pesticide product plus any recommended vehicles and adjuvants.

(9) Any additional substance which could act as a synergist to the product for which registration is sought.

(10) Any combination of substances in paragraphs (b) (1) through (9) of this section.

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§158.80 Acceptability of data.

(a) *General policy.* The Agency will determine whether the data submitted to fulfill the data requirements specified in this part are acceptable. This determination will be based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data fulfill the purpose(s) of the data requirement. In evaluating experimental design, the Agency will consider whether generally accepted methods were used, sufficient numbers of measurements were made to achieve statistical reliability, and sufficient controls were built into all phases of the experiment. The Agency will evaluate the conduct of each experiment in terms of whether the study was conducted in conformance with the design, good laboratory practices were observed, and results were reproducible. The Agency will not reject data merely because they were derived from studies which, when initiated were in accordance with an Agency-recommended protocol, even if the Agency subsequently recommends a different protocol, as long as the data fulfill the purposes of the requirements as described in this paragraph.

(b) *Previously developed data.* The Agency will consider that data developed prior to the effective date of this Part would be satisfactory to support applications provided good laboratory practices were followed, the data meet the purposes of this part, and the data permit sound scientific judgments to be made. Such data will not be rejected merely because they were not developed in accordance with suggested protocols.

(c) *Data developed in foreign countries.* The Agency considers all applicable data developed from laboratory and field studies anywhere to be suitable to support pesticide registrations except for data from tests which involved field test sites or a test material, such as a native soil, plant, or animal, that is not characteristic of the United States. When studies at test sites or with materials of this type are anticipated, applicants should take steps to assure that United States materials are used or be prepared to supply data or information to demonstrate the lack of substantial or relevant differences between the selected material or test site and the United States material or test site. Once comparability has been established, the Agency will assess the acceptability of the data as described in paragraph (a) of this section.

(d) *Data from monitoring studies.* Certain data are developed to meet the monitoring requirements of FIFRA sections 5, 8 or 20. Applicants may wish to determine whether some of these data may meet the requirements of this part. In addition, data developed independently of FIFRA regulations or requirements may also satisfy data requirements in this part. Consultation with appropriate EPA Product Managers would be helpful if applicants are unsure about suitability of such data.

§ 158.85 Revision of data requirements and guidelines.

(a) Data requirements will be revised from time to time to keep up with policy changes and technology. Revisions to this Part will be made in accordance with the Administrative Procedure Act (5 U.S.C. 551 *et seq.*). Changes having a significant impact on the registration process, applicants, testers, or other parties, or on the outcome and evaluation of studies, will be made only after public notice and opportunity for comment. Until final rules reflecting a change have been promulgated, the Agency can implement changes in the data requirements on a case-by-case basis.

(b) The Agency invites registration applicants, registrants, and the general public to suggest changes in the data requirements or the Pesticide Assessment Guidelines. Suggestions may be submitted at any time. Those making suggestions are requested to contact, in writing, the Director of the Hazard Evaluation Division. When suggestions consist of new suggested methods, representative test results should accompany the submittals.

Subpart B—Data Requirements

§ 158.100 How to determine registration data requirements.

To determine the specific kinds of data needed to support the registration of each pesticide product, the registration applicant should:

(a) Refer to §§ 158.108 through 158.112 and 158.120 through 158.170. These sections contain the data requirements for each subject area. A list of the corresponding subdivisions contained in the Pesticide Assessment Guidelines is presented in § 158.115.

(b) Select the general use pattern(s) that best covers the use pattern(s) specified on the pesticide product label. Selection of the appropriate general use pattern(s) will usually be obvious. However, unique or ambiguous cases will arise occasionally. These situations may be clarified by reference to the Use Pattern Index presented in the Appendix to the Data Requirements for Registration. The applicant can look up a specific use pattern in Appendix A and it will be cross referenced to the appropriate general use patterns to be used in each Data Requirement table.

(c) Proceed down the appropriate general use pattern column in the table and note which tests (listed along the left hand side of the table) are required ("R"), conditionally required ("CR") or usually not required ("—"). After reading through each data requirement table, the applicant will have a complete list of required and conditionally required data for the pesticide product and the substance to be tested in developing data to meet each requirement. The data EPA must have available to review the registration of a specific product consists of all the data designated as required for that product and all the applicable data designated as conditionally required for that product.

§ 158.101 Required vs. conditionally required data.

(a) Data designated as "required" ("R") for products with a given general use pattern are needed by EPA to evaluate the risks or benefits of a product having that use pattern unless the data requirement has been waived under § 158.45 for that particular product or unless the product is covered by a specific exception set forth in a note accompanying the requirement.

(b) Data designated as "conditionally required" ("CR") for products with a given general use pattern are needed by EPA to evaluate the risks or benefits of a product having that use pattern if the product meets the conditions specified in the corresponding notes accompanying the data requirements table. As indicated in the notes, the determination of whether the data must be submitted is based on the product's use pattern, physical or chemical properties, expected exposure of nontarget organisms, and/or results of previous testing (e.g., tier testing). Applicants must evaluate each applicable note to determine whether or not conditionally required data must be submitted as indicated by the conditions and criteria specified in the accompanying notes unless the Agency has granted a waiver request submitted by the registrant in accordance with § 158.45.

(c) For certain of the required or conditionally required data, the "R" or "CR" designations and are enclosed in brackets (i.e., [R], [CR]). The brackets designate those data that are required or conditionally required to support a product when an experimental use permit is being sought. In all other situations (i.e., other than support of an experimental use permit), the brackets have no meaning and the designations R and CR are equivalent to [R] and [CR], respectively.

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§ 158.102 Distinguishing between what data are required and what substance is to be tested.

(a) Readers should be careful to distinguish between what data are required and what substance is to be tested, as specified in this part and in each corresponding section of the guidelines. Each data requirement table under §§ 158.120 through 158.170) specifies whether a particular data requirement is required to support the registration of manufacturing-use products, end-use products, or both. The test substance column specifies which substance is to be subjected to testing. Thus, the data from a certain kind of study may be required to support the registration of each end-use product, but the test substance column may state that the particular test shall be performed using, for example, the technical grade of the active ingredient(s) in the end-use product.

(b) Manufacturing-use products (MP) and end-use products (EP) containing a single active ingredient and no inert ingredients are identical in composition to each other and to the technical grade of the active ingredient (TGAI) from which they were derived, and therefore, the data from a test conducted using any one of these as the test substance (e.g., TGAI) is also suitable to meet the requirement (if any) for the same test to be conducted using either of the other substances (i.e., MP or EP).

§ 158.105 Purposes of the registration data requirements.

(a) *General.* The data requirements for registration are intended to generate data and information necessary to address concerns pertaining to the identity, composition, potential adverse effects and environmental fate of each pesticide.

(b) *Product chemistry.* Data submitted to meet product chemistry requirements include information on product composition, and chemical and physical characteristics of the pesticide.

(1) *Product composition.* (i) Data on product composition are needed to support the conclusions expressed in the statement of formula. These data include information on the beginning materials and manufacturing process, a discussion on formation of impurities, results of preliminary analysis of product samples, a certification of ingredient limits and an explanation of how the certified limits were determined, and the description of, and validation data for, analytical methods to identify and quantify ingredients.

(ii) Product composition (as indicated in the confidential statement of formula)

is compared with the composition of materials used in toxicity tests and other studies. This comparison indicates which ingredients in a pesticide product have been evaluated by a particular study, and might lead to a conclusion that another study is needed. Based on conclusions concerning the product's composition and its toxic properties, appropriate use restrictions, labeling requirements, or special packaging requirements may be imposed.

(iii) Product composition data including certified limits of ingredients are used in the review of applications for conditional registration. FIFRA section 3(c)(7)(A) authorizes the conditional registration of products which are "identical or substantially similar to any currently registered pesticide . . . or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment. . . ." In nearly every case, this determination involves an examination of an applicant's product and a comparison with the composition of currently registered products.

(2) *Physical and chemical characteristics.* (i) Data on the physical and chemical characteristics of active ingredients and pesticide products are used to confirm or provide supportive information on their identity. Such data also provide information used in reviewing the manufacturing or formulating process used to produce the chemical or product. For example, the data may provide evidence of significant changes in manufacture or formulation, and could indicate the need for additional information on product composition.

(ii) Certain information (e.g., color, odor, physical state) is needed by the Agency to respond to emergency requests for identification of unlabeled pesticides involved in accidents or spills. Physicians, hospitals, and poison control centers also request this information to aid in their identification of materials implicated in poisoning episodes.

(iii) Certain other physical and chemical data are used directly in the hazard assessment. These include stability, oxidizing and reducing action, flammability, explodability, storage stability, corrosion, and dielectric breakdown voltage. For example, a study of the corrosion characteristics of a pesticide is needed to evaluate effects of the product formulation on its container. If the pesticide is highly corrosive, then measures can be taken to ensure that lids, liners, seams, or container sides will not be damaged and cause the contents to leak during storage, transport, handling, or use. The storage stability study provides data on change (or lack of change) in product composition over time. If certain ingredients decompose, obviously other new chemicals are formed whose toxicity and other characteristics need to be considered.

(iv) Certain data are needed as basic or supportive evidence in initiating or evaluating other studies. For example, the octanol/water partition coefficient is used as one of the criteria to determine whether certain fish and wildlife toxicity or accumulation studies must be conducted. Vapor pressure data are needed, among other things, in order to determine suitable reentry intervals and other label cautions pertaining to worker protection. Data on viscosity and miscibility provide necessary information to support acceptable labeling for tank mix and spray applications.

(c) *Residue chemistry.* (1) Residue Chemistry Data are used by the Agency to estimate the exposure of the general population to pesticide residues in food and for setting and enforcing tolerances for pesticide residues in food or feed.

(2) Information on the chemical identity and composition of the pesticide product, the amounts, frequency and time of pesticide application, and results of test on the amount of residues remaining on or in the treated food or feed, are needed to support a finding as to the magnitude and identity of residues which result in food or animal feed as a consequence of a proposed pesticide usage.

(3) Residue chemistry data are also needed to support the adequacy of one or more methods for the enforcement of the tolerance, and to support practicable methods for removing residues that exceed any proposed tolerance.

(d) *Environmental fate*—(1) *General.* The data generated by environmental fate studies are used to: assess the toxicity to man through exposure of humans to pesticide residues remaining after application, either upon reentering treated areas or from consuming inadvertently-contaminated food; assess the presence of widely distributed and persistent pesticides in the environment which may result in loss of usable land, surface water, ground water, and wildlife resources; and, assess the potential environmental exposure of other nontarget organisms, such as fish and wildlife, to pesticides. Another specific purpose of the environmental fate data requirements is to help applicants and the Agency estimate expected environmental concentrations of pesticides in specific habitats where threatened or endangered species or other wildlife populations at risk are found.

(2) *Degradation studies.* The data from hydrolysis and photolysis studies are used to determine the rate of pesticide degradation and to identify pesticides that may adversely affect nontarget organisms.

(3) *Metabolism studies.* Data generated from aerobic and anaerobic metabolism studies are used to determine the nature and availability of pesticides to rotational crops and to aid in the evaluation of the persistence of a pesticide.

(4) *Mobility studies.* These data requirements pertain to leaching, adsorption/desorption, and volatility of pesticides. They provide information on the mode of transport and eventual destination of the pesticide in the environment. This information is used to assess potential environmental hazards related to: contamination of human and animal food; loss of usable land and water resources to man through contamination of water (including ground water); and habitat loss of wildlife resulting from pesticide residue movement or transport in the environment.

(5) *Dissipation studies.* The data generated from dissipation studies are used to assess potential environmental hazards (under actual field use conditions) related to: reentry into treated areas; hazards from residues in rotational crop and other food sources; and the loss of land as well as surface and ground water resources.

(6) *Accumulation studies.* Accumulation studies indicate pesticide residue levels in food supplies that originate from wild sources or from rotational crops. Rotational crop studies are necessary to establish realistic crop rotation restrictions and to determine if tolerances may be needed for residues on rotational crops. Data from irrigated crop studies are used to determine the amount of pesticide residues that could be taken up by representative crops irrigated with water containing pesticide residues. These studies allow the Agency to establish label restrictions regarding application of pesticides on sites where the residues can be taken up by irrigated crops. These data also provide information that aids the Agency in establishing any corresponding tolerances that would be needed for residues on such crops. Data from pesticides accumulation studies in fish are used to establish label restrictions to prevent applications in certain sites so that there will be minimal residues entering edible fish or shell fish. These residue data are also

used to determine if a tolerance or action level is needed for residues in aquatic animals eaten by humans.

(e) *Hazard to humans and domestic animals.* Data required to assess hazards to humans and domestic animals are derived from a variety of acute, subchronic and chronic toxicity tests, and tests to assess mutagenicity and pesticide metabolism.

(1) *Acute studies.* Determination of acute oral, dermal and inhalation toxicity is usually the initial step in the assessment and evaluation of the toxic characteristics of a pesticide. These data provide information on health hazards likely to arise soon after, and as a result of, short-term exposure. Data from acute studies serve as a basis for classification and precautionary labeling. For example, acute toxicity data are used to calculate farmworker reentry intervals and to develop precautionary label statements pertaining to protective clothing requirements for applicators. They also: provide information used in establishing the appropriate dose levels in subchronic and other studies; provide initial information on the mode of toxic action(s) of a substance; and determine the need for child resistant packaging. Information derived from primary eye and primary dermal irritation studies serves to identify possible hazards from exposure of the eyes, associated mucous membranes and skin.

(2) *Subchronic studies.* Subchronic tests provide information on health hazards that may arise from repeated exposures over a limited period of time. They provide information on target organs and accumulation potential. The resulting data are also useful in selecting dose levels for chronic studies and for establishing safety criteria for human exposure. These tests are not capable of detecting those effects that have a long latency period for expression (e.g., carcinogenicity).

(3) *Chronic studies.* Chronic toxicity (usually conducted by feeding the test substance to the test species) studies are intended to determine the effects of a substance in a mammalian species following prolonged and repeated exposure. Under the conditions of this test, effects which have a long latency period or are cumulative should be detected. The purpose of long-term oncogenicity studies is to observe test animals over most of their life span for the development of neoplastic lesions during or after exposure to various doses of a test substance by an appropriate route of administration.

(4) *Teratogenicity and reproduction studies.* The teratogenicity study is designed to determine the potential of the test substance to induce structural and/or other abnormalities to the fetus as the result of exposure of the mother during pregnancy. Two-generation reproduction testing is designed to provide information concerning the general effects of a test substance on gonadal function, estrus cycles, mating behavior, conception, parturition, lactation, weaning, and the growth and development of the offspring. The study may also provide information about the effects of the test substance on neonatal morbidity, mortality, and preliminary data on teratogenesis and serve as a guide for subsequent tests.

(5) *Mutagenicity studies.* For each test substance a battery of tests are required to assess potential to affect the mammalian cell's genetic components. The objectives underlying the selection of a battery of tests for mutagenicity assessment are:

(i) To detect, with sensitive assay methods, the capacity of a chemical to alter genetic material in cells.

(ii) To determine the relevance of these mutagenic changes to mammals.

(iii) When mutagenic potential is demonstrated, to incorporate these findings in the assessment of heritable effects, oncogenicity, and possibly, other health effects.

(6) *Metabolism studies.* Data from studies on the absorption, distribution, excretion, and metabolism of a pesticide aid in the valuation of test results from other toxicity studies and in the extrapolation of data from animals to man. The main purpose of metabolism studies is to produce data which increase the Agency's understanding of the behavior of the chemical in its consideration of the human exposure anticipated from intended uses of the pesticide.

(f) *Reentry Protection.* Data required to assess hazard to farm employees resulting from reentry into areas treated with pesticides are derived from studies on toxicity, residue dissipation, and human exposure. Monitoring data generated during exposure studies are used to determine the quantity of pesticide to which people may be exposed after application and to develop reentry intervals.

(g) *Pesticide Spray Drift Evaluation.* Data required to evaluate pesticide spray drift are derived from studies of droplet size spectrum and spray drift field evaluations. These data contribute to development of the overall exposure estimate and along with data on toxicity for humans, fish and wildlife, or plants are used to assess the potential hazard of pesticides to these organisms. A purpose common to all these tests is to provide data which will be used to determine the need for (and appropriate wording for) precautionary labeling to minimize the potential adverse effect to nontarget organisms.

(h) *Hazard to nontarget organisms—*

(1) *General.* The information required to assess hazards to nontarget organisms are derived from tests to determine pesticidal effects on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, subacute, reproduction, simulated field, and full field studies arranged in a hierarchial or tier system which progresses from the basic laboratory tests to the applied field tests. The results of each tier of tests must be evaluated to determine the potential of the pesticide to cause adverse effects, and to determine whether further testing is required. A purpose common to all data requirements is to provide data which determines the need for (and appropriate wording for) precautionary label statements to minimize the potential adverse effects to nontarget organisms.

(2) *Short term studies.* The short-term acute and subchronic laboratory studies provide basic toxicity information which serves as a starting point for the hazard assessment. These data are used: to establish acute toxicity levels of the active ingredient to the test organisms; to compare toxicity information with measured or estimated pesticide residues in the environment in order to assess potential impacts on fish, wildlife and other nontarget organisms; and to indicate whether further laboratory and/or field studies are needed.

(3) *Long term and field studies.* Additional studies (i.e., avian, fish, and invertebrate reproduction, lifecycle studies and plant field studies) may be required when basic data and environmental conditions suggest possible problems. Data from these studies are used to: estimate the potential for chronic effects, taking into account the measured or estimated residues in the environment; and to determine if additional field or laboratory data are necessary to further evaluate hazards. Simulated field and/or field data are used to examine acute and chronic adverse effects on captive or monitored fish and wildlife populations under natural or near-natural environments. Such studies are required only when predictions as to possible adverse effects in less extensive studies cannot be made, or when the potential for adverse effects is high.

(i) *Product performance.* Requirements to develop data on

product performance provide a mechanism to ensure that pesticide products will control the pests listed on the label and that unnecessary pesticide exposure to the environment will not occur as a result of the use of ineffective products. Specific performance standards are used to validate the efficacy data in the public health areas, including disinfectants used to control microorganisms infectious to man in any area of the inanimate environment and those pesticides used to control vertebrates (such as rodents, birds, bats and skunks) that may directly or indirectly transmit diseases to humans.

§ 158.108 Product identity and composition.

In accordance with §§ 158.120, 158.165 and 158.270, each product's registration must be supported by the following information:

(a) *Identity of the product.* This information includes:

(1) The product name.

(2) The trade name(s) (if different).

(3) The company code number(s) (optional).

(b) *Composition of the product.* The composition of the product for which the application is being submitted must be stated. A request for an amended registration other than for amending the statement of composition may state that an accurate and current description of the product's composition is already on file with the Agency's Registration Division, if that is the case. Information on product composition is normally supplied by completing a Confidential Statement of Formula form provided by the Agency. The following information is required:

(1) The name, nominal concentration, and certified limits for each ingredient and impurity as specified in § 158.110 (c), (d), and (e) and summarized in § 158.112(a).

(2) The purpose of each active ingredient and each intentionally-added inert ingredient.

(3) For each ingredient required to be listed by paragraph (b)(1) of this section, the chemical name from the Chemical Abstracts Index of Nomenclature or other well-defined name, and the Chemical Abstracts Service (CAS) Registry Number.

(4) For each active ingredient: the product name, trade name, and common name (if established); the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internal code number the company has assigned.

(c) *Definitions.* (1) The term *"beginning material"* means any substance which constitutes or contains any of the product's active or intentionally-added inert ingredients or which constitutes or contains a chemical precursor of any ingredient used in making the product.

(2) The term *"end-use product"* means a pesticide product intended to be labeled with instructions for direct use or application for pesticidal purposes.

(3) The term *"impurity"* means any substance in a pesticide product other than an active ingredient or an intentionally-added inert ingredient; the term includes beginning materials, side-reaction products, contaminants, and degradation products.

(4) The term *"impurity associated with an active ingredient"* means:

(i) Any impurity present in the technical grade of the active ingredient (e.g., a substance carried over from a beginning material, or from an intermediate, and impurities formed through side-reactions or by degradation of the active ingredient).

(ii) Those impurities which form in a pesticide product through reactions between the active ingredient and other substances in the product, or in the packaging of the product.

(5) The term *"integrated formulation system"* means a process for producing an end-use product through the use of any substance which contains an active ingredient and which:

(i) Is not a registered pesticide product; or

(ii) Was produced or acquired in a manner that does not permit its inspection by the Administrator under section 9(a) of FIFRA prior to its use in the process.

(6) The term *"intentionally-added inert ingredient"* means any ingredient of a product (other than an active ingredient) which is intentionally made a part of the product to serve some useful function.

(7) The term *"manufacturing-use product"* means any pesticide product other than an end-use product. Usually, these products contain only the technical grade of the active ingredient or a high concentration of the active ingredient with small amounts of inert ingredients such as stabilizers and similar substances.

(8) The term *"nominal concentration"* means the amount of an ingredient which is expected to be present in a typical sample of a pesticide product.

(9) The term *"technical grade of an active ingredient"* (which is synonymous with the term "technical chemical") means a material:

(i) Which contains an active ingredient.

(ii) Which is produced on a commercial or pilot-plant scale (whether or not it is ever held for sale).

(iii) To which no ingredient has been deliberately added for any purpose other than synthesis or purification of the active ingredient.

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§ 158.110 Certification of ingredient limits.

(a) *General.* Each registration must be supported by a certification that each upper and lower limit established in accordance with paragraph (c), (d), or (e) of this section will be maintained for all quantities of the product packaged, labeled, and released for shipment. Once certified limits have been established by the registrant and have been accepted by the Agency, normal quality assurance procedures will apply, and the registrant does not have to analyze each individual batch to demonstrate that the certified limits are met. Certified limits are used in two ways. First, the Agency will consider the certified limits in making the registration determination required by sections 3(c)(5), 3(c)(7), and 3(d) of the Act and in making other regulatory decisions required by the Act. Second, the Agency will collect commercial samples of the registered products and analyze for the active ingredient(s) and/or for the impurities determined by the Agency to be toxicologically significant. When, upon analysis with reliable analytical procedures (i.e., enforcement methodology) the composition of such samples is found to differ from that certified, the results may be used by the Agency in regulatory actions under section 12(a)(1)(C) and other pertinent sections of FIFRA.

(b) *Acceptable range between upper and lower certified limits.* The Agency suggests that the range between the upper and lower certified limits for each active ingredient and each intentionally added inert ingredient should be decided based on a consideration of the variability of each of these ingredients when normal quality assurance procedures are utilized in the production process. In order for certified limits to be acceptable for the purposes specified in § 158.110(a), the limits stated for each ingredient must not greatly exceed its actual variability in the product.

(c) *Manufacturing-use products containing no inert ingredients.* The statement of formula for a manufacturing-use product containing no intentionally added inert ingredients (i.e., containing only the technical grade

of the active ingredient) must contain certified limits:

(1) For each active ingredient, an upper and lower limit.

(2) For each impurity (or, if appropriate, for each group of structurally similar impurities) associated with an active ingredient that was indicated in the discussion required by § 158.120 as being potentially present at a level equal to or greater than 0.1 percent by weight, an upper limit.

(3) For each impurity (or, if appropriate, for each group of structurally similar impurities) associated with an active ingredient that was indicated in the discussion required by § 158.120 as being potentially present at a level less than 0.1 percent by weight, an upper limit if EPA determines that the impurity is toxicologically significant.

(4) For each other impurity (or, if appropriate, for each other group of structurally similar impurities) associated with an active ingredient that was found in any sample at a level equal to or greater than 0.1 percent by weight, an upper limit.

(5) For each impurity (or, if appropriate, for each group of structurally similar impurities) associated with an active ingredient that was found in any sample at a level less than 0.1 percent by weight, an upper limit, if EPA determines that the impurity is toxicologically significant.

(d) *Manufacturing-use products containing inert ingredients and those end-use products produced by an integrated formulation system.* The statement of formula for a manufacturing-use product containing inert ingredients or for an end-use product produced by an integrated formulation system must contain certified limits:

(1) For each active ingredient, an upper and lower limit.

(2) For each intentionally added inert ingredient, an upper and lower limit.

(3) For each impurity (or, if appropriate, for each group of structurally similar impurities) associated with an active ingredient that was indicated in the discussion required by § 158.120 as being potentially present at a level equal to or greater than 0.1 percent by weight of the technical chemical, an upper limit.

(4) For each impurity (or, if appropriate, for each group of structurally similar impurities) associated with an active ingredient that was indicated in the discussion required by § 158.120 as being potentially present at a level greater than 0.1 percent by weight of the technical chemical, an upper limit if EPA determines that the impurity is toxicologically significant.

(5) For each other impurity (or, if appropriate, for each other group of structurally similar impurities) associated with an active ingredient that was found in any sample at a level equal to or greater than 0.1 percent by weight of the technical chemical, an upper limit.

(6) For each other impurity (or, if appropriate, for each other group of structurally similar impurities) associated with an active ingredient that was found in any sample at a level less than 0.1 percent by weight of the technical chemical, an upper limit if EPA determines that the impurity is toxicologically significant.

(7) For each impurity (or if appropriate, for each group of structurally similar impurities) not associated with an active ingredient, an upper limit, if EPA determines that the impurity is toxicologically significant.

(e) *End-use products not produced by an integrated formulation system.* The statement of formula for an end-use product not produced by an integrated formulation system shall contain upper and lower certified limits:

(1) For each active ingredient, an upper and lower limit.

(2) For each intentionally added inert ingredient, an upper and lower limit.

(3) For each impurity (or if appropriate, for each group of structurally similar impurities) that EPA determines to be toxicologically significant, an upper limit.

(f) *Certified limits for additional ingredients and impurities.* The Agency may require, on a case-by-case basis:

(1) More precise limits.

(2) Certified limits for additional ingredients.

(3) More thorough explanation of how the certified limits were determined.

(4) Certified upper limits for impurities which will be present at levels lower than 0.1 percent (1,000 ppm) of the product.

(5) A narrower range between the upper and lower certified limits than that proposed by the applicant.

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§ 158.112 Nominal concentration and analytical enforcement method.

The nominal concentration of each ingredient and an analytical enforcement method for each ingredient is required to support each pesticide product, as specified in the following Summary. The requirements for certified limits specified in § 158.110 (c), (d) and (e) are also summarized here.

SUMMARY OF REQUIREMENTS FOR NOMINAL CONCENTRATION, CERTIFIED LIMITS AND ANALYTICAL METHODS FOR THE ENFORCEMENT OF LIMITS

Product/ingredient	Nominal concentration	Certified limit [1]		Enforcement method [2]
		Upper	Lower	
Manufacturing-Use Products Containing No Inert Ingredients				
Active Ingredient	R	R	R	R
Impurities associated with the active ingredient:				
>0.1 pct	R	R	NR	CR
<0.1 pct	CR	CR	NR	CR
Manufacturing-Use Products Containing Inert Ingredients and Those End-Use Products Produced by an Integrated Formulation System				
Active Ingredient	R	R	R	R
Impurities associated with the activie ingredient:				
>0.1 pct by weight of technical	R	R	NR	CR
<0.1 pct by weight of technical	CR	CR	NR	CR
Impurities not associated with the active ingredient	CR	CR	NR	CR
Intentionally added inerts	R	R	R	CR
End-Use Products Not Produced by an Integrated Formulation System				
Active Ingredient	R	R	R	R
Impurities	CR	CR	NR	CR
Intentionally added inerts	R	R	R	CR

Key: R=Required. CR=Required only if EPA determines the impurity or the intentionally added inert ingredient is toxicologically significant. NR=Not required.

[1] See guidelines reference #62-2, Subdivision D.

[2] See guidelines reference #62-3, Subdivision D.

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§ 158.115 Organization of the pesticide guidelines and relationship to data requirements.

(a) *List of subdivisions.* A list of the subdivisions included in the Pesticide Assessment Guidelines is provided in paragraph (b) of this section. The Pesticide Assessment Guidelines contain the standards for conducting acceptable tests, guidance on evaluation

and reporting of data, definition of terms, further guidance on when data are required, and examples of acceptable protocols. They are available through the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703–487–4650). The registration data requirements pertaining to each subdivision are also identified in paragraph (b) of this section.

(b) *List of Pesticide Assessment Guidelines Subdivisions and their relationship to the data requirements.*

Document title	NTIS Order No.	Corresponding section in this rule
Subdivision D—Product Chemistry	PB83–153890	158.108, 158.110, 158.112.
Subdivision E—Hazard Evaluation: Wildlife and Aquatic Organisms	PB83–153908	158.145.
Subdivision F—Hazard Evaluation: Humans and Domestic Animals	PB83–153916	158.135.
Subdivision G—Product Performance	PB83–153924	158.160.
Subdivision I—Experimental Use Permits	PB83–153932	158.20 thru 158.170.
Subdivision J—Hazard Evaluation: Nontarget Plants	PB83–153940	158.150.
Subdivision K—Reentry Protection	(Forthcoming)	158.140.
Subdivision L—Hazard Evaluation: Nontarget Insects	PB83–153957	158.155.
Subdivision M—Biorational Pesticides	PB83–153965	158.165 and 158.170.
Subdivision N—Environmental Fate	PB83–153973	158.130.
Subdivision O—Residue Chemistry	PB83–153961	158.125.
Subdivision R—Spray Drift Evaluation	PB84–189216	158.142.

§ 158.120 Product chemistry data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the product chemistry data requirements and the substance to be tested.

Kind of data required	All general use patterns		Test substance		Guidelines reference No.
	(b) Notes	(Requirements are the same for every use pattern)	Data to support MP	Data to support EP	
Product identity and composition:					
Product identity and disclosure of ingredients	(1)	[R]	MP	EP*	61–1
Description of beginning materials and manufacturing process	(2)	[R]	MP and TGAI	EP*	61–2
Discussion of formation of impurities	(3)	[R]	MP and TGAI	EP* and TGAI	61–2
Analysis and certification of product ingredients:					
Preliminary analysis	(4)	[CR]	MP and TGAI	EP* and TGAI	62–1
Certification of limits	(1), (5)	[R]	MP	EP*	62–2
Analytical methods to verify certified limit	(1)	[R]	MP	EP*	62–3
Physical and chemical characteristics:					
Color		[R]	MP and TGAI	EP* and TGAI	63–2
Physical state		[R]	MP and TGAI	EP* and TGAI	63–3
Odor		[R]	MP and TGAI	EP* and TGAI	63–4
Melting point	(6)	[R]	TGAI	TGAI	63–5
Boiling point	(7)	[R]	TGAI	TGAI	63–6
Density, bulk density, or specific gravity		[R]	MP and TGAI	EP* and TGAI	63–7
Solubility		[R]	TGAI or PAI	TGAI or PAI	63–8
Vapor pressure		[R]	TGAI or PAI	TGAI or PAI	63–9
Dissociation constant		[R]	TGAI or PAI	TGAI or PAI	63–10
Octanol/water partition coefficient	(8)	[CR]	PAI	PAI	63–11
pH	(9)	[CR]	MP and TGAI	EP* and TGAI	63–12
Stability		[R]	TGAI	TGAI	63–13
Oxidizing or reducing action	(10)	[CR]	MP	EP*	63–14
Flammability	(11)	[CR]	MP	EP*	63–15
Explodability	(12)	[R]	MP	EP*	63–16
Storage stability		[R]	MP	EP*	63–17
Viscosity	(13)	[CR]	MP	EP*	63–18
Miscibility	(14)	[CR]	MP	EP*	63–19
Corrosion characteristics		[R]	MP	EP*	63–20
Dielectric breakdown voltage	(15)	[CR]		EP*	63–21
Other requirements:					
Submittal of samples	(16)	[CR]	MP, TGAI, PAI	EP*, TGAI, PAI	64–1

Key: R=Required; CR=Conditionally required; [ ]=Brackets (i.e. [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought; MP=Manufacturing-use product; EP*=End-use-product, (asterisk indicates those requirements that end-use applicants (i.e. "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); TGAI=Technical grade of the active ingredient; PAI=Pure active ingredient.

(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Requirements pertaining to product identity and disclosure of ingredients, certification of limits, and analytical methods to verify limits are detailed further in §§ 158.108, 158.110 and 158.112 respectively.

(2) A schematic diagram and/or brief description of the manufacturing process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.

(3) If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.

(4) Required to support the registration of each manufacturing-use product and end-use products produced by an integrated formulation system. Data on other end-use products will be required on a case-by-case basis. For pesticides in the development stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.

(5) Certified limits are not required for inert ingredients in products proposed for experimental use.

(6) Data needed if technical chemical is a solid at room temperature.

(7) Data needed only if technical chemical is a liquid at room temperature.

(8) Data required if technical chemical is organic and non-polar.

(9) Required for test substances that are dispersible with water.

(10) Required if product contains an oxidizing or reducing agent.

(11) Data are required if product contains combustible liquids.

(12) Data only required for products that are potentially explosive.

(13) Data required if product is a liquid.

(14) Data required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.

(15) Required if end-use product is a liquid and is to be used around electrical equipment.

(16) Basic manufacturers are required to provide the Agency with a sample of each TGAI used to formulate a product produced by an integrated formulation system when the new TGAI is first used as a formulating ingredient in products registered under the FIFRA. A sample of the active ingredient (PAI) suitable for use as an analytical standard is also required at this time. Sample of end-use products produced by an integrated formulation system must be submitted on a case-by-case basis.

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§ 158.125 Residue chemistry data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the residue chemistry data requirements and the substances to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guide-lines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domes-tic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food corp	Nonfood	Food corp	Nonfood						
Chemical identity	(1)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	171–2
Directions for use	(2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]			171–3
Nature of the residue:													
Plants	(13), (14)	[R]		[R]		[R]			[CR]	[CR]	PAIRA	PAIRA	171–4
Livestock	(3), (13), (14)	[CR]		[CR]		[CR]			[CR]	[CR]	PAIRA and plant metabioites.	PAIRA and plant metabolites.	171–4
Residue analytical method.	(4), (13), (14), (15)	[R]		[R]		[R]			[CR]	[CR]	TGAI and metabolites.	TGAI and metabolites.	171–4
Magnitude of the residue:													
Crop field trials	(13), (14)	[R]		[R]		[R]			[CR]	[CR]	TEP	TEP	171–4
Processed food/feed	(5), (14)	[CR]		[CR]		[CR]				[CR]	EP	EP	171–4
Meat/milk/poultry/ eggs.	(6), (14)	[CR]		[CR]		[CR]				[CR]	TGAI or plant metabolites.	TGAI or plant metabolites.	171–4
Potable water	(7)			[R]	[R]						EP	EP	171–4
Fish	(8)			[R]	[R]						EP	EP	171–4
Irrigated crops	(9)			[CR]	[CR]						EP	EP	171–4
Food handling	(10), (14)									[CR]	EP	EP	171–4
Reduction of residue	(11), (14)	[CR]		[CR]		[CR]				[CR]	Residue of concern.	Residue of concern.	171–5
Proposed tolerance	(12), (14)	[R]		[R]		[R]				[CR]	Residue of concern.	Residue of concern.	171–6
Reasonable grounds in support of the petition.	(14)	[R]		[R]		[R]				[CR]			171–7
Submittal of analytical reference standards.	(14)	[R]		[R]		[R]				[CR]	PAIRA	PAIRA	171–13

Key: R=Required data; CR=Conditionally required data; TGAI=Technical grade of the active ingredient; PAIRA=Pure active ingredient, radio labeled; EP=End-use product; TEP=Typical end-use product; MP=Manufacturing-use product; [ ]=Brackets (i.e., [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought.

(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) The same chemical identity data as required under § 158.120 are required, with emphasis on impurities that could constitute a residue problem.

(2) Required information includes crops to be treated, rate of application, number and timing of applications, preharvest intervals, and relevant restrictions.

(3) Data on metabolism in livestock are required when residues occur on a livestock feed, or the pesticide is to be applied directly to livestock.

(4) A residue method for enforcement of tolerances is needed whenever a numeric tolerance is proposed. Exemptions from the requirement of a tolerance will also usually require an analytical method. Analytical methods used to enforce residue limits for emergency exemptions, temporary tolerances and permanent tolerances must be available for use by enforcement agencies and thus may not be claimed as confidential business information.

(5) Data on the nature and level of residue in processed food/feed are required when detectable residues could concentrate on processing and thus require establishment of a food additive tolerance.

(6) Livestock feeding studies are required whenever a pesticide occurs as a residue in a livestock feed. Use involving direct application to livestock, including poultry, will require animal treatment residue studies.

(7) Data on residues in potable water are required whenever a pesticide is to be applied directly to water, unless it can be determined that the treated water would not be used (eventually) for drinking purpose, by man or animals.

(8) Data on residue in fish are required whenever a pesticide is to be applied directly to water inhabited by fish.

(9) Data on residues in irrigated crops are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.

(10) Data on residues in food/feed in food handling establishments are required whenever a pesticide is to be used in food/feed handling establishments. Disinfectants and sanitizers used in food or feed handling establishment are exempt from this requirement if their residues are regulated by the Food and Drug Administration at 21 CFR 178.1010.

(11) Reduction of residue data are required when the assumption of tolerance level residues would result in predicted exposure at an unsafe level. Data on the level of residue in food as consumed will be used to obtain a more precise estimate of potential dietary exposure. The Agency recommends that such data be generated to support all pesticides requiring a tolerance in case new data are revealed which indicates the pesticide is more toxic than initially determined.

(12) The proposed tolerance must reflect the maximum residue likely to occur in crops and meat/milk/poultry eggs.

(13) Residue data for outdoor domestic uses are required if home gardens are to be treated and the home garden use pattern is different from the use pattern on which the tolerance was established.

(14) Required to support registration of an indoor use pesticide if such a use could result in residues in food or feed.

(15) For all food uses, data on whether the FDA/USDA multiresidue methodology would detect and identify the pesticide are required.

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§ 158.130 Environmental fate data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the environmental fate data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guide-lines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domes-tic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Degradation studies-lab													
Hydrolysis		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]		TGAI or PAIRA	TGAI or PAIRA	161–1
Photodegradation:													
In water		R	R	R	R			R			TGAI or PAIRA	TGAI or PAIRA	161–2
On soil	(1)	CR						CR			TGAI or PAIRA	TGAI or PAIRA	161–3
In air	(2)	CR									TGAI or PAIRA	TGAI or PAIRA	161–4
Metabolism studies-lab													
Aerobic soil		[R]	[R]			R	R	[R]	R		TGAI or PAIRA	TGAI or PAIRA	162–1
Anaerobic soil	(3)	R									TGAI or PAIRA	TGAI or PAIRA	162–2
Anaerobic aquatic				R	R			R			TGAI or PAIRA	TGAI or PAIRA	162–3
Aerobic aquatic				[R]	[R]						TGAI or PAIRA	TGAI or PAIRA	162–4
Mobility studies													
Leaching and adsorption/ desorption.		[R]	[R]	R	R	R	R	[R]	R		TGAI or PAIRA	TGAI or PAIRA	163–1

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Volatility:													
(Lab)	(2)	CR				CR	CR				TEP	TEP	163-2
(Field)	(2)	CR				CR	CR				TEP	TEP	163-3
Dissipation studies-field													
Soil		R	R						R		TEP	TEP	164-1
Aquatic (sediment)				R	R						TEP	TEP	164-2
Forestry								R			TEP	TEP	164-3
Combination and tank mixes.	(2)												164-4
Soil, long-term	(4)	CR		CR							TEP	TEP	164-5
Accumulation studies													
Rotational crops:													
(Confined)	(5)	[CR]		[CR]							PAIRA	PAIRA	165-1
(Field)	(6)	CR		CR							TEP	TEP	165-2
Irrigated crops	(7)			[CR]	CR						TEP	TEP	165-3
In fish	(8)	[CR]	[CR]	[CR]	[CR]			[CR]			TGAI or PAIRA	TGAI or PAIRA	165-4
In aquatic non-target organisms.	(8), (9)				CR			CR			TEP	TEP	165-5

Key: R=Required: CR=Conditionally required; [ ]=Brackets (ie. [R], [CR], indicate data requirements that apply when an experimental use permit is being sought; TGAI=Technical grade of the active ingredient, PAIRA="Pure" active ingredient-radio labeled; TEP=typical end use product; EP =End use product.

(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Not required if use involves application to soils solely by injection of the product into the soil or by incorporation of the product into the soil upon application.

(2) Required on case by case basis depending on product use pattern and other pertinent factors.

(3) Not required if anaerobic aquatic metabolism study has been conducted.

(4) Required if pesticide residues do not readily dissipate in soil.

(5) Confined accumulation study is required when it is reasonably foreseeable that any food or feed crop may be subsequently planted on the site of pesticide application.

(6) Field accumulation study is required if significant pesticide residue is likely to be present in soil at time of plant crop, as evidenced by residue data obtained from confined accumulation study.

(7) Required if it is reasonably foreseeable that water at treated site may be used for irrigation purposes.

(8) Required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms.

(9) Required unless tolerance or action level for fish has been granted.

(Approved by the Office of Management and Budget under control numbers 2000–0483 and 2000–0468.)

§ 158.135 Toxicology data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the toxicology data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Acute testing													
Acute oral toxicity—rat	(1)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP* or EP dilution* and TGAI.	81-1
Acute dermal toxicity	(1), (2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP* or EP dilution* and TGAI.	81-2
Acute inhalation toxicity—rat.	(16)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP* and TGAI	81-3
Primary eye irritation—rabbit.	(2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	81-4
Primary dermal irritation	(1), (2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	81-5
Dermal sensitization	(3)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	81-6
Acute delayed neurotoxicity—hen.	(4)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	81-7
Subchronic testing													
90-day feeding studies—rodent and nonrodent.	(17)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	TGAI	TGAI	82-1
21-day dermal	(18)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI and EP*	82-2
90-day dermal	(5), (19)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82-3
90-day inhalation—rat	(6)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82-4
90-day neurotoxicity:													
Hen	(7)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82-5
Mammal	(8)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82-5
Chronic testing													
Chronic feeding—2 spp. rodent and nonrodent.	(9), (13), (20)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	TGAI	TGAI	83-1
Oncogenicity study—2 Spp. rat and mouse preferred.	(9), (21)	R	CR	R	CR	R	CR	CR	CR	CR	TGAI	TGAI	83-2
Teratogenicity—2 species	(10), (15)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	TGAI	TGAI	83-3
Reproduction, 2-generation.	(11), (14)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	TGAI	TGAI	83-4
Mutagenicity testing													
Gene mutation	(22)	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	84-2

Kind of data required	(b) Notes	General use patterns								Test substance		Guide-lines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domes-tic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Structural chromosomal aberration.	(22)	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	84–2
Other genotoxic effects	(22)	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	84–4
Special testing													
General metabolism	(23)	R	CR	R	CR	R	CR	CR	CR	CR	PAI or PAIRA	PAI or PAIRA	85–1
Dermal penetration	(24)	CR	CR	CR	CR	CR	CR	CR	CR	CR	Choice	Choice	85–2
Domestic animal safety	(12)	CR	CR	CR	CR			CR	CR		Choice	Choice	86–1

Key: R=Required data; CR=Conditionally required; [ ]=Brackets (ie [R], [CR] indicate data requirements that apply when an experimental use permit is being sought; MP=manufacturing-use product; EP*=End-Use Product; (asterisk identifies those data requirements that end-use applicants (i.e. "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); TGAI=Technical grade of the active ingredient; PAI="Pure" active ingredient; PAIRA="Pure" active ingredient, radio-labeled; Choice=choice of several test substances, depending on studies required.

(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Not required if test material is a gas or highly volatile.

(2) Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as toxicity category I on the basis of potential eye and dermal irritation effects.

(3) Required unless repeated dermal exposure does not occur under conditions of use.

(4) Not required unless test material, is an organophosphate, or a metabolite or degradation product thereof which causes acetyl cholinesterase depression or is structurally related to a substance that causes delayed neurotoxicity.

(5) Required if use involves purposeful dermal application to, or prolonged exposure of, human skin.

(6) Required if use may result in repeated inhalation exposure at a concentration likely to be toxic. A test with duration of 21 days is required if pesticide is used on tobacco.

(7) Required if acute delayed neurotoxicity test showed neuropathy or neurotoxicity or if closely related structural to a compound which can induce these effects.

(8) Required if acute oral, dermal, or inhalation studies showed neuropathy or neurotoxicity.

(9)(i) Studies designed to simultaneously meet the requirements of both the chronic feeding and oncogenicity studies (i.e., a combined study) can be conducted.

(ii) Minimum acceptable test durations for chronic feeding and oncogenicity studies are as follows:

(A) Chronic rodent feeding study (food use pesticides)—24 months.

(B) Chronic rodent feeding study (non-food pesticides)—12 months is usually sufficient.

(C) Chronic nonrodent (i.e., dog) feeding study—12 months.

(D) Mouse oncogenicity study—18 months.

(E) Rat oncogenicity study—24 months.

(10) Required to support products intended for food uses and to supoort products intended for non-food uses if significant exposure of human females of child bearing age may reasonably be expected.

(11) Required to support products intended for food uses and to support products intended for non-food uses if use of the product is likely to result in human exposure over a portion of the human lifespan which is significant in terms of the frequency of exposure, magnitude of exposure, or the duration of exposure (for example; pesticides used in treated fabrics for wearing apparel, diapers, or bedding; insect repellents applied directly to human skin; swimming pool additives; constant-release indoor pesticides which are used in aerosol form).

(12) Required on a case by case basis.

(13) In most cases, where theoretical maximum residue contribution (TMRC) exceeds 50 percent of the maximum permitted intake (MPI), a one year (or longer) interim report on a chronic feed study is required to support a temporary tolerance.

(14) In most cases, where theoretical maxium residue contribution (TMRC) exceeds 50 percent of the maxium permitted intake (MPI), a first generation (or longer) interim report on a multigeneration reproduction study is required to support a temporary tolerance.

(15) A teratology study in one species is required to support a temporary tolerance.

(16) Required if the product consists of, or under conditions of use will result in, an inhalable material (e.g., gas volatile substances, or aerosol/particulate).

(17) Required if intended use(s) of the pesticide product is expected to result in human exposure to the product, under the following conditions:

(i) Human exposure is via the oral route.

(ii) Expected human exposure is over a limited portion of the human lifespan, yet is significant in terms of the frequency of exposure, magnitude of exposure, or the duration of exposure (for example, products requiring a temporary tolerance to support an experimental use permit or emergency exemption).

(18) Required if intended use(s) of the pesticide product is expected to result in human exposure to the product, under the following conditions:

(i) Human exposure is via skin contact.

(ii) Expected human skin contact is not purposeful, and such exposure is of limited frequence and duration (for example, such exposure could result from use of certain disinfectant, liquid fumigant or agricultural or home/garden pesticide products, and other circumstances where the Agency determines that more than acute dermal exposure is involved).

(iii) Data from a subchronic 90-day dermal toxicity study are not required.

(19) Required if pesticidal use will involve purposeful application to the human skin or will result in comparable human exposure to the product, (e.g., swimming pool algaecides, pesticides for impregnating clothing), and if either of the following criteria are met:

(i) Data from a subchronic oral study are not required.

(ii) The active ingredient of the product is known or expected to be metabolized differently by the dermal route of exposure than by the oral route, and a metabolite of the active ingredient is the toxic moiety.

(20) Required if either of the following criteria are met:

(i) Use of the pesticide product is likely to result in repeated human exposure to the product, over a significant portion of the human life-span (for example, products intended for use in and around residences, swimming pools, and enclosed working spaces or their immediate vicinity).

(ii) The use requires a tolerance for the pesticide or an exemption from the requirement to obtain a tolerance, or requires issuance of a food additive regulation.

(21) Required if any of the following criteria are met:

(i) The active ingredient(s) or any of its (their) metabolites, degradation products, or impurities:

(A) Is structually related to a recognized carcinogen.

(B) Is a substance that cause mutagenic effect as demonstrated by *in vitro* or *in vivo* testing.

(C) Produces in subchronic studies a morphologic effect (e.g., hyperplasia, metaplasia) in any organ that may lead to neoplastic change.

(ii) The use requires a tolerance for the pesticide or exemption from the requirement to obtain a tolerance, or requires the issuance of a food additive regulation.

(iii) Use of the pesticide product is likely to result in human exposure over a portion of the human lifespan which is significant in terms of either the time the exposure occurs or the duration of exposure (for example; pesticides used in treated fabrics for wearing apparel, diapers, or bedding; insect repellents applied directly to human skin; swimming pool additives; constant-release indoor pesticides which are used in aerosol form).

(22)(i) The required battery of mutagenicity tests must include tests appropriate to address the following three categories in accordance with the objectives set forth in § 158.105:

(A) Gene mutations.

(B) Structural chromosomal aberrations.

(C) Other genotoxic effects as appropriate for the test substance, e.g., numerical chromosome abberations, direct DNA damage and repair, mammalian cells transformation, target organ/cell analysis.

(ii) Currently recognized tests for each of these categories are listed with the National Technical Information Service (NTIS). Applicants shall explain their reasons for selecting specific tests from the battery of currently recognized tests. Because of the rapid improvements in this field, applicants are encouraged to discuss with the Agency: test selection, protocol design and results of preliminary testing.

(iii) Not required if the pesticide use pattern precludes human exposure (e.g., nonvolatile pesticides packaged and used in enclosed bait boxes).

(23) Required if chronic feeding or oncogenicity studies are required.

(24) Dermal absorption studies required for compounds having a serious toxic effect as identified by oral or inhalation studies, for which a significant route of human exposure is dermal and for which the assumption of 100 percent absorption does not produce an adequate margin of safety. Registrants should work closely with the Agency in developing an acceptable protocol and performing dermal absorption studies.

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§ 158.140 Reentry protection data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the reentry protection data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Foliar dissipation	(1)	CR	CR	CR	CR			CR			TEP	TEP	132-1
Soil dissipation	(1), (4)	CR	CR	CR	CR			CR			TEP	TEP	132-1
Dermal exposure	(1), (2), (3)	CR	CR	CR	CR			CR			TEP	TEP	133-3
Inhalation exposure	(1), (2), (3)	CR	CR	CR	CR			CR			TEP	TEP	133-4

Key: CR=Conditionally required; TEP=Typical end-use product.
(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.
(1) Data are required if the following conditions are met:
(i)(A) The acute dermal toxicity of the technical grade of active ingredient is less than 200 mg/kg (body weight); or
(B) The acute inhalation toxicity of the technical grade of active ingredient is less than 200 mg/m³ (for a one-hour exposure); or
(C) The acute oral toxicity of the technical grade of active ingredient is less than 50 mg/kg (body weight); or
(D) Neurotoxic, teratogenic, or oncogenic effects or other adverse effects as evidenced by subchronic, chronic, and reproduction studies would be expected from entry of persons into treated sites; or
(E) The Agency receives other scientifically validated toxicological or epidemiological evidence that a pesticide or residue of a pesticide could cause adverse effects on persons entering treated sites. In the last situation, reentry intervals and supporting data may be required on a case-by-case basis.
(ii) And if: end-use product is to be registered for:
(A) Application to growing crops, such as to or around horticultural and agronomic crops that are field- or orchard-grown.
(B) Application to outdoor tree nursery and forestry operations.
(C) Application to turf crops and commercial applications to turf.
(D) Application to parks and arboretums; or (E) application to aquatic crops.
(iii) And if: human exposure to residues of the pesticide can be reasonably foreseen. This applies primarily to pesticides that will be used on crops where human tasks will involve substantial exposure to residues of the pesticide.
(2) Data required if appropriate surrogate data are not available.
(3) Data required if the applicant chooses to use the allowable exposure level method for proposal of a reentry interval.
(4) Soil dissipation data required if agricultural practice involves human tasks that would cause substantial exposure to residues sorbed to soil.

(Approved by the Office of Management and Budget under control numbers 2000–0483 and 2000–0468.)

§ 158.142 Spray drift data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the aerial spray drift data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Droplet size spectrum	(1)	CR	CR	CR	CR			CR			TEP	TEP	201-1
Drift field evaluation	(1)	CR	CR	CR	CR			CR			TEP	TEP	202-1

Key: CR=Conditionally required; TEP=Typical end use product.
(b) NOTES.—The following are referenced in column two of the table contained in paragraph (a) of this section.
(1) This study is required when aerial applications (rotary and fixed winged) and mist blower or other methods of ground application are proposed and it is estimated that the detrimental effect level of those nontarget organisms expected to be present would be exceeded. The nontarget organisms include humans, domestic animals, fish and wildlife, and nontarget plants. This requirement may be satisfied by submittal of published or unpublished information regarding spray drift patterns that would be expected to be similar to the proposed product.
(2) [Reserved]

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§158.145 Wildlife and aquatic organisms data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the wildlife and aquatic organisms data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food Crop	Nonfood	Food crop	Nonfood						
Avian and mammalian testing													
Avian oral LD_{50} (preferably mallard or bobwhite).	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	71-1
Avian dietary LC_{50} (preferably mallard and bobwhite).	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	71-2
Wild mammal toxicity	(2)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	71-3
Avian reproduction (preferably mallard and bobwhite).	(3)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	71-4
Simulated and actual field testing—mammals and birds.	(2)	CR	CR	CR	CR			CR	CR		TEP	TEP	71-5
Aquatic organism testing													
Freshwater fish LC_{50} (preferably rainbow and bluegill).	(1), (7)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	72-1
Acute LC_{50} freshwater invertebrates (preferably *Daphnia*).	(1), (7)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	72-2
Acute LC_{50} estuarine and marine organisms.	(4), (7)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	72-3

Kind of data required	(b) Notes	General use patterns									Test substance		Guide-lines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food Crop	Nonfood	Food crop	Nonfood						
Fish early life stage and aquatic invertebrate life-cycle.	(5)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	72-4
Fish—life-cycle	(6)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	72-5
Aquatic organism accumulation.	(8)	CR	CR	CR	CR			CR	CR		TGAI, PAI, or degradation product.	TGAI, PAI, or degradation product.	72-6
Simulated or actual field testing—aquatic organisms.	(2)	CR	CR	CR	CR			CR	CR		TEP	TEP	72-7

Key: R=Required; CR=Conditonally required; [ ]=Brackets (ie. [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought; TGAI=Techical grade of the active ingredient; TEP=Typical end-use product; PAI="Pure" active ingredient.

(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1)(i) Data are required as follows to support manufacturing use products and those end-use products for indoor use for which there is no registered manufacturing use product:

(A) Solid formulation indoor use products require avian oral LD_{50} (bobwhite), avian dietary LC_{50} (bobwhite), freshwater fish LC_{50} (rainbow trout) and acute LC_{50} freshwater invertebrate (*Daphnia*).

(B) Liquid formulation indoors use products require all tests listed under (b)(1)(i) of this section except the avian oral LD_{50}.

(ii) Data are not required to support:

(A) Indoor end-use products consisting of a gas/highly volatile liquid or a highly reactive solid.

(B) Indoor end-use products for which there is a manufacturing use product registration.

(2) Tests required on a case-by-case basis depending on the results of lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics.

(3) Data required if one or more of the following criteria are met:

(i) Birds may be subjected to repeated or continued exposure to the pesticide or any of its major metabolite degradation products, especially preceding or during the breeding season.

(ii) The pesticide or any of its major metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in avian feed.

(iii) The pesticide or any of its major metalolites or degradation products is stored or accumulated in plant animal tissues, as indicated by its octanol/water partition coefficient, accumulation studies, metabolic release and retention studies, or as indicated by structural similarity to known bioaccumulative chemicals.

(iv) Any other information, such as that derived from mammalian reproduction studies that indicates the reproduction in terrestrial vertebrates may be adversely affected by the anticipated use of the pesticide product.

NOTE: Prior to conducting this test to support the registration of an avicide, the applicant should consult the Agency.

(4) Data required if the product is intended for direct application to the estuarine or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility pattern.

(5) Data from fish early life-stage tests or life-cycle tests with aquatic invertebrates (on whichever species is most sensitive to the pesticide as determined from the results of the acute toxicity tests) are required if the product is applied directly to water or expected to be transported to water from the intended use site, and when any one or more of the following conditions apply:

(i) If the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity.

(ii) If any LC_{50} or EC_{50} value determined in acute toxicity testing is less than 1 mg/l; or

(iii) If the estimated environmental concentration in water is equal to or greater than 0.01 of any EC_{50} or LC_{50} determined in acute toxicity testing.

(iv) If the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any EC_{50} or LC_{50} determined in acute toxicity testing and any of the following conditions exist:

(A) Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected.

(B) Physiochemical properties indicate cumulative effects.

(C) The pesticide is persistent in water (e.g., half-life in water greater than 4 days).

(6) Data are required if end-use product is intended to be applied directly to water or expected to transport to water from the intended use site, and when any of the following conditions apply:

(i) If the estimated environmental concentration is equal to or greater than one-tenth of the no-effect level in the fish early life-stage or invertebrate life-cycle test.

(ii) If studies of other organisms indicate the reproductive physiology of fish may be affected. NOTE: The applicant should consult the Agency prior to these tests to support the registration of a pesticide.

(7) Data from testing with the applicant's end-use product or a typical end-use product is required to support the registration of each end-use product which meets any one of the following conditions:

(i) The end-use pesticide will be introduced directly not an aquatic environment when used as directed.

(ii) The LC_{50} or EC_{50} of the technical grade of active ingredient is equal to or less than the maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment when the end-use pesticide is used as directed.

(iii) An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.

(8) Required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms.

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§ 158.150 Plant protection data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the plant protection data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guide-lines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Target area phytotoxicity	(1)										EP	EP	121-1
Nontarget area phytotoxicity.													
Tier I:													
Seed germination/ seedling emergence.	(2)		R		R			R			TGAI	TGAI	122-1
Vegetative vigor	(2)		R		R			R			TGAI	TGAI	122-1
Aquatic plant growth	(2)		R		R			R			TGAI	TGAI	122-2
Tier II:													
Seed germination/ seedling emergence.	(3)		CR		CR			CR			TGAI	TGAI	123-1
Vegetative vigor	(3)		CR		CR			CR			TGAI	TGAI	123-1
Aquatic plant growth	(4)		CR		CR			CR			TGAI	TGAI	123-2
Tier III:													
Terrestrial field	(3)		CR		CR			CR			TEP	TEP	124-1
Aquatic field	(4)		CR		CR			CR			TEP	TEP	124-2

Key: CR=Conditionally required; TGAI=Technical grade of the active ingredient; EP=End-use product; TEP=Typical end-use product.

(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Data are required for Special Review and certain public health situations.

(2) Data are required for pesticides to be used in forests and natural grasslands. For herbicide used in forest site preparation; the acquatic plant growth tests will be required. Data are required to support products to be used in other locations when any of the following conditions are met:
(i) Phytotoxicity problems concerning the product arise and open literature data are not available to address the problems.
(ii) The product may pose hazards to endangered or threatened species.
(iii) Special Review has been initiated on the product.
(3) Required if a 25 percent or greater detrimental effect was found in 1 or more plant species in the corresponding test of the previous tier.
(4) Required if a 50 percent or greater detrimental effect was found on any plant species in the corresponding test of the previous tier.

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§ 158.155 Nontarget insect data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the nontarget insect data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use pattern									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Nontarget insect testing—pollinators													
Honey bee acute contact LD_{50}	(1)	[CR]	[CR]	[CR]	[CR]			[CR]	[CR]		TGAI	TGAI	141-1
Honey bee—toxicity of residues on foliage	(1), (2)	CR	CR	CR	CR			CR	CR		TEP	TEP	141-2
Honey bee subacute feeding study	(3)												141-4
Field testing for pollinators	(4)	CR	CR	CR	CR			CR	CR		TEP	TEP	141-5
Nontarget insect testing—aquatic insects													
Acute toxicity to aquatic insects	(5)												142-1
Aquatic insect life-cycle study	(5)												142-1
Simulated or actual field testing for aquatic insects	(5)												142-3
Nontarget insect testing—predators and parasites	(5)												143-1 thru 143-3

Key: CR=Conditionally required; [ ]=Brackets (ie, [CR]) indicate data requirements that apply to products for which an experimental use permit is being sought; TGAI=Technical grade of the active ingredient; TEP=Typical end-use product.
(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.
(1) Required only if proposed use will result in honey bee exposure.
(2) Required only when formulation contains one or more active ingredients having an acute LD_{50} of less than 1 microgram/bee.
(3) This requirement is reserved pending development of test methodology.
(4) May be required under the following conditions:
(i) Data from the honey bee subacute feeding study indicate adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.).
(ii) Data from residual toxicity studies indicate extended residual toxicity.
(iii) Data derived from studies with organisms other than bees indicate properties of the pesticide beyond acute toxicity, such as the ability to cause reproductive or chronic effects.
(5) This requirement is reserved pending further evaluation to determine what and when data should be required, and to develop appropriate test methods.

(Approved by the Office of Management and Budget under control numbers 2000-0483 and 2000-0468.)

§ 158.160 Product performance data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the product performance data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Efficacy of antimicrobial agents													
Products for use on hard surfaces	(1)									CR		EP*	91-2
Products requiring confirmatory data	(1)									CR		EP*	91-3
Products for use on fabrics and textiles	(1)									CR		EP*	91-4
Air sanitizers	(1)									CR		EP*	91-5
Products for control of microbial pests associated with human and animal wastes	(1)									CR		EP*	91-7
Products for treating water systems	(1)			[CR]						CR		EP*	91-8
Efficacy of fungicides and nematicides													
Products for control of organisms producing mycotoxins	(1)	[CR]		[CR]		[CR]						EP*	93-16

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Efficacy of vertebrate control agents													
Avian toxicants	(2)											EP*	96-5
Avian repellents	(2)											EP*	96-6
Avian frightening agents	(2)											EP*	96-7
Bat toxicants and repellents.	(2)											EP*	96-9
Commensal rodenticides	(2)										TEP	EP*	96-10
Rodenticides on farm and rangelands.	(2)											EP*	96-12
Rodent fumigants	(2)											EP*	96-13
Rodent reproductive inhibitors.	(2)											EP*	96-16
Mammalian predacides	(2)											EP*	96-17

Key: R=Required; CR=Conditionally required; [ ]=Brackets (i.e., [R], [CR]) indicate data requirements that apply to products for which an experimental use permit is being sought; EP=End-use product* (asterisk identifies those data requirements that end-use applicants (i.e., "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); MP=Manufacturing use product; TEP=Typical end-use product.

(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) The Agency has waived all requirements to submit efficacy data except if use of the pesticide bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment. However, all registrants must be able to ensure that their products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration when necessary.

(2) Data requirements to determine the efficacy of vertebrate control agents are reserved at this time.

(Approved by the Office of Management and Budget under control numbers 2000-0483 and 2000-0468.)

§ 158.165 Biochemical pesticides data requirements.

(a) *Biochemical pesticide product analysis data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the biochemical pesticides—product analysis data requirements and the substance to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Product identity		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	151-10
Manufacturing process	(i)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP* and TGAI	151-11
Discussion of formation of unintentional ingredients.	(ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP* and TGAI	151-12
Analysis of samples	(iii)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGAI	EP* and TGAI	151-13
Certification of limits		[R]	R	[R]	R	[R]	R	R	R	R	MP	EP*	151-15
Analytical methods		R	R	R	R	R	R	R	R	R	MP	EP*	151-16
Physical and chemical properties.		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP* and TGAI	151-17
Submittal of samples	(iv)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGAI, PAI.	EP*, TGAI and PAI.	151-18

Key: R=Required CR=Conditionally required; MP=Manufacturing-use product; EP*=End-use product (asterisk identifies those data requirements that end-use applicants (i.e., "formulators") must satisfy, provided that their active ingredient(s) (are) purchased from a registered source); TGAI=Technical grade of the active ingredient; [ ]=Brackets (i.e., [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought.

(2) NOTES. The following notes are referenced in column two of the table contained in paragraph (a)(1) of this section.

(i) If an experimental use permit is being sought, a schematic diagram and/or description of the manufacturing process will suffice if the pesticide is not already under full scale production.

(ii) If the product is not already under full scale production and an experimental use permit is being sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.

(iii) Required to support registration of each manufacturing-use product and end use products produced by an integrated formulation system. Data on other end use products will be required on a case-by-case basis. For pesticides in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.

(iv) Routinely required for products produced by an integrated formulation system. Required on a case-by-case basis for other products or materials.

(b) *Biochemical pesticides residue data requirements.* (1) Table. Sections 158.50 and 158.100 though 158.102 describe how to use this table to determine the biochemical pesticides—residue data requirements and the substance to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Chemical identity	(i), (ii), (xiv)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	TGAI	TGAI	153-3
Directions for use	(i), (iii), (xiv)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]			153-3
Nature of the residue:													
Plants	(i), (xiv)	[CR]		[CR]		[CR]			[CR]		PAIRA	PAIRA	153-3
Livestock	(i), (iv), (xiv)	[CR]		[CR]		[CR]			[CR]		PAIRA and plant metabolites.	PAIRA and plant metabolites.	153-3
Residue analytical method.	(i), (v), (xiv)	[CR]		[CR]		[CR]			[CR]		TGAI and metabolites.	TGAI and metabolites.	153-3
Magnitude of the residue:													
Crop field trials	(i), (xiv)	[CR]		[CR]		[CR]			[CR]		TEP	TEP	153-3
Processed food/feed	(i), (vi)	[CR]		[CR]		[CR]					EP	EP	153-3
Meat/mild/poultry/eggs.	(i), (vii)	[CR]		[CR]		[CR]				[CR]	TGAI or plant metabolites.	TGAI or plant metabolites.	153-3
Potable water	(i), (viii)			[CR]	[CR]						EP	EP	153-3

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Fish	(i), (ix)			[CR]	[CR]						EP	EP	153-3
Irrigated crops	(i), (x)			[CR]	[CR]						EP	EP	153-3
Food handling	(i), (xi)									[CR]	EP	EP	153-3
Reduction of residue	(i), (xii)	[CR]		[CR]		[CR]					Residue of concern.	Residue of concern.	153-3
Proposed tolerance	(i), (xiii)	[CR]		[CR]		[CR]					Residue of concern.	Residue of concern.	153-3
Reasonable grounds in support of the petition.		[CR]		[CR]		[CR]							153-3

Key: CR=Conditionally required data; TGAI=Technical grade of the active ingredient; PAIRA=Pure active ingredient, radio labeled; TEP=typical end-use product, MP=Manufacturing-use product; [ ]=Brackets (i.e., [CR]) indicate data requirements that apply when an experimental use permit is being sought.

(2) NOTES.—The following notes are referenced in column two of the table contained in paragraph (b)(1) of this section.

(i) Residue chemistry data requirements shall apply to biochemical pesticide products when any one or more of the following conditions apply:

(A) Tier II or III toxicology data are required, as specified for biochemical agents in (c)(1) of this section.

(B) The application rate of the product exceeds 0.7 ounces (20 grams) active ingredient per acre per application.

(C) The application rate of the product exceeds a level determined to be comparable to 0.7 ounces active ingredient per application but the application rate is not expressable in terms of ounces per acre per application.

(ii) The same chemical identity data as required in (a)(1) of this section are required, with emphasis on impurities that could constitute a residue problem.

(iii) Required information includes crops to be treated, rate of application, number and timing of applications, preharvest intervals, and relevant restrictions.

(iv) Data on metabolism in livestock are required when residues occur on a livestock feed, or the pesticide is to be applied directly to livestock.

(v) A residue method suitable for enforcement of tolerances is needed whenever a numeric tolerance is proposed Exemptions from the requirement of a tolerance will also usually require an analytical method.

(vi) Data on the nature and level of residue in processed food/feed are required when detectable residues could concentrate on processing and thus require establishment of a food additive tolerance.

(vii) Livestock feeding studies are required whenever a pesticide occurs as a residue in an livestock feed. Direct application to livestock uses will require animal treatment residue studies.

(viii) Data on residues in potable water are required whenever a pesticide is to be applied directly to water, unless it can be determined that the treated water would not be used (eventually) for drinking purpose, by man or animals.

(ix) Data on residues in fish are required whenever a pesticide is to be applied directly to water.

(x) Data on residues in irrigated crops are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.

(xi) Data or residues in food/feed in food handling establishments are required whenever a pesticide is to be used in food/feed handling establishments.

(xii) Reduction of residue data are required when the assumption of tolerance level residues results in an unsafe level of exposure. Data on the level of residue in food as consumed will be used to obtain a more precise estimate of potential dietary exposure.

(xiii) The proposed tolerance must reflect the maximum residue likely to occur in crops and meat/milk/poultry/eggs.

(xiv) Residue data for outdoor domestic uses are required if home gardens are to be treated and the home garden use pattern is different from the use pattern on which the tolerances were established.

(c) *Biochemical pesticides toxicology data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the biochemical pesticides—toxicology data requirements and the substances to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Tier I:													
Acute oral toxicity	(i)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP* or EP dilution* and TGAI.	152-10
Acute dermal toxicity	(i), (ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP* or EP dilution* and TGAI.	152-11
Acute inhalation	(xiv)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP* and TGAI	152-12
Primary eye irritation	(ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP	152-13
Primary dermal irritation.	(i), (ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP	152-14
Hypersensitivity study	(iii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	MP	EP	152-15
Hypersensitivity incidents.	(iv)	CR	CR	CR	CR	CR	CR	CR	CR	CR			152-16
Studies to detect genotoxicity.	(v)	[R]	[CR]	[R]	[CR]	[R]	[CR]	[CR]	[CR]	[CR]	TGAI	TGAI	152-17
Immune response		[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	152-18
90-day feeding (1 spp.).	(vi)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-20
90-day dermal (1 spp.).	(vii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-21
90-day inhalation (1 spp.).	(viii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-22
Teratogenicity (1 spp.).	(ix)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-23
Tier II:													
Mammalian mutagenicity tests.	(x)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-19
Immune response	(xi)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-24
Tier III:													
Chronic exposure	(xii)	CR		CR		CR				CR	TGAI	TGAI	152-26
Oncogenicity	(xiii)	CR		CR		CR				CR	TGAI	TGAI	152-29

Key: R=Required; CR=Conditionally Required; MP=Manufacturing-use product; EP*=End-use product (asterisk identifies those data requirements that end-use applicants (i.e. "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); TGAI=Technical Grade of the Active Ingredient; [ ]=Brackets (i.e., [R], [CR]) indicate data requirement that apply when an experimental use permit is being sought.

(2) NOTES.—The following notes are referenced in column two of the table contained in paragraph (c)(1) of this section.

(i) Not required if test material is a gas or is highly volatile.

(ii) Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified toxicity category I on the basis of potential eye and dermal irritation effects.

(iii) Required if repeated contact with human skin results under condition of use.

(iv) Incidents must be reported, if they occur.

(v) Required to support non-food uses if use is likely to result in significant human exposure; or the active ingredient or its metabolites is (are) structurally related to a known mutagen, or belongs(s) to any chemical class of compounds containing known mutagens.

(vi) Required if the use requires a tolerance or an exemption from the requirement for a tolerance, or its use requires a food additive regulation; or the use of the product is otherwise likely to result in repeated human exposure by the oral route.

(vii) Required if pesticidal use will involve purposeful application to the human skin or will result in comparable prolonged human exposure to the product, (e.g., swimming pool algaecides, pesticides for impregnating clothing), and if either of the following criteria are met:
(A) Data from a subchronic oral study are not required.
(B) The active ingredient of the product is known or expected to be metabolized differently by the dermal route of exposure than by the oral route, and a metabolite of the active ingredient is the toxic moiety.
(viii) Required if pesticidal use may result in repeated inhalation exposure at a concentration which is likely to be toxic.
(ix) Required if any of the following criteria are met:
(A) Use of the product under widespread and recognized practice may reasonably be expected to result in significant exposure to female humans.
(B) Its use requires a tolerance or an exemption from the requirement for a tolerance, or its use requires issuance of a food additive regulation.
(x) Required if results from any one of the Tier I mutagenicity tests were positive.
(xi) Required if adverse effects are observed in the Tier I immune response studies.
(xii) Required if the potential for adverse chronic effects are indicated based on:
(A) The subchronic effect levels established in the Tier I subchronic oral toxicity studies, the Tier I subchronic dermal toxicity studies or the Tier I subchronic inhalation toxicity studies.
(B) The pesticide use pattern (e.g., rate, frequency, and site of application).
(C) The frequency and level of repeated human exposure that is expected.
(xiii) Required if the product meets either of the following criteria:
(A) The active ingredient(s) or any of its (their) metabolites, degradation products, or impurities produce(s) in Tier I subchronic studies a morphologic effect (e.g., hyperplasia, metaplasia) in any organ that potentially could lead to neoplastic change.
(B) If adverse cellular effects suggesting oncogenic potential are observed in Tier I or Tier II immune response studies or in Tier II mammalian mutagenicity assays.
(xiv) Required if the product consists of, or under conditions of use results in, an inhalable material (e.g., gas, volatile substance, or aerosol/particulate).

(d) *Nontarget organism, fate and expression data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the biochemical pesticides non-target organism, fate and expression data requirements and substances to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Tier I:													
Avian acute oral	(i), (ii)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154-6
Avian dietary	(i), (ii), (vi)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154-7
Freshwater fish LC_{50}	(i), (ii), (v)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154-8
Freshwater invertebrate LC_{50}	(i), (ii), (vii)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154-9
Nontarget plant studies	(iii)		R		R			R			TGAI	TGAI	154-10
Nontarget insect testing	(iv), (v)	CR	CR	CR	CR	CR	CR	CR	CR		TGAI	TGAI	154-11
Tier II:													
Volatility	(viii)	CR	CR	CR	CR			CR	CR		TEP	TEP	155-4
Dispenser-water leaching	(ix)	CR	CR	CR	CR			CR	CR		EP	EP	155-5
Adsorption-desorption	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155-6
Octanol/Water Partition	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155-7
U.V. absorption	(xi)	CR	CR	CR	CR			CR	CR		PAI	PAI	155-8
Hydrolysis	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155-9
Aerobic soil metabolism	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155-10
Aerobic aquatic metabolism	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155-11
Soil photolysis	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155-12
Aquatic photolysis	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155-13
Tier III:													
Terrestrial wildlife testing	(xii)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	15-12
Aquatic animal testing	(xiii)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154-13
Nontarget plant studies	(xiv)										TGAI	TGAI	154-14
Nontarget insect testing	(xv)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154-15

Key: R=Required; CR=Conditionally required; [ ]=Brackets (i.e., [R], [CR]) indicates data requirements that apply to products for which an experimental use permit is being sought; MP=Manufacturing-use product; TEP=Typical end-Use product; TGAI=Technical grade of the active ingredient; EP=End-use product, PAI="Pure" active ingredient.
(2) NOTES.—The following notes are referenced in column two of the table contained in paragraph (d)(1) of this section.
(i) Tests for pesticides intended solely for indoor application will be required on a case-by-case basis, depending on use pattern, production volume, and other pertinent factors.
(ii) Preferable test species are: bobwhite quail or mallard for avian acute oral and avian dietary studies; rainbow trout for freshwater fish studies; and *Daphnia* for freshwater invertebrate studies on biochemicals.
(iii) Data are required for pesticides to be used in forests and natural grasslands. For herbicides used in forest site preparation; the aquatic plant growth tests will be required. Data are required when to support products to be used in other locations when any of the following conditions are met.
(A) Phytotoxicity problems arise and open literature data are not available.
(B) The product may pose hazards to endangered or threatened species.
(C) A rebuttable presumption against registration Special Review has been initiated on the product.
(iv) Required depending on pesticide mode of action and results of any available product performance data.
(v) Biochemicals introduced directly into an aquatic environment when used as directed shall be tested as specified in § 158.145.
(vi) Not required if pesticide is highly volatile (estimated volatility greater than 5×10^{-8} atm. m^3/mol).
(vii) If the pesticide will be introduced directly into an aquatic environment when used as directed, then it must be tested as indicated in § 158.145.
(viii) Required when results of any one or more of the Tier I tests indicate potential adverse effects on nontarget organisms and the biochemical agent is to be applied on land.
(ix) Required when results of any one or more of the Tier I tests indicate potential adverse effects on nontarget organisms and the biochemical agent is to be applied on land in a passive dispenser.
(x) Required on a case-by-case basis when results of Tier I tests indicate environmental fate data are needed.
(xi) Required when results of Tier I tests indicate potential adverse effects on beneficial insects and the intended route of exposure of the pesticide is through vapor phase contact.
(xii) Required if either of the following criteria are met:
(A) Environmental fate characteristics indicate that the estimated concentration of the biochemical pesticide in the terrestrial environment is equal to or greater than ⅛ the avian dietary LC_{50} or the avian single dose oral LD_{50} (converted to ppm).
(B) The pesticide or any of its metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in the avian feed.
(xiii) Required if environmental fate characteristics indicate that the estimated environmental concentration of the biochemical agent in the aquatic environment is equal to or greater than 0.01 of any EC_{50} or LC_{50} determined in testing required by Tier I aquatic tests.
(xiv) Required if the product is expected to be transported from the site of application by air, soil, or water. The extent of movement will be determined by the Tier II environmental fate tests.
(xv) Required when results of Tier I tests indicate potential adverse effects on nontarget insects and results of Tier II tests indicate exposure of nontarget insects.

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§ 158.170 Microbial pesticides—Product analysis data requirements.

(a) *Microbial pesticides product analysis data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the microbial pesticides—product analysis data requirements and the substance to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Product identity manufacturing process.		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	151-20
	(i)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP* and TGAI	151-21
Discussion of formation of unintentional ingredients.	(ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP* and TGAI	151-22
Analysis of samples	(iii)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGAI	EP* and TGAI	151-23
Certification of limits		[R]	R	[R]	R	[R]	R	R	R	R	MP	EP*	151-25
Analytical methods		R	R	R	R	R	R	R	R	R	MP	EP*	151-
Physical and chemical properties.		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP* and TGAI	151-26
Submittal of Samples	(iv)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGAI, PAI.	EP* TGAI and PAI.	151-27

Key: R=Required; CR=Conditionally required; MP=Manufacturing-use product: EP*=End-use product (asterisk identifies those data requirements that end-use applicants (i.e., "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); TGAI=Technical grade of the active ingredient; [ ]=Brackets (i.e., [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought.

(2) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a)(1) of this section.

(i) If an experimental use permit is being sought, a schematic diagram and/or description of the manufacturing process will suffice if the pesticide is not already under scale production.

(ii) If the product is not already under full scale production and an experimental use permit is being sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.

(iii) Required to support registration of each manufacturing-use product and end use products produced by an integrated formulation system. Data on other end use products will be required on a case-by-case basis. For pesticide in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.

(iv) Routinely required for products produced by an integrated formulation system. Required on a case-by-case basis for other products or materials.

(b) *Microbial pesticides residue data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the microbial pesticides-residue data requirements and the substances to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Residue data	(i)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]			153-4

Key: CR=Conditionally required data; EP=End-use product; MP=Manufacturing-use product; [ ]=Brackets (i.e., [CR]) indicate data requirements that apply when an experimental use permit is being sought.

(2) NOTES.—The following notes are referenced in column two of the table contained in paragraph (b)(1) of this section.

(i) Residue data requirements shall apply to microbial pesticides when Tier II or Tier III toxicology data are required, as specified for microbial pesticides in (c)(1) of this section.

(ii) [Reserved]

(c) *Microbial pesticides toxicology data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the microbial pesticides—toxicology data requirements and the substances to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Tier I:													
Acute oral		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP* or EP* dilution and TGAI.	152-30
Acute dermal		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP* or EP dilution and TGAI.	152-31
Acute inhalation	(i)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI	EP* or EP Dilution* and TGAI.	152-32
I.V., I.C., I.P. injection	(ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	152-33
Primary dermal		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	152-34
Primary eye		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	152-35
Hypersensitivity study	(iii)	R	R	R	R	R	R	R	R	R	MP	EP*	152-36
Hypersensitivity incidents.	(iv)	CR	CR	CR	CR	CR	CR	CR	CR	CR			152-37
Immune response		[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	152-38
Tissue culture	(v)	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	152-39
Tier II:													
Acute oral	(vi)	CR	CR	CR	CR	CR	CR	CR	CR	CR	MP	EP*	152-40
Acute inhalation	(vii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	MP	EP*	152-41
Subchronic oral	(viii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-42
Acute I.P., I.C.	(ix)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-43
Primary dermal	(x)	CR	CR	CR	CR	CR	CR	CR	CR	CR		EP*	152-44
Primary eye	(xi)	CR	CR	CR	CR	CR	CR	CR	CR	CR		EP*	152-45
Immune response	(xii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-46
Teratogenicity	(xiii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-47
Virulence enhancement.	(xiv)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-48

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Mammalian mutagenicity.	(xv)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-49
Tier III:													
Chronic feeding	(xvi)	CR		CR		CR				CR	TGAI	TGAI	152-50
Oncogenicity	(xvii)	CR		CR		CR				CR	TGAI	TGAI	151-51
Mutagenicity	(xviii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-52
Teratogenicity	(xix)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-53

Key: R=Required; CR=Conditionally required; MP=Manufacturing-use product; EP*=End use product (asterisk identifies those data requirements that end-use applicants (i.e., "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); TGAI=Technical Grade of the Active Ingredient; [ ]=Brackets (i.e., [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought.

(2) NOTES.—The following notes are referenced in column two of the table contained in paragraph (c)(1) of this section.

(i) Required if 20 percent or more of the aerodynamic equivalent of the product (as registered or under conditions of use) is composed of particulates less than 10 microns in diameter.

(ii) Data required for products as follows:

(A) Intravenous ("IV") infectivity study for bacterial, and viral agents;

(B) Intracerebral ("IC") infectivity study for viral and protozoan agents; and

(C) Intraperitoneal ("IP") infectivity study for fungal and protozoan agents.

(iii) Required if commonly recognized use practices will result in repeated human contact by inhalation or dermal routes.

(iv) Hypersensitivity incidents must be reported, if they occur.

(v) Data required for products whose active ingredient is a virus.

(vi) Required if survival, replication, infectivity, toxicity, or persistence of the microbial agent (virus or protozoa) is observed in the test animals treated in the Tier I acute oral infectivity tests or the intraperitoneal or intracerebral injection test for protozoa.

(vii) Required if survival, replication, infectivity, toxicity, or persistence of the microbial agent (virus or protozoa) is observed in the test animals treated in the comparable Tier I acute inhalation tests.

(viii) Required if there is evidence of survival, replication, infectivity, or persistence of the protozoan agent in the Tier I oral infectivity test.

(ix) Required if in Tier I acute oral infectivity testing, Tier I dermal toxicity/infectivity testing, or Tier I intraperitoneal or intracerebral injection testing, the test microorganism (bacteria, fungi, or protozoa) survived for more than 2 weeks, caused toxic effects, or caused a severe illness response in an experimental animal as evidenced by irreversible gross pathology, severe weight loss, toxemia, or death.

(x) Required if infectivity or if marked edema or broad erythema was observed in the Tier I dermal irritation study.

(xi) Required if infectivity or if severe ocular lesions are observed in the Tier I primary eye irritation study.

(xii) Required if results of the Tier I immune response test indicate abnormalities.

(xiii) Required when Tier I tests on viral agents show replication of the virus in mammalian hosts and significant damage to mammalian cells.

(xiv) Required when Tier I infectivity tests on bacteria or fungi indicate prolonged survival (including presence of viable microbial agents in test animal excreta) and/or multiplication (infectivity) of the bacteria or fungal agent, respectively.

(xv) Required if any of the following criteria are met:

(A) Acute infectivity tests are positive in Tier I studies.

(B) Adverse effects are observed in immune response studies.

(C) Positive results are obtained in tissue culture tests with viral agents.

(xvi) Required when the potential for chronic adverse effects (e.g., replication or persistence of viral or subviral constituents, protozoans, fungi, or bacteria) are demonstrated by any of the Tier II tests (except primary dermal, primary ocular, and mammalian mutagenicity tests).

(xvii) Required when the potential for oncogenic effects is indicated (e.g., adverse cellular effects due to presence, replication, or persistence of viral or subviral constituents, or bacteria, fungi or protozoans; or mutagenic effects) by any of the Tier II tests except the primary dermal and primary ocular studies.

(xviii) Required when the potential for mutagenic effects is indicated (e.g., adverse cellular effects due to presence, replication, or persistence of viral or subviral constituents, bacteria, fungi or protozoa) by any of the Tier II tests except primary dermal or primary ocular studies.

(xix) Required when the potential for teratogenic effects is expected based on the presence of persistence of fungi, bacteria, viruses, or protozoa in mammalian species as a result of testing performed in Tier II, except primary dermal and primary ocular studies.

(d) *Microbial pesticides non-target organism and environmental expression data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the microbial pesticides non-target organism and environmental expression data requirements and substances to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Tier I:													
Avian oral	(i), (ii), (iii)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154-16
Avian injection test	(i), (ii), (iii)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154-17
Wild mammal testing	(iv)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154-18
Freshwater fish testing.	(i)	[R]	[R]	[R]	[R]	CR	CR	[R]	CR	CR	TGAI	TGAI	154-19
Freshwater aquatic invertebrate testing.	(i)	[R]	[R]	[R]	[R]	CR	CR	[R]	CR	CR	TGAI	TGAI	154-20
Estuarine and marine animal testing.	(v)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154-2
Nontarget plant studies.		[R]	[R]	[R]	[R]			[R]	[R]	CR	TEP	TEP	154-2
Nontarget insect testing.		[R]	[R]	[R]	[R]	CR	CR	[R]	[R]		TGAI	TGAI	154-23
Honey bee testing		[R]	[R]	[R]	[R]	CR	CR	[R]	[R]		TGAI	TGAI	154-24
Tier II:													
Terrestrial environmental testing.	(vi)	CR	CR	CR	CR			CR	CR		TGAI or TEP	TGAI or TEP	155-18
Freshwater environmental expression tests.	(vii)	CR	CR	CR	CR			CR	CR		TGAI or TEP	TGAI or TEP	155-19
Marine or estuarine environmental expression tests.	(xiii), (ix)	CR	CR	CR	CR			CR	CR		TGAI or TEP	TGAI or TEP	155-20
Tier III:													
Terrestrial wildlife and aquatic organism testing.	(x)	CR	CR	CR	CR			CR	CR		TGAI or TEP	TGAI or TEP	154-25
Avian pathogenicity/ reproduction test.	(xi)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154-26
Definitive aquatic animal tests.	(xii)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154-27
Aquatic embryo larvae and life cycle studies.	(xiii)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154-28

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Aquatic ecosystem test.	(xiv)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TGAI	TGAI	154-29
Special aquatic tests (reserved).	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	154-30
Nontarget plant studies.	(xv)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TGAI	TEP	154-31
Tier IV:	(xvi)												
Simulated and actual field tests (birds, mammals).	(xiii)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TEP	TEP	154-33
Simulated and actual field tests (aquatic organisms).	(xvii), (xviii)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TEP	TEP	154-34
Simulated and actual field tests (insect predators, parasites) (reserved).	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	154-35
Simulated and actual field tests (insect pollinators) (reserved).	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	154-36

Key: R=Required; CR=Conditionally required; [ ]=Brackets (i.e., [R], [CR]) indicates data requirements that apply to products for which an experimental use permit is being sought; MP=Manufacturing-use Product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; EP=End-use product; PAI="Pure" active ingredient.

(2) NOTES.—The following notes are referenced in column two of the table contained in paragraph (d)(1) of this section.

(i) Tests for pesticides intended solely for indoor application will be required on a case-by-case basis, depending on use pattern, production volume, and other pertinent factors.

(ii) Preferable test species are: bobwhite quail or mallard for avian acute oral and avian dietary studies; rainbow trout for freshwater fish studies.

(iii) Data from *either* the avian acute oral *or* the avian injection study are required to support an experimental use permit.

(iv) Required on a case-by-case basis if results of tests required by paragraph (c)(1) of this section are inadequate or inappropriate for assessment of hazards to wild animals.

(v) Required when product is intended for direct application into the estuarine or marine environment or expected to enter this environment in significant concentrations because of expected use or mobility pattern.

(vi) Required when toxic or pathogenic effects are observed in any of the following Tier I tests for microbial pest control agents:
(A) Avian single dose oral toxicity and pathogenicity tests.
(B) Avian injection pathogenicity tests.
(C) Wild mammals toxicity and pathogenicity test.
(D) Plant studies—terrestrial.
(E) Honey bee toxicity/pathogenicity test.
(F) Testing for toxicity/pathogenicity to insect predators and parasites.

(vii) Required when toxic or pathogenic effects are observed in any of the following Tier I test for microbial pest control agents:
(A) Freshwater fish toxicity and pathogenicity testing.
(B) Freshwater aquatic invertebrate toxicity and pathogenicity test.
(C) Plant studies—aquatic.

(viii) Required if product is applied on land or in fresh water and toxic or pathogenic effects are observed in any of the following Tier I tests for microbial pest control agents:
(A) Estuarine and marine animal toxicity and pathogenicity test.
(B) Plant studies—estuarine or marine.

(ix) Required if product is applied in marine or estuarine environments and toxic or pathogenic effects are observed in any of the following Tier I tests:
(A) Avian single dose oral toxicity and pathogenicity test.
(B) Avian injection pathogenicity test.
(C) Estuarine and marine animal toxicity and pathogenicity test.

(x) Required when toxic effects on nontarget terrestrial wildlife or aquatic organisms are reported in one or more Tier I tests and results of Tier II tests indicate exposure of the microbial agent to the affected nontarget terrestrial wildlife or aquatic organisms.

(xi) Required when:
(A) Pathogenic effects are observed in Tier I avian tests at a level equal to the adjusted host equivalent amount.
(B) Chronic, carcinogenic, or teratogenic effects are reported in tests required by paragraph (c)(1) of this section for evaluating hazard to humans and domestic animals.
(C) Tier II Environmental expression testing indicates that exposure of terrestrial animals to the microbial agent is likely.

(xii) Required when product is intended for use in water or expected to be transported to water from the intended use site, and when pathogenicity or infectivity was observed in Tier I tests.

(xiii) Required when both of the following conditions are met:
(A) Pathogenic effects at actual or expected field residue exposure levels are reported in Tier III.
(B) The agency determines that quarantine methods will prevent the microbial pest control agent from contaminating areas adjacent to the test area.

(xiv) Required if, after an analysis of the microbial agent's properties, the individual use patterns, and the results of previous nontarget organism and environmental expression tests, it is determined that use of the microbial agent may result in adverse effects on the nontarget organisms in aquatic environments, including those of the water column and bottom sediments. When a microbial pest control agent is used in or is expected to transport to water from the intended use site, major considerations for requiring these infectivity tests include, but are not limited to:
(A) Infectivity or pathogenicity demonstrated in previous testing.
(B) Viability of the microorganism in natural waters as demonstrated in Tier II tests.

(xv) Required if the product is transported from the site of application by air, soil, or water or transmission by other animals. The extent of movement will be determined by the environmental expression tests in Tier II.

(xvi) The Agency expects that Tier IV requirements would be imposed retrospectively—after product registration as post registration monitoring, since it is unlikely a registrant would pursue registration of a microbial agent posing potential hazards such that testing beyond Tier III is required.

(xvii) Short term simulated or actual field studies are required when it is determined that the product is likely to cause adverse short-term or acute effects, based on consideration of available laboratory data, use patterns, and exposure rates.

(xviii) Data from a long-term simulated field test (e.g., where reproduction and growth of confined populations are observed) and/or an actual field test (e.g., where reproduction and growth of natural populations are observed) are required if laboratory data indicate adverse long-term, cumulative, or life-cycle effects may result from intended use.

(Approved by Office of Management and Budget under control numbers 2000-0483 and 2000-0468.)

Appendix A to Part 158—Data Requirements for Registration: Use Pattern Index

How to use this Index:

1. Identify the Pesticide Use Site Group listed below (e.g., agricultural crops, forests, ornamental plants) that covers the specific use pattern of interest to you.

2. Find your specific use pattern under the appropriate Pesticide Use Site Group.

3. Identify the general use pattern that corresponds to your specific use pattern.

4. Use the general use pattern in determining applicable data requirements on the Data Requirements tables presented in §§ 158.120 through 153.170.

Pesticide use site group

1. Agricultural Crops.
2. Ornamental Plants and Forest Trees.
3. General Soil Treatment and Composting.
4. Processed or Manufactured Products, and food or feed containers or dispensers.
5. Pets and Domestic Animals.
6. Agricultural Premises and Equipment.
7. Household.
8. Wood or Wood Structure Protection Treatments.
9. Aquatic sites.
10. Noncrop, wide area, and general indoor/outdoor treatments.
11. Antifouling treatments.
12. Commercial and Industrial Uses.
13. Domestic and Human Use.
14. Miscellaneous Indoor Uses.

Specific use patterns—listed according to use site group	Corresponding general use pattern
1. *Agricultural crops*	
Small fruits	Terrestrial food crop
Caneberries (e.g., raspberry, dewberry)	
Bushberries (e.g., blueberry, currant)	

Specific use patterns—listed according to use site group	Corresponding general use pattern
Vine fruits (e.g., grape, kiwi fruit)	
Strawberry	
Cranberry	
Pome fruits (e.g., apple, quince)	
Stone fruits (e.g., peach, cherry)	
Nut crops—tree & shrub (e.g., pecan, filbert)	
Other temperate fruits (e.g., persimmon, pawpaw)	
Tropical and subtropical fruits	
Citrus	
Banana and plantain	
Palm fruits and nuts (e.g., date, coconut)	
Pineapple	
Other fruits and nuts	
Beverage crops	
Woody—cocoa, coffee, tea	
Herbaceous—chicory, mint	
Flavoring and spice crops	
Woody—leaf/stem, root, seed and pod	
Herbac.—leaf/stem, root, seed and pod	
Vegetables—leaf/stem, root, seed and pod, fruiting vegetables, cucurbits	
Commercial annual (e.g., tomato, bean)	
Commercial perennial (e.g., asparagus, rhubarb)	
Greenhouse (commercial)	Greenhouse food crop
Mushrooms	
Nursery/seed crop/medical crop/tobacco	Greenhouse non-food crop
Fiber crops	Terrestrial food crop
Cotton	
Others—(e.g., flax)	
Forage crops	
Typical grasses—annual (e.g., sudan grass)	
Typical grasses—perennial (e.g., bromegrass)	
Corn and sorghum	
Small grains for forage (e.g., rye)	
Perennial legumes (e.g., white clover)	
Annual legumes (e.g., crotalaria, soybean)	
Crop harvest residue (peanut vines, beet tops, etc.)	
Grain and edible seed crops	
Corn	
Rice	Aquatic food crop
Wheat, barley, rye, oats	Terrestrial food crop
Sorghum	
Alfalfa	
Other grains	
Other nongrains (e.g., squash, pumpkin)	
Buckwheat	
Sesame	
Peanut	
Sunflower	
Seed sprout crops	
Mung bean, red clover, soybean, alfalfa, etc.	
Nonlegume crops (e.g., wheat, radish, black mustard).	
Crops grown exclusively for seed for planting	
Sugar crops	
Stored raw agricultural commodities	Indoor
Honey (principal nectar-producing crops)	
Sugar beet	
Sugar cane	
Sugar maple	
Sorghum (for sugar)	
Crops for smoking and chewing	Terrestrial nonfood crop
—field	
—shade	
—storage	
—greenhouses	
Sapodilla (for chewing gum)	Terrestrial food crop
Oil crops	
Annual herbaceous crops	
Perennial herbaceous crops	
Tropical/subtropical woody crops	
Drug and medicinal crops	Terrestrial nonfood crop
Annual herbaceous crops	
Perennial herbaceous crops	
Temperate woody crops	
Tropical/subtropical wood crops	
2. Ornamental plants and forest trees	
Ornamental plants	Terrestrial nonfood crop
Annual garden plants	
Temperate perennial nonfood garden herbs	
Commercial greenhouse crops	Greenhouse nonfood crop
Houseplants	Indoor
Home and retail greenhouse and conservatory plants	
Public display plantings	Terrestrial nonfood crop
Bulb, corm, and tuber ornamentals	
Subtropical/tropical garden evergreen plants (dry—e.g., agave)	
Subtropical/tropical garden evergreen plants (moist—e.g., ferns)	
Groundcovers	
Aquatic plants (e.g., waterlilies)	Aquatic nonfood use
Ornamental trees, shrubs, and vines (woody)	Terrestrial nonfood crop
Deciduous temperate broadleaf	
Evergreen temperate broadleaf	
Deciduous temperate conifer	
Evergreen temperate conifer	
Tropical/subtropical broadleaf	
Tropical/subtropical conifer	
Tropical/subtropical miscellaneous (e.g., cycad, tree fern, bamboo)	
Lawn and turf grasses—ornamental	Terrestrial nonfood crop or domestic outdoor
Cool season Winter grasses (bent, bluegrass, fescue, etc.)	
Summer grasses (zoysia, bermudagrass, etc.)	
Ornamental bunch grasses (pampasgrass, blue fescue)	
Forest trees—nonornamental—trees forests, plantings	Forestry
Deciduous temperate (broadleaf)	
Evergreen temperate (broadleaf)	
Deciduous and evergreen conifers	
Tropical/subtropical broadleaf	
Tropical/subtropical conifer	
Forest tree nurseries—Temperate broadleaf trees	
Temperate conifer trees	
Forest trees: dead trees/logs/stumps in the forest or in plantings	
3. General soil treatment and composting	
General soil treatments	Terrestrial nonfood crop
Soil application with no mention of crops to be grown (potting soil, top soil).	
Manure	
Composts	
Cull Piles	
Mulches	
4. Processed or manufactured products, and food or feed containers or dispensers	
Processed vegetables, fruits, and nuts	Indoor
Fruits	
Leafy vegetables	
Root vegetables	
Fruited vegetables	
Nuts	
Peanuts	
Seeds (sesame, sunflower)	
Dried processed	
Fruits	
Vegetables	
Tobacco	
Beverages (tea, coffee)	
Herbsand spices	
Animal Feeds	
Cattle (beef)	
Cattle (dairy)	
Goat (nondairy)	
Goat (dairy)	
Horse, mule, donkey	
Poultry (chicken, turkey, etc.)	
Sheep (meat)	
Sheep (wool)	
Swine	
Dog	
Cat	
Other pets (including birds)	
Fur-bearing stock	
Other meat-producing stock (e.g., rabbit)	
Fish food (commercial)	
Fish food (pet)	
Birdseed	
Processed grain products for human consumption	
Corn	
Soybean	
Wheat	
Other grains (rice, barley, etc.)	
Cereal foods	
Flour	
Baked goods	
Farinaceous products	
Processed animal products for human consumption	
Cheese	
Egg Yolks	
Meats, including fish and poultry	
Milk	
Processed plant products for human consumption	
Chocolate	
Candy	
Sugar	
Yeast	
Citrus pulp	
Chewing gum	
Cigarettes, etc.	
Herbs and spices	
Pickles	
Glazed fruits	
Jellies	
Seed oils	
Fruit syrups (e.g., cola)	
Fruit juices	
Fermentation beverages (wine, beer, whiskey, vinegar)	
Processed or manufactured nonfood plant and animal products	
Textiles, fabrics, fibers	
Fur and hair products	
Leather products	
Food and feed containers, dispensers, and processing equipment	
Airtight storages—large (empty/full)	
Airtight storages—small (empty/full)	
Fumigation chambers	
Bins	
Elevators	
Storage areas—(empty/full)	
Processing or handling equipment and machinery (other than food processing)	
5. Pets and domestic animals—animals and their man-made premises	
Dairy Cattle—lactating	Indoor
Dairy cattle—nonlactating	
Dairy cattle—heifers, calves	
Goats—lactating	
Goats—nonlactating	
Goats—young (kids)	
Fur- and wool-bearing animals	
Goats	
Sheep	
Mink	
Chinchilla	
Rabbit	
Fox	
Nutria	
Meat animals (mammals)	
Cattle (and calves)	
Goats (and kids)	
Horses	
Rabbits	
Sheep (and lambs)	
Swine	
Bison	
Reindeer	
Poultry (meat, eggs)	
Chickens	
Turkeys	
Ducks, geese	
Guineas, pheasants, quail, etc.	
Honey production	

Specific use patterns—listed according to use site group	Corresponding general use pattern
Bees	
Beehives	
Honeycombs	
Fish and shellfish production	Aquatic food use
Hatchery buildings	
Culture ponds, containers	
Animals for labor, display, riding, racing, lab use, etc.	Indoor
Dogs	
Horses, donkeys, mules	
Guinea pigs	
Mice	
Rats	
Gerbils	
Hamsters	
Monkeys	
Cats	
Chickens, birds	
Wild rodents	
Alfalfa leafcutting bee (pollinator)	
Alkaline bee (pollinator)	
Zoo ruminants	
Zoo ungulates	
Zoo canines	
Zoo felines	
Zoo primates	
Zoo reptiles	
Zoo amphibians	
Zoo birds	
Zoo—others	
Aquarium fish	
Animals for pets, including their cages, bedding, nests, etc.	
Dogs	
Cats	
Birds	
Rodents	
Lagomorphs	
Fish	
Amphibians	
Reptiles	
Primates	
Other vertebrates	
6. Agricultural premises and equipment	
Egg Handling Facilities and Equipment	Indoor
Egg washers	
Egg rooms	
Hatching egg treatments	
Hatching egg rooms	
Hatching egg equipment	
Egg packing plants and hatcheries	
Milk Handling Facilities and Equipment	
Milk storage rooms	
Milking stalls and parlors	
Milking machines, milk tanks, etc.	
Teat cups, liners, etc.	
Milk processing equipment	
7. Household	
Non-food area and sites	Indoor
Closets, storage areas	
Basements, cellars	
Bedrooms	
Attics	
Recreation rooms	
Living rooms	
Baseboards, window sills, etc.	
Plumbing fixtures	
Sickrooms	
Food-handling and food storage areas	
Kitchens	
Dining rooms	
Pantry and food storage shelving	
Household contents and space	
Air	
Beds	
Rugs	
Book cases	
Furs, fabrics, blankets	
Play pens	
Sickroom utensils	
Filters for air vents, air conditioners, furnaces, etc.	
Outdoor areas (Noncommercial homeowner use)	Domestic outdoor or terrestrial food crop
Home garden, orchards	
Porches	Domestic outdoor
Patios	
Foundations	
Steps	
Eaves	
Yards, lawn, turf	
Domestic ornamental plantings	
8. Wood or Wood Structure Protection Treatments	
Buildings (for termite, powderdust beetle controls, etc.)	Domestic outdoor or indoor
Unseasoned forest products.	
Seasoned forest products	
Finished wood products	
Wood pressure treatments	
Plant-growing wood structures and containers	
Wood containers for nonfood, nonfeed uses	
9. Aquatic sites	
Food processing water systems	Aquatic food crop
Poultry and livestock drinking water	
Pulp and papermill systems	Aquatic noncrop
Swimming pool water	
Industrial disposal systems	
Industrial ponds	
Human drinking water	Aquatic food crop
Cooling water towers	Aquatic noncrop
Agricultural irrigation water, and ditches	Aquatic food crop
Agricultural drainage water and ditches	
Sewage systems and drainfields	Aquatic noncrop
Dishwashing water	Indoor
Domestic and commercial nonpotable water	Aquatic noncrop
Lakes, ponds, impounded water	
Streams, rivers, canals	
Swamps, marshes, wetlands	
Air conditioner water	
Humidifier water	
Air washer water systems	
Secondary oil recovery injection water	
Heat exchange water system	
Polluted water	
Bait boards (floating—for vertebrate control)	
Catch basins, puddles, tree holes	
Estuaries, tidal marshes	
Commercial and sport fish-bearing waters	Aquatic food crop
10. Noncrop, wide area, and general indoor/outdoor treatments	
Uncultivated agricultural areas (non-food producing)	Terrestrial noncrop
Farmyards	
Fuel storage areas	
Fence rows	
Rights-of-way	
Fallow land	Terrestrial food crop
Soil bank land	Terrestrial noncrop
Barrier strips	
Uncultivated nonagricultural areas (outdoor)	
Airports	
Recreation areas, fairgrounds, race tracks, tennis courts, etc.	
Campgrounds	
Recreation area structures	
Highway rights-of-way	
Railroad rights-of-way	
Utility rights-of-way	
Sewage disposal areas	
Industrial sites (lumberyards, tank farms, etc.)	
Paved areas	
Private roads and walks	
Fencerows and hedgerows (nonagricultural)	
Directed Pest Control to Pests' Nests, etc., and for Traps	Terrestrial noncrop or indoor
Diseased beehives	
Nuisance bee nests	
Ant mounds, hills, dens	
Termite mounds	
Insect traps (chemical lures)	
Repellents and irritants to pests (when not covered by other sites)	
Wide area and general indoor/outdoor treatments	
Rural areas (unspecified)	
Urban areas (unspecified)	
Public buildings and structures	
Animal burrow entrances, dens, tunnels	
Animal nests	
Animal trails	
Mammal feeding areas	
Nonagricultural areas for public health treatments	
Bird roosting, nesting areas	
Bird feeding areas	
11. Antifouling Treatments	
Sites for marine exposures	Aquatic noncrop
Boat bottoms and other submersed structures	
Steel	
Fiberglass	
Aluminum	
Wood	
Plastic	
Other substances and materials	
Crab pots and lobster pots	
Sites for fresh water exposures	
Cooling tower influent conduits	
12. Commercial and Industrial Uses	
Transportation Facilities	Indoor
Bus	
Truck and Trailer	
Containerized units	
Railroad cars	
Aircraft	
Ships/barges	
Auto, taxis	
Recreational vehicles	
Shipping containers	
Food and feed processing plants	
Bakeries	
Bottlers	
Canneries	
Dairies, creameries, milk processing plants	
Feed mills, feed stores	
Fresh fruit packing and processing	
Meat processing	
Poultry processing	
Wineries, wine cellars	
Flour mills, machinery, warehouses, bins, elevators	
Egg processing	
Candy and confectionary plants	
Sugar processing, cane mills, etc.	
Cider mills	
Dry food products plants	
Tobacco processing	
Air treatment for processing and transportation of foods	
Beverage processing	
Nut processing	
Cereal processing	
Seafood processing	
Vegetable oil processing	
Spice mills	
Vinegar processing	
Farinaceous processing (noodles, etc.)	
Mushroom processing	
Dried fruit processing	
Pickle processing	
Ice plants	
Chocolate processing	
Fruit juice processing	
Eating establishments (all)	
Food handling areas	
Food serving areas	
Eating establishment nonfood areas	
Air treatment for eating establishments	
Food storage equipment (coolers, refrigerators, etc.)	
Eating and serving utensils (spoons, etc.)	
Food marketing, storage, and distribution	
Food dispensing and vending equipment	
Food stores, markets, stands	
Meat and fish markets	
Food catering facilities	
Food marketing, storage, and distribution equipment and utensils	
Hospitals and related institutions and facilities	

Specific use patterns—listed according to use site group	Corresponding general use pattern
Critical premises (e.g., burn wards, etc.)	
Hospital patient premises (wards, emergency rooms, etc.)	
Noncritical premises (labs, lounges, lobbies, storage)	
Critical items (hypodermic needles, dental instruments, catheters, etc.)	
Noncritical items (bedpans, carpets, furniture, etc.)	
Air treatment (also to ambulances)	
Janitorial equipment	
Barber and beauty shop instruments and equipment	
Morgues, mortuaries, and funeral homes	
Premises (embalming rooms, etc.)	
Equipment (tables, etc.)	
Instruments	
Burial vaults, mausoleums	
Air treatment	
Commercial, institutional, and industrial	
Maintenance, Buildings, and Structures	
Locker rooms, equipment	
Gyms, bowling alleys, and equipment	
Telephones and booths	
Shower rooms, mats, and equipment	
Cotton mill premises and equipment	
Auditoriums and stadiums	
Factories	
Rendering plants	
Loading areas, ramps	
School buildings and equipment	
Office buildings	
Laundries	
Fuels from Crops (alcohol, methane)	
Fossil fuels (e.g., oils, jet fuel)	
Seed oils	
Paper	
Pesticide materials preservation and protection	
Rodenticide baits (protection against insects)	
Dried plant parts (pyrethrum, red squill, rotenone, sabadilla)	
Paints	
Preservatives and protectants	
Grains	
Hay, silage	
Adhesives	
Coatings (asphalt and lacquer)	
Fuels	
Leather and leather products	
Leather processing liquors	
Metalworking cutting fluids	
Oil recovery drilling muds and packer fluids	
Paints (latex)	
Paper and paper products	
Plastic products	
Resin emulsions	
Rubber (natural) products	
Specialty products (polishes, cleansers, dyes, etc.)	
Textiles, textile fibers, and cordage	
Wet-end additives, etc. (pulp sizing, alum, casein, printing pastes)	
Disposable diapers	
Wool, hair, mohair, furs, felt, feathers, etc.	
Electrical supplies, cables, and equipment	
13. *Domestic and Human Use*	
Human Body and Hair	Indoor
Fiber product protection (Moth-, mildew-proofing)	
Clothing	
Upholstery	
Ornamental fabrics (draperies, tapestries)	
Ropes	
Sail cloth	
Human articles and materials	
Bedding, blankets, mattresses	
(Treatments to) hair, body, clothing (while being worn)	
Clothing	
Face gear (goggles, face masks, etc.)	
Headgear (safety helmets, headphones, etc.)	
Wigs	
Contact lenses	
Dentures, toothbrushes, mouthpieces to musical instruments, etc.	
Brick, asbestos, etc.	
Wood surfaces	
Leather surfaces	
Fabric surfaces	
Paper/paperboard surfaces	
Specialty uses	
Museum collectors (preserved animal and plant specimens)	
Military uses—not specified	
Quarantine uses—not specified	
DHHS/FDA uses—not specified	
Filters (air conditioning, air, and furnace)	
Biological specimens	
Underground cables	
Cuspidors, spittoons	
Vomitus	
Human wastes	
Air sanitizers	
Diapers	
Laundry equipment (carts, chutes, tables, etc.)	
Dust control—products and equipment (mops, etc.)	
Dry cleaning	
Carpets	
Upholstery	
Bathrooms, toilets bowls, and related sites	
Bathroom premises	
Toilet bowls and urinals	
Toilet tanks	
Portable toilets, chemical toilets	
Vehicular holding tanks	
Bathroom air treatment	
Diaper pails	
Refuse and solid waste	
Refuse and solid waste containers	
Refuse and solid waste transportation and handling equipment	
Garbage dumps	
Household trash compactors	
Garbage disposal units, food disposals	
Incinerators	
14. *Miscellaneous Indoor Uses*	
Surface Treatments	Indoor
Hard nonporous surfaces (painted, tile, plastic, metal, glass, etc.)	
Hard porous surfaces (cement, plaster)	
Camping equipment and gear	
Grooming instruments (brushes, clippers, razors, etc.)	
Laundry, cleaning, and dry cleaning	

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