Priority III

Programs similar to those described under Priority I and II for 15 to 19 year olds from the U.S. and countries other than the participants in the Economic Summit.

Proposals for grant support for Priority I, II and III may be for:

Project support to expand existing or create new exchange activities.

Activities to enrich existing exchange programs with regard to cultural and language orientation, counseling and program support, and other activities to enrich the participant experience.

While the emphasis will be on Priority I projects during 1983, a limited number of pilot program proposals for Priority II and III projects may be funded from fiscal 1983 monies. These programs should be limited in size and scope and designed to provide replicable models for expanded youth exchanges with countries primarily of the developing world and/or for programs meeting the needs of non-academic youth.

These grants are not intended to fund research studies.

Grant Guidelines

USIA grant assistance will normally constitute only a portion of total project funding. Continuing projects for which USIA assistance is requested must include an acceptable plan for becoming self-sustaining. USIA support will not normally be extended for a period longer than three years. All grant proposals, either new or continuing, will be ranked in an annual competitive process and are subject to the annual level of appropriated funds available for this initiative.

USIA currently estimates that approximately $700,000 will be available during fiscal year 1983 to fund modest grant agreements to further the purposes outlined above.

This is Not a Solicitation for Grant Proposals

Emphasis during the consultative process will be on the identification of not-for-profit organizations whose proposed activities most clearly complement or coincide with the purposes of the President's Initiative and are competent to address the program concepts outlined. Such organizations should also have substantial potential for obtaining funding in addition to USIA support.

Interested organizations are invited to forward (to the address given below) a brief, two to three page, concept paper outlining the objectives of their proposed grant agreement. Please also include a discussion of the organization's capabilities to achieve these objectives and a budget summary which notes the organization's contribution towards the total cost of the project. USIA will review these promptly and contact the organization to recommend whether a full proposal should be submitted and at that time will forward detailed guidelines for preparing a proposal.

The submission of a concept paper will serve to provide both the applicant and USIA a basis on which to decide whether preparation of a full proposal is warranted. It should be understood, however, that USIA's recommendation to prepare a detailed grant proposal does not necessarily guarantee the eventual approval of the proposal.

In order to be considered for fiscal year 1983 funding, concept papers should be received by USIA not later than January 10, 1983 and detailed proposals must be received by February 28, 1983.

For further information on participation in the President's International Youth Exchange Initiative, interested organizations should contact: The International Youth Exchange Staff, Bureau of Educational and Cultural Affairs; (E/YX), U.S. Information Agency, Washington, D.C. 20547, or call (202) 724–9596.

Dated: November 19, 1982.

Charles Z. Wick,

Director, United States Information Agency.

[FR Doc. 82-32191 Filed 11-23-82; 8:45 am]

BILLING CODE 8230-01-M

VETERANS ADMINISTRATION

Scientific Review and Evaluation Board for Rehabilitation Research and Development; Meeting

In accordance with Public Law 92–463 the Veterans Administration gives notice of a meeting of the Scientific Review and Evaluation Board for Rehabilitation Research and Development. This meeting will convene at the Embassy Square Hotel, at 2000 N Street, NW, Washington, DC 20036 on Wednesday, December 15, 1982, beginning at 9 a.m. The purpose of the meeting is to review rehabilitation research and development applications for scientific and technical merit and to make recommendations to the Director, Rehabilitation Research and Development (Rehab R&D) Service regarding their funding.

The meeting will be open to the public (to the seating capacity of the room) at the start of the session for approximately one hour to review administrative matters and to discuss the general status of the program. During the closed session, the Board will be reviewing applications relating to the organization, conduct and delivery of rehabilitation research and development. This review involves oral comments, and discussion of site visits, critiques of research protocols by board members and consultants, and similar documents that necessitate the consideration of personnel qualifications and the performance and competence of individual investigators. Disclosure of such information would constitute a clearly unwarranted invasion of personal privacy. Proprietary data from contractors and private firms will also be presented and this information should not be disclosed in a public session. Premature disclosure of Board recommendations would be likely to significantly frustrate implementation of final proposed actions. Thus, the closing is in accordance with section 552b, subsections (c)(4), (c)(6), and (c)(9)(B), Title 5, United States Code and the determination of the Administrator of Veterans Affairs pursuant to section 10(d) of the Federal Advisory Committee Act, Title 5, U.S.C., Appendix I.

Due to the limited seating capacity of the room, those who plan to attend the open session should contact Mr. Chester Bazel, Program Analyst, Rehabilitation Research and Development Service, Veterans Administration Central Office at 810 Vermont Avenue, NW, Washington, DC 20420, Phone: (202) 389–5177 at least 5 days before the meeting.

Dated: November 15, 1982.

By direction of the Administrator:

Rosa Maria Fontanez,

Committee Management Officer.

[FR Doc. 82-32169 Filed 11-23-82; 8:45 am]

BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register
Vol. 47, No. 227
Wednesday, November 24, 1982

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94–409) 5 U.S.C. 552b(e)(3).

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1

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 11:05 a.m. on Friday, November 19, 1982, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session, by telephone conference call, to consider a resolution making funds available for the payment of insured deposits in Ranchlander National Bank, Melvin, Texas, in anticipation of, and contingent upon, its expected closure by the Comptroller of the Currency.

At that same meeting, the Board of Directors considered two recommendations regarding the receivership of Penn Square Bank, National Association, Oklahoma City, Oklahoma (Case No. 45,509–NR, and Case No. 45,510–NR).

In calling the meeting, the Board determined, on motion of Chairman William M. Isaac, seconded by Director Irvine H. Sprague (Appointive), concurred in by Director C. T. Conover (Comptroller of the Currency), that Corporation business required its consideration of the matters 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 ursuant to subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B) and (c)(10)).

Dated: November 19, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S–1698–82 Filed 11–22–82; 11:28 am]

BILLING CODE 6714–01–M

2

FEDERAL RESERVE SYSTEM

(Board of Governors)

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 47 FR 51844, Wednesday, November 17, 1982.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10 a.m., Monday, November 22, 1982.

CHANGES IN THE MEETING: One of the items announced for inclusion at this meeting was consideration of any agenda items carried forward from a previous meeting; the following such closed items(s) was added:

Federal Reserve Bank and Branch director appointments. (This item was originally announced for a closed meeting on November 1, 1982.)

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board (202) 452–3204.

Dated: November 22, 1982.

James McAfee,

Associate Secretary of the Board.

[S–1700–82 Filed 11–22–82; 3:46 pm]

BILLING CODE 621082–01–M

3

FEDERAL TRADE COMMISSION

TIME AND DATE: 3 p.m., Tuesday, November 23, 1982.

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

STATUS: Open.

MATTERS TO BE CONSIDERED: Proposed Amendment to Games of Chance Trade Regulation Rule.

CONTACT PERSON FOR MORE INFORMATION: Susan B. Ticknor, Office of Public Affairs: (202) 523–3830; Recorded Message: (202) 523–3806.

[S–1699–82 Filed 11–22–82; 3:16 pm]

BILLING CODE 6750–01–M

4

LEGAL SERVICES CORPORATION

Meeting of the Audit Appropriations Committee.

PREVIOUSLY ISSUED: November 17, 1982.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING:

2–5 p.m., Sunday, December 5, 1982; 9 a.m.–4 p.m., Monday, December 6, 1982.

PREVIOUSLY ANNOUNCED PLACE OF MEETING: Cathedral Hill Hotel, Mezzanine Level, Van Ness and Geary Streets, San Francisco, CA 94109.

CHANGE IN THE MEETING: Changes in the time, date and place of meeting. Time and date: 9:00 a.m. to 5:00 p.m., Monday, December 6, 1982.

Place: Legal Services Corporation 733 15th Street, NW. Washington, D.C. 20005 8th Floor Conference Room.

CONTACT PERSON FOR MORE INFORMATION: Anne Tracy, Office of the President (202) 272–4040.

Dated: November 19, 1982.

Clinton Lyons,

Acting President.

[S–1701–82 Filed 11–22–82; 3:46 pm]

BILLING CODE 6820–35–M

5

LEGAL SERVICES CORPORATION

Meeting of the Special Committee on Grant and Contract Procedures

PREVIOUSLY ISSUED: November 17, 1982.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING:

9–5 p.m., Saturday, December 4, 1982; 9–Noon, Sunday, December 5, 1982.

PREVIOUSLY ANNOUNCED PLACE OF MEETING: Cathedral Hill Hotel, Mezzanine Level, Van Ness and Geary Streets, San Francisco, CA 94109.

CHANGE IN MEETING: Changes in the time, date and place of meeting. Time and Date: 9 a.m. to 5 p.m., Saturday, December 4, 1982.

Place: Legal Services Corporation, 733 15th Street, NW., Washington, D.C. 20005, Eighth Floor Conference Room.

CONTACT PERSON FOR MORE INFORMATION: Anne Tracy, Office of the President, (202) 272–4040.

Dated: November 19, 1982.

Clinton Lyons,

Acting President.

[S-1702-82 Filed 11-22-82; 3:46 pm]

BILLING CODE 6820-35-M

6

NATIONAL MEDIATION BOARD

TIME AND DATE: 3 p.m., Monday, December 6, 1982.

PLACE: Board Hearing Room, eighth floor, 1425 K Street, NW.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Ratification of Board actions taken by notation voting during the month of November, 1982.
2. Other priority matters which may come before the Board for which notice will be given at earliest practicable time.

SUPPLEMENTARY INFORMATION: Copies of the monthly report of the Board's notation voting actions will be available from the Executive Secretary's office following the meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Rowland K. Quinn, Jr., Executive Secretary; Tel: (202) 523-5920.

Date: November 17, 1982.

[S-1697 Filed 11-22-82; 11:28 am]

BILLING CODE 7550-01-M

7

PACIFIC NORTHWEST ELECTRIC POWER AND CONSERVATION PLANNING COUNCIL

(Northwest Power Planning Council)

TIME AND DATE: 9 a.m., December 1–2, 1982.

PLACE: The Western Forestry Center, Portland, Oregon.

MATTERS TO BE CONSIDERED:

Council Decision on Option Concept
Council Decision on Fuel Switching for Existing Structures and Fuel Choice for New Structures
Council Discussion on Model Conservation Standards
Council Decision on Rate Design Issues
Council Decision on Surcharge Methodology
Scientific and Statistical Advisory Committee Resources Task Force Report
Staff Presentation on Development of Resource Targets
Staff Presentation on Establishing Conservation Targets
Council Business
Public Comment
The Fish and Wildlife Committee of the Council will meet on December 1 or 2, 1982 during a recess of the Council meeting. The time of the meeting will be announced at the Council meeting. The Fish and Wildlife Committee meeting will be open to the public.

Bobbe Strizek,

Liaison Officer.

[S-1695-82 Filed 11-19-82; 5:09 pm]

BILLING CODE 0000-00-M

8

SYNTHETIC FUELS CORPORATION

Board of Directors: Meeting.

ACTION: Notoce of Meeting.

SUMMARY: Interested members of the public are invited to attend and observe a meeting of the Board of Directors of the United States Synthetic Fuels Corporation to be held at the time, date and place specified below. This public announcement is made pursuent to the open meeting requirements of Section 116(f) (1) of the Energy Security Act (9 Stat. 611, 637; 42 U.S.C. 8701, 8712(f)(1)) and Section 4 of the Corporation's Statement of Policy on Public Access to Board Meetings. During the meeting, the Board of Directors will consider a resolution to close a portion of the meeting pursuant to Article II Section 4 of the Corporation's By-laws, Section 116(f) of the said Act and Sections 4 and 5 of the said policy.

MATTERS TO BE CONSIDERED: *Open Session:*

1. Approval of Minutes of Prior Meeting.
2. Report of the President.
3. Operations Report of the Executive Vice President.
4. Election of Corporation Officers.

In addition, the Board of Directors will consider such other matters as may be properly brought before the meeting.

Closed Session:

Consideration of draft solicitation and project-specific reports.

TIME AND DATE: 8:30 a.m., December 2, 1982.

PLACE: Room 503, 2121 K Street, N.W., Washington, D.C. 20586.

PERSON TO CONTACT FOR MORE INFORMATION: If you have any questions regarding this meeting, please contact Mr. Owen J. Malone, Office of General Counsel (202) 822-6336.

Dated: November 19, 1982.

Jimmie R. Bowden,

Executive Vice President,

United States Synthetic Fuels Corporation.

[S-1692-82 Filed 11-22-82; 9:47 am]

BILLING CODE 0000-00-M

federal register

Wednesday
November 24, 1982

Part II

Environmental Protection Agency

Porcelain Enameling Point Source Category; Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 466

[WH-FRL 2229-1]

Porcelain Enameling Point Source Category; Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: This regulation establishes effluent limitations and standards limiting the discharge of pollutants into navigable waters and into publicly owned treatment works by existing and new sources that conduct porcelain enameling operations. The Clean Water Act and a consent decree require EPA to issue this regulation.

The purpose of this regulation is to specify effluent limitations for "best practicable technology," "best available technology," and "new source performance standards" for direct dischargers and to establish pretreatment standards for indirect dischargers.

DATES: In accordance with 40 CFR 100.01 (45 FR 26048), this regulation shall be considered issued for purposes of judicial review at 1:00 p.m. Eastern time on December 8, 1982. These regulations shall become effective January 7, 1983, except Section 466.03 which contains information collection requirements which are under review at OMB. The compliance date for the BAT regulations is as soon as possible, but in any event no later that July 1, 1984. The compliance date for new source performance standards and new source pretreatment standards is the date the new source begins operation. The compliance date for Pretreatment Standards for Existing Sources is November 25, 1985.

Under Section 509(b)(1) of the Clean Water Act judicial review of this regulation can be made only by filing a petition for review in the United States Court of Appeals within 90 days after the regulation is considered issued for purposes of judicial review. Under Section 509(b)(2) of the Clean Water Act, the requirement in this regulation may not be challenged later in civil or criminal proceedings brought by EPA to enforce these requirements.

ADDRESSES: The basis for this regulation is detailed in four major documents. See Supplementary Information under "XIV Availability of Technical Information" for a description of each document.

Technical information may be obtained by writing to Ernst P. Hall, Effluent Guidelines Division (WH-552), EPA, 401 M Street, SW., Washington, D.C. 20460, or through calling (202) 382-7126. Copies of the technical and economic documents may be obtained from the National Technical Information Service, Springfield, Virginia 22161 (703/487-4600).

The Record will be available for public review not later than January 28, 1983, in EPA's Public Information Reference Unit, Room 2404 (Rear) (EPA Library), 401 M Street, SW., Washington, D.C. The EPA information regulation (40 CFR Part 2) provides that a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Mr. Ernst P. Hall, (202) 382-7126.

SUPPLEMENTARY INFORMATION:

Organization of This Notice

I. Legal Authority
II. Scope of This Rulemaking
III. Summary of Legal Background
IV. Methodology and Data Gathering Efforts
V. Control Treatment Options and Technology Basis for Final Regulations
  A. Summary of Category
  B. Control and Treatment Options
  C. Technology Basis for Final Regulation
VI. Costs and Economic Impacts
VII. Non-Water-Quality Environmental Impacts
  A. Air Pollution
  B. Solid Waste
  C. Consumptive Water Loss
  D. Energy Requirements
VIII. Pollutants and Subcategories Not Regulated
  A. Exclusion of Pollutants
  B. Exclusion of Subcategories
IX. Public Participation and Response to Major Comments
X. Best Management Practices
XI. Upset and Bypass Provisions
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XIII. Relationship to NPDES Permits
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List of Subjects in 40 CFR Part 466

Appendices
A. Abbreviations, Acronyms, and Other Terms Used in This Notice
B. Toxic Pollutants Not Detected
C. Toxic Pollutants Detected Below the Analytical Quantification Limit
D. Toxic Pollutants Detected in Only a Small Number of Plants Which Are Uniquely Related to That Plant
E. Toxic Pollutants Detected in Amounts Too Small To Be Effectively Reduced by Technologies Considered in Preparing This Regulation
F. Toxic Pollutants Which Will Be Effectively Controlled by the Promulgated BAT Limitations or PSES Even Though They Are Not Specifically Regulated

I. Legal Authority

This regulation is being promulgated under the authority of Sections 301, 304, 306, 307, and 501 of the Clean Water Act (the Federal Water Pollution Control Act Amendments of 1972, 33 U.S.C. 1251 *et seq.*, as amended by the Clean Water Act of 1977, Pub. L. 95-217), also called the "Act." It is also being promulgated in response to the Settlement Agreement in *Natural Resources Defense Council, Inc.*, v. *Train*, 8 ERC 2120 (D.D.C. 1976), *modified*, 12 ERC 1833 (D.D.C. 1979).

II. Scope of This Rulemaking

This regulation establishes effluent limitations and standards for existing and new porcelain enameling operations. Porcelain enameling consists of that sequence or combination of steps or operations which prepare the metal surface and apply a porcelain or fused silicate coating to the metal basis material.

EPA's 1973 to 1976 round of rulemaking emphasized the achievement of best practicable technology currently available (BPT) by July 1, 1977. In general, BPT represents the average of the best existing performances of well-known technologies for control of familiar (i.e., "classical") pollutants. This effort did not include rulemaking specific to porcelain enameling.

The current round of rulemaking aims for the achievement by July 1, 1984, of the best available technology economically achievable (BAT) that will result in reasonable further progress toward the national goal of eliminating the discharge of all pollutants. At a minimum, BAT represents the performance of the best available technology economically achievable in any industrial category or subcategory. Moreover, as a result of the Clean Water Act of 1977, the emphasis of EPA's program has shifted from "classical" pollutants to the control of toxic pollutants.

EPA is promulgating limitations based on BPT and BAT, new source performance standards (NSPS), pretreatment standards for existing sources (PSES), and pretreatment standards for new sources (PSNS) for Subpart A—Steel Basis Material, Subpart B—Cast Iron Basis Material, and Subpart C—Aluminum Basis Material. EPA is promulgating NSPS and PSNS for Subpart D—Copper Basis Material.

III. Summary of Legal Background

The Federal Water Pollution Control Act Amendments of 1972 established a comprehensive program to "restore and maintain the chemical, physical, and

biological integrity of the Nation's waters" (Section 101(a)). To implement the Act, EPA was to issue effluent limitations guidelines, pretreatment standards, and new source performance standards for industry dischargers.

The Act included a timetable for issuing these guidelines. However, EPA was unable to meet many of the deadlines and, as a result, in 1976, the Agency was sued by several environmental groups. In settling this lawsuit, EPA and the plaintiffs executed a court-approved "Settlement Agreement." This Agreement required EPA to develop a program and adhere to a schedule in promulgating effluent limitations, new source performance standards and pretreatment standards for 65 "priority" pollutants and classes of pollutants in 21 major industries. See *Natural Resources Defense Council, Inc.* v. *Train*, 8 ERC 2120 (D.D.C. 1976), *modified*, 12 ERC 1833 (D.D. 1979).

Many of the basic elements of this Settlement Agreement program were incorporated into the Clean Water Act of 1977. Like the Agreement, the Act stressed control of toxic pollutants, including the 65 "priority" pollutants. In addition, to strengthen the toxic control program, Section 304(e) of the Act authorizes the Administrator to prescribe "best management practices" (BMPs) to prevent the release of toxic and hazardous pollutants from plant site runoff, spillage or leaks, sludge or waste disposal, and drainage from raw material storage associated with, or ancillary to, the manufacturing or treatment process.

Under the Act, the EPA program is to set a number of different kinds of effluent limitations. These are discussed in detail in the preamble to the proposed regulation for this category and in the development document supporting this final regulation. They are summarized briefly below:

1. *Best Practicable Control Technology (BPT).*

BPT limitations are generally based on the average of the best existing performance by plants of various sizes, ages, and unit processes within the industry or subcategory.

In establishing BPT limitations, we balance the total cost of applying the technology against the effluent reduction benefits achievable. This is a limited balancing, in that we are not required to quantify benefits in monetary terms.

2. *Best Available Technology (BAT).*

BAT limitations, in general, represent the best existing performance in the industrial subcategory or category. The Act establishes BAT as the principal national means of controlling the direct discharge of toxic and nonconventional pollutants to navigable waters.

In arriving at BAT, the Agency retains considerable discretion in assigning the weight to be accorded costs. We need only consider the cost of applying the technology; no cost-benefit analysis is required.

3. *Best Conventional Pollutant Control Technology (BCT).*

The 1977 Amendments added Section 301 (b)(2)(E) to the Act establishig "best conventional pollutant control technology" (BCT) for discharges of conventional pollutants, from existing industrial point sources.

BCT is not an an additional limitation but replaces BAT for the control of conventional pollutants, TSS, BOD, oil and grease, pH and fecal coliforms. In addition to other factors specified in section 304 (b)(4)(B), the Act requires that BCT limitations be assessed in light of a two part "cost-reasoableness" test. *American Paper Institute* v. *EPA*, 660 F. 2d 954 (4th Cir 1981). The first test compares the cost for private industry to reduce its conventional pollutants with the costs to publicly owned treatment works for similar levels of reduction in their discharge of these pollutants. The second test examines the cost-effectiveness of additional industrial treatment beyond BPT. EPA must find that limitations are "reasonable" under both tests before establishing them as BCT. In no case may BCT be less stringent than BPT.

EPA published its methodology for analyzing BCT costs on August 29, 1979 (44 FR 50732). In the case noted above, the Court of Appeals ordered EPA to correct data errors underlying EPA's calculation of the first test, and to apply the second cost test. (EPA had argued that a second cost test was not required.)

EPA has determined that the technology which is the basis for porcelain enameling BAT can remove significant amounts of conventional pollutants. However, EPA has not yet promulgated a revised BCT methodology in response to the *American Paper Institute* v. *EPA* decision mentioned earlier. Accordingly, EPA is deferring a decision on the appropriate final BCT limitations.

4. *New Source Performance Standards (NSPS).*

NSPS are based on the best available demonstrated technology (BDT). New plants have the opportunity to install the best and most efficient production processes and wastewater treatment technologies.

5. *Pretreatment Standards for Existing Sources (PSES).*

PSES are designed to prevent the discharge of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of publicly owned treatment works (POTW). They must be achieved within three years of promulgation. The Clean Water Act of 1977 requires pretreatment for toxic pollutants that pass through the POTW in amounts that would violate direct discharger effluent limitations or limit POTW sludge management alternatives, including the beneficial use of sludges on agricultural lands. The legislative history of the 1977 Act indicates that pretreatment standards are to be technology-based, analogous to the best available technology for removal of toxic pollutants. The general pretreatment regulations (40 CFR Part 403), which serve as the framework for pretreatment regulations were published in 46 FR 9104 (January 28, 1981).

6. *Pretreatment Standards for New Sources (PSNS).*

Like PSES, PSNS are to prevent the discharge of pollutants which pass through, interfere with, or are otherwise incompatible with the operations of the POTW. PSNS are to be issued at the same time EPA promulgates NSPS. New indirect dischargers, like new direct dischargers, have the opportunity to incorporate the best available demonstrated technologies. The Agency considers the same factors in promulgating PSNS as it considers in promulgating PSES.

IV. Methodology and Data Gathering Efforts

The data gathering efforts and methodology used in developing the proposed regulations are summarized in the Preamble to the Proposed Porcelain Enameling Industrial Point Source Category Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards (46 FR 8860, January 27, 1981). The *Development Document for Effluent Limitations Guidelines and Standards for the Porcelain Enameling Industrial Point Source Category* describes the data gathering efforts and methodologies used in developing this final regulation.

Since proposal, the Agency has re-analyzed treatment effectiveness data and treatment costs. In the proposed porcelain enameling regulation, the Agency relied on the data we collected from sampling and analysis of raw and treated wastewaters from the aluminum forming, battery manufacturing, copper forming, coil coating, porcelain enameling and electroplating categories to determine the effectiveness of the

lime and settle, technologies upon which proposed limitations and standards were based. The preamble to the proposed regulation explains why pooled data were used to determine treatment effectiveness. Subsequent to proposal an analysis of variance of both raw and treated pollutant concentrations was made to determine the homogeneity of the data base. The electroplating data was found to substantially reduce the homogeneity of the pooled data while including or removing data from any other category did not meaningfully alter the homogeneity of the data pool. Therefore, the electroplating data was removed from the pooled data base and only data from the remaining five categories were used for determining the treatment effectiveness of the technologies. Section VII of the development document and other documents in the administrative record for this rulemaking explain how the Agency re-analyzed these data.

Subsequent to proposal, the Agency refined its analysis of the cost of model treatment systems used to calculate limitations and standards. As a consequence, estimated costs of compliance were increased. Section VIII of the technical development document and related documents in the record explain the basis for the revised costs estimates.

V. Control Treatment Options and Technology Basis for Final Regulations

A. Summary of Category

"Porcelain enameling" is a term used to describe the combination of processing steps involved in applying a thermally fused glass-like coating to a metal basis material. This glass-like procelain coating gives both decorative and engineering properties to the basis material making it useful in a wide range of products.

Four basis materials are most frequently used for porcelain enameling; steel (sometimes called enameling iron), cast iron, aluminum and copper. Gold is frequently procelain enameled for dental restorations and precious and semiprecious metals are porcelain enameled for jewelry and art objects. Generally, these small volume uses of porcelain enamel are not controlled by this regulation because precious metals are not included as a basis material.

The Agency considered regulating porcelain enameling on precious metals and decided against developing a national regulation because of the apparent nature of this aspect of porcelain enameling. Generally the pieces procelain enameled (and hence the total area processed) are quite small (for example, a dental crown might have a porcelain enameled area of 0.1 in^2 while a locket might be about 1.0 in^2). The locations at which such activities take place vary widely—e.g. dentists offices, dental laboratories, hobby shops, schools, etc. Most of these operations are believed to be small indirect dischargers which would not be covered by the categorical standards established in this regulation. For these reasons the Agency decided not to regulate porcelain enameling of precious metals.

Generally, there are two major groups of operations in porcelain enameling. The first group of operations is metal preparation in which oil and dirt are removed, the metal surface roughened by etching or sand blasting to assist adherence of the coating, and application of a bonding material such as nickel, cobalt, or chromium to promote chemical bonding of the enamel to the basis metal. The second group or coating operations includes ball milling, manufacturing the wet coating material or slip, slip application, and firing or fusing the porcelain enamel coating.

Water is used throughout most of the porcelain enameling process. Metal preparation of steel, aluminum and copper is usually a wet process involving alkaline cleaning to remove oil, and etching to roughen the metal surface and immersion plating or conversion coating to apply the bonding material. Rinsing to clean the workpiece after each metal preparation step generates substantial volumes of process wastewater. In the coatings operations, water is part of the coating material, is used to cool and clean the ball mill, and to clean unwanted slip from both the workpiece and the work area.

The most important resulting pollutants or pollutant properties are: (1) Toxic metals—antimony, arsenic, cadmium, chromium, copper, cyanide, lead, nickel, selenium and zinc; (2) conventional pollutants—TSS and pH; and (3) nonconventional pollutants—aluminum and iron. Toxic organic pollutants were not found in the samples analyzed.

Because of the large amounts of toxic metals present, the sludges generated by wastewater treatment generally contain substantial amounts of toxic metals.

Within the subcategories covered by this regulation, there are 28 direct dischargers and 88 indirect dischargers.

B. Control and Treatment Options

The control and treatment technologies considered by EPA in developing this regulation include both in-process and end-of-pipe treatments. A wide range of treatment options were considered before proposing the porcelain enameling regulation and are detailed in the preamble to the proposed regulation. Major technology options considered after proposal are discussed in this document while minor options which were considered in developing the proposed rule are not specifically discussed here but are discussed in the development document.

In-process treatment includes a variety of water flow reduction steps and major process changes such as treated wastewater reuse where product quality is not affected by the quality of the water used and countercurrent cascade rinsing to reduce the amount of wastewater treated and pollutants discharged.

End-of-pipe treatment includes: cyanide oxidation or precipitation; hexavalent chromium reduction; chemical precipitation of metals using hydroxides, carbonates, or sulfides; and removal of precipitated metals and other materials using settling, filtration, and combinations of these technologies. As a result of comments received on the proposal, EPA evaluated a sump settling technology as a possible basis for BPT limitations or PSES standards.

The effectiveness of these treatment technologies has been evaluated and established by examining the performance of these technologies on porcelain enameling and other similar wastewaters. The data base for the performance of hydroxide precipitation-sedimentation technology is a composite of data drawn from EPA sampling and analysis of copper and aluminum forming, battery manufacturing, porcelain enameling, and coil coating. This data, called the combined metal data base, reports influent and effluent concentrations for nine pollutants. These wastewaters are judged to be similar in all material respects for treatment because they contain a range of dissolved metals which can be removed by precipitation and solids removal.

In the proposed porcelain enameling regulation, the Agency relied on the data we collected from sampling and analyzing raw and treated wastewaters from the aluminum forming, battery manufacturing, copper forming, coil coating, porcelain enameling and electroplating categories to determine the effectiveness of the lime and settle, and lime, settle and filter technologies. Subsequent to proposal an analysis of variance of both raw and treated pollutant concentrations of the pooled data was made to determine its

homogeneity. The electroplating data was found to substantially reduce the homogeneity of the pooled data while the inclusion or removal of data from any other category did not meaningfully alter the homogeneity of the data pool. Therefore, the electroplating data were removed from the pooled data base and only data from the remaining five categories was used for determining treatment effectiveness of the technologies.

The effectiveness of lime and settle technology in removing other pollutant was calculated from data from other categories. See Section VII of the development document.

Twenty eight porcelain enameling plants have some form of lime and settle treatment; six of these have polishing filters; several apply the L&S to only part of their wastewater; some are poorly operated (based on plant supplied data) and many cannot be evaluated because they did not supply data. Only about four plants appear to be well designed and operated. Data solely from these plants are not used as the bases for limitations and standards since more data is needed for proper statistical analysis. These plants are included in the combined metals data base which is used as the basis for limitations and standards.

To establish the treatment effectiveness of lime, settle and filter, the technologies used as the basis for NSPS and PSNS, EPA used data from three plants that had the recommended technology in place: two porcelain enameling plants and one other plant whose wastewater was similar to the wastewater generated at porcelain enameling plants. In generating long-term average standards for NSPS and PSNS , EPA applied variability factors from the combined metals data base because the combined data base provided a better statistical basis for computing variability than the data from the three plants sampled. The combined data base is composed of data showing the treatment effectiveness of lime and settle without filtration. For pollutants for which there were no data from the L&S plants, long-term concentrations were developed assuming that filtration would remove 33 percent more pollutants than lime and settle. This assumption was based upon a comparison of removals of several pollutants by lime and settle and lime, settle, and filter technologies. The pooled data base which contained data from four porcelain enameling plants was used to provide treatment effectiveness values. The larger pooled data set allowed the Agency to calculate variability factors with greater confidence in the derived values than the small data set would provide.

The lime and settle treatment effectiveness values used in the proposed regulation were derived from the full pooled data set described above using statistical methodology which assumed the data set was normally distributed. Variability factors for estimating a one day and thirty day average value were transferred from electroplating pretreatment. The treatment effectiveness values used in this promulgation are derived from the reduced data set using a statistical methodology which assumed its data set was log normally distributed. One day maximum and ten day and 30 day average regulatory values and variability factors are derived directly from the data set. These variability factors are supplied to long term mean values to derive treatment effectiveness for other pollutants. The derivation of the treatment effectiveness values is detailed in Section VII of the technical development document. The Agency performed this analysis to assure itself that performance data from other industries reflects the ability of the technology to achieve the established results in porcelain enameling facilities. Similarly precipitation-sedimentation and filtration technology performance is based on the performance of full scale commercial systems treating multicategory wastewaters which also are essentially similar to porcelain enameling wastewaters. This also is discussed fully in Section VII of the development document.

The limitations and standards established for this category are mass based (mass of pollutant allowed to be discharged per unit of production) and are derived as the product of the regulatory flow and the overall treatment effectiveness. The regulatory flows are derived from sampling and measurement of flows in porcelain enameling manufacturing operations. Because flow reduction is a significant part of the overall pollutant reduction technology, the Agency has concluded that mass based limitations and standards (except for PSES) are necessary to ensure adequate pollution control is achieved.

C. Technology Basis for Final Regulations

A brief summary of the technology basis for the regulation is presented below. A more detailed summary is presented in the "Preamble to the Proposed Porcelain Enameling Point Source Category Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards" (46 FR 8860, January 27, 1981) and the (final) *Development Document for Effluent Limitations Guidelines and Standards for the Porcelain Enameling Point Source Category.*

The technologies outlined below apply to all of the porcelain enameling subcategories, and the final effluent concentrations resulting from the application of the technology are identical for all four subcategories. However, the mass limitations for each subcategory vary due to different water uses among the subcategories and the absence of some pollutants in some subcategories. These water use factors are developed and displayed in Section IX of the technical development document.

The Agency is revising certain monitoring and compliance requirements of the proposed regulation in response to comments. The Agency has reduced the number of pollutants regulated to six metals and three conventional pollutants. This level of control and regulation will effectively ensure that the treatment technology is installed and properly operated. The pollutants not being regulated are metals which are effectively removed by properly operated lime and settle technology and will be removed coincidentally with removal of the regulated pollutants.

Chromium is a regulated pollutant in the aluminum subcategory because it is sometimes used as a metal preparation process chemical and in all subcategories because it may be an ingredient of the slip. However, chromium may not be used in the process or present in the wastewater of many plants. Provision has been made to allow a plant to demonstrate the absence of chromium in its wastewater and be relieved of the necessity of routine monitoring for chromium.

The 30 day average limitations and standards that were proposed have been replaced with a monthly average limitation based on the average of ten consecutive sampling days. The ten day average value was selected as the minimum number of consecutive samples which need to be averaged to arrive at a stable slope on the statistically based curve relating one day and 30 day average values and it approximates the most frequent monitoring requirement of direct discharge permits. Monthly averages based on ten days of data are slightly less stringent than monthly averages based on 30 days of data. The monthly average figures shown in the regulation are to be used by plants with combined

wastestreams that use the "combined wastestream formula" set forth at 40 CFR 403.6(e) and by permit writers in writing direct discharge permits.

BPT: This regulation imposes BPT requirements on the steel, cast iron, and aluminum subcategories. The technology basis for the BPT limitations being promulgated is the same as for the proposed limitations and includes flow normalization, hexavalent chromium reduction (for facilities which perform porcelain enameling on aluminum), oil skimming, pH adjustment, and sedimentation to remove the resultant precipitate and other suspended solids. No discharge of process wastewater pollutants for metal preparation is required in the cast iron subcategory because the metal preparation method usually employed does not result in a discharge of process wastewater. The BPT technology applies to three of the porcelain enameling subcategories. BPT (as well as BAT) limitations are not being promulgated for the copper subcategory because there are no direct dischargers in this subcategory.

The water flow allowances for the steel and aluminum subcategories were increased significantly over the proposed allowances as a result of the public comments and a reexamination of the data. The Agency decided not to use flow data from one plant as part of the basis for BPT after concluding that some of the practices and technology utilized were not practicable as BPT for other plants. As a result of this and other recalculations, the water use factors and BPT effluent limitations and standards for both subcategories were increased. These revised water use factors are developed and displayed in Section IX of the technical development document.

The pollutants selected for regulation at BPT are: chromium, lead, nickel, zinc, aluminum, iron, oil and grease, TSS, and pH. The Agency considered the regulation of several additional pollutants at proposal, but concluded that regulating the selected list of pollutants would adequately insure the installation and proper operation of appropriate control technology and thereby adequately control the remaining pollutants.

Implementation of the BPT limitations will remove annually an estimated 96,700 kg of toxic pollutants and 7,640,000 kg of other pollutants (from estimated current discharge) at a capital cost above equipment in place of $6.3 million and an annual cost of $3.6 million. These costs will be borne by 27 (of the 28) direct dischargers.

The Agency estimates that these costs may result in one plant closure, two production line closures and 59 job losses.

BAT: This regulation imposes BAT requirements on the steel, cast iron and aluminum subcategories. The BAT limitations being promulgated are changed from the proposed BAT limitations. The technology basis for the proposed BAT was flow normalization, chromium reduction, oil & grease removal, and lime, settle and filter treatment. The technology basis for the final regulation is flow normalization, reuse of treated wastewater in most coatings water using operations, chromium reduction, oil & grease removal and lime and settle end-of-pipe treatment.

EPA has removed filtration from the BAT model treatment system and added reuse of process wastewaters. At proposal, the Agency solicited comments on an option that included reuse of water for all coating operations (except for an allowance equal to the amount of water used for ball mill washout) as part of the BAT model treatment system.

Comments on the alternative option stated that the ball mill allowance should be higher than the amount specified in the proposal. Flow reduction by reusing treated wastewater for all coating water needs except ball mill washout is being included as part of the BAT model technology. This will reduce wastewater discharge from coating operations by about 95 percent and the overall wastewater discharge by about 15–18 percent.

Industry comments opposed filtration as a basis for BAT because of its cost and because it could present technological problems for porcelain enamelers whose operations are integrated with operations covered by other regulations.

After considering comments on the proposed regulations, the Agency has decided to delete filtration from the BAT model treatment system. About 60 percent of the existing porcelain enameling plants have waste streams from other categories that are compatible for co-treatment with procelain enameling wastewaters. The Agency considered the technical complications which might be caused by co-treating wastewaters to standards based on different technologies and concluded that requiring filters in porcelain enameling would tend to discourage co-treatment of compatible wastewaters. The Agency also concluded that BAT limitations based on filtration technology would be too costly for existing dischargers. The proposed BAT lime, settle and filter treatment would have had an incremental (above BPT) investment cost of $2.2 million and additional annualized costs of $0.6 million over BPT. Additional (incremental above BPT) toxic pollutants removed by this level of treatment would have been 1,460 kg/yr.

The pollutants selected for regulation are: chromium, lead, nickel, zinc, aluminum and iron. The toxic pollutants considered for regulation at proposal, but not selected for regulation, are antimony, arsenic, cadmium, copper, cyanide and selenium. The technology that would be necessary to meet the limitations for the regulated pollutants will effectively control the unregulated pollutants.

The direct dischargers are expected to move directly to compliance with BAT limitations from existing treatment because the flow reduction used to meet BAT limitations will allow the use of smaller—and less expensive—lime and settle equipment than would be used to meet BPT limitations without flow reduction. This option and the water flow reduction and other pertinent effects are described fully in Section X of the technical development document.

Implementation of the BAT limitations will remove annually an estimated 97,350 kg/yr of toxic pollutants and 7,650,000 kg/yr of other pollutants (from estimated current discharge) at a capital cost above equipment in place of $6.7 million and an annual cost of $3.7 million.

BAT will remove 650 kg/yr of toxic pollutants and 10,000 kg/yr of other pollutants incrementally above BPT; the incremental investment cost is $0.4 million and the additional total annual cost is $0.1 million. These incremental costs are associated with a small change in the cost of production for most product groups (only one-tenth of one percent). The Agency projects no additional plant or line closures as a result of these costs.

NSPS: This regulation establishes NSPS for all four subcategories. The NSPS being promulgated are changed from the NSPS proposed.

The proposed NSPS were based on the following technology: 90 percent reduction of metal preparation wastewater by countercurrent rinsing followed by lime, settle and filter end-of-pipe treatment. Elimination of all coatings wastewater was part of the model treatment technology and was to be achieved by use of electrostatic dry powder coatings, a dry process that eliminates the generation of wastewater. Industry comments opposed eliminating coating wastewater. Many companies stated that powder coatings are not

appropriate for their products because of problems associated with enameling complex shapes and aluminum materials. No adverse comment was received on the countercurrent rinsing and lime, settle and filter end-of-pipe treatment technology proposed for metal preparation wastewater.

We are promulgating NSPS based on multi-stage countercurrent cascade rinsing after each metal preparation operation, reuse of water for most coating operations as is required for BAT, oil and grease removal and lime, settle and filter end-of-pipe treatment technology for all wastewaters. The Agency has eliminated dry electrostatic powder coating as a technology basis for NSPS because this coating is not universally applicable. The application of countercurrent rinsing compensates for the elimination of electrostatic powder coating.

Filtration has been retained in the NSPS model because filters are substantially less costly for new sources after substantial flow reduction than for existing sources. Filtration and flow reduction will remove an estimated 94 percent of the toxic pollutants and nonconventional and conventional pollutants discharged after BAT. The mass of pollutants removed by NSPS treatment and discharged after NSPS treatment for a normal plant are tabulated in Section XI of the development document.

New plants can evaluate the potential for co-treating compatible wastewaters from porcelain enameling and other categories before locating and constructing the porcelain enameling facility. This allows the plant to exercise treatment and location options not usually available to existing sources. For plants with a high proportion of non-porcelain enameling wastewater, such as metal finishing, this may allow co-treatment of the wastewater and meeting the applicable limitations without filtering the combined wastewater stream. In other cases new plants with a high proportion of porcelain enameling wastewaters may find it necessary to treat the porcelain enamel wastewater separately. In estimating the cost for new sources, it has been assumed that there would be no co-treatment of wastewater; co-treatment using larger equipment in a combined treatment system should reduce the total cost for the new plant below cost of separate treatment of each wastestream. Even if no co-treatment occurs the cost of complying with NSPS will not inhibit the construction of new porcelain enameling facilities. Accordingly, EPA has determined that these additional costs are justified.

The pollutants regulated are: Chromium, lead, nickel, zinc, aluminum, iron, oil and grease TSS and pH. The capital investment for new sources to meet NSPS is about 7 percent above that needed by existing sources to comply with BAT. Since these costs would represent less than 0.5 percent of expected revenues, NSPS are not expected to result in any barrier to entry into the category.

PSES: This regulation establishes PSES for the steel, cast iron and aluminum subcategories. The technology used as a basis for developing PSES standards is identical to the technology for BAT. In establishing pretreatment standards, EPA considers whether pollutants interfere with, pass-through or otherwise are incompatible with the POTW. EPA determined there is pass-through of toxic metal pollutants because POTW removals of major toxic pollutants found in porcelain enameling wastewater average about 50 percent (Cr-18%, Cu-58%, CN-52%, Zn-65%) while BAT technology treatment removes more than 99 percent of these pollutants. This difference in removal effectiveness clearly indicates pass-through of pollutants will occur unless porcelain enameling wastewaters are adequately pretreated. The pollutants to be regulated by PSES include chromium, lead, nickel, and zinc.

The Agency proposed PSES using technology analogous to the proposed BAT; flow normalization, chromium reduction, and lime, settle and filter end-of-pipe treatment. For the reasons discussed under BAT we are removing filtration from the PSES model technology and adding reuse of process wastewater. The model technology on which the promulgated PSES is based is analogous to the promulgated BAT model technology; flow reduction by reuse of treated process wastewater, chromium reduction, and lime and settle end-of-pipe treatment. The proposed PSES would have cost $4.8 million capital cost, $1.4 million annualized cost and removed 1,500 kg/yr toxic pollutants more than the PSES being promulgated.

The Agency determined that PSES are not economically achievable for small plants. Application of PSES to all indirect dischargers would have resulted in eight plant closures predominately among plants which produce less than 1,600 m^2/day product and discharge less than 60,000 l/day. EPA determined that this would present a disproportionate impact on this segment of the category. Accordingly, these plants are not controlled by the categorical standards established by this regulation. All indirect discharging plants must, however, conform to the provisions of 40 CFR Part 403. The exclusion point is reasonable since the next projected plant closure is about twice the cutoff level. This cut-off exempts from the categorical PSES regulation 38 small indirect dischargers which represent about 5 percent of the total industry production and 7 percent of the production by indirect dischargers. Further details of the small plant analysis are presented in the economic analysis document.

The Agency has determined that there is no less stringent technology that could be the basis of pretreatment standards for small plants. EPA evaluated a less expensive, sump settling technology suggested by public comments for small indirect dischargers. However, the Agency determined that this technology has not been adequately demonstrated in the industry and probably would not appreciably reduce the discharge of toxic pollutants.

The 38 small indirect dischargers not regulated by this PSES generate 21,800 kg/yr toxic pollutants and 1,426,000 kg/yr other pollutants. If PSES applied to these facilities they would introduce into POTW only 605 kg/yr toxic pollutants and 8,500 kg/yr other pollutants.

Concentration based standards, rather than the proposed mass-based standards, are promulgated for PSES with mass-based alternate standards made available for use where desired by the POTW. The Agency recognizes that concentration based standards may be more easily implemented and in this specific case resulting additional pollutant discharge will not be substantial.

Implementation of the PSES standards will remove annually an estimated 179,500 kg of toxic pollutants and 14,200,000 kg of other pollutants (from estimated current discharge) at a capital cost above equipment in place of $18.7 million and an annual cost of $9.9 million.

The pollutants selected for regulation are: chromium, lead, nickel, zinc, aluminum and iron. The toxic pollutants considered for regulation at proposal, but not selected for regulation, are antimony, arsenic, cadmium, copper, cyanide and selenium. The technology that would be necessary to meet the limitations for the regulated pollutants will effectively control the unregulated pollutants.

We expect that 50 of the 88 indirect dischargers will incur costs to comply

with PSES. The Agency estimates that those costs may result in two plant closures, two production line closures, and 90 job losses.

The Agency has considered the time for compliance for PSES. Few if any of the porcelain enameling plants have installed and are properly operating the treatment technology for PSES. Additionally, the readjustment of internal processing conditions to achieve reduced wastewater flows may require more time than for only the installation of end-of-pipe treatment equipment. Additionally, many plants in this and other industries will be installing the treatment equipment suggested as model technologies for this regulation and this may result in delays in engineering, ordering, installing, and operating this equipment. For all these reasons, the Agency has decided to set the PSES compliance date at three years after promulgation of this regulation.

PSNS: This regulation establishes PSNS for all four subcategories. The treatment technology basis for the PSNS being promulgated is identical to the treatment technology set forth as the basis for the NSPS being promulgated.

This regulation establishes mass-based standards. Although mass-based standards may be somewhat more difficult for a POTW to enforce, mass-based standards are necessary for PSNS to ensure that the considerable effluent-reduction benefits of flow reduction techniques are obtained. Overall flow and pollutant reduction of about 90 percent can be achieved by countercurrent cascade rinsing, and countercurrent cascade rinsing is not excessively costly in new plants. Since POTW removal of toxic pollutants is only about 50 percent, pass-through of toxic pollutants will occur.

The incremental capital investment (above the capital that would have been required if PSES requirements applied) for new source standards is less than 0.5 percent of expected revenues and is not expected to result in any barrier to entry into the category.

Regulated pollutants at PSNS are chromium, lead, nickel and zinc.

VI. Costs and Economic Impacts

Executive Order 12291 requires EPA and other agencies to perform regulatory impact analysis of major rules. Major rules are defined as rules that impose an annual cost to the economy of $100 million or more, or meet other economic impact criteria. On the basis of these criteria, EPA does not consider this final regulation to be a major rule. This rulemaking satisfies the requirements of the Executive Order for a non-major rule.

The economic impact assessment is presented in *Economic Impact Analysis of Effluent Standards and Limitations for the Porcelain Enameling Industry*, EPA 440/2–82–005. The analysis details the investment and annual costs that the industry will incur as result of this regulation. The report assesses the impact of effluent control costs in terms of price changes, production changes, plant closures, and unemployment effects.

Since proposal, the economic impact analysis has been revised to reflect several changes. Revised compliance costs are based on a modified computer cost model program. These compliance costs are engineering estimates for the effluent control systems described earlier in this preamble. Compliance cost estimates account for the equipment in place at each plant. The revised cost estimates address many of industry's comments on the proposal. A discussion of the revisions to the cost model is presented in Section VIII of the development document. In addition, these costs reflect the conclusion that porcelain enameling process wastewater treatment sludges generated by the model technology will not be hazardous wastes, as defined in the Resource Conservation and Recovery Act. The appropriate sludge disposal costs are included in the economic analysis document. The analysis also reflects other industry comments and additional information provided since proposal and uses more current information on financial and economic characteristics of the industry. For example, the cost of capital used in the analysis reflects a 16 percent interest rate.

EPA has identified 116 plants that perform porcelain enameling operations. Total investment cost for existing dischargers (BAT and PSES combined) is estimated to be $25.3 million, with annual costs of $13.6 million, including depreciation and interest. These costs are expressed in 1982 dollars (updated from 1978 dollars using a construction cost index) and are based on the determination that plants will move from existing treatment to either BAT or PSES. The major economic impacts projected as a result of this regulation are three plant closures and 149 job losses—substantially less than one percent of total employment for plants conducting porcelain enameling. Maximum increases in cost of production range from 0.1 to 2.6 percent. Balance of trade effects are not significant.

The Agency concludes that the final regulation is economically achievable, and the impacts are justified in light of the effluent reductions achieved.

In order to measure the potential economic impacts, the industry was subcategorized by the type of product being enameled (e.g., ranges, sanitary ware, architectural panels). The analytical approach includes a financial analysis of 106 individual plants that focused on profitability and capital requirements. Specific closure projections are characterized as "plant closures" when an entire facility is expected to stop operations and as "line closures" when only the porcelain enameling functions are expected to close. In the latter case, the porcelain enameling operations are not the major production activity at the plant, and other activities would not be directly affected by this regulation.

BPT: Investment requirements for 27 direct dischargers are $6.3 million, and total annualized costs are $3.6 million. The major impacts associated with the costs of the BPT treatment option are one plant closure and two production line closures. The potential closures will affect 59 employees.

BAT: The incremental investment costs of BAT over BPT are $0.4 million, and the additional annualized costs are $0.1 million. The analysis projects no additional plant closures or production line closures. The incremental compliance costs results in additional costs of production of only 0.1 percent.

PSES: The final categorical pretreatment standards will affect approximately 50 of the 88 indirect dischargers (57 percent). Investment costs are $18.7 million, and total annualized costs are $9.9 million. Under the proposed regulation, all indirect dischargers would have been subject to PSES. The final categorical PSES, however, applies only to indirect dischargers with flow greater than 60,000 l/day or production over 1,600 mL/day. This change is necessary to avoid excessive economic impact on this segment of the industry. If all indirect dischargers were required to meet the final PSES, the analysis of compliance costs projects 8 plant closures and 10 line closures, with unemployment of 429. Instead, the impacts of PSES are two plant closures (2 percent of indirect dischargers) and two line closures. The potential closures will affect 90 employees, which represents 0.1 percent of total employment for indirect dischargers.

NSPS and PSNS: An analysis of new source standards uses a model plant research approach. The incremental investment cost of the NSPS and PSNS limitations for the model plant would be $0.15 million; the annualized cost would be $0.04 million. The new source

analysis focuses on two parameters: (1) Annual compliance costs as a percent of expected revenues and (2) capital investment as a percent of revenues. In both cases, the results indicate that the incremental costs of new source standards are relatively low. For all subcategories, the first ratio is 0.1 percent; results for the second ratio are less than 0.5 percent. Thus, new source standards are not expected to present barriers to entry into the industry.

Regulatory Flexibility: Public Law 96–354 requires that a Regulatory Flexibility Analysis (RFA) be prepared for regulations that have a significant impact on a substantial number of small entities. An RFA for this regulation is included as part of the economic impact analysis. The Agency has concluded that this regulation will not have a significant impact on a substantial number of small entities. In the preamble to the proposed rule (46 FR 8868), the Agency solicited comment on the issue of small plant impacts. Based on the industry's comments and additional economic analysis, the industry was divided into size segments according to flow rate, number of employees, and value of shipments. The economic impacts were found to be concentrated on small indirect discharge plants. The Agency considered, but was unable to identify, less costly technologies than the selected PSES option that would remove significant amounts of toxic pollutants. The sump settling option suggested by the industry was not determined to be reliably effective. Thus, the only way to avoid the severe economic impact on small plants was to make the pretreatment standards for this regulation applicable to the large plants only. This approach effectively excludes indirect dischargers with flow rates under 60,000 l/day (15,850 gal/day) that produce less than 1,600 m^2/day (17,220 ft^2) from this catergorical pretreatment standard.

VII. Non-Water-Quality Environmental Impacts

Eliminating or reducing one form of pollution may cause other environmental problems. Sections 304(b) and 306 of the Act require EPA to consider the non-water-quality environmental impacts (including energy requirements) of certain regulations. In compliance with these provisions, we considered the effect of this regulation on air pollution, solid waste generation, water scarcity, and energy consumption. While it is difficult to balance pollution problems against each other and against energy use, we believe that this regulation will best serve often competing national goals.

This regulation was circulated to and reviewed by EPA personnel responsible for non-water quality programs.

The following non-water-quality environmental impacts (including energy requirements) are associated with the final regulation:

A. Air Pollution

Imposition of BPT and BAT limitations and NSPS, PSES, and PSNS will not create any substantial air pollution problems. The technologies used as the basis for this regulation precipitate pollutants found in wastewater which are then settled or filtered from the discharged wastewater. These technologies do not emit pollutants into the air.

B. Solid Waste

We estimate that porcelain enameling facilities generated 30,000 kkg/yr of solid wastes (wet basis) in 1976. These wastes are comprised of wastewater treatment system sludges containing toxic metals, including chromium, copper, lead, nickel and zinc. We estimate that the BPT limitations will contribute an additional 47,100 kkg/yr of solid wastes. BAT and PSES will increase these wastes by approximately 360 kkg/yr beyond BPT levels. We estimate PSES will contribute 88,000 kg/yr solid waste above the 20,000 kg solid waste currently discharged. These sludges will necessarily contain additional quantities (and concentrations) of toxic metal pollutants.

Wastewater treatment sludges from this category are expected to be non-hazardous under RCRA when generated using the model technology. Treatment of similar wastewaters from other categories using this technology has resulted in non-hazardous sludges. Costs for disposal of non-hazardous wastes are included in the annual costs

For new sources, we estimate that a new normal plant in the steel subcategory will generate 1,700 kkg/yr solid waste.

C. Consumptive Water Loss

Treatment and control technologies that require extensive recyling and reuse of water may require cooling mechanisms. Evaporative cooling mechanisms can cause water loss and contribute to water scarcity problems—a primary concern in arid and semi-arid regions. While this regulation assumes some water reuse the overall amount of reuse is low (below 50 percent) and the quantity of water involved is not significant. We conclude that the consumptive water loss is insignificant and that the pollution reduction benefits of recycle technologies outweigh their impact on consumptive water loss.

D. Energy Requirements

We estimate that the achievement of BPT effluent limitatons will result in a net increase in electrical energy consumption of approximately 16.7 million kilowatt-hours per year. BAT limitations are projected to add another 15.1 million kilowatt-hours to electrical energy consumption. To achieve the BPT and BAT effluent limitation, a typical direct discharger will increase total energy consumption by less than one percent one percent of the energy consumed for production purposes.

The Agency estimates that PSES will result in a net increase in electrical energy consumption of approximately 11.3 million kilowatt-hours per year. To achieve PSES, a typical existing indirect discharger will increase energy consumption less than one percent of the total energy consumed for production purposes.

The energy requirements for new sources (both NSPS and PSES) are similar to the BAT energy requirements. For a new normal plant in the steel subcategory the net increase in energy from water pollution control would be 0.28 million kilowatt-hours per year, less than one percent of the plants total energy consumption.

VIII. Pollutants and Subcategories Not Regulated

The Settlement Agreement contains provisions authorizing the exclusion from regulation, in certain circumstances, of toxic pollutants and industry subcategories.

A. Exclusion of Pollutants

Paragraph 8(a)(iii) of the Revised Settlement Agreement allows the Administrator to exclude from regulation toxic pollutants not detectable by Section 304(h) analytical methods or other state-of-the-art methods. The toxic pollutants not detected and therefore, excluded from regulation are listed in Appendix B to this notice—first those excluded from all subcategories, then by subcategory those not excluded in all subcategories.

Paragraph 8(a)(iii) allows the Administrator to exclude from regulation toxic pollutants detected in amounts too small to be effectively reduced by technologies known to the Administrator. Appendix C to this notice lists the toxic pollutants in each subcategory which were detected in amounts at or below the nominal limit of analytical quantification, which are too small to be effectively reduced by

technologies and which, therefore, are excluded from regulation.

Paragraph 8[a](iii) allows the Administrator to exclude from regulation toxic pollutants detectable in the effluent from only a small number of sources within the subcategory which are uniquely related to those sources. Appendix D to this notice lists for each subcategory the toxic pollutants which were detected in the effluents of only a small number of plants which are uniquely related to that plant, and are not related to the manufacturing processes under study.

Paragraph 8(a)(iii) also allows the Administrator to exclude from regulation, toxic pollutants present in amounts too small to be effectively reduced by technologies considered applicable to the category. Appendix E lists those toxic pollutants found in quantifiable amounts which are not treatable using the technologies considered.

Paragraph 8(a)(iii) also allows the Administrator to exclude from regulation toxic pollutants which will be effectively controlled by the technologies used as the basis for other effluent limitations and guidelines, standards of performance, or pretreatment standards. Appendix F list those toxic pollutants which will be effectively controlled by the BAT limitations or PSES standards being promulgated even though they are not specifically regulated.

B. Exclusion of Subcategories

BPT and BAT limitations are not being promulgated for the copper basis material subcategory because there are no direct discharging plants in this subcategory. PSES is not being promulgated because the only copper basis material manufacturing plants that discharge to POTW are excluded from the categorical standards established by this regulation by the small plant exclusion.

No limitations are established for porcelain enameling on precious metals (gold, silver and platinum group metals) because as previously stated they are believed to be very small sources and virtually all would be excluded from regulation by the small indirect discharger exemption.

IX. Public Participation and Responses to Major Comments

Numerous agencies and groups have participated during the development of these effluent guidelines and standards. Following the publication of the proposed rules on January 27, 1981 in the **Federal Register**, we provided the technical development document and the economic document supporting the proposed rules to industry, government agencies, and the public sector for comments. A workshop was held on the Porcelain Enameling BAT Rulemaking in Washington, D.C., on April 15, 1981. On April 16, 1981, in Washington, D.C., a pretreatment public hearing was held at which 18 persons presented testimony.

The comment period was scheduled to close on April 27, 1981 but was extended to May 8, 1981. Fifty-one responses containing 274 comments on the proposed regulation were received from the following: Alliance Wall, Corp.; Bootz Manufacturing Co, Inc.; Bootz Plumbing Fixtures Inc.; Caloric Corp.; California Metal Enameling Co.; Chi-Vit Corp., Roy C. Cobb; County Sanitation Districts of Los Angeles; Erie Ceramic Arts Co.; Ervite Corp.; Ferro Enameling Co.; Ferro Corp.; General Housewares Corp.; Hobart Corporation; Jenn-Air Corp.; Macola, Inc.; Magic Chef West; Mansfield Products; The Maytag Company; GII Corp.; Mirawall; Mirro Corp.; Mobay Chemical; The O. Hommel Co.; Office of the Governor, Indiana; Porcelain Industries, Inc., Porcelain Metals Corp., A. O. Smith Corp., A. O. Smith Harvestore Products Inc.; Southwestern Porcelain Inc.; State Industries Inc.; Vitreous Steel Products Co.; Wear-Ever Aluminum Inc; Weber-Stephen Products Co.; The West Bend Co.; Whirlpool Corp.; White Consolidated Industries; Porcelain Enamel Institute, Inc., private individual.

All comments received have been carefully considered, and appropriate changes in the regulation have been made whenever available data and information supported those changes. Major issues raised by the comments are addressed in this section of the preamble and in the public record. A summary of the comments received and our detailed responses are included in a document entitled "Public Comments and Responses for Porcelain Enameling" which has been placed in the public record for this regulation.

A. Economic Impact of the Regulation

Many comments expressed concern that the proposed regulation would be too expensive and cause many plants, especially small plants, to close. As discussed above, in response to comments EPA has decided to promulgate less stringent PSES and BAT than were proposed; small indirect dischargers need not comply with categorical PSES, and filtration has been deleted from the BAT and PSES model technologies.

The Agency's revised economic impact analysis projects that among the direct dischargers, one plant and two production lines may close, with unemployment of 0.3 percent, as a result of complying with BAT requirements. For indirect dischargers, the projected closures are two plants and two production lines with unemployment of 0.1 percent. The Agency believes that these economic impacts are justified in light of the effluent reduction benefits of this regulation.

B. Impact of the Regulation on Integrated Plants

Several commenters asserted that EPA has failed to account for the additional compliance cost of the proposed regulation on integrated plants with combined wastestreams. The commenters believe that plants with combined wastestreams would require treatment of the entire plant discharge to the limits for porcelain enameling; they believe that the cost of line segregation is prohibitive.

The cost of compliance and technological ramifications of this regulation on integrated plants has been fully considered. The Agency's analysis of the economic impact of the regulation includes the cost of segregating porcelain enameling wastewater from other process wastes with separate treatment of the porcelain enameling wastewater. Cotreatment of porcelain enameling wastewaters with other process wastewaters would reduce the cost below these estimates for porcelain enameling alone.

The Agency is aware that many plants prefer not to segregate wastes in order to take advantage of economies of scale in treatment costs. The Agency has not performed an analysis of the cost of combined treatment for integrated porcelain enameling plants, but we expect combined treatment to be less costly than separate treatment of each wastewater stream. However, the Agency has performed an analysis of combined treatment by metal finishers, and at least 35 percent of the porcelain enamelers with combined wastestreams are included in the metal finishing estimates. Since none of these plants are indicated as closures in the metal finishing economic study, these estimates for metal finishing indicate that the cost of combined treatment will not result in closures among porcelain enamelers.

As noted previously, the Agency deleted filtration from the BAT and PSES model technologies in part to reduce barriers to co-treatment of compatible wastewaters.

C. Calculation of Achievable Concentrations

Several comments object to limits more stringent than those that apply to electroplaters (40 CFR Part 413) based on the use of multiple industry data pooling, which included electroplating data, to determine achievable concentrations following treatment. Industry comments suggest that the proposed concentrations are not achievable with the precipitation technology. The commenters asserted that data pooling was not reasonable because of greater concentrations of some pollutants in porcelain enamelers' raw waste.

The effluent characteristics of the six catetories that were used to derive the pooled performance data were believed to be sufficiently homogeneous to justify this approach. However, as discussed previously in this preamble, a statistical analysis performed after proposal shows that the effluent from porcelain enameling is different from that of electroplating. Therefore, the recommended effluent limitations for promulgation are based on a pooled industry data base that excludes electroplating. These limitations are based on a revised statistical analysis that better represents the effectiveness and variability of the treatment technology in porcelain enameling facilities. Although the recommended limits are more stringent than electroplating limits based on a similar technology the Agency's rinsed data based demonstrated that porcelain enamelers can meet these limits. Section VII of the Development Document explains revisions in the concentrations used to calculate the limitations and standards in the final regulation.

D. Number of Pollutants Regulated

Several comments stated that the 19 pollutants proposed for regulation were unnecessary additions to compliance monitoring costs. The comments suggest that the limits for nontoxic, nonconventional pollutants be eliminated.

The Agency has reconsidered the number of pollutants to be regulated and decided that it is unnecessary to establish limits for all pollutants. A model treatment system meeting the limitations or key pollutants will provide adequate removal of all pollutants which can be treated by the technology. As a result of this reconsideration, we reduced the number of regulated pollutants to nine (chromium, lead, nickel, zinc, aluminum, iron, oil and grease, TSS, and pH) for direct dischargers and four (chromium, lead, nickel, zinc) for indirect dischargers. This reduced number of regulated pollutants is expected to ensure adequate removal of all pollutants in porcelain enameling wastewaters. Aluminum and iron are not regulated in pretreatment because these elements, which are sometimes added by the POTW as coagulants, are not expected to pass through the POTW.

E. Accuracy of Treatment Cost Estimates

Comments on the treatment cost estimates presented in the proposed regulation suggest that EPA had underestimated the cost of compliance by at least 100 percent, not including the costs of combined treatment. Among other things, the comments criticized design criteria for equipment and the Agency's estimates of the cost of installing equipment.

Approximately 70 percent of the difference between the original EPA costs and industry costs is explained by inflation and the industry's inclusion of equipment sized for flows larger than those necessary based on our study. Some industry plant cost estimates also included backup equipment such as redundant pumps and emergency storage basins to ensure that a catastrophic treatment plant breakdown will not force a plant shutdown. The Agency does not believe storage basins and redundant pumps are appropriate or common industry practice for the relatively simple treatment technologies recommended for this category. The Agency's cost estimate omits the 5 to 10 percent additional cost of this backup equipment but includes 20 to 40 percent excess tank capacity to accommodate flow surges and short term (less than one day) equipment breakdowns.

In addition to the cost of the back-up equipment, a 20 to 30 percent difference still remains between EPA's cost estimates and the industry's. The major items that account for the difference are site specific costs such as land acquisition and site improvements. While these costs are easily calculated for an individual plant, they are highly variable from plant to plant. As a result, the Agency has not included these costs. However, site specific costs have been taken into account by a sensitivity analysis in the economic impact analysis which examined the potential economic impact of a 30 percent increase in compliance costs. This analysis showed that only one additional line closure would result from this increase.

F. Effect of Sampling Frequency on Achievable Limits

Two industry commenters were critical of the proposal of 30 day average limitations. They point out that the limits are based on 30 samples collected per month. The commenters believe that collecting 30 samples per month was unnecessarily expensive. Instead, the comments suggest that the Agency issue limits based on less frequent sampling, such as four days per month.

The final regulation establishes monthly average limits that are based on the average of ten consecutive sampling days (not necessarily consecutive calendar days). The Agency believes that the monthly average limits based on ten-day averages eliminate unnecessary costs to industry while they assure retention of most all of the effluent reduction benefits that the 30-day averages would have achieved. The Agency rejected shorter time periods for averaging into a monthly average because they do not reasonably approximate the averaging of daily values over one month and because shorter time periods such as a four day average used for a monthly average would allow much greater discharges of pollutants. To assure implementation of this new monthly average the Agency is requiring that the monthly average set forth in this regulation be used as the basis for monthly limits in permits and in pretreatment standards.

X. Best Management Practices

Section 304(e) of the Clean Water Act gives the Administrator authority to prescribe "best management practices" (BMP). However, EPA at this time is not considering development of BMP specific to the porcelain enameling category.

IX. Upset and Bypass Provisions

A recurring issue of concern has been whether industry guidelines should include provisions authorizing noncompliance with effluent limitations during periods of "upset" or "bypass." An upset, sometimes called an "excursion", is an unintentional noncompliance occurring for reasons beyond the reasonable control of the permittee. It has been argued that an upset provision in EPA's effluent limitations is necessary because such upsets will inevitably occur even in properly operated control equipment. Because technology based limitations require only what technology can achieve, it is claimed that liability for such situations is improper. When confronted with this issue, courts have disagreed on whether an explicit upset

or excursion exemption is necessary, or whether upset or excursion incidents may be handled through EPA's exercise of enforcement discretion. Compare *Marathon Oil Co.* v. *EPA*, 564 F. 2d 1253 (9th Cir. 1977) with *Weyerhaeuser* v. *Costle, supra*, and *Corn Refiners Association, et al.* v. *Costle*, No. 78–1069 (8th cir., April 2, 1979). See also *American Petroleum Institute* v. *EPA*, 540 F.2d 1023 (10th Cir. 1976); *CPC International, Inc.* v. *Train*, 540 F.2d 1320 (8th cir. 1976); *FMC Corp.* v. *Train*, 539 F.2d 973 (4th Cir. 1976).

An upset is an unintentional episode during which effluent limits are exceeded; a bypass however, is an act of intentional noncompliance during which waste treatment facilities are circumvented in emergency situations. We have, in the past, included bypass provisions in NPDES permits.

We determined that both upset and bypass provisions should be included in NPDES permits and have promulgated consolidated permit regulations that include upset and bypass permit provisions (See 40 CFR 122.60, 45 FR 33290 (May 19, 1980). The upset provision established an upset as an affirmative defense to prosecution for violation of technology-based effluent limitations. The bypass provision authorizes bypassing to prevent loss of life, personal injury, or severe property damage. Consequently, although permittees in the porcelain enameling industry will be entitled to upset and bypass provisions in NPDES permits, this final regulation does not address these issues.

XII Variances and Modifications

Upon the promulgation of this regulation, the effluent limitations for the appropriate subcategory must be applied in all federal and state NPDES permits thereafter issued to direct dischargers in the porcelain enameling category. In addition, on promulgation, the pretreatment limitations are directly applicable to any indirect dischargers.

For the BPT effluent limitations, the only exception to the binding limitations is EPA's "fundamentally different factors" variance. See *E. I. du Pont de Nemours & Co.* v. *Train*, 430 U.S. 112 (1977); *Weyerheuser Co.* v. *Costle, supra*. This variance recognizes factors concerning a particular discharger that are fundamentally different from the factors considered in this rulemaking. Although this variance clause was set forth in EPA's 1973–1976 industry regulations, it is now included in the NPDES regulations and will not be included in the procelain enameling or other industry regulations. See the NPDES regulations at 40 CFR Part 125, Subpart D.

The BAT limitations in this regulation are also subject to EPA's "fundamentally different factors" variance. BAT limitations for nonconventional pollutants are subject to modifications under Sections 301(c) and 301(g) of the Act. These statutory modifications do not apply to toxic or conventional pollutants. According to Section 301(j)(1)(B), applications for these modifications must be filed within 270 days after promulgation of final effluent limitations guidelines. See 43 FR 40895 (September 13, 1978). Pretreatment standards for existing sources are subject to the "fundamentally different factors" variance and credits for pollutants removed by POTW. (See 40 CFR 403.7, 403.13).

The economic modification section (301(c)) gives the Administrator authority to modify BAT requirements for nonconventional pollutants[1] for dischargers who file a permit application after July 1, 1978, upon a showing that such modified requirements will (1) represent the maximum use of technology within the economic capability of the owner or operator and (2) result in reasonable further progress toward the elimination of the discharge of pollutants. The environmental modification section (301(g)) allows the Administrator, with the concurrence of the State, to modify BAT limitations for nonconventional pollutants from any point source upon a showing by the owner or operator of such point source satisfactory to the Administrator that:

(a) Such modified requirements will result at a minimum in compliance with BPT limitations or any more stringent limitations necessary to meet water quality standards;

(b) Such modified requirements will not result in any additional requirements on any other point or nonpoint source; and

(c) Such modification will not interfere with the attainment or maintenance of that water quality which shall assure protection of public water supplies, and the protection and propagation of a balanced population of shellfish, fish, and wildlife, and allow recreational activities, in and on the water and such modification will not result in the discharge of pollutants in quantities which may reasonably be anticipated to pose an unacceptable risk to human health or the environment because of bioaccumulation, persistency in the environment, acute toxicity, chronic toxicity (including carcinogenicity, mutagenicity or teratogenicity), or synergistic propensities.

Section 301(j)(1)(B) of the Act requires that application for modifications under section 301 (c) or (g) must be filed within 270 days after the promulgation of an applicable effluent guideline. Initial applications must be filed with the Regional Administrator and, in those States that participate in the NPDES Program, a copy must be sent to the Director of the State program. Initial applications to comply with 301(j) must include the name of the permittee, the permit and outfall number, the applicable effluent guideline, and whether the permittee is applying for a 301(c) or 301(g) modification or both.

XIII. Relationship to NPDES Permits

The BPT and BAT limitations and NSPS in this regulation will be applied to individual porcelain enameling facilities through NPDES permits issued by EPA or approved state agencies, under Section 402 of the Act. As discussed in the preceding section of this preamble, these limitations must be applied in all Federal and State NPDES permits except to the extent that variances and modifications are expressly authorized. Other aspects of the interaction between these limitations and NPDES permits are discussed below.

One issue that warrants consideration is the effect of this regulation on the powers of NPDES permit-issuing authorities. The promulgation of this regulation does not restrict the power of any permitting authority to act in any manner consistent with law or these or any other EPA regulations, guidelines, or policy. For example, even if this regulation does not control a particular pollutant, the permit issuer may still limit such pollutant on a case-by-case basis when limitations are necessary to carry out the purposes of the Act. In addition, to the extent that State water quality standards or other provisions of State or Federal law require limitation of pollutants not covered by this regulation (or require more stringent limitations on covered pollutants), such limitations must be applied by the permit-issuing authority.

A second topic that warrants discussion is the operation of EPA's NPDES enforcement program, many aspects of which were considered in developing this regulation. We emphasize that although the Clean Water Act is a strict liability statute, the initiation of enforcement proceedings by

[1] Section 301(a) precludes the Administrator from modifying BAT requirements for any pollutants which are on the toxic pollutant list under Section 307(1)(1) of the Act.

EPA is discretionary. We have exercised and intend to exercise that discretion in a manner that recognizes and promotes good-faith compliance efforts.

XIV. Availability of Technical Information

The basis for this regulation is detailed in four major documents. Analytical methods are discussed in *Sampling and Analysis Procedures for Screening of Industrial Effluent for Priority Pollutants.* EPA's technical conclusions are detailed in *Development Document for Effluent Guidelines, New Source Performance Standards and Pretreatment Standards for the Porcelain Enameling Point Source Category.* The Agency's economic analysis is presented in *Economic Impact Analysis of Effluent Limitations and Standards for the Porcelain Enameling Industry.* A summary of the public comments received on the proposed regulation is presented in a report *Responses to Public Comments, Proposed Porcelain Enameling Industry Effluent Guidelines and Standards,* which is a part of the public record for this regulation.

Technical information may be obtained by writing to Ernst P. Hall, Effluent Guidelines Division (WH–552), EPA, 401 M Street, SW., Washington, D.C. 20460, or through calling (202) 382–7126.

Additional information concerning the economic impact analysis may be obtained from Ms. Debra Maness, Economic Analysis Staff (WH–586), EPA, 401 M Street, SW., Washington, D.C. 20460 or by calling (202) 382–5385.

Copies of the technical and economic documents may be obtained from the National Technical Information Service, Springfield, Virginia 22161 (703/487–4600).

The regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291. Any comments from OMB to EPA and any EPA response to those comments are available for public inspection at Room M2404, U.S. EPA, 401 M Street, SW., Wash., D.C. 20460 from 9:00 a.m. to 4:00 p.m. Monday–Friday excluding federal holidays.

In accordance with the Paperwork Reduction Act of 1980 (Pub. L. 96–511), the reporting or recordkeeping provisions that are included in this regulation will be submitted for approval to the Office of Management and Budget (OMB). They are not effective until OMB approval has been obtained and the public notified to that effect through a technical amendment to this regulation.

List of Subjects in 40 CFR Part 466

Porcelain enameling, Steel basis metal, Aluminum basis metal, Cast iron basis metal, Copper basis metal, Enamel slip.

Dated: November 5, 1982.

Anne M. Gorsuch,

Administrator.

APPENDICES

Appendix A—Abbreviations, Acronyms, and Other Terms Used in This Notice

Act—The Clear Water Act.

Agency—The U.S. Environmental Protection Agency.

BAT—The best available technology economically achievable under Section 304(b)(2)(B) of the Act.

BCT—The best conventional pollutant control technology, under Section 304(b)(4) of the Act.

BMPs—Best management practices under Section 304(e) of the Act.

BPT—The best practicable control technology currently available under Section 304(b)(1) of the Act.

Clean Water Act—The Federal Water Pollution Control Act Amendments of 1972 (33 U.S.C. 1251 *et seq.*), as amended by the Clean Water Act of 1977 (Pub. L. 95–217).

Direct discharger—A facility which discharges or may discharge pollutants into waters of the United States.

Indirect discharger—A facility which discharges or may discharge pollutants into a publicly owned treatment works.

NPDES permit—A National Pollutant Discharge Elimination System permit issued under Section 402 of the Act.

NSPS—New source performance standards under Section 306 of the Act.

POTW—Publicly owned treatment works.

PSES—Pretreatment standards for existing sources of indirect discharges under Section 307(b) of the Act.

PSNS—Pretreatment standards for new sources of indirect discharges under Section 307 (b) and (c) of the Act.

RCRA—Resource Conservation and Recovery Act (Pub. L. 94–580) of 1976, Amendments to Solid Waste Disposal Act.

Appendix B—Toxic Pollutants Not Detected in Wastewaters

(a) Toxic Pollutants Not Detected in Wastewaters of Any Subcategory

001 Acenaphthene
002 Acrolein
003 Acrylonitrile
004 Benzene
005 Benzidine
006 Carbon tetrachloride (tetrachloromethane)
007 Chlorobenzene
008 1,2,4-trichlorobenzene
009 Hexachlorobenzene
010 1,2-dichloroethane
011 1,1,1-trichlorethane
012 Hexachloroethane
013 1,1-dichloroethane
014 1,1,2-trichloroethane
015 1,1,2,2-tetrachloroethane
016 Chloroethane
017 Bis (chloromethyl) ether
018 Bis (2-chloroethyl) ether
019 2-chloroethyl vinyl ether (mixed)
020 2-chloronaphthalene
021 2,4,6-trichlorophenol
022 Parachlorometa cresol
023 Chloroform (trichloromethane)
024 2-chlorophenol
025 1,2-dichlorobenzene
026 1,3-dichlorobenzene
027 1,4-dichlorobenzene
028 3,3-dichlorobenzidine
029 1,1-dichloroethylene
030 1,2-trans-dichloroethylene
031 2,4-dichlorophenol
032 1,2-dichloropropane
033 1,2-dichloropropylene (1,3-dichloropropene)
034 2,4-dimethylphenol
035 2,4-dinitrotoluene
036 2,6-dinitrotoluene
037 1,2-diphenylhydrazine
038 Ethylbenzene
039 Fluoranthene
040 4-chlorophenyl phenyl ether
041 4-bromophenyl phenyl ether
042 Bis(2-chloroisopropyl) ether
043 Bis(2-chloroethoxy) methane
044 Methylene chloride (dichloromethane)
045 Methyl choride (dichloromethane)
046 Methyl bromide (bromomethane)
047 Bromoform (tribromomethane)
048 Dichlorobromomethane
049 Trichlorofluoromethane
050 Dichlorodifluoromethane
051 Chlorodibromomethane
052 Hexachlorobutadiene
053 Hexachloromyclopentadiene
054 Isophorone
055 Naphthalene
056 Nitrobenzene
057 2-nitrophenol
058 4-nitrophenol
059 2,4-dinitrophenol
060 4,6-dinitro-o-cresol
061 N-nitrosodimethylamine
062 N-nitrosodiphenylamine
063 N-nitrosodi-n-propylamine
064 Pentachlorophenol
065 Phenol
067 Butyl benzyl phthalate
068 Di-N-Butyl Phthalate
070 Diethyl Phthalate
071 Dimethyl phthalate
072 1,2-benzanthracene (benzo(a)anthracene)
073 Benzo(a)pyrene (3,4-benzopyrene)

074 3,4-Benzofluoranthene (benzo(b)fluoranthene)
075 11,12-benzofluoranthene (benzo(b)fluoranthene)
076 Chrysene
077 Acenaphthylene
078 Anthracene
079 1,12-benzoperylene (benzo(ghi) perylene)
081 Phenanthrene
082 1,2,4,5,6-dibenzanthracene (dibenzo(,h)anthracene)
083 Ideno(1,2,3-cd) pyrene (2,3-O-phenylene pyrene)
084 Pyrene
085 Tetrachloroethylene
088 Vinyl chloride (chloroethylene)
089 Aldrin
090 Dieldrin
091 Chlordane (technical mixture and metabolites)
092 4,4-DDT
093 4,4-DDE (p,p-DDX)
094 4,4-DDD (p,p-TDE)
095 Alpha-endosulfan
096 Beta-endosulfan
097 Edosulfan sulfate
098 Endrin
099 Endrin aldehyde
100 Heptachlor
101 Heptachlor epoxide (BHC-hexachlorocyclohexane)
102 Alpha-BHC
103 Beta-BHC
104 Gamma-BHC (lindane)
105 Delta-BHC (PCB-polychlorinated biphenyls)
106 PCB–1242 (Arochlor 1242)
107 PCB–1254 (Arochlor 1254)
108 PCB–1221 (Arochlor 1221)
109 PCB–1232 (Arochlor 1232)
110 PCB–1248 (Arochlor 1248)
111 PCB–1260 (Arochlor 1260)
112 PCB–1016 (Arochlor 1016)
113 Toxaphene
116 Asbestos
123 Mercury
126 Silver
127 Thallium
129 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD)

(b) Toxic Pollutants Not Detected in Wastewaters of the Steel Basis Material Subcategory

014 1,1,2-trichloroethane
066 Bis(2-ethylhexyl)phthalate
069 Di-n-octyl phthalate
080 Fluorene
086 Toluene
121 Cyanide, Total

(c) Toxic Pollutants Not Detected in Wastewaters of the Cast Iron Basis Material Subcategory

014 1,1,2-trichloroethane
069 Di-n-octyl phthalate
080 Fluorene
086 Toluene
087 Trichloroethylene
121 Cyanide, Total

(d) Toxic Pollutants Not Detected in Wastewaters of the Aluminum Basis Material Subcategory

014 1,1,2-trichloroethane
080 Fluorene
086 Toluene
087 Trichloroethylene

(e) Toxic Pollutants Not Detected in Wastewaters of the Copper Basis Material Subcategory

066 Bis(2-ethylhexyl)phthalate
069 Di-n-octyl phthalate
087 Trichloroethylene
121 Cyanide, Total

Appendix C—Toxic Pollutants Detected Below the Analytical Quantification Limit

(a) Steel Basis Material Subcategory

087 Trichloroethylene

(b) Cast Iron Basis Material Subcategory

None

(c) Aluminum Basis Material Subcategory

None

(d) Copper Basis Material Subcategory

014 1,1,2-trichloroethane
080 Fluorene
086 Toluene
087 Trichloroethylene

Appendix D—Toxic Pollutants Found in a Small Number of Plants

(a) Steel Basis Material Subcategory

117 Beryllium

(b) Cast Iron Basis Material Subcategory

117 Beryllium

(c) Aluminum Basis Material Subcategory

117 Beryllium

(d) Copper Basis Material Subcategory

117 Beryllium

Appendix E—Toxic Pollutants Found in Quantifiable Amounts Which Are Not Treatable Using Technologies Considered

(a) Steel Basis Material Subcategory

None

(b) Cast Iron Basis Material Subcategory

None

(c) Aluminum Basis Material Subcategory

066 Bis(2-ethylhexyl) phthalate
069 Di-n-octyl phthalate
121 Cyanide

(d) Copper Basis Material Subcategory

None

Appendix F—Toxic Pollutants Which Will Be Effectively Controlled by the BAT Limitations or PSES Standards Promulgated Even Though They Are Not Specifically Regulated

(a) Steel Basis Material Subcategory

114 Antimony
115 Arsenic
118 Cadmium
120 Copper
125 Selenium

(b) Cast Iron Basis Material Subcategory

114 Antimony
115 Arsenic
118 Cadmium
120 Copper
125 Selenium

(c) Aluminum Basis Material Subcategory

114 Antimony
115 Arsenic
118 Cadmium
120 Copper
125 Selenium

(d) Copper Basis Material Subcategory

114 Antimony
115 Arsenic
118 Cadmium
120 Copper
125 Selenium

A new Part 466 is added to read as follows:

PART 466—PORCELAIN ENAMELING POINT SOURCE CATEGORY

General Provisions

Sec.
466.01 Applicability.
466.02 General definitions.
466.03 Monitoring and reporting requirements.
466.04 Compliance date for PSES.

Subpart A—Steel Basis Material Subcategory

466.10 Applicability; description of the steel basis material subcategory.
466.11 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.
466.12 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable.
466.13 New source performance standards.
466.14 Pretreatment standards for existing sources.

Sec.

466.15 Pretreatment standards for new sources.
466.16 [Reserved]

Subpart B—Cast Iron Basis Material Subcategory

466.20 Applicability; description of the cast iron basis material subcategory.
466.21 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.
466.22 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable.
466.23 New source performance standards.
466.24 Pretreatment standards for existing sources.
466.25 Pretreatment standards for new sources.
466.26 [Reserved]

Subpart C—Aluminum Basis Material Subcategory

466.30 Applicability; description of the aluminum basis material subcategory.
466.31 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.
466.32 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable.
466.33 New source performance standards.
466.34 Pretreatment standards for existing sources.
466.35 Pretreatment standards for new sources.
466.3 [Reserved]

Subpart D—Copper Basis Material Subcategory

466.40 Applicability; description of the copper basis material subcategory.
466.41 [Reserved]
466.42 [Reserved]
466.43 New source performance standards.
466.44 [Reserved]
466.45 Pretreatment standards for new sources.
466.46 [Reserved]

Authority: Secs. 301, 304 (b), (c), (e), and (g), 306 (b) and (c), 307 and 501 of the Clean Water Act (the Federal Water Pollution Control Act Amendments of 1972, as amended by the Clean Water Act of 1977) (the "Act"); 33 U.S.C. 1311, 1314 (b), (c), (e) and (g), 1316 (b) and (c), 1317 (b) and (c), and 1361; 86 Stat. 816, Pub. L. 92-500; 91 Stat. 1567, Pub. L. 95-217.

General Provisions

§ 466.01 Applicability.

(a) Except as provided in paragraphs (b) and (c) of this section, the provisions of this part apply to any porcelain enameling facility which discharges pollutants to waters of the United States or introduces pollutants into a publicly owned treatment works.

(b) Any existing porcelain enameling facility which prepares or coats less than 1600 m^2/day and which introduces less than 60,000 1/day of wastewater into a publicly owned treatment works is not controlled by the pretreatment standards for existing sources established by this regulation. Such facilities must comply with the provisions of 40 CFR Part 403.

(c) This part does not apply to the porcelain enameling on precious metal basis material.

§ 466.02 General definitions.

In addition to the definitions set forth in 40 CFR Part 401, the following definitions apply to this part:

(a) "Porcelain enameling" means the entire process of applying a fused vitreous enamel coating to a metal basis material. Usually this includes metal preparation and coating operations.

(b) "Basis material" means the metal part or base onto which procelain enamel is applied.

(c) "Area processed" means the total basis material area exposed to processing solutions.

(d) "Area coated" means the area of basis material covered by each coating of enamel.

(e) "Coating operations" means all of the operations associated with preparation and application of the vitreous coating. Usually this includes ballmilling, slip transport, application of slip to the workpieces, cleaning and recovery of faulty parts, and firing (fusing) of the enamel coat.

(f) "Metal preparation" means any and all of the metal processing steps preparatory to applying the enamel slip. Usually this includes cleaning, pickling and applying a nickel flash or chemical coating.

(g) The term "Control Authority" is defined as the POTW if it has an approved pretreatment program; in the absence of such a program, the NPDES state if it has an approved pretreatment program or EPA if the State does not have an approved program.

(h) The term "precious metal" means gold, silver, or platinum group metals and the principal alloys of those metals.

§466.03 Monitoring and reporting requirements.

(a) Periodic analyses for chromium as may be required under Parts 122 or 403 of this chapter is not required when both of the following conditions are met.

(1) The first wastewater sample of each calendar year has been analyzed and found to contain less than 0.08 mg/l chromium.

(2) The owner or operator of the porcelain enameling facility certifies in writing to the control authority or permit issuing authority that chromium is not contained in the raw materials or process chemicals of that facility and will not be used in the facility.

(b) The "monthly average" regulatory values shall be the basis for the monthly average discharge in direct discharge permits and for pretreatment standards. Compliance with the monthly discharge limit is required regardless of the number of samples analyzed and averaged.

§ 466.04 Compliance date for PSES.

The compliance date for pretreatment standards for existing sources is November 25, 1985.[2]

Subpart A—Steel Basis Material Subcategory

§ 466.10 Applicability; description of the steel basis material.

This subpart applies to discharges to waters of the United States, and introduction of pollutants into publicly owned treatment works from porcelain enameling on steel basis materials.

§ 466.11 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations for metal preparation operations and for coating operations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

SUBPART A.—BPT EFFLUENT LIMITATIONS

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Metal preparation	Coating operation	Metal preparation	Coating operation
	Metric units—mg/m^2 of area processed or coated			
Chromium	16.82	3.41	6.81	1.38
Lead	6.01	1.21	5.21	1.06
Nickel	56.46	11.43	40.05	8.11
Zinc	53.26	10.78	22.43	4.54
Aluminum	182.20	36.87	74.47	15.07
Iron	49.26	9.97	25.23	5.11
Oil and grease	800.84	162.10	480.51	97.23
TSS	1642.00	332.20	800.90	162.00
pH	(1)	(1)	(1)	(1)

[2] The Consent Decreee in NRDC v. Train, 12 ERC (D.D.C. 1979) specifies a compliance date for PSES of no later than June 30, 1984. EPA will be moving for a modification of that provision of the Decree. Should the Court deny that motion, EPA will be required to modify this compliance date accordingly.

SUBPART A.—BPT EFFLUENT LIMITATIONS—Continued

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Metal preparation	Coating operation	Metal preparation	Coating operation
English Units—pounds per 1 million ft² of area processed or coated				
Metric units—mg/m² of area processed or coated				
Chromium	3.45	0.07	1.40	0.29
Lead	1.23	0.25	1.07	0.22
Nickel	11.57	2.34	8.20	1.66
Zinc	10.91	2.21	4.60	0.93
Aluminum	37.32	7.55	15.26	3.09
Iron	10.09	2.04	5.17	1.05
Oil and grease	164.03	33.19	98.42	19.92
TSS	337.00	68.10	164.00	33.20
pH	(1)	(1)	(1)	(1)

(1) Within the range 7.5 to 10.0 at all times.

§ 466.12 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable.

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable:

SUBPART A.—BAT EFFLUENT LIMITATIONS

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Metal preparation	Coating operation	Metal preparation	Coating operation
Metric units—mg/m² of area processed or coated				
Chromium	16.82	0.27	6.81	0.11
Lead	6.01	0.10	5.21	0.09
Nickel	56.50	0.90	40.05	0.64
Zinc	53.30	0.85	22.43	0.36
Aluminum	182.00	2.90	74.48	1.19
Iron	49.30	0.79	25.23	0.41
English Units—pounds per 1 million ft² of area processed or coated				
Chromium	3.45	0.06	1.4	0.022
Lead	1.23	0.02	1.07	0.017
Nickel	11.57	0.19	8.20	0.13
Zinc	10.91	0.18	4.60	0.08
Aluminum	37.32	0.6	15.26	0.25
Iron	10.09	0.16	5.17	0.09

§ 466.13 New source performance standards.

Any new source subject to this subpart must achieve the following new source performance standards:

SUBPART A.—NSPS

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Metal preparation	Coating operation	Metal preparation	Coating operation
Metric units—mg/m² of area processed or coated				
Chromium	1.33	0.24	0.54	0.1
Lead	0.36	0.70	0.33	0.06
Nickel	1.97	0.35	1.32	0.24
Zinc	3.65	0.65	1.51	0.27
Aluminum	10.90	1.93	4.44	0.79
Iron	4.40	0.79	2.26	0.40
Oil and grease	35.75	6.36	35.75	6.36
TSS	53.7	9.54	39.4	7.0
pH	(1)	(1)	(1)	(1)
English units—pounds per 1 million ft² of area processed or coated				
Chromium	0.27	0.05	0.11	0.02
Lead	0.06	0.013	0.07	0.012
Nickel	0.41	0.08	0.27	0.05
Zinc	0.75	0.14	0.31	0.06
Aluminum	2.22	0.4	0.91	0.17
Iron	0.90	0.16	0.46	0.09
Oil and grease	7.33	1.31	7.33	1.31
TSS	10.99	1.96	8.06	1.44
pH	(1)	(1)	(1)	(1)

(1) Within the range 7.5 to 10.0 at all times.

§ 466.14 Pretreatment standards for existing sources.

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for existing sources.

SUBPART A.—PSES

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Metal preparation	Coating operation	Metal preparation	Coating operation
Milligrams per liter (mg/l)				
Chromium		0.42		0.17
Lead		0.15		0.13
Nickel		1.41		1.00
Zinc		1.33		0.56

(b) In cases where POTW find it necessary to impose mass effluent pretreatment standards the following equivalent mass standards are provided:

SUBPART A.—PSES

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Metal preparation	Coating operation	Metal preparation	Coating operation
Metric units—mg/m² of area processed or coated				
Chromium	16.82	0.27	6.81	0.11
Lead	6.01	0.10	5.21	0.09
Nickel	56.5	0.90	40.1	0.64

SUBPART A.—PSES—Continued

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Metal preparation	Coating operation	Metal preparation	Coating operation
Zinc	53.3	0.85	22.5	0.36
English units—pounds per 1 million ft² of area processed or coated				
Chromium	3.45	0.06	1.4	0.022
Lead	1.23	0.19	1.07	0.02
Nickel	11.6	0.19	8.20	0.13
Zinc	10.9	0.18	4.6	0.08

§ 466.15 Pretreatment standards for new sources.

Except as provided in 40 CFR 403.7 and 403.13, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources:

SUBPART A.—PSNS

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Metal preparation	Coating operation	Metal preparation	Coating operation
Metric units—mg/m² of area processed or coated				
Chromium	1.33	0.24	0.54	0.10
Lead	0.36	0.07	0.33	0.06
Nickel	1.97	0.35	1.33	0.24
Zinc	3.65	0.65	1.51	0.27
English units—pounds per 1 million ft² of area processed or coated				
Chromium	0.27	0.05	0.11	0.02
Lead	0.07	0.013	0.07	0.012
Nickel	0.41	0.08	0.27	0.05
Zinc	0.75	0.14	0.31	0.06

§ 466.16 [Reserved]

Subpart B—Cast Iron Basis Material Subcategory

§ 466.20 Applicability; description of the cast iron basis material subcategory.

This subpart applies to discharges to waters of the United States and introductions of pollutants into publicly owned treatment works from porcelain enameling of cast iron basis materials.

§ 466.21 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

Except as provided in 40 CFR 125.30–.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best

practicable control technology currently available.

(a) There shall be no discharge of process wastewater pollutants from metal preparation operations.

(b) The discharge of process wasterwater pollutants from all porcelain enameling coating operations shall not exceed the values set forth below:

SUBPART B.—BPT EFFLUENT LIMITATIONS

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Mg/m² (pounds per/1million ft²) of Area Coated			
Chromium	0.29	(0.06)	0.12	(0.024)
Lead	0.11	(0.02)	0.09	(0.02)
Nickle	0.98	(0.02)	0.7	(0.15)
Zinc	0.93	(0.19)	0.39	(0.08)
Aluminum	3.16	(0.65)	1.29	(0.27)
Iron	0.86	(0.18)	0.44	(0.09)
Oil and grease	13.86	(2.84)	8.32	(1.71)
TSS	28.42	(5.82)	13.86	(2.84)
pH	(1)	(1)	(1)	(1)

[1] Within the range 7.5 to 10.0 at all times.

§ 446.22 Effluent limitation representing the degree of effluent reduction attainable by the application of the best available technology economically achievable.

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable.

(a) There shall be no discharge of process wastewater pollutants from metal preparation operations.

(b) The discharge of process wastewater pollutants from all porcelain enameling coating operations shall not exceed the values set forth below:

SUBPART B.—BAT EFFLUENT LIMITATIONS

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Mg/m² (pounds per/million ft²) of area coated			
Chromium	0.27	(0.06)	0.11	(0.022)
Lead	0.10	(0.02)	0.09	(0.017)
Nickle	0.90	(0.19)	0.64	(0.13)
Zinc	0.85	(0.18)	0.36	(0.08)
Aluminum	2.90	(0.60)	1.19	(0.25)
Iron	0.79	(0.16)	0.40	(0.09)

§ 466.23 New source performance standards.

Any new source subject to this subpart must achieve the following new source performance standards.

(a) There shall be no discharge of process wastewater pollutants from metal preparation operations.

(b) The discharge of process wastewater pollutants from all porcelain enameling coating operations shall not exceed the values set forth below:

SUBPART B.—NSPS

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Mg/m² (pounds per million ft²) of area coated			
Chromium	0.24	(0.05)	0.10	(0.02)
Lead	0.07	(0.013)	0.06	(0.012)
Nickel	0.35	(0.08)	0.24	(0.05)
Zinc	0.65	(0.14)	0.27	(0.06)
Aluminum	1.93	(0.4)	0.79	(0.17)
Iron	0.79	(0.16)	0.40	(0.09)
Oil and grease	6.36	(1.31)	6.36	(1.31)
TSS	9.54	(1.95)	7.00	(1.44)
pH	(1)	(1)	(1)	(1)

[1] Within the range 7.5 to 10.0 at all times.

§ 466.24 Pretreatment standards for existing sources.

(a) Except as provided in 40 CFR § 403.7 and § 403.13, any existing source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for existing sources.

(1) There shall be no discharge of process wastewater pollutants from metal preparation operations.

(2) The discharge of process wastewater pollutants from all porcelain enameling coating operations shall not exceed the values set forth below:

SUBPART B.—PSES

Pollutant or pollutant property	Maximum for any 1 day	Maximum for monthly average
	Milligrams per liter (mg/l)	
Chromium	0.42	0.17
Lead	0.15	0.13
Nickel	1.41	1.00
Zinc	1.33	0.56

(b) In cases when POTW find it necessary to impose mass pretreatment standards the following equivalent mass standards are provided.

(1) There shall be no discharge of process wastewater pollutants from metal preparation operations.

(2) The discharge of process watewater pollutants from all porcelain enameling costing operations shall not exceed the values set forth below:

SUBPART B.—PSES

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Metric units—mg/m² (English Units—pounds per million ft²) of area coated			
Chromium	0.27	(0.06)	0.11	(0.022)
Lead	0.10	(0.02)	0.09	(0.017)
Nickel	0.90	(0.19)	0.64	(0.13)
Zinc	0.85	(0.18)	0.36	(0.08)

§ 466.25 Pretreatment standards for new sources.

Except as provided in 40 CFR 403.7, any new source subject to this subpart which introduces pollutants into a publicy owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources.

(a) There shall be no discharge of process wastewater pollutants from metal preparation operations.

(b) The discharge of process wastewater pollutants from all procelain enameling coating operations shall not exceed the values set forth below:

SUBPART B.—PSNS

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Mg/m² (pounds per million ft²) of area coated			
Chromium	0.24	(0.05)	0.10	(0.02)
Lead	0.07	(0.02)	0.06	(0.012)
Nickel	0.35	(0.08)	0.24	(0.05)
Zinc	0.65	(0.14)	0.27	(0.06)

§ 466.26 [Reserved]

Subpart C—Aluminum Basis Material Subcategory

§ 466.30 Applicability; description of the aluminum basis material subcategory.

This subpart applies to discharges to waters of the United States and introductions of pollutants into publicly owned treatment works from porcelain enameling of aluminum basis materals.

§ 466.31 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable:

SUBPART C.—BPT EFFLUENT LIMITATIONS

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Metal preparation	Coating operation	Metal preparation	Coating operation
	Metric units—mg/m² of area processed or coated			
Chromium	16.34	6.32	6.63	2.56
Lead	5.84	2.26	5.06	1.96
Nickel	54.85	21.21	38.90	15.04
Zinc	51.73	20.01	21.79	8.43
Aluminum	176.98	68.44	72.35	27.98
Iron	47.85	18.50	24.51	9.48
Oil and grease	777.92	300.84	466.76	108.50
TSS	1,594.74	616.68	777.92	300.82
pH	(1)	(1)	(1)	(1)
	English units—pounds per 1 million ft² of area processed or coated			
Chromium	3.35	1.30	1.37	0.53
Lead	1.20	0.47	1.04	0.40
Nickel	11.24	4.35	7.97	3.08
Zinc	10.6	4.10	4.46	1.73
Aluminum	36.25	14.02	14.82	5.73
Iron	9.80	3.79	5.02	1.94
Oil and grease	159.33	61.61	95.60	36.97
TSS	326.62	126.33	159.33	61.61
pH	(1)	(1)	(1)	(1)

(1) Within the range 7.5 to 10.0 at all times.

§ 466.32 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable.

Except as provided in 40 CFR 125.30–125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable.

SUBPART C.—BAT EFFLUENT LIMITATIONS

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Metal preparation	Coating operation	Metal preparation	Coating operation
	Metric units—mg/m² of area processed or coated			
Chromium	16.34	0.27	6.62	0.11
Lead	5.84	0.10	5.06	0.09
Nickel	54.85	0.90	38.90	0.64
Zinc	51.74	0.85	21.79	0.36
Aluminum	176.98	2.9	72.35	1.19
Iron	47.85	0.79	24.51	0.40
	English units—pounds per 1 million ft² of area processed or coated			
Chromium	3.35	0.06	1.36	0.022
Lead	1.20	0.02	1.04	0.02
Nickel	11.24	0.19	7.97	0.13
Zinc	10.60	0.18	4.46	0.08
Aluminum	36.25	0.60	14.82	0.25
Iron	9.80	0.16	5.02	0.09

§ 466.33 New source performance standards.

Any new source subject to this subpart must achieve the following new source performance standards:

SUBPART C.—NSPS

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Metal preparation	Coating operation	Metal preparation	Coating operation
	Metric units—mg/m² of area processed or coated			
Chromium	1.29	0.24	0.52	0.1
Lead	0.35	0.07	0.32	0.05
Nickel	1.91	0.35	1.29	0.24
Zinc	3.55	0.65	1.46	0.27
Aluminum	10.53	1.93	4.31	0.79
Iron	4.28	0.79	2.19	0.40
Oil and grease	34.73	6.36	34.73	6.36
TSS	52.1	9.54	38.21	7.00
pH	(1)	(1)	(1)	(1)
	English units—pounds per 1 million ft² of area processed or coated			
Chromium	0.27	0.05	0.11	0.02
Lead	0.07	0.013	0.07	0.012
Nickel	0.39	0.08	0.27	0.05
Zinc	0.73	0.14	0.3	0.06
Aluminum	2.16	0.4	0.89	0.17
Iron	0.88	0.16	0.45	0.09
Oil and grease	7.12	1.31	7.12	1.31
TSS	10.67	1.96	7.83	1.44
pH	(1)	(1)	(1)	(1)

(1) Within the range 7.5 to 10.0 at all times.

§ 466.34 Pretreatment standards for existing sources.

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for existing sources.

SUBPART C.—PSES

Pollutant or pollutant property	Maximum for any 1 day	Maximum for monthly average
	Milligrams per liter (mg/l)	
Chromium	0.42	0.17
Lead	0.15	0.13
Nickel	1.41	1.00
Zinc	1.33	0.56

(b) In cases when POTW find it necessary to impose mass pretreatment standards the following equivalent mass standards are provided:

SUPART C.—PSES

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Metal preparation	Coating operation	Metal preparation	Coating operation
	Metric units—mg/m² of area processed or coated			
Chromium	16.34	0.28	6.62	0.11
Lead	5.84	0.10	5.06	0.09
Nickel	54.85	0.90	38.9	0.64
Zinc	51.74	0.85	21.79	0.36
	English units—pounds per 1 million ft² of area processed or coated			
Chromium	3.35	0.06	1.36	0.022
Lead	1.20	0.02	1.04	0.017
Nickel	11.24	1.19	7.97	0.13
Zinc	10.6	0.18	4.46	0.08

§ 466.35 Pretreatment standards for new sources.

Except as provided in 40 CFR 403.7, any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources.

SUBPART C.—PSNS

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Metal preparation	Coating operation	Metal preparation	Coating operation
	Metric units—mg/m² of area processed or coated			
Chromium	1.29	0.24	0.52	0.1
Lead	0.35	0.07	0.32	0.06
Nickel	1.91	0.35	1.29	0.24
Zinc	3.55	0.65	1.46	0.27
	English units—pounds per 1 million ft² of area processed or coated			
Chromium	0.27	0.05	0.11	0.02
Lead	0.07	0.013	0.07	0.02
Nickel	0.39	0.08	0.27	0.05
Zinc	0.73	0.14	0.3	0.06

§ 466.36 [Reserved]

Subpart D—Copper Basis Material Subcategory

§ 466.40 Applicability; description of the copper basis material subcategory.

This subpart applies to discharges to waters of the United States and introductions of pollutants into publicly owned treatment works from porcelain enameling of copper basis materials.

§ 466.41—466.42 [Reserved]

§ 466.43 New source performance standards.

Any new source subject to this subpart must achieve the following new source performance standards:

SUBPART D.—NSPS

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Metal preparation	Coating operation	Metal preparation	Coating operation
	Metric units—mg/m² of area processed or coated			
Chromium	2.23	0.24	0.90	0.1
Lead	0.60	0.07	0.54	0.06
Nickel	3.31	0.35	2.23	0.24
Zinc	6.13	0.65	2.53	0.27
Aluminum	18.21	1.93	7.46	0.79
Iron	7.4	0.79	3.79	0.40
Oil and grease	60.1	6.36	60.1	6.36
TSS	90.15	9.54	66.11	7.0
pH	(1)	(1)	(1)	(1)
	English units—pounds per 1 million ft² of area processed or coated			
Chromium	0.46	0.05	0.19	0.02
Lead	0.13	0.013	0.11	0.012
Nickel	0.68	0.08	0.46	0.05
Zinc	1.26	0.14	0.52	0.06
Aluminum	3.73	0.4	1.53	0.17
Iron	1.52	0.16	0.78	0.09
Oil and grease	12.31	1.31	12.31	1.31
TSS	18.47	1.96	13.54	1.44
pH	(1)	(1)	(1)	(1)

[1] Within the range 7.5 to 10.0 at all times.

§ 466.44 [Reserved]

§ 466.45 Pretreatment standards for new sources.

Any new source subject to this subpart which introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and achieve the following pretreatment standards for new sources:

SUBPART D.—PSNS

Pollutant or pollutant property	Maximum for any 1 day		Maximum for monthly average	
	Metal preparation	Coating operation	Metal preparation	Coating operation
	Metric units—mg/m² of area processed or coated			
Chromium	2.23	0.24	0.90	0.1
Lead	0.6	0.07	0.54	0.06
Nickel	3.31	0.35	2.53	0.28
Zinc	6.13	0.65	2.53	0.28
	English units—pounds per 1 million ft² of area processed or coated			
Chromium	0.46	0.05	0.19	0.02
Lead	0.13	0.013	0.11	0.012
Nickel	0.68	0.08	0.46	0.05
Zinc	1.26	0.14	0.52	0.06

§ 466.46 [Reserved]

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Part III

Environmental Protection Agency

Pesticides Registration; Proposed Data Requirements

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 158

[OPP-30063; PH-FRL 2147-4]

Pesticides Registration; Proposed Data Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Part 158 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. The submitted data and information enable EPA to make regulatory judgements with respect to the safety of each pesticide proposed for registration or experimental use. Part 158 will provide pesticide registrants with explicit instructions concerning the data requirements and therefore enable more efficient pesticide development and registration.

DATE: Written comments on this proposed rule, identified by the document control number "[OPP-30063]" must be received on or before (*insert date 90 days after date of publication in the* Federal Register).

ADDRESS: Submit written comments to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St. SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Frederick S. Betz, Hazard Evaluation Division (TS-769), Office of Pesticide Programs, Environmental Protection Agency, Rm 821A, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-7351).

SUPPLEMENTARY INFORMATION:

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 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

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 include 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 to reorganize the guidelines and limit the regulation to a concise presentation of the data requirements and when they are required. Therefore, data requirements for pesticide registration pertaining to all former subparts of the guidelines are now specified in Part 158. 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., Guidelines) is available as an advisory document through the National Technical Information Service (NTIS).

For the convenience of the reader, the following redesignation table provides a cross reference from the data requirements appearing in each proposed subpart or public draft of the guidelines (as of October 1981) to the data requirements as they are presented in Part 158.

REDESIGNATION TABLE

Old guidelines subpart (title, source, data)	Old sections	New subpart (title)	New sections (regulatory)	Guidelines reference (non-regulatory)
Subpart A (Reserved)	163 thru 163.69	None	None	None
Subpart B (Introduction to the Guidelines, Proposed Rule, July 10,1978).	163.40-1 thru 163.40-6	Subpart A (General Provisions)	158.20 thru 158.85	None.
Subpart C (Registration Procedures, Proposed Rule, Sept. 8, 1975).	163.50 thru 163.56	None	None	None.
Subpart D (Chemistry Requirements: Product Chemistry, Public Draft, May 9, 1980).	163.61-1 thru 163.61-9	Subpart B (Registration Data Requirements).	158.110 and 158.120	61-1 thru 65-1.
Subpart E (Hazard Evaluation: Wildlife and Aquatic Organisms, Public Draft, Mar. 7 1980).	163.71 thru 163.72-7	Subpart B (Registration Data Requirements).	158.145	71-1 thru 72-7.
Subpart F (Hazard Evaluation: Humans and Domestic Animals, Proposed Rule, Aug. 22, 1978).	163.81 thru 163.86-1	Subpart B (Registration Data Requirements).	158.135	81-1 thru 86-1.
Subpart G (Product Performance Public Draft, June 22, 1979).	163.91 thru 163.96-19	Subpart B (Registration Data Requirements).	158.160	91-2 thru 96-19.
Subpart H (Labeling Requirements for Pesticides and Devices, Public Draft, Aug. 27, 1981).	163.100 thru 163.106	None (to be published later as a separate Part).	None	100-1 thru 106.
Subpart I (Experimental Use Permits, Public Draft, June 22, 1979).	163.112-1 thru 163.112-6	Subpart B (Registration Data Requirements).	158.120 thru 158.165	112-1 thru 112-6.
Subpart J (Hazard Evaluation: Nontarget Plants, Proposed Rule, Nov. 3, 1980).	163.121-1 thru 163.126-4	Subpart B (Registration Data Requirements).	158.150	121-1 thru 124-2.
Subpart K (Exposure Data Requirements: Reentry Protection, Public Draft, May 4, 1981).	163.132-1 thru 163.133-4	Subpart B (Registration Data Requirements).	158.140	132-1-133-4.
Subpart L (Hazard Evaluation: Nontarget Insects, Public Draft, May 9, 1981).	163.141-1 thru 163.143-3	Subpart B (Registration Data Requirements).	158.155	141-1-143-3.
Subpart M (Biorational Pesticides, Public Draft, Sept. 29, 1980).	163.151-10 thru 163.155-20	Subpart B (Registration Data Requirements).	158.165	151-1-155-20.
Subpart N (Chemistry Requirements Environmental Fate, Public Draft, Oct. 3, 1980).	163.161-1 thru 163.165-4	Subpart B (Registration Data Requirements).	158.130	161-1-165-5.

REDESIGNATION TABLE—Continued

Old guidelines subpart (title, source, data)	Old sections	New subpart (title)	New sections (regulatory)	Guidelines reference (non-regulatory)
Subpart O (Chemistry Requirements: Residue Chemistry, Previously Unpublished).	None	Subpart B (Registration Data Requirements).	158.125	171-2 thru 171-7.
Subpart P (Disposal Data Requirements Reserved).	None	None (to be published later as a separate part).	None	None.
Subpart Q (Good Laboratory Practices, Proposed Rule, Apr. 18, 1980).	163.190-1 thru 163.199-2	None (to be published later as a separate part).	None	190-1 thru 199-2.

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 OPTS Reading Room E-107, 401 M St. SW., Washington, D.C. 20460, from 8:00 a.m. to 4:00 p.m., Monday through Friday, except holidays.

III. Organization and Philosophy of Part 158

The data requirements for registration presented in Part 158 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.

Part 158 consists of two Subparts, A and B. Subpart A contains the general provisions and policies pertaining to the registration data requirements. Section 158.25 of Subpart A explicitly details the applicability of the data requirements to registrants of pesticide products. 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 biorational pesticides (§ 158.65) acceptable protocols (§ 158.70), requirements for additional data (§ 158.75), acceptability of data (§ 158.80), revisions of requirements and guidelines (§ 158.85).

Subpart B contains the data requirements (§ 158.100), a discussion of their purposes (§ 158.105), and a discussion of the organization of the guidelines with respect to the data requirements (§ 158.115). Sections 158.120 through 158.165 of Subpart B contain the data requirements for each subject area corresponding to each subdivision of the guidelines. Each of these sections states the kinds of data that are required to support a pesticide registration application or experimental use permit. Each data requirement is specified as being required, conditionally required, or not required, depending on the general use pattern intended for the pesticide product being sought for registration, the physical and chemical properties of the product, expected human and environmental exposure, and/or results of previous testing. These §§ 158.120 through 158.165 also specify the substance to be tested in developing data to support the registration of pesticide products.

IV. Request for Comments

As specified in the redesignation table at I.B. of this preamble, most of the data requirements for the registration of pesticides have already been publicly reviewed. As a result, the Agency has already received numerous public comments and has revised the data requirements, as appropriate, during the past several years. Nevertheless, the Agency welcomes public comment on all the data requirements at this time.

The Agency particularly requests comments on those data requirements that have not previously received public review and comment (i.e., Residue Chemistry requirements) and those data requirements that have been revised, added or deleted as discussed in V.A. through V.K.

The Agency realizes that an efficient waiver policy is essential in order to appropriately specify all the data requirements for the registration or reregistration of each pesticide product. Therefore, the Agency requests public comment on whether the waiver policy set forth in § 158.45 is sufficiently detailed.

The Agency requests comments on the need for and methodology for establishment of reentry intervals, or other methods to protect fieldworkers from deleterious eye effects or dermal irritation or sensitization effects that may be caused by pesticide residues.

The Agency requests public comment on the definition of biorational pesticides presented at § 158.65, particularly with respect to the biochemical pest control agents and the data requirements for these agents as presented in § 158.165. The Agency also is soliciting public comment on its use of the term "biorational" to describe microbial and biochemical pest control agents and would welcome recommendations for an alternative term, if appropriate.

The Agency requests public comment on an alternative approach to presenting the data requirements for Product Chemistry. In addition to listing the data requirements, as in § 158.120, the Agency is considering a separate regulation for product chemistry as a detailed supplement to Part 158. This separate regulation would provide an in-depth description of the types of information that must be submitted in the areas of product identity and composition, and analysis and certification of product ingredients. Therefore, the Agency is soliciting comment on whether the product chemistry requirements presented in Part 158 provide sufficient detail, or whether a detailed regulation would be preferable.

Finally, the mutagenicity requirements proposed by the Agency in 1978 received considerable public comment. In light of these comments and the numerous developments in this field since then, the Agency has, in this proposal, sought to achieve a more flexible approach to specifying the mutagencity requirements than was proposed in 1978. Therefore, the Agency is soliciting further public comment on the current proposal which is described in V.E. of this preamble and specified in §§ 158.105 and 158.135. In order to ensure that this proposal receives a comprehensive review and consideration by the public, the Agency also seeks comment on the specific kinds of tests that could be conducted to fulfill the requirements in this part. The Agency also invites comment on how specific or nonspecific Part 158 should be regarding the acceptability of the various tests available. These tests will be published as a part of the Guidelines through the National Technical Information Service (NTIS). For each test substance, a battery of tests is required to assess the potential to cause gene mutations, structural chromosome aberrations or other genotoxic effects as listed below. It is recognized that more than one endpoint may be covered by a single test, e.g., combination of gene and chromosome aberration and sister

chromatid exchange in mammalian cells in culture.

1. *Gene mutation tests.* (i) Microorganisms: Bacteria, Eucaryotic microorganisms.

(ii) Submammalian organisms: sex-linked recessive lethal: Drosophila melanogaster.

(iii) Mammalian cells in culture, forward or reverse mutations at specific loci.

(iv) Mammals, specific locus.

2. *Structural Chromosome aberration tests.* (i) Eucaryotic microorganisms, mitotic segregation.

(ii) Submammalian organisms: Drosopohila chromosome tests.

(iii) Mammalian cells in culture: Sister chromatid exchange, Cytogenetic analysis.

(iv) Mammals: Micronucleus test, sister chromatid exchange, cytogenetic analysis, dominant lethal, heritable translocation.

3. *Tests for other genotoxic effects.* (i) DNA damage and repair: Differential toxicity in bacteria, mitotic recombination/gene conversion in eucaryotic microorganisms, unscheduled DNA synthesis (mammalian cells in culture or mouse), DNA alkaline elution, sister chromatid exchange.

(ii) Numerical chromosomal aberrations: (a) Eucaryotic microorganisms, mitotic segregation, (b) Mitotic interference: (whole mammals or cells in culture), (c) Micronucleus test (whole mammals or cells in culture).

(iii) Mammalian cells transformation: (Cells in culture).

(iv) Target organ/cell analysis: (a) Sperm morphology, (b) DNA synthesis inhibition, (c) DNA alkylation.

V. Summary of the Major Changes in the Data Requirements for Registering Pesticides

Part 158 is, for the most part, a compilation of all the data requirements previously specified in proposed rules (in the case of the requirements formerly found in Subparts F and J) or in the most recent public draft of guidelines subparts (in the case of the requirements formerly found in draft Subparts D, E, G, I, K, L, M, N,). However, Part 158 does reflect some major changes in certain data requirements, and these changes are summarized in the following paragraphs. This discussion is limited to changes that are major, such as the addition or deletion of data requirements, or changes that significantly affect the cost of testing or the number of registrants required to perform the testing.

A. General

The Agency is proposing to revise certain test substance requirements and bring them in line with current Agency policy. Data requirements for which the substance to be tested was formerly specified as technical grade of the active ingredient may now be fulfilled using the technical grade or a material considered representative of the technical grade of the active ingredient. This flexibility is possible since the level of impurities in technical material may usually vary without being expected to show variation in test results.

This change provides the registrant with more flexibility in selecting the test substance. This added flexibility would be important if, as may be the case with a new pesticide, testing is to be conducted before the technical grade material is available from the production plant. In this situation, a representative technical grade of the active ingredient would consist of a product containing the registrant's estimate of the technical product composition (including impurities) that he intends to manufacture. This change will provide needed flexibility in that it (1) will allow testing before the technical grade material is available from the production plant, (2) can accommodate changes in the production process or variability in raw materials or (3) will permit the Agency to use data from a scientific standpoint to predict effects from several substantially similiar technical products produced by different manufacturers.

The concept of a representative technical grade would also be useful where there are two or more technical products containing the same active ingredient which are subject to defensive data requirements. In this situation, if the Agency determines the products are all sufficiently similar to each other, then a single representative technical grade product could be selected and tested as required. Test results could then be applied to the other products and this would avoid the need to conduct separate tests on each product.

B. Product Chemistry

Since the most recent public draft, dated May 9, 1980, the existing data requirements for Product Chemistry have been reorganized and renumbered as specified in the redesignation table at I.B.

The Agency has been considering use of a battery of in vitro microbial assays (e.g., "Ames" test, DNA repair test in E. coli, Prophage induction test, and mitotic recombination test) to screen pesticide products for the presence of potentially genotoxic low level components (e.g., present at less than 1,000 ppm). However, the Agency is concerned about the number of false positive and/or false negative results typically generated by these assays and therefore is concerned about the overall validation of this battery of tests and its ability to achieve its intended purpose. Therefore, the Agency has withdrawn the requirement to conduct biological screening tests at this time. Instead, the Agency is proposing that all impurities occurring in manufacturing-use products or end-use products in quantities greater than 0.1 percent of the product (by weight) be identified. In addition, the Agency will require further chemical analysis on a case-by-case basis when the manufacturing process or other product chemistry data suggests the presence of low level, yet highly toxic, impurities. The Agency solicits comments on these issues.

C. Residue Chemistry

The Agency has required the submittal of residue chemistry data since 1970. These requirements are based largely on the FDA non-regulatory guidelines issued in 1968. As a result, the Agency did not formulate the data requirements as a subpart of the guidelines as it did for other disciplines such as toxicology (Subpart F) or environmental fate (Subpart N). For completeness, Part 158 now includes the residue chemistry data requirements, as well as instructions as to when these data are required and what test substance should be used. The methods for developing these data are presented in the guidelines for registering pesticides, to be published by the National Technical Information Service (NTIS). The data requirements are presented in § 158.125 and are summarized below:

1. Chemical identity.
2. Directions for use.
3. Nature of the residues (plants, livestock).
4. Residue analytical method.
5. Magnitude of the residue.
6. Reduction of residue.
7. Proposed tolerance.
8. Reasonable grounds in support of the petition.

D. Environmental Fate

Several major changes have been incorporated since the most recent public draft of the Environmental Fate data requirements, dated October 3, 1980.

The requirement for pesticide photodegradation studies in air,

§ 158.130 (formerly § 163.161–4) has been modified to delete the waiver for pesticides with vapor pressure less than 1 x 10–7 torr and replaced with a provision for requiring the data on a case-by-case basis (refer to § 158.130). This change ensures that the data are required only in situations when the pesticide product and its use pattern indicate potential for significant human exposure.

Data requirements pertaining to the effects of microbes on pesticides (formerly § 162.162–5), the effects of pesticides on microbes (formerly § 162.162–6) and activated sludge metabolism studies (formerly § 163.162–7) have been deleted pending development of properly designed and validated protocols from which useful regulatory conclusions can be drawn regarding the role of microbes in the overall environmental fate of pesticides.

Data requirements for adsorption/desorption studies § 158.130 (formerly § 163.163–2) have been merged with the leaching studies § 158.130 (formerly § 163.163–1). With certain limitations, the Agency now provides the applicant the choice of conducting either an adsorption/desorption (batch equilibrium) study or a laboratory leaching study. Volatility studies § 158.130 (formerly § 163.163–3) have been split into two separate requirements, one pertaining to lab studies and the other pertaining to field studies. The requirement for both volatility studies has been modified to delete the waiver for pesticides with vapor pressure less than 1 x 10–7 torr and replaced with a provision for requiring the data on a case-by-case basis (refer to § 158.130). This change ensures that the data are required only in situations when the pesticide product and its use pattern indicate potential for significant human exposure.

The requirement for specialized aquatic studies has been incorporated into the requirements for field dissipation studies for aquatic uses at § 158.130 (formerly 163.164–3).

The requirement for dissipation studies of combination products and tank mixes § 158.130 (formerly § 163.164–5) will be imposed only on a case-by-case basis, rather than for all products intended for use as components in tank mixtures. This change ensures that the data will be required only when there is a likelihood that the presence of one pesticide would influence the environmental fate of another pesticide.

The data requirement for accumulation studies on rotational crops § 158.130 (formerly § 163. 165–1) has been split into two requirements, one pertaining to confined studies and the other pertaining to field studies. The Agency has also redefined the criteria relative to the significance of $_{c}14$ residues detected in the confined study test crops, that in turn determines if a field accumulation study will be required. In addition, under the provisions of a January 13, 1981, Agency policy statement entitled "Tolerance for Pesticide Residues in Rotational and Follow-up crops, Meat, Milk, Poultry and Eggs, and for other Indirect or Inadvertent Residues" the registration applicant now has the option of requesting tolerances for pesticide residues resulting from crop rotations or crop replacement practices in lieu of requesting a rotational crop label restriction.

Also, the Agency has established criteria for when laboratory (flowthrough) accumulation studies in fish are required. The criteria are the same as those specified for similar tests in the nontarget organisms data requirements. They stipulate that these studies are 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. In addition, the Agency has deleted the requirements for a static (catfish) laboratory accumulation study based on public comments citing difficulties in performing the test and in interpreting the data from these studies.

E. Toxicology

The toxicology data requirements presented in § 158.135 are quite similar to those specified in proposed Subpart F dated August 22, 1978. However, some major changes have been incorporated which pertain to mutagenicity testing requirements and the recommended test species and test duration for certain other studies.

The non-rodent subchronic feeding study proposed in Subpart F § 158.135 (formerly § 163.82–1) stipulated a 6-month test duration. Also, the chronic feeding study, § 158.135 (formerly § 163.83–1) was to be conducted with at least one mammalian species (usually the rat) for a period of 24 months (for the rat). In Part 158, however, the Agency no longer requires the 6-month non-rodent study.

Instead, the Agency now proposes that two mammalian species (one rodent, one non-rodent) be tested in the chronic study. The rodent study would be of approximately 24 months duration, the majority of the expected life span of the strain. A 12-month test duration would be sufficient for the non-rodent chronic study. The Agency reiterates that the 3-month subchronic studies will be required to support temporary tolerances and experimental use permits. These changes were made because the Agency now believes that the 3-month studies are the most appropriate for assessing subchronic effects, and that 12- and 24-month studies are more appropriate than the 6- and 24-month studies for assessing chronic effects. The Agency now believes that the 24-month chronic study is consistent with its policy concerning food-use pesticides, and this is based on the Agency's experience in reviewing data from chronic feeding studies in rodents. The Agency will accept 12-month chronic data in rodents for non-food use pesticides and 12-month chronic data in non-rodents. This policy, the Agency believes, will satisfactorily harmonize its guidelines with those published by other federal governmental agencies and international groups (OECD) as well as provide scientifically defensible data to assess the chronic effects of a pesticide.

The Agency believes that conducting oncogenic and chronic feeding studies is valuable for several reasons. The oncogenicity study focuses on the detection of malignant and benign tumors and preneoplastic lesions. The chronic feeding study is designed primarily to evaluate other chronic effects. EPA thinks that the time periods are long enough to allow tumors and other chronic effects to develop, yet short enough to assure that a reasonable percentage of the animals will survive to the scheduled termination point. In addition, since neoplastic growths can be detected in both chronic and oncogenic studies, they are designed so that geriatric diseases will not make diagnosis of these neoplastic growths difficult. Thus the proposed durations are also designed to produce meaningful histology by terminating the studies before such disease normally becomes a significant problem.

Major changes have been made in the requirement for mutagenicity testing, § 158.135 (formerly § 163.84–1) in order to keep up with the continually expanding testing technology, to bring the requirements into line with current Agency practice, and in response to recommendations from the former FIFRA Scientific Advisory Panel. For each test substance, a battery of tests is required to assess the potential to cause gene mutations, structural chromosome aberrations or other genotoxic effects. The objectives of mutagenicity testing are sensitive screening, establishment of relevance to mammals, and when

mutagenic activity is found, assessment of heritable risk and other relevant health risks. The battery will be designed with the nature of the test substance in mind and the selection of tests within the battery should be justified.

In the multigeneration reproduction study, § 158.135 (formerly § 163.83–4) the duration of feeding the parents has been shortened from 100 days to a range of 56 to 70 days, the minimum dosage period required to ensure pesticide exposure at all stages of germ cell development.

F. Reentry Protection

The requirements for data relating to human exposure in buildings and other enclosures have been withdrawn at the recommendation of 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 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 and the Agency will develop other requirements that address interior use patterns.

G. Plant Protection

Proposed Subpart J published in the **Federal Register** of November 3, 1980 (45 FR 72948) contained Tier I data requirements for nontarget area plant studies, § 158.150 (formerly §§ 163.122–1 through 163.122–3) to support the registration of all products intended for outdoor pesticide application. The Agency is now proposing in Part 158 that these data generally not be required except in instances when warranted on a case-by-case basis, as specified in § 158.150. This change is based on the Agency's perception that registrants routinely conduct extensive testing to assess the phytotoxicity of their products on their own, either to assess efficacy (in the case of herbicides), and/or to develop appropriate use instructions and precautionary labeling in order to ensure that their products do not impart any determental effects (particularly on crops, ornamentals and other desirable plants) for which they could be liable.

Upon evaluation of public comments, the Agency decided to withdraw the requirement for plant mutagenicity testing, § 158.150 (formerly §§ 163.122–3 and 163.124–3) until further validation studies can be performed to more fully evaluate the usefulness of this type of testing.

All field studies specified in the proposed rule have been combined, and now appear in the Tier III testing level in § 158.150 (formerly §§ 163.124–1, 163.124–2, 163.125–1, and 163.125–2).

All testing of microorganisms has been removed from Part 158, including the requirement for studies to determine nitrogen fixation potential, § 158.150 (formerly §§ 163.125–3). These data requirements will be considered for inclusion later as a separate discipline.

The requirement for studies on readily sorbed materials (formerly § 163.125–4) has been deleted because the Agency believes that this kind of exposure data can be determined from studies obtained from other data requirements. Also, studies to evaluate spray drift specified under special testing in the proposed rule (formerly §§ 163.126–1 through 163–126–4) have been deleted from Part 158 at this time, and will be considered for inclusion later as a separate discipline.

H. Nontarget Insects

The most recent public draft of this subpart, dated May 9, 1980 contained the requirement for a honey bee subacute feeding study specified in § 163.141–4 and requirements for testing aquatic invertebrates in §§ 163.141–1, 163.141–2 and 163.141–3. These requirements have been designated as reserved in Part 158, and will not be reproposed as a requirement until the Agency has had further opportunity to evaluate the methodology and the conditions under which this data would be required.

I. Product Performance

As previously discussed, in 1979 the Agency issued regulations implementing several important provisions of the 1978 FIFRA amendments. Among the provisions implemented was the efficacy data waiver authority provided by FIFRA section 3(c)(5) under 40 CFR Part 162 published in the **Federal Register** of May 11, 1979 (44 FR 27933). The Agency defined in § 162.18–2(D) the circumstances when efficacy data were required to be submitted as a matter of course. Other requirements that efficacy data be submitted were generally waived.

The Agency is proposing in the Regulations for Registration, Reregistration and Classification Procedures, under 40 CFR Part 162, Subpart A, to extend the efficacy data waiver to additional use patterns, and it will include all registration actions, both conditional and unconditional. As stated in its previous waiver, the Agency's primary mandate under FIFRA is to evaluate the health and safety aspects of pesticides. Experience under the previous waiver policy indicates that there have been few complaints to the Agency of non-efficacious products being marketed, and the Agency is confident that its efficacy data waiver has occasioned little, if any, serious user dissatisfaction.

Those products for which an efficacy data requirement was continued in 1979 were products which, if they lacked efficacy, could potentially have significantly public health effects, such as mosquito control products, rodenticides, certain other invertebrate and vertebrate control agents, and antimicrobial products. The Agency now believes that because many of the "public health" use patterns identified at that time are more of an aesthetic and nuisance problem than one of public health and are in any case adequately covered by other regulatory mechanisms offering assurance that the products are efficacious, and because the efficacy of products for other of these uses are adequately discernible by the user, marketing of inefficacious products is unlikely. The public health authorities of states and localities, for example, have the experience to determine the efficacy of products used for rodent control. Mosquito control districts offer similar expertise with respect to mosquito control products.

State pesticide regulatory Agencies continue to require efficacy data to evaluate the pesticide under conditions of use within the State. The State Cooperative Extension Services use such data in making recommendations to growers within the State. Efficacy data are particularly important to States in administering registrations for special local needs under FIFRA section 24(c), and in determining suitable pesticides for use under the emergency exemption provisions of FIFRA section 18.

The Agency is proposing to extend its current waiver to efficacy data for all uses of pesticides except those where control cannot reasonably be observed or determined by the user and lack of control is a clear adverse health effect. Efficacy data would continue to be required for products bearing claims for control of 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, and for products claiming control of mycotoxin-producing fungi. All other efficacy data requirements would normally be waived. The specific uses that require efficacy data are specified in this subpart in § 158.160 with references to the testing methodology

and protocols in Subdivision G—Product Performance.

The Agency expects and believes that registrants will ensure that their products are efficacious when used in accordance with label directions and commonly accepted pest control practices. Under the statute, the registrant still has the responsibility to insure that a product satisfies its label claims. The Agency would take corrective action on a product including, when necessary, enforcement or cancellation actions, since the registrants must still comply with the law. In addition, pesticide producers are aware that they are potentially subject to damage suits by the user community if their products prove ineffective in actual use. Such litigation can be damaging to the company's reputation and future sales. It is in a company's own best interest to continue high quality efficacy data development and to market only products demonstrated to be effective.

Under this proposal, the Agency retains the right to require the submission of efficacy test data or other evidence, on a case-by-case basis, for any pesticide product, registered or proposed for registration, for which a lack of efficacy has been reported, for evaluation of product benefits when product risks are substantial, or when other factors exist which make submission of such data necessary or desirable to support the presumption that it is efficacious. If there is evidence (such as a significant rise in complaints from user groups, scientific societies, trade associations, or the general public) to establish that this regulatory relief policy is being abused, the Agency would reconsider its waiver policy. The Agency is building links to these various organizations that are knowledgeable of efficacy matters through an efficacy surveillance network. Also, the Agency is actively pursuing the establishment of formal relations with various Departments, such as the U.S. Department of the Interior's Fish and Wildlife Laboratory in Denver to conduct rodenticide surveillance, and with professional organizations such as the National Pest Control Association and the American Hospital Association to aid in efficacy evaluation when the surveillance network or other sources indicate the need.

J. Biorational Pesticides

A public draft of the guidelines for registering biorational pesticides was made available on September 29, 1980. Several requirements have been deleted or shifted into higher testing tiers in Part 158. Also, two conditional data requirements have been deleted as specified below.

As with product chemistry requirements for conventional pesticides, the biological screening tests to detect potentially genotoxic low level impurities has been withdrawn.

Mutagenicity testing for biochemicals has been revised to include only microbial assays in Tier I. The requirement for the mammalian assays has been deferred until Tier II. The Tier II oncogenicity study (formerly § 163.152–19) has been deleted; this study is now only required under Tier III testing. These changes were made in order to improve the efficiency of the testing scheme and to ensure that it functions as a tier system rather than a battery of tests.

A requirement to report any hypersensitivity incidents during production or use had been inadvertently omitted and therefore was added to the Tier I data requirements for microbial agents. Also, a requirement was added for conducting mammalian mutagenicity assays at Tier II for microbial agents in order to improve the efficiency of the tier testing scheme.

Three Tier III toxicology data requirements for microbial agents were determined to be duplicative and have been deleted. They are: Acute oral infectivity with bacteria, § 158.165 (formerly § 163.152–50); infectivity tests with bacteria, parenteral exposure, § 158.165 (formerly § 163.152–51); and acute inhalation infectivity with bacteria, § 158.165 (formerly § 163.152–52).

In response to the recommendation from the FIFRA Scientific Advisory Panel, the avian dietary pathogenicity test in Tier III has been deleted and replaced with the long term avian pathogenicity and reproduction tests which formerly appeared in Tier IV. This change condenses the nontarget organism tier testing scheme from five tiers to four (including environmental fate and expression testing at Tier II), and is now more consistent with the organization of the toxicology tier testing scheme.

K. Experimental Use Permits

Guidelines detailing the data required to support an experimental use permit (Subpart I) were issued as a public draft dated June 22, 1979. The additions and deletions of data requirements, and other major changes discussed in V.A. through V.H. of this preamble generally apply to the corresponding requirements pertaining to experimental use permits as specified in §§ 158.120 through 158.165.

VI. Regulatory Analysis

A. Paperwork Reduction

The Office of Pesticide Programs has, as its basic function, the registration of new pesticide products and new uses of pesticide products, and the reregistration of currently registered products and uses mandated by Section 3(g) of FIFRA. 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.

Under the Paperwork Reduction Act, EPA must identify any information collection burdens which would be imposed by this proposed regulation and must obtain clearance from the OMB for any such collection activities. Obviously, the development of the data specified in Part 158 would constitute 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 II. of this Preamble.

The data requirements set forth in Part 158 have 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 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 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 annualized 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 of recordkeeping (information) provisions in this rule have been submitted for approval to the OMB under section 3504(h) of the Paperwork Reduction Act of 1980 U.S.C. 3501 et seq. Rather than submitting a single Information Clearance Request for OMB approval, which would include all occasions upon which the Agency might require development of data specified in Part 158, the Agency has submitted several Information Clearance Requests which correspond to discrete steps in developing, registering, and maintaining the registration of a pesticide. The Regulatory Impact Analysis considered the information collection burdens associated with each of these individual registration steps in estimating the total annualized cost of the information collection burden associated with Part 158. The specific Information Clearance Requests submitted to the OMB for approval include:

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.
6. Tolerence petition for pesticides on food.
7. New inert ingredient clearance request.
8. Registration standards/data call-in.
9. Registration standards bibliography.

Any final rule specifying data requirements for pesticide registration, will explain how its reporting or recordkeeping requirements respond to any OMB or public comments.

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 it has been 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 registration data requirements would have only limited impacts on formulators that do not produce basic active ingredients of pesticides because of the "formulators' exemption." 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 on 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 § 158.9, 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 cost 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.

Accordingly, I certify that this regulation does not require a separate regulatory flexibility analysis under the Regulatory Flexibility Act. (Sec. 25(B) (Pub. L. 95–396, 92 Stat. 819, 7 U.S.C. 136 *et seq.*)).

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 specially taken into account as required by section 25 of FIFRA.

VII. 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 Pesticides and Toxic Substances (OPTS) Reading Room E–107 from 8:00 a.m. to 4:00 p.m. Monday through Friday except legal holidays, 401 M St., SW., Washington, D.C. 20460. 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.

VIII. Statutory Review

In accordance with FIFRA Sec. 25, copies of an earlier draft of this regulation were submitted in June 1982 to the U.S. Department of Agriculture. The U.S. Department of Agriculture (USDA) commented on this regulation in a letter dated July 15, 1982. USDA noted that they have commented on various parts of the data requirements during the past several years and were generally pleased that many of their comments and suggestions have been adopted. However, USDA also reiterated their belief that the Agency should continue to require efficacy data for most products, and that waivers

should be granted only on a case-by-case basis. USDA therefore opposes the efficacy data waiver. EPA has stated in granting the initial efficacy data waiver its reasons for doing so published in the **Federal Register** of May 11, 1979 (44 FR 27932). The Agency's position at that time was that the marketplace could function effectively to remove ineffective products, and, in the absence of evidence to the contrary, EPA continues to hold that belief. EPA is aware of no serious problems with its existing efficacy data waiver, and therefore no persuasive reason to forgo further regulatory relief in this area. The Agency also notes that it retains the right to require submission of efficacy test data or other evidence at its discretion, such as when there is an indication that an inefficacious product is or is sought to be registered, and to take legal regulatory action against ineffective products as stated at I. of this Preamble.

Copies were also supplied 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. Comments were received from the House Committee on Agriculture, Subcommittee on Government Operations, Research and Foreign Agriculture. Each of these comments is discussed below, together with the Agency's response.

1. The Agency's proposal to allow registrants to test the pure grade of the active ingredient could preclude the Agency from knowing whether an impurity is present in the technical grade product which might affect the toxicity of the pesticide.

EPA Response: If testing of the pure grade of the active ingredient were allowed, additional testing could be required on the impurities in the technical grade product in order to assess their toxic effects. However, this approach may not be cost effective and would not address the potential for synergistic effects between impurities and the active ingredient. Therefore, EPA has modified the regulation to require testing on the technical grade or a representative technical grade of the active ingredient.

2. The Agency should propose that impurities be identified to a level low enough to have effectively identified the TCDD contamination in 2,4,5–T.

EPA Response: In order to implement this recommendation, all impurities present in quantities greater than 0.01 percent (100 ppm) and perhaps even less, would have to be identified. Based on public response to previous proposals to require this level of identification, the Agency knows that this is often technically impossible to achieve, or if achievable, it is extremely expensive, and most often is not cost effective. However, the Agency believes that if low level (<1,000 ppm) but highly toxic impurities are present, their effects may well be detected during the course of chronic and subchronic toxicology tests conducted on the technical grade of the active ingredient. Moreover, if based on the product chemistry and the nature of the chemical reactions in the manufacturing process, the Agency believes that certain highly toxic chemicals are present as impurities, it will on a case-by-case basis require chemical analysis to identify them.

3. Because the Agency proposes to delete certain spray drift requirements, the Agency's ability to ascertain environmental hazards associated with spray drift may be hampered.

EPA Response: EPA agrees and is currently working with state authorities in order to define the appropriate role for EPA in this important area.

4. The percent of pesticide development costs caused by the Part 158 requirements should be expressed in two ways: as done in the draft regulation, and on the basis of total costs less the estimated cost of building the pesticide manufacturing plant.

EPA Response: EPA agrees that plant construction is a relevant portion of the cost of developing a new pesticide and has modified the preamble to incorporate this suggestion.

5. When a data requirement is waived for one applicant, all other registrants who qualify for such a waiver should be informed, and the Agency should notify the public that it is considering such a waiver.

EPA Response: This comment pertains to waiver decisions that apply to more than one specific product and EPA has modified the regulation to incorporate this recommendation as follows. In these instances the Agency may, if appropriate, send a notice to all registrants or publish a pesticide registration (PR) notice or a notice in the **Federal Register** announcing its decision, as specified in § 158.45. Therefore, other registrants who qualify for such a waiver will normally be informed. EPA has also specifically solicited public comments on its waiver policy earlier in this preamble.

6. The Agency should explain its basis and criteria for that portion of the minor use policy which states that EPA will continue to make tolerance decisions based on assessments of actual residue intake, rather than on observations that the acceptable daily intake (ADI) has been theoretically exceeded.

EPA Response: EPA's basis and criteria for these decisions have been detailed in its policy on minor uses published in the **Federal Register** of March 5, 1979 (44 FR 12097). EPA views the ADI as a guidepost against which estimates of actual intake may be compared. When theoretical maximum intake estimates (represented by the TMRC) exceed the ADI, we understand that the ADI still may not be exceeded in reality. Actual residue levels to which the public are exposed are generally considerably lower than the theoretical maximum level, for a variety of reasons. When the ADI is theoretically exceeded, therefore, EPA attempts to estimate the actual residues which are likely to occur from the total food or feed uses of the pesticide. The Agency then makes a tolerance decision in accordance with that estimate of actual hazard, rather than on an observation that the ADI has been theoretically exceeded.

The specific comments of the U.S. Department of Agriculture and the U.S. Congress are available for review at the Agency's Office of Pesticides and Toxic Substances Reading Rm. E–107 at the address given above, and in Regional Offices of the Agency.

List of Subjects in 40 CFR Part 158

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

Dated: September 10, 1982.

Anne M. Gorsuch,

Administrator.

It is proposed that Title 40, Chapter I, be amended by adding a new Part 158 to read as follows:

PART 158—DATA REQUIREMENTS FOR REGISTRATION

Subpart A—General Provisions

Sec.

158.20 Overview.
158.25 Applicability of data requirements.
158.30 Application status and submittal times.
158.35 Flexibility of the data requirements.
158.40 Consultation with the Agency.
158.45 Waivers.
158.50 Formulators' exemption.
158.55 Agricultural vs non-agricultural pesticides.
158.60 Minor uses.
158.65 Biorational pesticides.
158.70 Acceptable protocols.
158.75 Requirements for additional data.
158.80 Acceptability of data.
158.85 Revisions of data requirements and guidelines.

Subpart B—Registration Data Requirements

Sec.

158.100 Overview.

Sec.
158.105 Purposes of the registration data requirements.
158.110 Certification of ingredient limits.
158.115 Organization of pesticide guidelines and relationship to data requirements.
158.120 Product chemistry data requirements.
158.125 Residue chemistry data requirements.
158.130 Environmental fate data requirements.
158.135 Toxicology data requirements.
158.140 Reentry protection data requirements.
158.145 Wildlife and aquatic organism data requirements.
158.150 Plant protection data requirements.
158.155 Nontarget insect data requirements.
158.160 Product performance data requirements.
158.165 Biorational pesticide data requirements.

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

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.* (1) The legislative authority for pesticide registration is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (7 U.S.C. 136 et seq.). The Administrator of the Environmental Protection Agency is authorized by Sec. 3(c)(5) of FIFRA to register a pesticide if he determines that, when considered with any restrictions imposed upon FIFRA sec. 3(d):

(i) Its composition is such as to warrant proposed claims for it;

(ii) Its labeling and other material to be submitted comply with the requirements of the Act;

(iii) It will perform its intended function without unreasonable adverse effect on the environment; and

(iv) When used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

If the Administrator determines that all of these requirements are satisfied, the registration application will be approved. (See § 162.7(d) of this chapter.) To permit this determination, the applicant for registration of a pesticide must provide data defining its composition, establishing its efficacy (if necessary), and demonstrating its toxicity to specified organisms so the Agency can evaluate the potential hazards posed by its intended use(s).

(2) Section 3(c)(2)(A) of FIFRA states that "The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide".

(3) Section 3(c)(1)(D) of FIFRA states that "Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—. . . a full description of the tests made and the results thereof upon which the (labeling) claims are based, or alternately a citation to data that appears in the public literature or that has been previously submitted to the Administrator . . .".

(b) *Purpose of this part.* The purpose of this part is to specify the types of data and information the Agency requires to make regulatory judgements with respect to the safety of each pesticide product proposed for registration, reregistration or experimental use. Hereafter, use of the term registration will pertain to new registrations as well as reregistrations accomplished under section 3(g).

(c) *Relation to previous subparts.* This part supersedes all Subparts of the Guidelines for Registering Pesticides in the United States previously published in the **Federal Register**, except Subpart Q, Good Laboratory Practice. Subpart Q was published as a proposed rule on April 18, 1980. The Agency intends to publish a final rule pertaining to good laboratory practice, separate from this part.

(d) *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, wildlife and aquatic organisms, plant protection, nontarget insects, organisms product performance, and biorational pesticides. 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 this part. This information is available as an advisory document (Pesticide Registration Guidelines) through the National Technical Information Service.

(e) *Relation to other statutes.* Statutes other than FIFRA may affect the production, distribution and use of chemicals used as pesticides. Specifically, producers of pesticides subject to registration under FIFRA may also be subject to provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.*; the Federal Water Pollution Control Act, 33 U.S.C. 1251 *et seq.*; the Federal Hazardous Substances Act, 15 U.S.C. 1261 *et seq.*; the Occupational Safety and Health Act, 29 U.S.C. 651 *et seq.*; the Resource Conservation and Recovery Act of 1976, 42 U.S.C. 6901 *et seq.*; and the Endangered Species Act of 1973, Pub. L. 93–205 (87 Stat. 884).

§ 158.25 Applicability of data requirements.

(a) This part specifies the kinds of data and information that must be submitted to support an application for registration, amended registration, reregistration or experimental use permit under FIFRA. This part also specifies the test substance to be used in tests conducted to fulfill the data requirements.

(b) Each applicant must submit the kinds of data and information specified in §§ 158.120 through 158.165 as "required" (R) for his type of product. Registrants must also submit the kinds of data and information specified in those sections as "conditionally required (CR)" if the product's proposed pattern of use, results of other tests, or other pertinent factors meet the criteria for submission specified in those sections. The required data, and the applicable conditionally required data, must be submitted unless the Agency determines that such data are not required. The terms "required" (R) and "conditionally required" (CR) are further discussed in § 158.100 of Subpart B.

(c) 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 Application status and submittal times.

The requirements imposed by this part apply to products already registered as well as those being proposed for registration. The Agency will notify registrants of already registered products when they must satisfy the data requirements of this part.

(a) Current product registrations will remain valid so long as registrants comply with terms of the subsequent Agency notification.

(b) For conditional registration of identical or substantially similar products under FIFRA section 3(c)(7)(A), applicants must satisfy the data requirements of this part at the same time as that set for comparable products already registered.

(c) For conditional registration of new uses or formulations under FIFRA section 3(c)(7)(B), applicants must satisfy the data requirements on the same schedule as that set for comparable products already registered, unless such data are necessary to complete an incremental risk assessment on the proposed new use or

formulation for the product. In that case, the data requirements must be satisfied prior to conditional registration under FIFRA section 3(c)(7)(B).

(d) For conditional registration of new chemicals under FIFRA section 3(c)(7)(C), the Agency will make case-by-case determinations as to when the data requirements must be satisfied.

(e) For registration under FIFRA section 3(c)(5), applicants must satisfy the data requirements prior to full registration.

§ 158.35 Flexibility of the data requirements.

The data requirements for registration are flexible in order to meet the specific needs of registration applicants and the Agency. Several examples of this flexibility are explained below and discussed elsewhere in this part.

(a) All applicants for registration and new applicants, particularly, are encouraged to consult with the Agency to resolve questions relating to the protocols or the data requirements for registration before undertaking extensive testing. (See § 158.40).

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

(c) 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 (See § 158.80).

(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, and allow case-by-case decisionmaking to determine the specific needs for each kind of use (See § 158.60).

(e) An applicant may satisfy the requirements contained in this part by submitting the required information and by citing data previously submitted to support the registration of another product (See 162.60 of this chapter and § 158.70).

§ 158.40 Consultation with the Agency.

(a) This Part establishes sets of data requirements applicable to various specific pesticide use patterns. This fact, coupled with the likelihood of changing requirements (mandated by the FIFRA statement that the Administrator "shall revise such guidelines from time to time") 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.

(b) Resolving problems resulting from unique or unanticipated situations will frequently generate suggestions for changes to improve clarity, accuracy, or some other aspect of the data requirements set forth in this Part. Specific suggestions for improvement are encouraged. This can help reduce the likelihood that others will have to arrange consultation on the same topic at a later time.

§ 158.45 Waivers.

(a) *Rationale and policy.* (1) The Agency realizes that the data requirements specified in this part will not always be appropriate for every product. Some products may be characterized by unique physical, chemical, or biological properties or unique use patterns which would make particular data requirements unnecessary or would result in submittal of information that is not useful in the Agency's evaluation of hazard or risk. Accordingly, in those situations it will be the policy of the Agency to waive inappropriate data requirements. Thus, when an applicant persuades the Agency that producing an item of data generally required by this Part would not assist EPA to make a valid or useful decision, EPA will waive that data requirement. The Agency will implement this policy in a reasonable manner to insure that sufficient data are available for proper evaluation, and also that applicants are not burdened with unnecessary data requirements.

(2) The Agency intends to issue case-by-case waivers of data requirements, taking into account, when appropriate, factors enumerated in sections 3(c)(2)(A) and 25(a)(1) of FIFRA. Section 3(c)(2)(A) provides that:

> The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, and the level and degree of potential exposure of man and the environment to the pesticide.
>
> In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data.

Section 25(a)(1) provides that:

> The Administrator is authorized
>
> . . . to prescribe regulations to carry out the provisions of this Act. Such regulations shall 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 nonagricultural pesticides.

(3) In addition, EPA will waive data requirements on its own initiative when it determines that certain data, information, or evidence are not needed for Agency review or decisionmaking. Such waivers would generally be of a broad scope, affecting data requirements to support a number of pesticide products.

(b) *Procedure for requesting waiver.* (1) An applicant should discuss his plans to request a waiver with his respective EPA Product Manager before developing and submitting extensive support information for the request. Generally, the applicant should explain to the Product Manager the reason(s) for requesting a waiver and describe any attempts made to generate the required data. If the waiver request is based on the practical difficulties of producing the data, EPA may suggest ways of obtaining the required information. However, because of the wide variety of use patterns of pesticides, it would be difficult to spell out all of the circumstances which would serve as a basis for waiving data requirements.

(2) To request a waiver, the registration applicant should send a letter to the Product Manager attaching all information which supports the request. There is no special form or fee for requesting a waiver, but the applicant should be certain to cite the exact data requirement of concern.

(c) *Notification of waiver decision.* The Agency will review each waiver request and applicants will be informed of its decision in either of two ways:

(1) For decisions that pertain only to a specific product or to its specific characteristics that are fundamentally different from other similar products, the Agency will notify the applicant(s) in writing; or

(2) For decisions that could readily apply to more than a specific product, the Agency may choose to publish a pesticide registration notice or a notice in the **Federal Register** announcing its decision, or to send a notice to all registrants.

(d) *Finality of decision; request based on new information.* An Agency decision denying a written request to waive a data requirement shall constitute final Agency action for purposes of FIFRA section 16(a). An

applicant may submit new data or information at any time and renew a request which has been denied. The Agency will review the additional data and notify the applicant of its new decision based upon review of the new information or data.

(e) *Availability of waiver decisions.* Decisions concerning waivers pertaining to many products or applicants will be available to the public at the Office of Pesticides and Toxic Substances Reading Room at EPA, Rm E107, 401 M St. SW., Washington, D.C. 20460 and at EPA Regional Offices. 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) The "formulators' exemption" policy contained in FIFRA section 3(c)(2)(D) applies to many of the data requirements set forth in this part. This exemption provides that an applicant for registration of an end-use product who purchases and legally uses a registered product to formulate the end-use product is not required to submit or cite any data pertaining to the purchased product. Such a purchased product must be registered and labeled for manufacturing use or for the same use as the end-use product being formulated by the applicant.

(b) Registrants of manufacturing-use products and registrants of end-use products manufactured from unregistered raw materials (i.e. end-use products produced by an integrated formulation system) must submit both those required data which are developed with the pesticide active ingredient as the test substance and those required data which are developed with the end-use product as the test substance.

(c) Registrants of end-use products formulated from registered manufacturing-use products usually will need to submit only those required data developed with the formulated product as the test substance. The data requirements that these registrants must usually satisfy are identified by the notation EP* in the corresponding test substance column of each data requirement table in Subpart B, §§ 158.120 through 158.165.

(d) This policy reflects Congress' intent that manufacturing-use product registrants will be the major source of registration data, and that end-use product formulators will, in most cases, need to supply much less data. End-use product formulators should be aware, however, that if data normally provided by the manufacturing-use product registrants are not available and the manufacturing-use product producer will not agree to provide these data, then the end-use product formulator must supply the required data to support the continued registration of his purchased manufacturing-use product or it may no longer be available to him for formulating his end-use product.

§ 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 presented in each data requirement table (§§ 158.120 through 158.165). In addition, a comprehensive list of pesticide use patterns, cross-referenced to the general use patterns appearing in the tables will further enable the reader to distinguish agricultural versus non-agricultural uses of pesticides (refer to the Use Pattern Index appended to this Part).

§ 158.60 Minor uses.

(a) *Minor use policy.* EPA has policies concerning registration and experimental use permits for minor uses of pesticides. Generally, a minor use of a pesticide is a use on a low acreage crop or which is otherwise limited such that there is not a large market volume for that use. The minor use policy includes the following elements:

(1) Minor uses have priority in the registration process in cases where no registered alternatives exist.

(2) 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.

(3) A new data requirement pertinent to both an unregistered minor use and an existing registered use will not be applied to the minor use applicant, until it is applied to the major use registrants.

(4) EPA will accept extrapolations and regional data to support establishment of individual minor use tolerances. Group tolerances will also be established to assist applicants for registration of products for minor uses.

(5) EPA will continue to make tolerance decisions based on assessments of actual residue intake, rather than on observation that the acceptable daily intake (ADI) has been theoretically exceeded.

(6) EPA will continue to conditionally register (for use on minor food/feed crops) pesticides undergoing RPAR review based on risks associated with human dietary exposure, if there are no available alternative pesticides that do not meet or exceed such risk criteria.

(b) *Advice on data requirements to support minor uses.* Registration applicants are advised to contact the appropriate EPA Product Manager or the Minor Use Officer of the Registration Division of the Office of Pesticide Programs for advice on developing data to support new applications for minor use of pesticides.

§ 158.65 Biorational pesticides.

Biorational pesticides are a distinct group, inherently different from conventional pesticides. Some of the characteristics that typically distinguish biorationals from conventional pesticides are their unique non-toxic mode of action, low use volume, target species specificity, and natural occurrence. Based on these characteristics, the Agency expects that many biorational pesticides pose lower potential risks than conventional pesticides. Therefore, these pesticides are subject to a different set of data requirements, as specified in § 158.165. Biorationals are comprised of two major categories of pesticides: biochemical and microbial pest control agents (e.g., microorganisms). Pesticides to be included in these categories are determined as follows:

(a) *Biochemical pest control agents.* A chemical must meet the following two criteria in order to be classified as a biochemical pest control agent and to be subject to the data requirements for registering biorational pesticides:

(1) The chemical must exhibit a mode of action other than direct toxicity in the target pest (e.g., growth regulation, mating disruption, attraction). Pesticides such as strychnine, rotenone, nicotine, and pyrethrin, which exhibit direct toxicity, are not considered biochemical pest control agents; and

(2) The chemical must be naturally-occurring, or if the chemical is synthesized by man, then it must be structurally identical to a naturally-occurring chemical. For a synthetic chemical to be identical in chemical structure to a naturally-occurring chemical, the molecular structure(s) of the major component(s) of the synthetic chemical(s) must be the same as the molecular structure(s) of the naturally-occurring analog(s). Minor differences between the stereochemical isomer

ratios (found in the naturally-occurring compound compared to the synthetic compound) will normally not rule out a chemical being classified as a biorational unless an isomer is found to have significantly different toxicological properties from those of another isomer. If, after reviewing the confidential statement of formula, the Agency determines that a biochemical pesticide contains an inert ingredient(s) that may pose a hazard, the appropriate data requirements will apply in the same manner as they would for inerts in a conventional pesticide.

(3) There are situations when a candidate chemical possesses many characteristics of a biorational pesticide, but does not technically meet the two criteria established for defining biochemical pest control agents. The Agency will evaluate chemicals that are substantially similar to biochemicals on a case-by-case basis to determine whether the chemical should be classified as a biorational or a conventional pesticide.

(b) *Microbial pest control agents.* The biorational pesticides referred to as microbial pest control agents include bacteria, fungi, viruses, and protozoans. The data requirements apply to all microbial pest control agents used as pesticides, including not only those that are naturally-occurring but also those that are strain-improved. Each variety or subspecies of a microbial pest control agent must be tested. Data requirements for genetically-engineered microbial pest control agents would be determined on a case-by-case basis except where data requirements for such agents are specified. Pest control organisms such as insect predators, nematodes, and macroscopic parasites are not considered biorational pesticides, and are exempt from the requirements of FIFRA as authorized by section 25(b) of FIFRA and specified in the Exemption from Regulation of Certain Biological Control Agents, 40 CFR 162.5(c).

§ 158.70 Acceptable protocols.

The Agency has published non-regulatory pesticide registration guidelines [as indicated in § 158.20(c)(2)] which contain suggested protocols for conducting tests to develop the data required by this part.

(a) *General policy.* Any pertinent 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 product. Accordingly, failure to follow a suggested protocol will not invalidate a test if another appropriate methodology is used.

(b) *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 product or application which would be affected. The Product Manager, in turn, will refer requests and questions to the scientific staff which will review them and make decisions on the appropriate requirements. The Product Manager will also make certain that responses are expeditiously provided to the applicant. Meetings will be arranged by the Product Manager with appropriate EPA scientists, when necessary, to resolve issues or questions.

§ 158.75 Requirements for additional data.

(a) *General policy.* A general testing program may not yield all of the information necessary to evaluate every different pesticide product. In the event that a product with unusual characteristics or use patterns is encountered, and 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 on a case-by-case basis. However, EPA expects that the information required by this Part will be adequate in most cases for an assessment of the properties of pesticides.

(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 analytically 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) The inert ingredients of an end-use 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 substances which could act as a synergist to the product for which registration is sought.

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

§ 158.80 Acceptability of data.

(a) *General policy.* The Agency will determine the acceptability of the data submitted to fulfill the data requirements specified in this part. 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 the Agency-recommended protocol, even if the Agency subsequently recommends a different protocol, as long as the data fulfill the purposes of the data requirements as described above.

(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 it meets the purposes of this part, good laboratory practices were observed, and it permits sound scientific judgements to be made. The Agency intends to apply the requirements of this Part to these data in a common sense manner. Such data will not be rejected merely because they were not developed in accordance with the suggested protocols.

(c) *Data developed in foreign countries.* The Agency considers all data developed from laboratory and field studies anywhere to be suitable for submittal with a pesticide registration application except for the use of field test sites or a test material, such as a native soil, plant, or animal, that is not inherently 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 adequate comparability data or information to demonstrate the lack of substantial or relevant difference 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 sec. 5, sec. 8 or sec. 20. Registration applicants should determine whether some of these data may be suitable for submittal to meet the requirements of this part. Other available data developed independently of FIFRA regulations or requirements should also be examined for suitability for submittal to support registration applications. Some of these data may have been developed using individual end-use products as the test substance. Consultation with appropriate EPA Product Managers would probably be helpful if applicants are unsure about suitability of such data.

§ 158.85 Revision of data requirements and guidelines.

(a) Data requirements and guidelines will be revised from time to time to keep up with policy changes and technology. Revisions will be made in accordance with the Administrative Procedure Act (5 U.S.C 551 *et seq.*). Under that Act, changes may be made without proposal and opportunity for public comment if the Agency for good cause finds such procedures are unnecessary or contrary to the public interest. Changes having a significant impact on the registration process, applicants, testers, or other parties, or on the outcome and evaluation of studies, would undergo public notice and opportunity for comment. Until any changes have been published as final rules, however, the Agency can implement them on a case-by-case basis.

(b) Registration applicants, registrants, and the general public are requested to supply suggestions for changes in the data requirements or guidelines. The most suitable time is during the public comment periods for proposals, but suggestions may be submitted at any time. Those making suggestions are requested to contact, in writing, the appropriate Product Manager in Registration Division or Division Director in the Office of Pesticide Programs. When suggestions consist of new suggested methods, then representative test results should accompany the submittals.

Subpart B—Registration Data Requirements

§ 158.100 Overview.

(a) *General.* Sections 158.120 through 158.165 of this part state which kinds of data (from the studies described in the guidelines) are required to support a pesticide registration application. These sections also specify the substance to be tested in performing such studies.

(b) *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:

(1) Begin at §§ 158.120 through 158.165. These sections contain the data requirements for each subject area corresponding to each subdivision of the guidelines. A list of the subdivisions contained in the guidelines is presented in § 158.115.

(2) 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 can 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.

(3) 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.

(c) *Required vs. conditionally required data.* (1) Data designated as required (R) to support the registration of a product for a particular general use pattern must be submitted by the registrant. However there are exceptions when the Agency would not impose these requirements. These exceptions are specified in the accompanying notes for each data requirement table. Generally, the exceptions to required data (R) occur in situations when the physical/chemical properties of the product, or the product's proposed use pattern render the data requirement impossible to fulfill, or if fulfilled, would not provide the Agency with information useful in making a regulatory judgement with respect to the safety of the product proposed for registration.

(2) Data designated as conditionally required (CR) to support the registration of a product for a particular general use pattern must be submitted by the registrant as specified in the corresponding notes presented in each data requirements table. As indicated in the notes, the determination as to whether or not the data must be submitted is based on the product's use pattern, expected exposure of nontarget organisms, and/or results of previous testing (e.g., tier testing requirements). Therefore, registrants must evaluate each applicable note to determine whether or not the criteria for submittal of conditionally required data apply to his product.

(3) Certain data are designated as required or conditionally required, and are enclosed in brackets (i.e., [R], [CR]). The brackets merely 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.

(d) *Distinguishing between what data are required and what substance is to be tested.* The registrant 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 (§§ 158.120–158.165) specifies whether a particular data requirement is required to support the registration of manufacturing-use products or 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 the manufacturing-use product.

(e) *Referring to general test guidance.* Readers are instructed to refer to the corresponding general sections of each subdivision of the guidelines in addition to the specific test sections. The general sections of a subdivision provide general testing reporting standard for most or all of the specific test sections of that subdivision. These general standards are usually not repeated in

the specific test sections but are nevertheless applicable unless the specific test section provides different instruction relative to a specific standard.

§ 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 ingedient 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 environmental characteristics and toxic properties of the pesticide, 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 pesticide chemicals and 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 take 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 studies must be conducted. When high vapor-pressure pesticides pose a potential hazard to workers, data on vapor pressure are used as an indication that reentry intervals or other worker protection standards need to be established. Data on viscosity and miscibility provide supportive information on tank mix proposals and spray application instructions.

(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 tests 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 the 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 practical 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 direct consequences to man through his exposure to pesticide residues remaining after application, either upon his reentering treated areas or from consuming inadvertently-contaminated food; assess the indirect consequences to man from the presence of widely distributed and persistent pesticide residues in the environment which may result in loss of usable land, water, and wildlife resources; and, assess the potential environmental exposure of other nontarget organisms, such as fish and wildlife, to pesticide residues. Another specific purpose of the environmental fate data requirements is to help registration applicants and the Agency estimate expected environmental concentrations of pesticides in specific habitats where endangered species or other 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 pesticide residues than 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 pesticide residues 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 groundwater); and habitat loss to 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 and 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 (from time of application to time when crops can be rotated) and to determine if tolerances may be needed for residues on such crops. Data from irrigated crop studies are used to determine the amount of pesticide residues taken up by representative crops from irrigation water transported from some other pesticide-treated area. These studies allow the Agency to establish label restrictions regarding application of pesticides on sites where the residues can transport to 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 pesticide accumulation studies in fish are used to establish label restrictions; e.g., to prevent applications in certain sites so that there will be minimal residues entering edible fish or shell fish such as catfish or crayfish inhabiting rice fields. 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, subacute and chronic 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 from 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 an initial step 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 possible health hazards likely to arise from repeated exposures over a limited period of time. They provide information on target organs and accumulation potential. They are of use in selecting dose levels for chronic studies and for establishing safety criteria for human exposure. These tests are not capable of determining those effects that have a long latency period for development (e.g., carcinogenicity and life shortening).

(3) *Chronic studies.* Chronic toxicity (e.g., feeding) 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 require a long latent period or are cumulative, should become manifest. The purpose of long-term oncogenicity studies is to observe test animals over a major portion 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. The teratogenicity study is designed to determine the potential of the test substance to induce structural and/or other abnormalities to the fetus which may arise from exposure of the mother during pregnancy. Two-generation reproduction testing is designed to provide general information concerning the 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.

(4) *Mutagenicity studies.* For each test substance a battery of tests are required to assess potential to affect the qualitative or quantitative integrity of 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, and when mutagenic potential is demonstrated,

(iii) To incorporate these findings in the assessment of heritable effects, oncogenicity, and possibly, other health endpoints.

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

(f) *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 hierarchical 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 determine the need for (and support the wording for) precautionary label statements to minimize the potential adverse effects to nontarget organisms.

(2) *Short term studies.* The short-term acute and subacute 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 to fish, wildlife and other nontarget organisms; and to indicate the need for further laboratory and/or field studies.

(3) *Long term and field studies.* Additional studies (i.e., avian, fish, and invertebrate reproduction and lifecycle 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 likely to be high.

§ 158.110 Certification of ingredient limits.

(a) 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 and analyze commercial samples of the registered products. When, upon analysis, 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 and those end-use products produced by an integrated formulation system.* The statement of formula for a manufacturing-use product or for an end-use product by an integrated formulation system must contain certified limits:

(1) For each active ingredient and each intentionally-added inert 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 other impurity (or, if appropriate, for each other group of structurally similar impurities) associated with an active ingredient that was found in any sample in quantities equal to or greater than 0.1 percent by weight, an upper limit.

(d) *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 for each active ingredient and each intentionally-added inert ingredient.

(e) *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 thant 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.

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

(a) *List and description of subdivisions.* A list and brief description of the subdivisions included in the pesticide registration guidelines is provided below. The pesticide registration guidelines contain the standards for conducting acceptable tests, guidance on evaluation and reporting of data, further guidance on when data are required, and examples of acceptable protocols. They are available through the National Technical Information Service. The registration data requirements pertaining to each subdivision are also identified below.

(b) *Subdivision D—Product Chemistry.* This subdivision contains guidance for development of data on formation, identification, and quantification of the intentionally-added ingredients and the impurities in pesticide products; on chemical and physical characteristics of the products and their components. The data requirements presented in § 158.120 pertain to subdivision D of the guidelines.

(c) *Subdivision E—Hazard Evaluation: Wildlife and Aquatic Organisms.* This subdivision provides guidance on conducting studies used to evaluate potential adverse effects on birds, wild mammals, fish and aquatic organisms. The data requirements presented in § 158.145 pertain to subdivision E of the guidelines.

(d) *Subdivision F—Hazard Evaluation: Humans and Domestic Animals.* This subdivision provides guidance on conducting studies of pesticide effects in laboratory animals and microorganisms for assessment of potential hazards to humans and domestic animals. The data requirements presented in § 158.135 pertain to subdivision F of the guidelines.

(e) *Subdivision G—Product Performance.* This subdivision provides guidance on developing the data to demonstrate that pesticide products will control the pests specified in the claims on product labels. The data requirements presented in § 158.160 pertain to subdivision G of the guidelines.

(f) *Subdivision H—Guidelines for Pesticides and Devices.* This subdivision describes all essential parts of a pesticide product label, including how labeling must comply with the requirements of FIFRA and how claims, precautions, and directions must correspond to evidence developed in tests performed by (or for) the registration applicant. No requirements pertaining to subdivision H of the guidelines are presented in this part.

(g) *Subdivision I—Experimental Use Permits.* This subdivision provides guidance on developing the data and labeling to be submitted in support of an application for an experimental use permit. It also defines procedures to be followed to obtain a permit and indicates the kinds of studies generally undertaken under the permit. The data requirements specified as being applicable to experimental use permits are specified in §§ 158.120 through 158.165 and pertain to subdivision I of the guidelines.

(h) *Subdivision J—Hazard Evaluation: Nontarget Plants.* This subdivision provides guidance on developing data to evaluate the potential for adverse effects on plants in nontarget areas and on desirable plants in target areas. The data requirements presented in § 158.150 pertain to subdivision J of the guidelines.

(i) *Subdivision K—Reentry Protection.* This subdivision provides guidance on means to calculate the length of time required before persons can safely enter a pesticide-treated site, and the data

needed for the calculation. The data requirements presented in § 158.140 pertain to subdivision K of the guidelines.

(j) *Subdivision L—Hazard Evaluation: Nontarget Insects.* This subdivision provides guidance on developing the data to assess potential adverse effects on bees and other pollinating or otherwise beneficial nontarget insects. The data requirements presented in § 158.155 pertain to subdivision L of the guidelines.

(k) *Subdivision M—Biorational Pesticides.* This subdivision provides guidance on developing data on biochemical and microbial pest control agents to determine their fate and evaluate potential adverse effects to humans and other nontarget organisms. Biochemical agents are naturally-occurring chemicals (or identical synthetic chemicals) isolated or derived from natural biological sources. Biochemicals include pheromones, natural plant regulators, and insect growth regulators. Microbial agents include bacteria, fungi, viruses, and protozoa intended for pest control purposes. The data requirements presented in § 158.165 pertain to subdivision M of the guidelines.

(l) *Subdivision N—Environmental Fate.* This subdivision provides guidance on developing the data to demonstrate the fate of pesticides in the environment through degradation, metabolism, mobility, dissipation, and accumulation. The data requirements presented in § 158.130 pertain to subdivision N of the guidelines.

(m) *Subdivision O—Residue Chemistry.* This subdivision provides guidance regarding the development of 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 subdivision also addresses data development for residues in fish used for human food, when such data are required by the Agency, and for pesticide residues in tobacco and certain other nonfood/nonfeed items where residues can pose harm to humans or domestic animals. The data requirements presented in § 158.125 pertain to subdivision O of the guidelines.

§ 158.120 Product chemistry data requirements.

(a) TABLE.—SECTIONS 158.50 AND 158.100 DESCRIBE HOW TO USE THIS TABLE TO DETERMINE THE PRODUCT CHEMISTRY DATA REQUIREMENTS AND THE SUBSTANCE TO BE TESTED

Data requirement	(b) Notes	Product chemistry data requirements; 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:													
Identity of ingredients		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	R	MP	EP*	61-1
Statement of composition		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	R	MP	EP*	61-2
Discussion of formation of ingredients.	(1)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	R	MP	EP*	61-3
Analysis and certification of product ingredients:													
Preliminary analysis	(2)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	CR	MP	EP	62-1
Certification of limits	(3)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	R	MP	EP*	62-2
Analytical methods for enforcement of limits.		R	R	R	R	R	R	R	R	R	MP	EP*	62-3
Physical and chemical characteristics:													
Color		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	R	MP & TGAI	EP* & TGAI	63-2
Physical state		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	R	MP & TGAI	EP* & TGAI	63-3
Odor		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	R	MP & TGAI	EP* & TGAI	63-4
Melting point	(4)	[R]	[R]	[R]	[R]	[R]	R	[R]	[R]	R	TGAI	TGAI	63-5
Boiling point	(5)	[R]	[R]	[R]	[R]	[R]	R	[R]	[R]	R	TGAI	TGAI	63-6
Density, bulk density, or specific gravity.		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	R	MP & TGAI	EP* & TGAI	63-7
Solubility		[R]	[R]	[R]	[R]	[R]	R	R	[R]	R	TGAI or PAI	TGAI or PAI	63-8
Vapor pressure		[R]	[R]	[R]	[R]	[R]	R	R	[R]	R	TGAI or PAI	TGAI or PAI	63-9
Dissociation constant		[R]	[R]	[R]	[R]	[R]	R	R	[R]	R	TGAI or PAI	TGAI or PAI	63-10
Octanol/water partition coefficient.	(6)	[CR]	CR	CR	CR	CR	CR	CR	CR	CR	PAI	PAI	63-11
pH	(7)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	CR	MP & TGAI	EP* & TGAI	63-12
Stability		[R]	R	R	R	[R]	R	[R]	R	R	TGAI	TGAI	63-13
Oxidizing or reducing action.	(8)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	CR	MP	EP*	63-14
Flammability	(9)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	CR	MP	EP*	63-15
Explodability	(10)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	R	MP	EP*	63-16
Storage stability		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	R	MP	EP*	63-17
Viscosity	(11)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	CR	MP	EP*	63-18
Miscibility	(12)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	CR	MP	EP*	63-19
Corrosion characteristics		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	R	MP	EP*	63-20
Dielectric breakdown voltage.	(13)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	CR		EP*	63-21
Other requirements:													
Submittal of samples	(14)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	CR		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 that registrants of end-use products which are formulated from registered manufacturing-use products are responsible for submission of this data); 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) 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.

(2) 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.

(3) If tests are to be conducted on beginning materials, the Agency will waive the requirements for innocuous inert ingredients such as corn meal, water, silica and similar materials. The requirement for certification of ingredient limits is detailed further in § 158.110. Certified limits are not required for inert ingredients in products proposed for experimental use.

(4) Data needed if technical material is a solid at room temperature.

(5) Data needed only if technical material is a liquid at room temperature.

(6) Data required if technical material is organic and non-polar.

(7) Required for technical materials and products that are dispersible with water.

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

(9) Data are required if product is formulated with combustible liquids.
(10) Data only required for products that are potentially explosive.
(11) Data required if product is a liquid.
(12) Data required if product is a emulsifiable liquid.
(13) Required if end-use product is a liquid and is to be used around electrical equipment.
(14) Routinely required for products produced by an integrated formulation system; required for other products or materials on a case-by-case basis; (i.e., MP, EP, TGAI, inerts, impurities, or degradation products).

§ 158.125 Residue chemistry data requirements.

(a) TABLE.—SECTIONS 158.50 AND 158.100 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	Residue chemistry data requirements; 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	(1), (13)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	171-2
Directions for use	(2), (13)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]			171-3
Nature of the residue plants	(13)	[R]		[R]		[R]			[CR]		PAIRA	PAIRA	171-4
Livestock	(3), (13)	[CR]		[CR]		[CR]			[CR]		PAIRA & plant metabolites.	PAIRA & plant metabolites.	171-4
Residue analytical method	(4), (13)	[R]		[R]		[R]			[CR]		TGAI & metabolites.	TGAI & metabolites.	171-4
Magnitude of the residue:													
Crop field trials	(13)	[R]		[R]		[R]			[CR]		TEP	TEP	171-4
Processed food/feed	(5)	[CR]		[CR]		[CR]					EP	EP	171-4
Meat/milk/poultry/eggs	(6)	[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)									[CR]	EP	EP	171-4
Reduction of residue	(11)	[CR]		[CR]		[CR]					Residue of concern.	Residue of concern.	171-5
Proposed tolerance	(12)	[R]		[R]		[R]					Residue of concern.	Residue of concern.	171-6
Reasonable grounds in support of the petition.		[R]		[R]		[R]							171-7

Key: R=Required data; 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., [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 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.
(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 any livestock feed. Direct application to livestock uses 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 residues in fish are required whenever a pesticide is to be applied directly to water.
(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.
(11) 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.
(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.

§ 158.130 Environmental fate data requirements.

(a) TABLE.—SECTIONS 158.50 AND 158.100 DESCRIBE HOW TO USE THIS TABLE TO DETERMINE THE ENVIRONMENTAL FATE DATA REQUIREMENTS AND THE SUBSTANCES TO BE TESTED.

Kind of data required	(b) Notes	Environmental fate data requirements; general use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Date 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						TGAI or PAIRA	TGAI or PAIRA	162-3
Aerobic aquatic				[R]	[R]						TGAI or PAIRA	TGAI or PAIRA	162-4
Mobility studies													
Leaching (adsorption/desorption).		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]		TGAI or PAIRA	TGAI or PAIRA	163-1
Volatility:													
(Lab)	(2)	[CR]				[CR]	[CR]				TEP	TEP	163-2
(Field)	(2)	[CR]				[CR]	[CR]				TEP	TEP	163-3

(a) TABLE.—SECTIONS 158.50 AND 158.100 DESCRIBE HOW TO USE THIS TABLE TO DETERMINE THE ENVIRONMENTAL FATE DATA REQUIREMENTS AND THE SUBSTANCES TO BE TESTED.—Continued

Kind of data required	(b) Notes	Environmental fate data requirements; 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						
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 nontarget organisms.	(8), (9)				[CR]			[CR]			TEP	TEP	165-5

Key: R=Required; CR=Conditionally required; [ ]=Brackets (i.e. [R], [CR]) indicate 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 reasonably foreseeable that any food or feed crop may be subsequently planted on the site of pesticide application.
(6) Field accumulated 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 resonably 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.

§ 158.135 Toxicology data requirements

(a) TABLE.—SECTIONS 158.50 AND 158.100 DESCRIBE HOW TO USE THIS TABLE TO DETERMINE THE TOXICOLOGY DATA REQUIREMENTS AND THE SUBSTANCE TO BE TESTED

Kind of data required	(b) Notes	Toxicology data requirements; 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													
Oral LD_{50}—rat	(1)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP & TGAI	EP* or EP dilution* & TGAI.	81-1
Dermal LD_{50}	(1), (2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP & TGAI	EP* or EP dilution* & TGAI.	81-2
Inhalation LC_{50}—rat	(16)	[R]	[R]	[R]	[R]	[R]	[R]		[R]	[R]	MP & TGAI	EP* & 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—rodent, nonrodent.	(17)	[R]		[R]		[R]				[CR]	TGAI	TGAI	82-1
21-day dermal	(18)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	TGAI	TGAI & 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		[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	TGAI	TGAI	82-5
Hen	(7)												
Mammal	(8)												
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]	[CR]	[R]	[CR]	[R]	[CR]	[CR]	[CR]	[CR]	TGAI	TGAI	84-2
Chromosomal aberration	(22)	[R]	[CR]	[R]	[CR]	[R]	[CR]	[CR]	[CR]	[CR]	TGAI	TGAI	84-2
Other mechanisms of mutagenicity.	(22)	[R]	[CR]	[R]	[CR]	[R]	[CR]	[CR]	[CR]	[CR]	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

(a) TABLE.—SECTIONS 158.50 AND 158.100 DESCRIBE HOW TO USE THIS TABLE TO DETERMINE THE TOXICOLOGY DATA REQUIREMENTS AND THE SUBSTANCE TO BE TESTED—Continued

Kind of data required	(b) Notes	Toxicology data requirements; 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						
Special requirement													
Domestic animal safety	(12)	[CR]	[CR]	[CR]	[CR]			[CR]	[CR]		Choice	Choice	86-1

Key: R=Required data; 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 that registrants of end-use products formulated from registered manufacturing-use products are responsible for submission of this data); 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 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) Not required if repeated contact with human skin does not result under condition of use.
(4) Not required unless test material, is an organophosphate, or a metabolite or degradation product there of 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 structurally to a compound which can induce these effects.
(8) Required if acute oral, dermal, or inhalation studies showed neuropathy or neurotoxicity.
(9) Studies designed to simultaneously meet the requirements of both the chronic feeding and oncogenicity studies can be conducted. If the pesticide is used on food, the chronic rodent feeding study must be least 24 months and the chronic nonrodent (i.e., dog) feeding study must be at least 12 months. For non-food uses, a duration of at least 12 months for the chronic rodent feeding study would usually be sufficient.
(10) Required to support products intended for food uses and to support 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% 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% of the maximum permitted intake (MPI), a first generation (or longer) interim report on a multigeneration reproduction study is required to support a temporary tolerance.
(15) A terotology study in one species is required to support a temporary tolerance.
(16) Required on a case-by-case basis to support registration of products for indoor use.
(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; and
(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 frequency 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 at issue); and
(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., swinning 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; or
(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, products 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); or
(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 structurally related to a recognized carcinogen; or
(B) Is a substance that cause mutagenic effect as demonstrated by *in vitro* or *in vitro* testing; or
(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; or
(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 repellants applied diretly to human skin; swimming pool additives; constant-release indoor pesticides which are used in aerosol form).
(22)(i) Required if any of the following criteria are met:
(A) The pesticide product is to be used on food or feed; or
(B) The pesticide product is likely to result in significant human exposure, or
(C) The active ingredient(s) or any of its (their) metabolites is structurally related to a mutagen or oncogen, or belongs to any chemical class of compounds containing mutagens or oncogens.
(ii) 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 substances, e.g., numerical chromosome abberations, direct DNA damage and repair.
(iii) Currently recognized tests for each of these categories are listed with the National Technical Information Service (NTIS). Selection of tests within the battery shall be supported, taking into account the limitations of the individual assay. Because of the rapid improvements in this field, registrants are encouraged to discuss with the Agency: testing battery selection, protocol design and results of preliminary testing.
(23) Required if chronic feeding and oncogenicity studies are required.

§ 158.140 Reentry protection data requirements

(a) TABLE.—SECTIONS 158.50 AND 158.100 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	Reentry protection data requirements; general use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Date 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 LD_{50} of the technical grade of active ingredient is less than 200 mg/kg (body weight); or (B) the acute inhalation LC_{50} of the technical grade of active ingredient is less than 200 mg/m^3 (for a one-hour exposure); or (C) the acute oral LD_{50} of the technical grade of active ingredient is less than 50 mg/kg (body weight); or (D) neurotoxic, teratogenic, or oncogenic effect or other adverse effects as evidenced by subchronic, chronic, and reproduction studies would be expected 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 to 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.

§ 158.145 Wildlife and aquatic organism data requirements

(a) TABLE.—SECTIONS 158.50 AND 158.100 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	Wildlife and aquatic organisms data requirements; general use patterns									Test substance		Guideline reference No. 1
		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}	(1)	[R]	[R]	[R]	[R]	[CR]	[CR]	[R]	[R]	[CR]	TGAI	TGAI	71-1
Avian dietary LC_{50}	(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	(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}	(1), (7)	[R]	[R]	[R]	[R]	[CR]	[CR]	[R]	[R]	[CR]	TGAI	TGAI	72-1
Acute LC_{50} freshwater invertebrates.	(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
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.	(2)	[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.	(8)	[CR]	[CR]	[CR]	[CR]	.....	.....	[CR]	[CR]	.....	TEP	TEP	72-7

Key: R=Required; CR=Conditionally Required; [ ]=Brackets (i.e. [R], [CR] indicative data requirements that apply when an experimental use permit is being sought; TGAI=Technical 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) 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.

(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 metabolites or 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 metabolites or degradation products is stored or accumulated in plant or 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 that 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; or

(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 acutue toxicity testing; or

(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 of the following conditions exist:

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

(B) Physiochemical properties indicate cumulative effects; or

(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-stage or invertebrate life-cycle test; or

(ii) If studies of other organisms indicate the reproductive physiology of fish may be affected.

(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 into 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; or

(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.

§ 158.150 Plant protection data requirements.

(a) TABLE.—SECTIONS 158.50 AND 158.100 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	Plant protection data requirements; general use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Date 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)										TGAI	TGAI	122-1
Vegetative vigor	(2)										TGAI	TGAI	122-1
Aquatic plant growth	(2)										TGAI	TGAI	122-2
Tier II:													
Seed germination/seedling emergence.	(3)										TGAI	TGAI	123-1
Vegetative vigor	(3)										TGAI	TGAI	123-1
Aquatic plant growth	(4)										TGAI	TGAI	123-2
Tier III:													
Terrestrial field	(3)										TEP	TEP	124-1
Aquatic field	(4)										TEP	TEP	124-2

Key: TGAI = Technical grade of the active ingredient; EP = End-use product; TEUP = 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 on a case-by-case basis to support: (i) Products for which phytotoxicity problems arise and open literature data are not available; (ii) products that may pose hazards to endangered or threatened species, or (iii) products for which a rebuttable presumption against registration (Special Review) has been initiated.

(3) Required if a 25% 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% or greater detrimental effect was found on any plant species in the corresponding test of the previous tier.

§ 158.155 Nontarget insect data requirements.

(a) TABLE.—SECTIONS 158.50 AND 158.100 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	Nontarget insect data requirements; 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						
Nontarget insect testing—pollinators													
Honey bee acute contact LD_{50}	(1)	[R]	[R]	[R]	[R]			[R]	[R]		TGAI	TGAI	141-1
Honey bee—toxicity of residues on foliage.	(1), (2)	[CR]	[CR]	[CR]	[CR]			[CR]	[CR]		TEP	TEP	141-2
Wild bees important in alfalfa pollination—toxicity of residues on foliage.	(3)	[CR]									TEP	TEP	141-3
Honey bee subacute feeding study (reserved).													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 (reserved).													142-1
Aquatic insect life-cycle study (reserved).													142-1
Simulated or actual field testing for aquatic insects (reserved).													142-3
Nontarget insect testing—predators and parasites (reserved).													143-1—143-3

Key: CR = Conditionally required: R = Required; [ ] = Brackets (ie [R], [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 paragaph (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 11 micrograms/bee.

(3) Required only for products intended for foliar application to alfalfa grown for seed.

(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; or

(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.

§ 158.160 Product performance data requirements.

(a) TABLE.—SECTIONS 158.50 AND 158.100 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	Product performance data requirements; general use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Date 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
Product 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]	[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

Key: CR=Conditionally Required; [ ]=Brackets (i.e., [CR]) indicate data requirements that apply to products for which an experimental use permit is being sought; EP=End-use product (asterisk indicates that registrants of end-use products formulated from registered manufacturing use products are responsible for submission of these data).

(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.

§ 158.165 Biorational Pesticide Data Requirements

(a) TABLE.—SECTIONS 158.50 AND 158.100 DESCRIBE HOW TO USE THIS TABLE TO DETERMINE THE BIORATIONAL PESTICIDES—PRODUCT ANALYSIS DATA REQUIREMENTS AND THE SUBSTANCE TO BE TESTED

Kind of data required	(b) Notes	Biorational pesticides—product analysis data requirements; 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 analysis biochemical and microbial agents													
Product identity		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	151-10, 20
Manufacturing process	(1)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	151-11, 21
Discussion of formation of unintentional ingredients.	(1)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	151-12, 22
Analysis of samples	(2)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP	EP*	151-13, 23
Certification of limits	(3)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	151-15, 25
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 & TGAI	EP* & TGAI	151-17, 26
Submittal of samples	(4)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP	MP	151-18, 27

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

(1) 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.
(2) For pesticides in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.
(3) If tests are to be conducted on beginning materials, the Agency will waive the requirements for innocuous inert ingredients such as corn meal, water, silica and similar materials.
(4) Routinely required for products produced by an integrated formulation system. Required on a case-by-case basis for other products or materials.

(c) TABLE.—SECTIONS 158.50 AND 158.100 DESCRIBE HOW TO USE THIS TABLE TO DETERMINE THE BIORATIONAL PESTICIDES—RESIDUE DATA REQUIREMENTS AND THE SUBSTANCES TO BE TESTED

Kind of data required	(d) Notes	Biorational pesticides—residue data requirements; 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						
Biochemical agents:													
Chemical identity	(1), (2), (14)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	TGAI	TGAI	153-3
Directions for use	(1), (3), (14)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]			153-3
Nature of the residue	(1), (14)												
Plants		[CR]		[CR]		[CR]			[CR]		PAIRA	PAIRA	153-3
Livestock	(1), (4), (14)	[CR]		[CR]		[CR]			[CR]		PAIRA & plant metabolites.	PAIRA & plant metabolites.	153-3
Residue analytical method	(1), (5), (14)	[CR]		[CR]		[CR]			[CR]		TGAI & metabolites.	TGAI & metabolites.	153-3
Magnitude of the residues:													
Crop field trials	(1), (14)	[CR]		[CR]		[CR]			[CR]		TEP	TEP	153-3
Processed food/feed	(1), (6)	[CR]		[CR]		[CR]					EP	EP	153-3
Meat/milk/poultry/eggs	(1), (7)	[CR]		[CR]		[CR]				[CR]	TGAI or plant metabolites.	TGAI or plant metabolites.	153-3
Potable water	(1), (8)			[CR]	[CR]						EP	EP	153-3
Fish	(1), (9)			[CR]	[CR]						EP	EP	153-3
Irrigated crops	(1), (10)			[CR]	[CR]						EP	EP	153-3
Food handling	(1), (11)									[CR]	EP	EP	153-3
Reduction of residue	(1), (12)	[CR]		[CR]		[CR]					Residue of concern.	Residue of concern.	153-3
Proposed tolerance	(1), (13)	[CR]		[CR]		[CR]					Residue of concern.	Residue of concern.	153-3
Resonable grounds in support of the petition.		[CR]		[CR]		[CR]							153-3
Microbial agents	(15)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]			153-4

Key: R=Required data; 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., [R], [CR] indicate data requirements that apply when an experimental use permit is being sought.

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

(1) Residue chemistry data requirements shall apply to biochemical pest control agent products when one or both of the following conditions apply:
(i) Tier II or III toxicology data are required, as specified for biochemical agents in table (e) of this section, or
(ii) The application rate of the product exceeds 0.7 ounces (20 grams) active ingredient per acre per application.
(2) The same chemical identity data as required under § 158.120 are required, with emphasis on impurities that could constitute a residue problem.
(3) Required information includes crops to be treated, rate of application, number and timing of applications, preharvest intervals, and relevant restrictions.
(4) Data on metabolism in livestock are required when residues occur on a livestock feed, or the pesticide is to be applied directly to livestock.
(5) A residue method suitable for enforcement of tolerance is needed whenever a numeric tolerance is proposed. Exemptions from the requirement of a tolerance will also usually require an analytical method.
(6) 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.
(7) 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.
(8) 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.
(9) Data on residues in fish are required whenever a pesticide is to be applied directly to water.
(10) 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.
(11) Data on residues in food/feed in food handling establishments are required whenever a pecticide is to be used in food/feed handling establishments.
(12) 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.
(13) The proposed tolerance must reflect the maximum residue likely to occur in crops and meat/milk/poultry/eggs.
(14) 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.
(15) Residue data requirements shall apply to microbial pest control products when Tier II or Tier III toxicology data are required as specified for microbial agents in table (e) of this section.

(e) TABLE.—SECTIONS 158.50 AND 158.100 DESCRIBE HOW TO USE THIS TABLE TO DETERMINE THE BIORATIONAL PESTICIDES—TOXICOLOGY DATA REQUIREMENTS AND THE SUBSTANCES TO BE TESTED

Kind of data required	(f) Notes	Biorational pesticides—toxicology data requirements; 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						
Toxicology: biochemical agents													
Tier I:													
Acute oral	(1)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP & TGAI	EP* or EP dilution* & TGAI.	152-10
Acute dermal	(1), (2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP & TGAI	EP* or EP dilution* & TGAI.	152-11
Acute inhalation	(2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP & TGAI	EP* & TGAI	152-12
Primary eye irritation	(1), (2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP	152-13
Primary dermal irritation	(3)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP	152-14
Hypersensitivity study	(3)	CR	CR	CR	CR	CR	CR	CR	CR	CR	MP	EP	152-15
Hypersensitivity incidents	(4)	CR	CR	CR	CR	CR	CR	CR	CR	CR			152-16
Studies to detect genotoxicity.	(5)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	TGAI	TGAI	152-17
Cellular immune response		[R]	R	[R]	R	R	R	R	R	R	TGAI	TGAI	152-18

(e) TABLE.—SECTIONS 158.50 AND 158.100 DESCRIBE HOW TO USE THIS TABLE TO DETERMINE THE BIORATIONAL PESTICIDES—TOXICOLOGY DATA REQUIREMENTS AND THE SUBSTANCES TO BE TESTED

Kind of data required	(f) Notes	Biorational pesticides—toxicology data requirements; 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 II:													
Mammalian mutagenicity tests.	(6)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-19
Subchronic oral	(7)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-20
Subchronic dermal	(8)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-21
Subchronic inhalation	(9)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-22
Teratogenicity	(10)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-23
Cellular immune response	(11)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-24
Tier III:													
Chronic exposure	(12)	CR		CR		CR				CR	TGAI	TGAI	152-26
Oncogenicity	(13)	CR		CR		CR				CR	TGAI	TGAI	152-29
Toxicology: Microbial agents													
Tier I:													
Acute oral		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP & TGAI	EP* or EP dilution* & TGAI.	152-30
Acute dermal		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP & TGAI	EP* or EP dilution* & TGAI.	152-31
Acute inhalation	(14)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP & TGAI	EP* & EP dilution & TGAI.	152-32
I.V., I.C., I.P injection	(15)	[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	(16)	R	R	R	R	R	R	R	R	R	MP	EP*	152-36
Hypersensitivity incidents	(4)	CR	CR	CR	CR	CR	CR	CR	CR	CR			152-37
Cellular immune response		[R]	R	[R]	R	[R]	[R]	R	R	R	TGAI	TGAI	152-38
Tissue culture	(17)	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	152-39
Tier II:													
Acute oral	(18)	CR	CR	CR	CR	CR	CR	CR	CR	CR	MP	EP*	152-40
Acute inhalation	(19)	CR	CR	CR	CR	CR	CR	CR	CR	CR	MP	EP*	152-41
Subchronic oral	(20)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-42
Acute I.P., I.C.	(21)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-43
Primary dermal	(22)	CR	CR	CR	CR	CR	CR	CR	CR	CR		EP*	152-44
Primary eye	(23)	CR	CR	CR	CR	CR	CR	CR	CR	CR		EP*	152-45
Cellular immune response	(24)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-46
Teratogenicity	(25)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-47
Virulence enhancement	(26)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-48
Mammalian mutagenicity	(27)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-49
Tier III:													
										CR	TGAI	TGAI	152-50
Chronic feeding	(28)	CR		CR		CR				CR	TGAI	TGAI	152-51
Oncogenicity	(29)	CR		CR		CR				CR	TGAI	TGAI	152-52
Mutagenicity	(30)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-53
Teratogenicity	(31)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152-47

(f) *Notes.*—The following notes are referenced in column two of the table contained in paragraph (e) of this section.

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

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

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

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

(5) 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 belong(s) to any chemical class of compounds containing known mutagens.

(6) Required if results from any one of the Tier I mutagenicity tests were positive.

(7) Required if acute adverse effects were observed in the Tier I acute oral test and 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 likely to result in repeated human exposure by the oral route.

(8) Required if acute adverse effects were observed during Tier I acute dermal toxicity studies and pesticide use is likely to result in repeated human skin contact with the product, its active ingredients, or its breakdown products.

(9) Required if acute adverse effects were observed during the Tier I acute inhalation and pesticidal use may result in repeated inhalation exposure at a concentration which is likely to be toxic.

(10) Required if adverse effects were observed during Tier I acute oral studies and any of the following criteria are met: (i) Use of the product under widespread and recognized practice may reasonably be expected to result in significant exposure to female humans; or (ii) its use requires a tolerance or an exemption from the requirement for a tolerance, or its use requires issuance of a food additive regulation.

(11) Required if adverse effects are observed in the Tier I cellular immune response studies.

(12) Required if the potential for adverse chronic effects are indicated based on: (i) The subchronic effect levels established in the Tier II subchronic oral toxicity studies, the Tier II subchronic dermal toxicity studies or the Tier II subchronic inhalation toxicity studies; (ii) The pesticide use pattern (e.g., rate, frequency, and site of application); and (iii) The frequency and level of repeated human exposure that is expected.

(13) Required if the product meets either of the following criteria: (i) The active ingredient(s) or any of its (their) metabolites, degradation products, or impurities produce(s) in Tier II subchronic studies a morphologic effect (e.g., hyperplasia, metaplasia) in any organ that potentially could lead to neoplastic change; or (ii) If adverse cellular effects suggesting oncogenic potential are observed in Tier I or Tier II cellular immune response studies or in Tier II mammalian mutagenicity assays.

(14) Required if 20 percent or more of the aerodynamic equivalent of the product (as registered or under conditions of use) is composed of particulates under 10 microns in diameter.
(15) Data required for products as follows: (i) Intravenous ("IV") infectivity study for bacterial, and viral agents; (ii) Intracerebral ("IC") infectivity study for viral and protozoan agents; and (iii) Intraperitoneal ("IP") infectivity study for fungal and protozoan agents.
(16) Required if commonly recognized use practices will result in repeated human contact by inhalation or dermal routes.
(17) Data required for products whose active ingredient is a virus.
(18) 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 intracerebral injection test for protozoa.
(19) 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.
(20) Required if there is evidence of survival, replication, infectivity, or persistence of the protozoan agent in the Tier I oral infectivity test.
(21) Required if in Tier I acute oral infectivity testing, Tier I dermal toxicity/infectivity testing, or Tier I intraperitoneal and 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.
(22) Required if marked edema or broad erythema was observed in the Tier I dermal irritation study.
(23) Required if severe ocular lesions are observed in the Tier I primary eye irritation study.
(24) Required if results of the Tier I cellular immune response test indicate abnormalities.
(25) Required when Tier I test on viral agents show replication of the virus in mammalian hosts and significant damage to mammalian cells.
(26) 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 bacterial or fungal agent, respectively.
(27) Required if any of the following criteria are met: (i) Acute infectivity tests are positive in Tier I studies; (ii) Adverse cellular effects are observed in cellular immune response studies; or (iii) Positive results are obtained in tissue culture tests with viral agents.
(28) 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).
(29) 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.
(30) 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.
(31) Required when the potential for teratogenic effects is expected based on the presence or 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.

(g) TABLE.—SECTIONS 158.50 AND 158.100 DESCRIBE HOW TO USE THIS TABLE TO DETERMINE THE BIORATIONAL PESTICIDES NON-TARGET ORGANISM, FATE AND EXPRESSION DATA REQUIREMENTS AND SUBSTANCES TO BE TESTED

Kind of data required	(h) Notes	Biorational pesticide-nontarget organism, fate and expression data requirements; 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						
Nontarget organism and environmental fate: Biochemicals													
Tier I:													
Avian acute oral	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154-8
Avian dietary	(1), (4)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154-7
Freshwater fish LC_{50}	(1), (5)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154-8
Freshwater invertebrate LC_{50}	(1), (6)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154-9
Plant studies	(2)										TGAI	TGAI	154-10
Nontarget insect testing	(3), (4)	CR	CR	CR	CR	CR	CR	CR	CR		TGAI	TGAI	154-11
Tier II:													
Volatility	(7)	CR	CR	CR	CR			CR	CR		TEP	TEP	155-4
Dispenser-water leaching	(8)	CR	CR	CR	CR			CR	CR		EP	EP	155-5
Adsorption-desorption	(9)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155-6
Octanol/water partition	(9)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155-7
U.V. absorption	(10)	CR	CR	CR	CR			CR	CR		PAI	PAI	155-8
Hydrolysis	(9)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155-9
Aerobic soil metabolism	(9)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155-10
Aerobic aquatic metabolism.	(9)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155-11
Soil photolysis	(9)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155-12
Aquatic photolysis	(9)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155-13
Tier III:													
Terrestrial wildlife testing	(11)	CR	CR	CR	CR		CR	CR	CR		TGAI	TGAI	154-12
Aquatic animal testing	(12)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154-13
Plant studies	(13)										TGAI	TGAI	154-14
Nontarget insect testing	(14)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154-15
Nontarget organisms and environmental expression: Microbial agents													
Tier I:													
Avian oral	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154-16
Avian injection test	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154-17
Wild mammal testing	(15)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154-18
Freshwater fish testing	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	CR	CR	TGAI	TGAI	154-19
Freshwater aquatic invertebrate testing.	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	CR	CR	TGAI	TGAI	154-20
Estuarine and marine animal testing.	(16)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154-21
Plant studies:		[R]	[R]	[R]	[R]			[R]	[R]	CR	TEP	TEP	154-22
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.	(17)	CR	CR	CR	CR			CR	CR		TGAI or TEP	TGAI or TEP	155-18
Freshwater environmental expression tests.	(16)	CR	CR	CR	CR			CR	CR		TGAI or TEP	TGAI or TEP	155-19
Marine or estuarine environmental expression tests.	(19), (20)	CR	CR	CR	CR			CR	CR		TGAI or TEP	TGAI or TEP	155-20
Tier III:													
Terrestrial wildlife & aquatic organism testing.	(21)	CR	CR	CR	CR			CR	CR		TGAI or TEP	TGAI or TEP	154-25
Avian pathogenicity/Reproduction test.	(22)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154-26
Definitive aquatic animal tests.	(23)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154-27

(g) TABLE.—SECTIONS 158.50 AND 158.100 DESCRIBE HOW TO USE THIS TABLE TO DETERMINE THE BIORATIONAL PESTICIDES NON-TARGET ORGANISM, FATE AND EXPRESSION DATA REQUIREMENTS AND SUBSTANCES TO BE TESTED—Continued

Kind of data required	(h) Notes	Biorational pesticide-nontarget organism, fate and expression data requirements; 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 embryo larvae and life cycle studies.	(23)	CR	CR	CR	CR			CR *	CR		TGAI	TGAI	154-28
Aquatic ecosystem test	(24)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154-29
Special aquatic tests (reserved).													154-30
Plant studies	(25)	CR	CR	CR	CR			CR	CR		TGAI	TEP	154-31
Tier IV:													
Simulated and actual field tests (birds, mammals).	(26)	CR	CR	CR	CR			CR	CR		TGAI	TEP	154-33
Simulated and actual field tests (aquatic organisms).	(27), (28)	CR	CR	CR	CR			CR	CR		TGAI	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 (asterisk indicates that registrants of end-use products formulated from registered manufacturing use products are responsible for submission of these data); PAI="Pure" active ingredient.

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

(1) 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.

(2) Data are required on a case-by-case basis to support: (i) products for which phytotoxicity problems arise and open literature data are not available; (ii) products that may pose hazards to endangered or threatened species, or (iii) products for which a rebuttable presumption against registration (Special Review) has been initiated.

(3) Required on a case-by-case basis depending on pesticide mode of action and results of any available efficacy test results.

(4) Biochemicals introduced directly into an aquatic environment when used as directed shall be tested as specified in § 158.145.

(5) Not required if pesticide is highly volatile (estimated volatility greater than 5×10^{-5} atm. m^3/mol).

(6) 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.

(7) 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.

(8) 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.

(9) Required on a case-by-case basis when results of Tier I tests indicate environmental fate data are needed.

(10) 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.

(11) Required if: (i) 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); or (ii) The pesticide or any or its metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in the avian feed.

(12) 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.

(13) 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.

(14) 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.

(15) Required on a case-by-case basis if results of tests required by table (e) of this section are inadequate or inappropriate for assessment of hazards to wild mammals.

(16) 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.

(17) Required when toxic or pathogenic effects are observed in any of the following Tier I tests for microbial pest control agents: (i) Avian single dose oral toxicity and pathogenicity tests; (ii) Avian injection pathogenicity test; (iii) Wild mammal toxicity and pathogenicity test; (iv) Plant studies—terrestrial; (v) Testing for toxicity/pathogenicity to insect predators and parasites; or (vi) Honey bee toxicity/pathogenicity test.

(18) Required when toxic or pathogenic effects are observed in any of the following Tier I tests for microbial pest control agents: (i) Freshwater fish toxicity and pathogenicity testing; (ii) Freshwater aquatic invertebrate toxicity and pathogenicity test; or (iii) Plant studies—aquatic.

(19) 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: (i) Estuarine and marine animal toxicity and pathogenicity test; or (ii) Plant studies—estuarine or marine.

(20) 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: (i) Avian single dose oral toxicity and pathogenicity test; (ii) Avian injection pathogenicity test; (iii) Estuarine and marine animal toxicity and pathogenicity test.

(21) 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.

(22) Required when: (i) Pathogenic effects are observed in Tier I avian tests at a level equal to the adjusted host equivalent amount; or (ii) Chronic carcinogenic, or teratogenic effects are reported in tests required by table (e) of this section for evaluating hazard to humans and domestic animals; and (iii) Tier II Environmental expresssion testing indicates that exposure of terrestrial animals to the microbial agent is likely.

(23) 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.

(24) 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: (i) Infectivity or pathogenicity demonstrated in previous testing; and (ii) Viability of the microorganism in natural waters as demonstrated in Tier II tests.

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

(26) Required when: (i) Pathogenic effects at actual or expected field residue exposure levels are reported in Tier III; and (ii) The Agency determines that quarantine methods will prevent the microbial pest control agent from contaminating areas adjacent to the test area.

(27) 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.

(28) 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 result from intended use.

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., crops, forests, ornamentals) 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 158.165.

Pesticide Use Site Group

1. Crops
2. Forests
3. Ornamentals
4. Produce, Processed Food and Feed Products
5. Food and Feed Containers, Dispensers, and Processing Equipment
6. Animals and Their Man-made Premises
7. Animals for Pets, Including Their Cages, Bedding, Nests, etc.
8. Egg Handling Facilities and Equipment
9. Milk Handling Facilities and Equipment
10. Directed Pest Control to Pests' Nests, etc., and for Traps
11. Households (Private and Commercial Domestic Areas)
12. Wood Protection
13. Aquatic Areas
14. Uncultivated Agricultural Areas (Non-food Producing)
15. Uncultivated Agricultural Areas (Outdoor)
16. Wide Area and General Indoor/Outdoor Treatments
17. Antifouling Sites

18. Transportation Facilities
19. Food and Feed Processing Plants
20. Eating Establishments (all)
21. Food Marketing, Storage, and Distribution
22. Hospitals and Related Institutions and Facilities
23. Barber and Beauty Shop Instruments and Equipment
24. Morgues, Mortuaries, and Funeral Homes
25. Commercial, Institutional, and Industrial Maintenance, Buildings, and Structures
26. Fiber Product Protection (Moth- and Mildew- Proofing)
27. Preservatives and Protectants
28. Human Articles and Materials
29. Laundry Cleaning and Dry Cleaning
30. Bathrooms, Toilet Bowls, and Related Sites
31. Refuse and Solid Waste
32. Surface Treatments
33. Specialty Uses

Specific use patterns—listed according to use site group	Corresponding general use pattern
1. Crops:	
Small fruits [subgroup]	Terrestrial Food Crop.
Caneberries (e.g., raspberry, dewberry) [item].	Do.
Bushberries (e.g., blueberry, current).	Do.
Vine fruits (e.g., grape, kiwi fruit).	Do.
Strawberry	Do.
Cranberry	Do.
Pome fruits (e.g., apple, quince).	Do.
Stone fruits (e.g., peach, cherry).	Do.
Nut crops—tree & shrub (e.g., pecan, filbert).	Do.
Other temperate fruits (e.g., persimmon, pawpaw).	Do.
Tropical and subtropical fruits	Do.
Citrus	Do.
Banana and plantain	Do.
Palm fruits and nuts (e.g., date, coconut).	Do.
Pineapple	Do.
Other fruits and nuts	Do.
Beverage crops	Do.
Woody—cocoa, coffee, tea	Do.
Herbaceous—chicory, mint	Do.
Flavoring and spice crops	Do.
Woody—leaf/stem, root, seed and pod.	Do.
Herbac.—leaf/stem, root, seed and pod.	Do.
Vegetables—leaf/stem, root, seed and pod.	Do.
Commercial annual (e.g., tomato, bean.	Do.
Commercial perennial (e.g., asparagus, rhubarb).	Do.
Home graden	Domestic Outdoor.
Greenhouse (commerical)	Greenhouse-Food Crop.
Mushrooms	Do.
Fiber crops	Terrestrial Food Crop.
Cotton	Do.
Others—(e.g., flax)	Do.
Forage crops	Do.
Typical grasses—annual (e.g., sudan grass).	Do.
Typcial grasses—perennial (e.g., bromegrass.	Do.
Corn and sorghum	Do.
Small grains for forage (e.g., rye).	Do.
Perennial legumes (e.g., white clover).	Do.
Annual legumes (e.g., crotalaria, soybean).	Do.
Crop harvest residue (peanut vines, beet tops, etc.).	Do.
Grain and edible seed crops	Do.
Corn	Do.
Rice	Aquatic Food Crop.
Wheat, barley, rye, oats	Terrestrial Food Crop.
Sorghum	Do.
Alfalfa	Do.
Other grains	Do.
Other non-grains (e.g., squash, pumpkin).	Do.
Buckwheat	Do.
Sesame	Do.
Sunflower	Do.
Seed sprout crops	Do.
Mung bean, red clover, soybean, etc.	Do.
Non-legume crops (e.g., wheat, radish, black mustard).	Do.
Crops grown exclusively for seed for planting.	Terrestrial Non-Food Crop.
Sugar crops	Terrestrial Food Crop.
Honey (principal nectar-producing crops).	Do.
Sugar beet	Do.
Sugar cane	Do.
Sugar maple	Do.
Sorghum (for sugar)	Do.
Crops for smoking and chewing.	Terrestrial Non-Food Crop.
Tobacco—seedbed	Do.
—field	Do.
—shade	Do.
—storage	Do.
Sapodilla (for chewing gum).	Do.
Oil crops	Do.
Annual herbaceous crops	Do.
Perennial herbaceous crops.	Do.
Temperate wood crops	Do.
Tropical/subtropical woody crops.	Do.
Drug and medicinal crops	Do.
Annual herbaceous crops	Do.
Perennial herbaceous	Do.
Temperate herbaceous crops.	Do.
Tropical/subtropical woody crops.	Do.
2. Forest:	
Forest trees—non-ornamental—trees, forest, plantings.	Forestry.
Deciduous temperate (broadleaf).	Do.
Evergreen temperate (broadleaf).	Do.
Deciduous and evergreen conifers.	Do.
Tropical/subtropical broadleaf.	Do.
Tropical/subtropical conifer	Do.
Forest tree nurseries—	Do.
Temperate broadleaf trees	Do.
Temperate conifer trees	Do.
Forest trees: dead trees/logs/stumps in the forest or in plantings.	Do.
3. Ornamentals:	
Ornamental plants	Terrestrial Non-Food Crop.
Annual garden plants	Do.
Temperate perennial garden herbs.	Do.
Commercial greenhouse crops.	Greenhouse Non-Food Crop.
Houseplants	Indoor.
Home and retail greenhouse and conservatory plants.	Do.
Public display plantings	Terrestrial Non-Food Crop.
Bulb, corm, and tuber ornamentals.	Do.
Subtropical/tropical garden evergreen plants (dey—e.g., agave).	Do.
Subtropical/troprical garden evergreen plants (moist—e.g., ferns).	Do.
Groundcovers	Do.
Aquatic plants (e.g., waterlilies).	Aquatic Non-Food Crop.
Ornamental trees, shrubs, and vines (woody).	Terrestrial Non-Food Crop.
Deciduous temperate broadleaf.	Do.
Evergreen temperate broadleaf.	Do.
Deciduous temperate conifer.	Do.
Evergreen temperate conifer.	Do.
Tropical/subtropical broadleaf.	Do.
Tropical/subtropical conifer	Do.
Tropical/subtropical miscellaneous (e.g., cycad, tree fern, bamboo).	Do.
Lawn and turf grasses—ornamental.	Do.
Cool season Winter grasses (bent, bluegrass, fescue, etc.).	Do.
Summer grasses (zoysia, bermudagrass, etc.).	Do.
Ornamental bunch grasses (pampasgrass, blue fescue).	Do.
4. Produce, Processed Food and Feed Products:	
Vegetable, fruit, and nut produce.	Indoor.
Fruits	Do.
Leafy vegetables	Do.
Root vegetables	Do.
Fruited vegetables	Do.
Nuts	Do.
Peanuts	Do.
Seeds (sesame, sunflower)	Do.
Dried processed	Do.
Fruits	Do.
Vegetables	Do.
Tobacco	Do.
Beverages (tea, coffee)	Do.
Herbs and spices	Do.
Animal Feeds	Do.
Cattle (beef)	Do.
Cattle (dairy)	Do.
Goat (nondairy)	Do.
Goat (dairy)	Do.
Horse, mule, donkey	Do.
Poultry (chicken, turkey, etc.).	Do.
Sheep (meat)	Do.
Sheep (wool)	Do.
Swine	Do.
Dog	Do.
Cat	Do.
Other pets (excluding birds).	Do.
Fur-bearing stock	Do.
Other meat-producing stock (e.g., rabbit).	Do.
Fish food (commercial)	Do.
Fish food (pet)	Do.
Birdseed	Do.
Processed grain products for human consumption.	Do.
Corn	Do.
Soybean	Do.
Wheat	Do.
Other grains (rice, barley, etc.).	Do.
Cereal foods	Do.
Flour	Do.
Baked goods	Do.
Farinaceous products	Do.
Processed animal products for human consumption (see also Food and Feed Processing).	Do.
Cheese	Do.
Egg yolks	Do.
Meats, including fish and poultry.	Do.
Milk	Do.
Processed plant products for human consumption (see also Food and Feed Processing).	Do.
Chocolate	Do.
Candy	Do.
Sugar	Do.
Yeast	Do.
Citrus pulp	Do.
Chewing gum	Do.
Cigarettes, etc.	Do
Herbs and spices	Do.
Pickles	Do.
Glazed fruits	Do.
Jellies	Do.

Specific use patterns—listed according to use site group	Corresponding general use pattern
Seed oils	Do.
Fruit syrups (e.g., cola)	Do.
Fruit juices	Do.
Fermentation beverages (wine, beer, whiskey, vinegar).	Do.
Processed or manufactured nonfood plant and animal products (see also Preservatives and Protectants).	Do.
Textiles, fabrics, fibers	Do.
Fur and hair products	Do.
Leather products	Do.
Fuels from crops (alcohol, methane).	Do.
Fossil fuels (e.g., oils, jet fuel).	Do.
Seed oils	Do.
Lumber, wood (see also Wood Protection).	Do.
Paper	Do.
Pesticide materials preservation and protection.	Do.
Rodenticide baits (protection against insects).	Do.
Dried plant parts (pyrethrum, red squill, rotenone, sabadilla).	Do.
Paints (protection from deterioration; see also Preservatives and Protectants).	Do.
5. Food and Feed Containers, Dispensers, and Processing Equipment:	
Airtight storages—large (empty/full).	Indoor.
Airtight storages—small (empty/full).	Do.
Fumigation chambers	Do.
Bins	Do.
Elevators	Do.
6. Animals and their Man-made Premises:	
Dairy cattle—lactating	Indoor.
Dairy cattle—nonlactating	Do.
Dairy cattle—heifers, calves	Do.
Goats—lactating	Do.
Goats—nonlactating	Do.
Goats—young (kids)	Do.
Fur—and wool-bearing animals.	Do.
Goats	Do.
Sheep	Do.
Mink	Do.
Chinchilla	Do.
Rabbit	Do.
Fox	Do.
Nutria	Do.
Meat animals (mammals)	Do.
Cattle (and calves)	Do.
Goats (and kids)	Do.
Horses	Do.
Rabbits	Do.
Sheep (and lambs)	Do.
Swine	Do.
Bison	Do.
Poultry (meat, eggs)	Do.
Chickens	Do.
Turkeys	Do.
Ducks, geese	Do.
Guineas, pheasants, quail, etc.	Do.
Honey production	Do.
Bees	Do.
Beehives	Do.
Honeycombs	Do.
Fish and shellfish production	Aquatic Food Crop.
Hatchery buildings	Do.
Culture ponds, containers	Do.
Animals for labor, display, riding, racing, lab use, etc.	Indoor.
Dogs	Do.
Horses, donkeys, mules	Do.
Guinea pigs	Do.
Mice	Do.
Rats	Do.
Gerbils	Do.
Hamsters	Do.
Monkeys	Do
Cats	Do.
Zoo ruminants	Do.
Zoo ungulates	Do.
Zoo canines	Do.
Zoo felines	Do.
Zoo primates	Do.
Zoo reptiles	Do.
Zoo amphibians	Do.
Zoo birds	Do.
Zoo—others	Do.
Aquarium fish	Do.
7. Animals for Pets, including their Cages, Bedding, Nests, etc:	
Dogs	Indoor.
Cats	Do.
Birds	Do.
Rodents	Do.
Lagomorphs	Do.
Fish	Do.
Amphibians	Do.
Reptiles	Do.
Primates	Do.
Other vertebrates	Do.
8. Egg Handling Facilities and Equipment:	
Egg washers	Indoor.
Egg rooms	Do.
Hatching egg treatments	Do.
Hatching egg rooms	Do.
Hatching egg equipment	Do.
9. Milk Handling Facilities and Equipment:	
Milk storage rooms	Indoor.
Milking stalls and parlors	Do.
Milking machines, milk tanks, etc.	Do.
Teat cups, liners, etc	Do.
Milk processing equipment	Do.
10. Directed Pest Control to Pests' Nests, etc., and for Traps:	
Diseased beehives	Terrestrial Non-Food Crop.
Nuisance bee nests	Do.
Ant mounds, hills, dens	Do.
Termite mounds	Do.
Insect traps (chemical lures)	Do.
Repellents and irritants to pests (when not covered by other sites.	Do.
11. Households (Private and Commercial Domestic Areas):	
Non-food areas and sites	Indoor.
Closets, storage areas	Do.
Basements, cellars	Do.
Bedrooms	Do.
Attics	Do.
Recreation rooms	Do.
Living rooms	Do.
Baseboards, window sills, etc.	Do.
Plumbing fixtures	Do.
Food-handling and food storage areas.	Do.
Kitchens	Do.
Dining rooms	Do.
Pantyry and food storage shelving.	Do.
Household contents and space.	Do.
Air	Do.
Beds	Do.
Rugs	Do.
Clothing	Do.
Book cases	Do.
Furs, fabrics, blankets	Do.
Play pens	Do.
Sickroom utensils	Do.
Filters for air vents, air conditioners, furnaces, etc.	Do.
12. Wood Protection:	
Buildings (for termite, powderpost beetle control, etc.).	Terrestrial Non-Food or Indoor.
Unseasoned forest products	Do.
Seasoned forest products	Do.
Finished wood products	Do.
Plant-growing wood structures and containers.	Do.
Wood containers for food and feed.	Do.
13. Aquatic Areas:	
Food processing water systems.	Aquatic Food Crop.
Pulp and papermill systems	Aquatic Non-Crop.
Poultry and livestock drinking water.	Do.
Swimming pool water	Do.
Industrial disposal systems	Do.
Industrial process water	Do.
Industrial ponds	Do.
Human drinking water	Aquatic Food Crop.
Cooling water towers	Aquatic Non-Crop.
Agricultural irrigation water, and ditches.	Aquatic Food Crop.
Agricultural drainage water and ditches.	Do.
Sewage systems and drainfields.	Aquatic Non-Crop.
Dishwashing water	Indoor.
Domestic and commercial nonpotable water.	Aquatic Non-Crop.
Lakes, ponds, impounded water.	Do.
Streams, rivers, canals	Do.
Swamps, marshes, wetlands	Do.
Catch basins, puddles, tree holes.	Do.
Estuaries, tidal marshes	Do.
Commercial and sport fishbearing waters.	Aquatic Food Crop.
14. Uncultivated Agricultural Areas (Non-food Producing):.	
Farmyards	Terrestrial Non-Crop.
Fuel storage areas	Do.
Fence rows	Do.
Rights-of-way	Do.
Fallow land	Do.
Soil bank land	Do.
Barrier strips	Do.
15. Uncultivated Nonagricultural Areas (Outdoor):	
Airports	Do.
Recreation areas, fair grounds, race tracks, tennis courts, etc.	Do.
Campgrounds	Do.
Recreation area structures	Do.
Highway rights-of-way	Do.
Railroad rights-of-way	Do.
Utility rights-of-way	Do.
Sewage disposal areas	Do.
Industrial sites (lumberyards, tank farms, etc.).	Do.
Paved areas	Do.
Private roads and walks	Do.
Fencerows and hedgerows (non-agricultural).	Do.
16. Wide Area and general Indoor/Outdoor Treatments:.	
Rural areas (unspecified)	Terrestrial Non-Crop or Indoor.
Urban areas (unspecified)	Do.
Public buildings and structures.	Do.
Animal burrow entrances, dens, tunnels.	Do.
Animal nests	Do.
Animal trails	Do.
Mammal feeding areas	Do.
Non-agricultural areas for public health treatments.	Do.
Bird roosting, nesting areas	Do.
Bird feeding areas	Do.
17. Antifouling Sites:	
Sites for marine exposures	Aquataic Non-Crop.
Boat bottoms and other submersed structures.	Do.
Steel	Do.
Fiberglass	Do.
Aluminum	Do.
Wood	Do.
Plastic	Do.
Other substances and materials.	Do.
Crab pots and lobster pots	Do.
Sites for fresh water exposures.	Do
18. Transportation Facilities:.	
Bus	Indoor.
Truck & trailer	Do.
Containerized units	Do.

Specific use patterns—listed according to use site group	Corresponding general use pattern
Railroad cars	Do.
Aircraft	Do.
Ships/barges	Do.
Autos, taxis	Do.
Recreational vehicles	Do.
19. Food and Feed Processing Plants:	
Bakeries	Do.
Bottlers	Do.
Breweries	Do.
Canneries	Do.
Dairies, creamerise, milk processing plants.	Do.
Feed mills, feed stores	Do.
Fresh fruit packing and processing.	Do.
Meat processing	Do.
Poultry processing	Do.
Wineries. wine cellars	Do.
Flour mills, machinery, warehouses, lines, elevators..	Do.
Egg processing	Do.
Candy and confectionary plants.	Do.
Sugar processing, cane mills, etc.	Do.
Cider mills	Do.
Dry food products plants	Do.
Tobacco processing	Do.
Air treatment for processing and transportation of foods.	Do.
Beverage processing	Do.
Nut processing	Do.
Cereal processing	Do.
Seafood processing	Do.
Vegetable oil processing	Do.
Spice mills	Do.
Vinegar processing	Do.
Farinaceous processing (noodles, etc.).	Do.
Mushroom processing	Do.
Dried fruit processing	Do.
Pickle processing	Do.
Ice plants	Do.
Chocolate processing	Do.
Fruit juice processing	Do.
20. Eating Establishments (all):	
Food handling areas	Do.
Food serving areas	Do.
Eating establishment non-food areas.	Do.
Air treatment for eating establishments.	Do.
Food storage equipment (coolers, refrigerators, etc.).	Do.
Eating and serving utensils (spoons, etc.).	Do.
21. Food Marketing, Storage, and Distribution:	
Food dispensing and vending equipment.	Do.
Food stores, markets, stands	Do.
Meat and fish markets	Do.
Food catering facilities	Do.
Food marketing, storage, and distribution equipment and utensils.	Do.
Outdoor storage facilities for items in Group 17.	Terrestrial Non-Crop.
22. Hospitals and related Institutions and Facilities:	
Critical premises (e.g., burn wards, etc.).	Indoor.
Hospital patient premises (wards, emergency rooms, etc.).	Do.
Non-critical premises (labs, lounges, lobbies, storage.	Do.
Critical items (hypodermic needles, dental instruments, catheters, etc.).	Do.
Non-critical items (bedpans, carpets, furniture, etc.).	Do.
Air treatment (also to ambulances).	Do.
Janitorial equipment	Do.
23. Barber and Beauty Shop Instruments and Equipment.	Do.
24. Morgues, Mortuaries, and Funeral Homes:	
Premises, (embalming rooms, etc.).	Do.
Equipment (tables, etc.)	Do.
Instruments	Do.
Burial vaults, mausoleums	Do.
Air treatment	Do.
25. Commercial, Institutional, and Industrial Maintenance, Buildings, and Structures:	
Locker rooms, equipment	Do.
Gyms, bowling alleys, and equipment.	Do.
Telephones and booths	Do.
Shower rooms, mats, and equipment.	Do.
Cotton mill premises and equipment.	Do.
Auditoriums and stadiums	Do.
Factories	Do.
Rendering plants	Do.
Loading areas, ramps	Do.
School buildings and equipment.	Do.
Office buildings	Do.
26. Fiber Product Protection (Moth-, mildew-proofing):	
Clothing	Do.
Rugs	Do.
Upholstery	Do.
Ornamental fabrics (draperies, tapestries).	Do.
Ropes	Do.
Sail cloth	Do.
27. Preservatives and Protectants:	
Grains	Indoor.
Hay, silage	Do.
Adhesives	Do.
Coatings (asphalt and lacquer).	Do.
Fuels	Do.
Leather and leather products	Do.
Leather processing liquors	Do.
Metalworking cutting fluids	Do.
Oil recovery drilling muds and packer fluids.	Do.
Paints (latex)	Do.
Paper and paper products	Do.
Plastic products	Do.
Resin emulsions	Do.
Rubber (natural) products	Do.
Specialty products (polishes, cleansers, dyes, etc.).	Do.
Textiles, textile fibers, and cordage.	Do.
Wet-end additives, etc. (pulp sizing, alum, casein, printing pastes).	Do.
Disposable diapers	Do.
Wool, hair, mohair, furs, felt, feathers, etc.	Do.
Electrical supplies, cables, and equipment.	Do.
28. Human Articles and Materials:	
Bedding, blankets, mattresses.	Indoor.
(Treatments to) Hair, body, clothing (while being worn).	Do.
Clothing	Do.
Face gear (goggles, face masks, etc.).	Do.
Footwear (including inner soles).	Do.
Headgear (safety helmets, headphones, etc.).	Do.
Wigs	Do.
Contact lenses	Do.
Dentures, toothbrushes, mouthpieces to musical instruments, etc.	Do.
Camping equipment and gear	Do.
Grooming instruments (brushes, clippers, razors, etc.).	Do.
29. Laundry, Cleaning, and Dry Cleaning:	
Laundries	Indoor.
Diapers, diaper pails	Do.
Laundry equipment (carts, chutes, tables, etc.).	Do.
Dust control—products and equipment (mops, etc.).	Do.
30. Bathrooms, Toilet Bowls, and related Sites:	
Bathroom premises	Indoor.
Toilet bowls and urinals	Do.
Toilet tanks	Do.
Portable toilets, chemical toilets.	Do.
Vehicular holding tanks	Do.
Bathroom air treatment	Do.
Cuspidors, spittoons	Do.
31. Refuse and Solid Waste:	
Refuse and solid waste containers.	Indoor.
Refuse and solid waste transportation and handling equipment.	Do.
Garbage dumps	Do.
Household trash compactors	Do.
Garbage disposal units, food disposals.	Do.
Incinerators	Do.
Human stools	Do.
Vomitus	Do.
32. Surface Treatments:	
Hard non-porous surfaces (painted, tile, plastic, metal, glass, etc.).	Indoor.
Hard porous surfaces (cement, plaster, brick, asbestos, etc.).	Do.
Wood surfaces	Do.
Leather surfaces	Do.
Fabric surfaces	Do.
Paper/paperboard surfaces	Do.
33. Specialty Uses:	
Biological specimens (urine, tissues, etc.).	Indoor.
Museum collections (preserved animal and plant specimens).	Do.
Military uses—not specified	Do.
Quarantine uses—not specified.	Do.
DHHS/FDA uses—not specified.	Do.

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