Issued on April 22, 1988.

Robert E. Johnson,

Division Administrator, Frankfort, Kentucky.

[FR Doc. 88-9807 Filed 5-3-88; 8:45 am]

BILLING CODE 4910-22-M

VETERANS ADMINISTRATION

Agency Form Under OMB Review

AGENCY: Veterans Administration.

ACTION: Notice.

The Veterans Administration has submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). This document lists the following information: (1) The department or staff office issuing the form, (2) the title of the form, (3) the agency form number, if applicable, (4) a description of the need and its use, (5) how often the form must be filled out, (6) who will be required or asked to report, (7) an estimate of the number of responses, (8) an estimate of the total number of hours needed to fill out the form, and (9) an indication of whether section 3504(h) of Pub. L. 96-511 applies.

ADDRESSES: Copies of the forms and supporting documents may be obtained from John Turner, Department of Veterans Benefits (203C), Veterans Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 233-2744. Comments and questions about the items on the list should be directed to the VA's OMB Desk Officer, Joseph Lackey, Office of Management and Budget, 726 Jackson Place, NW., Washington, DC 20503, (202) 395-7316.

DATES: Comments on the information collection should be directed to the OMB Desk Officer by June 3, 1988.

Dated: April 27, 1988.

By direction of the Administrator.

Frank E. Lalley,

Director, Information Management and Statistics.

Extension

1. Department of Veterans Benefits.
2. Request for Information to Make Direct Payment to Child Reaching Majority.
3. VA Form Letter 21-863.
4. This form letter is issued to gather the necessary information to enable the Veterans Administration to determine a child's continued eligibility to benefits and eligibility to receive direct payment at age of majority.
5. On occasion.
6. Individuals or households.
7. 22,600.
8. 3,767.
9. Not applicable.

[FR Doc. 88-9887 Filed 5-3-88; 8:45 am]

BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register
Vol. 53, No. 86
Wednesday, May 4, 1988

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).

FEDERAL COMMUNICATIONS COMMISSION

Cancellation of Closed Commission Meeting, Thursday, April 28th Following Oral Argument

The Federal Communications Commission has cancelled the close meeting for discussion of oral argument in Phase I of the KHJ-TV, Los Angeles, California comparative renewal proceeding (Docket Nos. 16679-80), previously scheduled to be held on April 28, 1988 at 1919 M Street NW., Washington, DC.

Issued: April 29, 1988.

Federal Communications Commission.

H. Walker Feaster III,

Acting Secretary.

[FR Doc. 88-9995 Filed 5-2-88; 2:02 pm]

BILLING CODE 6712-01-M

FEDERAL TRADE COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 53 FR, April 29, 1988, Page No. 15493.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10:00 am., Friday, April 29, 1988.

CHANGES IN THE AGENDA: The Federal Trade Commission has cancelled its previously announced open meeting at which it was to discuss Consideration of Notice of Proposed Rulemaking Initiating Amendment Proceeding for Funeral Rule.

Emily H. Rock,

Secretary.

[FR Doc. 88-9985 Filed 5-2-88; 12:54 pm]

BILLING CODE 6750-01-M

INTERNATIONAL TRADE COMMISSION

TIME AND DATE: Thursday, May 5, 1988 at 10:00 a.m.

PLACE: Room 101, 500 E Street, SW.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda
2. Minutes
3. Ratifications
4. Petitions and Complaints
5. Inv. 731-TA-383 (Final) (Certain Bimetallic Cylinders (from Japan)—briefing and vote.
6. Any items left over from previous agenda.

CONTACT PERSON FOR MORE IMFORMATION: Kenneth R. Mason, Secretary, (202) 252-1000.

Kenneth R. Mason,

Secretary.

April 29, 1988.

[FR Doc. 88-9927 Filed 5-2-88; 10:12 am]

BILLING CODE 7020-02-M

INTERNATIONAL TRADE COMMISSION

TIME AND DATE: Friday, May 6, 1988 at 4:00 p.m.

PLACE: Room 101, 500 E Street, SW.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Inv. 731-TA-390 (P) (Digital Readout Systems and Subassemblies from Japan)—briefing and vote.

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary (202) 252-1000.

Kenneth R. Mason,

Secretary.

April 29, 1988.

[FR Doc. 88-9928 Filed 5-2-88; 10:12 am]

BILLING CODE 7020-02-M

federal register

Wednesday
May 4, 1988

Part II

Environmental Protection Agency

40 CFR Parts 152, 153, 156, 158, and 162
Pesticide Registration Procedures; Pesticide Data Requirements; Final Rule

40 CFR Parts 153, 156, 158, 162, and 163
Cross References; Technical Amendments; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 152, 153, 156, 158, and 162

[OPP-30071C; FRL-3266-9b]

Pesticide Registration Procedures; Pesticide Data Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule revises procedures for the registration of pesticide products under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The rule sets out in Part 152 which products are considered to be pesticides, lists exemptions, and describes the procedures for registration, classification, cancellation, and suspension. This document also reorganizes and recodifies existing regulations for comprehension, readability and easy reference. In addition, this rule modifies pesticide data requirements in Part 158 to revise product chemistry requirements, to prescribe the format of data submissions and to establish criteria under which data submitters must that their submission contains information of particular interest to the Agency. This rule finalizes regulations contained in two separate proposals in the Federal Registers of September 26, 1984 (49 FR 37916) and October 3, 1985 (50 FR 40408).

EFFECTIVE DATE: This rule will become effective after 60 days of continuous congressional session from the date of promulgation as provided in FIFRA sec. 25(a)(4). After that period has elapsed, the Agency will issue for publication in the Federal Register a notice announcing the effective date of this rule.

FOR FURTHER INFORMATION CONTACT:
By mail:
Jean M. Frane, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.
Office location and room number: Rm. 1114, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703-557-0944).

SUPPLEMENTARY INFORMATION:

I. Organization of this Preamble

This rule finalizes a number of different proposals or portions of proposals and covers a number of disparate topics. Not all portions of the final rule are addressed in the preamble, only those for which the Agency received significant comment. Except as modified by this preamble, the preambles of EPA's prior proposals are incorporated in this document by reference. This preamble is organized as follows:

II. Background

In the Federal Register of September 26, 1984 (49 FR 37916), the EPA issued a proposal to modify its registration procedures contained in 40 CFR Part 162. These procedures were originally promulgated in 1975 in response to amendments to FIFRA in 1972, and applied to a broad range of pesticide regulatory actions authorized or affected by that legislation, including pesticide registration and classification. In succeeding years, as additional material was added to Part 162, it grew in volume and complexity.

The 1984 proposal was the first comprehensive revision of the 1975 regulations. One main purpose of the revision was to reorganize the material to eliminate overlapping, redundant, or obsolete requirements, and to make them clearer and more useful to applicants and registrants. A second objective was to update the requirements to conform to legislative changes since 1975, and to include policy and procedural changes that had evolved in that period. The Agency believes that the final rule responds to these needs, and will benefit the Agency, pesticide producers, and the public by clearly setting out policies and procedures.

In the Federal Register of October 3, 1985 (50 FR 40408), the Agency issued a proposal to establish criteria for the "flagging" by registrants or applicants of pesticide data they submit to the Agency, to indicate that the data contain significant information concerning potential adverse effects. The proposal would modify existing Part 158, and also parts of Part 152 as proposed in 1984. Comments on that proposal have been considered and are addressed in this document. Parts 158 and 152 as promulgated today contain the revisions proposed on October 3, 1985.

The regulations adopted here are an integral part of a larger set of regulations addressing pesticide regulatory activities, all of which have been organized to be comprehensive and complementary. Individual elements of the pesticide regulatory scheme have been segregated and are presented in separate Parts for easy understanding:

1. Part 152 sets out Federal pesticide registration procedures in their entirety. Procedures for State registration of pesticides under FIFRA sec. 24(c) have been retained as Part 162, Subpart D.

2. Part 153 contains general policies pertaining to registration or registered products, but distinct from the registration process itself. Today's final rule promulgates Subparts G, H and M of Part 153, concerning (a) declaration of certain ingredients as inert; (b) coloration/discoloration of pesticide products; and (c) devices. Additional Subparts A and D, concerning, respectively, pesticide advertising and reporting of adverse effects data have been proposed, but have not been made final.

3. Part 154, promulgated on November 27, 1985 (50 FR 49015), describes the Agency's Special Review process in its entirety.

4. Part 155, promulgated the same day (50 FR 49001), discusses the public participation procedures associated with the development and issuance of Registration Standards.

5. Part 156, which was proposed on September 26, 1984, revises labeling requirements for pesticides and devices, currently located in § 162.10. Today's rule document redesignates § 162.10 as § 156.10, retaining current requirements until the revised rules are promulgated.

6. Part 157, promulgated on June 11, 1986 (51 FR 21286), contains requirements for the packaging of pesticide products, currently limited to child-resistant packaging.

7. Part 158, promulgated on October 24, 1984 (49 FR 42881), contains data requirements applicable to pesticide products.

Each of these addresses a single regulatory topic, process or function, and can be used independently of the others.

In response to its 1984 proposal, the Agency received 30 comments. Commenters included individual pesticide producers, trade associations, user groups, an environmental group, and a Federal agency. The significant comments are addressed in Units III through XVIII and XX of this preamble. In response to its 1985 proposal, the Agency received 10 comments. These are addressed in Unit XIX of this preamble.

As part of its 1984 document, the Agency proposed to establish Part 157, containing regulations governing child-resistant packaging requirements for pesticides. Readers should note that the Agency has separately promulgated these regulations in final form, in the Federal Register of June 11, 1986 (51 FR 21276). Comments pertaining to child-resistant packaging of pesticides have been addressed in that final rule, and are not repeated here.

III. Definitions

A. Acute LD–50

The Agency proposed definitions for "acute oral LD_{50}," "acute dermal LD_{50}," and "acute inhalation LC_{50}," which defined these values as "statistically derived estimates" of the single dose (or concentration) that would cause mortality to 50 percent of the test species. Several commenters stated that the definitions are inconsistent with the Pesticide Assessment Guidelines, in that a statistically derived estimate requires a study using three dosage levels, while the Pesticide Assessment Guidelines permit the use of a single dosage "limit test" if it shows no mortality. They believe that the proposed definition precludes the use of the limits test.

EPA disagrees. The definitions are exactly the same as those contained in the Pesticide Assessment Guidelines themselves and are correct definitions for the terms. The use of these definitions in the Guidelines has not raised similar concerns among data developers, and the definitions have co-existed with the limits tests since the Guidelines were issued. Thus the definitions are not incompatible with the Pesticide Guidelines or the limits test.

EPA strongly supports the use of the limits test in defining acute toxicity limits, because its single dosage regimen can significantly reduce the number of test animals used. EPA also attempts to evaluate pesticides using data from structurally similar chemicals when appropriate. If classic acute toxicity studies are nonetheless required, the Agency encourages maximum utilization of the testing to evaluate multiple toxic endpoints rather than just simple lethality. The LD50s and LC50s derived from standard acute toxicity testing are used not only as indicators of acute toxicity (for purposes of labeling the product), but also serve as rangefinding levels for use in subchronic studies and chronic studies that follow.

B. Distribute and Sell

Seven commenters expressed concern at the definition of "distribute and sell" in § 152.3(j). In addition to the statutory language concerning distribution and sale, the definition deemed distribution to have occurred either when a finished product was both packaged and labeled in the manner in which it would be shipped or when it was stored in an area where such finished products are stored. The Agency's intent was to incorporate the current definition of "released for shipment" as part of the definition of "distribute and sell." The term "released for shipment" is used in FIFRA sec. 9 to define when a product may be inspected for compliance purposes.

According to industry commenters, the Agency's proposed inclusion of the criteria for "released for shipment" would create problems for the industry if it were used to determine whether a product has been introduced into commerce and thus can be found in violation of FIFRA. All commenters expressed concern that products which a registrant has not decided to "release for shipment" may meet the definition of "distribute or sell." According to commenters, the term "release for shipment" does not describe an identifiable and uniformly enforceable point in the distribution chain of a product. The commenters said that whether an individual product has been released for shipment depends on the policies of the producer involved, i.e., that a product has been released for shipment when the producer intends that it be shipped. Unless the producer admits that the product has been released for shipment, they suggest, the product cannot be inspected for compliance purposes, and therefore cannot be found in violation of FIFRA.

Moreover, commenters claim, the proposed definition runs counter to production and storage practices commonly used in the industry. Finished products that have been released for shipment are commonly stored with other products which are "on hold" for one reason or another. They state that a finished product may be in both "released for shipment" and not "released for shipment" status, and claim that the proposed definition does not recognize this distinction. Commenters feared that, if the definition were adopted, products that are on hold might frequently be deemed to have been distributed and sold.

EPA disagrees with the statements of commenters that there can be, or should be, a distinction made between products that have been released for shipment and those that have been deemed to be distributed or sold. A product that has been released for shipment by its producer is considered to have been distributed or sold as defined in the Act (which includes holding for sale). A producer cannot reasonably assert that two batches of registered product, identical in packaging and labeling and located in the same area of a warehouse or producing establishment, are different merely because one allegedly has been released for shipment and another has not. The Agency, in inspecting for compliance, will assume that a product that is packaged, labeled, and stored in an area where finished products are normally stored has been released for shipment.

The Agency would be severely hampered in its ability to enforce compliance if products released for shipment were not considered to have been distributed and sold, since violations of the Act depend on "distribution and sale" and not upon "release for shipment." Carried to its practical conclusion, if a product that had been released for shipment, and therefore could be inspected under FIFRA sec. 9, were to be found in violation, the Agency could not take enforcement action until the product had

actually been distributed and sold. If inspection of products released for shipment could not lead directly to enforcement action, but must await some further point at which it had been "distributed and sold," the Agency's enforcement efforts would be thwarted.

Consequently, in the final rule, the Agency has included the term "released for shipment" in the definition of "distribute and sell."

The Agency also considered defining the term "channels of trade," which has been used in past Agency documents (without definition) as an informal synonym for the litany of terms in FIFRA sec. 12 comprising "distribute and sell." EPA considers the two terms synonymous: a product that is being distributed and sold by any person is in channels of trade, and vice versa. It is therefore unnecessary to define "channels of trade" separately. Moreover, the Agency does not expect to use the term in future regulatory documents, but will rather specify the categories of persons who are prohibited from distributing or selling a product. Thus, the registrant may be prohibited from distributing or selling after a certain date, while other persons (e.g., retailers) may be prohibited from distributing or selling after a second date.

IV. Products Required To Be Registered

The Agency proposed to clarify its interpretation of what constitutes a pesticide, for purposes of compliance with the registration requirement of FIFRA sec. 3. Section 152.15 proposed to add new language stating that a substance may be intended for a pesticidal purpose (and therefore required to be registered) if any of a number of tests are met. The first of these is whether advertising or product labeling claims, implicitly or explicitly, that the product is a pesticide. This is the principal test contained in current regulations. No comments were received on this test, and it has been adopted as proposed.

EPA also proposed to treat as a pesticide any substance which has no significant commercially valuable use other than a pesticidal one. One commenter objected that the term "significant commercially valuable use" is judgmental. EPA acknowledges that a certain degree of judgment must be exercised in deciding whether a substance meets this definition. On the other hand, the Agency believes that a large percentage, if not the majority, of pesticide active ingredients are clearly identifiable either as pesticides or as multi-purpose substances, and that the Agency will rarely be compelled to use this criterion alone to judge whether a substance is a pesticide. The Agency has in the past focused its enforcement efforts on individual product claims, and EPA intends to continue this focus.

The Agency further proposed, as a third criterion, that if a person knows, or should reasonably know, that he is selling a product for a pesticidal purpose (even though the product itself bears no pesticidal claims), the product should be a pesticide subject to the registration requirement. This criterion would apply primarily to products which are currently not registered as pesticides (for example, multi-purpose substances having pesticide uses, but for which a particular product bears no pesticidal claims.)

Nine persons commented upon this provision. Several expressed concern that the language was imputing knowledge of pesticidal use and responsibility to manufacturers who have no control over their distributors and customers. This burden, they state, is unreasonable. Other commenters, while not objecting to the criterion per se, requested that the Agency clarify its intent, and sought reassurance that the criterion would be used for enforcement against the person making the claim and not against the producer. Some suggested that simply deleting the word "reasonably" from the criterion would resolve the problem satisfactorily. In general, commenters believed that definition was too broad and inclusive.

In response, the Agency has clarified the definition by replacing the "reasonable" knowledge terminology with language concerning "actual or constructive" knowledge of pesticidal use. Actual or constructive knowledge will be gauged as objectively as possible. The Agency issued in the Federal Register of March 25, 1987 (52 FR 9504) a proposal concerning establishment registration, which uses the same terminology to describe when a pesticide producer must register his producing establishment. In that document, the Agency described the criteria that it would consider in determining actual or constructive knowledge. These included promotional claims and advertising, common knowledge of the general business of the person to whom the substance is sold, and the commercial distance from a producer to a formulator. The same principles will guide the Agency in applying the "actual or constructive knowledge" test of pesticide for purposes of registration.

The Agency believes the fears of the commenters concerning "upstream penalties" are unfounded. The Agency does not intend to impose penalties upon the producer of a non-pesticide product, if, without his knowledge, a pesticidal claim is made for the product by someone else. EPA agrees that it would be unreasonable to require registration of a product whose primary uses are non-pesticidal merely because a retailer sold the product as a pesticide. On the other hand, EPA believes that a producer who sells a product with full knowledge of its intended pesticidal use should be held responsible for its registration. This situation might apply, for example, when a producer sells what would ordinarily be considered a basic chemical to a user whose only purpose in acquiring such a chemical would be to use it as a pesticide. If the seller of the product is aware of the nature of his customer's business, EPA may consider him to be selling a product for a pesticidal purpose. EPA acknowledges that application of this criterion for enforcement purposes will require subjective judgment.

The second and third criteria both are intended to address longstanding enforcement problems in which neither labeling nor advertising clearly states or implies that the product is a pesticide, but the product is sold under circumstances in which it is clear that the product is intended for a pesticidal purpose. For example, if the ingredients of a well-known wood preservative mixture are offered for sale (without pesticidal claims) in a trade magazine aimed primarily at wood processors and there is no other apparent reason for wood processors to be interested in the ingredients, it would not be unreasonable to regard the products as pesticides.

V. Exemptions

A. Exemptions under FIFRA Sec. 25(b)

Sections 152.20 and 152.25 describe exemptions based on FIFRA sec. 25(b) for, respectively, products adequately regulated by another Federal agency and products of a character not requiring FIFRA regulation.

One commenter suggested that the exemption for pheromones in § 152.25(a) be expanded to include pheromones other than those produced by an arthropod. Paragraph (a)(1) of that section defines a pheromone as a compound produced by arthropods. The Agency declines to adopt the commenter's suggestion. The Agency is not aware that pheromones produced by other animals are registered with the Agency. EPA was able to exempt arthropod pheromones based on information it possessed in its files on such products. Although the Agency

may choose to exempt such pheromones in the future (and would probably adopt the commenter's suggestion concerning revision of the definition if it does so), it does not choose to do so prospectively in the absence of information concerning their characteristics and effects.

Two commenters requested that an additional exemption be added to § 152.25 for preservatives used in "non-FDA regulated products," when used at levels consistent with Food and Drug clearances for drugs and cosmetics. The commenters stated that exemption would make available a greater variety of preservatives for use in household products.

It is not clear to the Agency what exemption is being proposed or for what preservatives. It appears that the commenters' concern is that the availability of preservatives for use in consumer products is limited because such preservatives are required to be registered as pesticides. The implication is that producers of some preservatives suitable for use in these products are unwilling to undertake the registration process for what is presumably a limited market. The commenter further suggests that if FDA-regulated preservatives were not required to be regulated under FIFRA, producers of preservative products would make more of them available.

Although the commenters' suggestion may have merit in certain situations, it is not specific enough for the Agency to act on in this final rule. The commenters provided proposed language for an exemption, but it was worded so broadly and ambiguously that EPA cannot properly evaluate it. No specific preservatives were mentioned, only those "used by the cosmetic and drug industry." Moreover, no levels or limits were indicated or even referred to; the proposed language simply stated "in amounts consistent with those 'used in FDA regulated products.' " EPA would be willing to entertain proposals for exemption of specific preservatives at specific levels, but is not willing to grant the blanket exemption suggested by the commenters.

In § 152.20(a)(3) of the final rule, the Agency has made a minor technical change. That section provides an exemption from FIFRA requirements for certain types of living organisms, except as provided. The list of exceptions (organisms that are not exempt) has been modified to use current terminology. The Agency is currently reviewing this exemption and its implications in light of recent advances in biotechnology. If changes in the exemption or new policies evolve from the Agency's review, this section may be modified after notice and comment.

B. Contract Manufacturing

The Agency proposed two changes affecting current contract manfacturing provisions. First, the Agency proposed to revise the definition of "operated by the same producer" in § 152.3(q). This definition is the key to an exemption from registration provided by the statute in FIFRA sec. 3(b). The Agency proposed to limit this definition to its clear statutory meaning, which would exclude from the definition contractual arrangements between different companies. The modified definition would include only facilities owned or leased by a single company.

At the same time, the Agency proposed to continue an exemption for certain contract manufacturing by specifically including contractual agreements in § 152.30, which exempts certain types of transfers from registration. EPA proposed to exempt from registration certain transfers of pesticide for the purpose of processing, packaging, or labeling, provided, among other things, that the transferor was the owner of the transferred pesticide and the registrant of the final product distributed or sold.

Thirteen commenters commented upon the two proposed sections. Although some addressed the definitional change and others the exemption, all expressed similar concerns. Commenters stated that, when considered together, the definitional change and the revised exemption provision would preclude the contract manufacturing operations that are extensively relied upon by producers. Commenters stated that many registrants contract out their entire production operation, including production, packaging and labeling; they may also contract out certain distribution by means of a supplemental registration (see § 152.132). The reasons cited for such extensive contracting operations are varied. For small companies not having a production facility, contracting may be the only way to distribute and sell a pesticide; for large companies, temporary contractual arrangements afford flexibility in producing a product while the registrant determines whether the marketing of a product warrants construction of a dedicated production facility.

These practices have been possible in the past, despite the language of the statute and regulations, because of an exercise of prosecutorial discretion by EPA. The Agency announced that it would not regard as an actionable violation of FIFRA the transfer of an unregistered pesticide pursuant to a contract, providing that the transferor would supply the pesticide in question to no one in the United States except the transferee contracting party. However, for reasons described in this unit of the preamble, EPA has determined that it will not continue this enforcement policy.

A common arrangement has been for a contractor who is formulating the product for the registrant to obtain quantities of an unregistered technical grade active ingredient from a producer other than the registrant. The registrant of the formulated product is not the owner of the transferred technical material, as required by proposed § 152.30, nor is the formulating process carried out in a facility "operated by the same producer" within the meaning of the proposed definition. Consequently, under the proposed rule, the transfer of that technical chemical to the contract formulator would be in violation of the Act unless the technical chemical is a registered pesticide product.

In general, commenters asserted that the proposed changes would have the effect of eliminating the current contract manufacturing system, and would be burdensome to formulators, who rely on contract manufacturing. They believed EPA should reinstate the definition to provide that contractual relationships be deemed to be "operated by the same producer" and that § 152.30 should be modified to accommodate industry contracting practices. In short, they objected to the proposed revision and urged that the current provisions be restored. The Agency has considered the comments, but has decided to retain the definition change and the exemption provided by § 152.30 (the language of that section has been modified, however, as explained in this preamble unit).

The commenters are correct in their analysis of the effect of the proposed change; as stated in the preamble to the proposal, "[t]he practical effect would be that a product would have to be registered prior to any transfer representing a sale or change in ownership." It was the Agency's intention to require that pesticides be registered before they are sold or transferred from one person to another, even for further formulation under contract. The final rule will not preclude contract manufacturing, but will limit the use of unregistered pesticides in contract manufacturing.

The Agency has cogent reasons for its decision to require the registration of all technical products. First, the Agency

does not believe that Congress intended the exemption from registration in FIFRA sec. 3(b) to be so broadly defined. A straightforward reading of FIFRA sec. 3(b) suggests that the exemption it provides should be limited as the Agency is doing.

Second, EPA is concerned about the lack of regulation of the large volume of unregistered pesticides that it believes are being transferred. The previous exemption permitted an unquantified volume of unregulated distribution and sale of pesticides. Pesticide production reports submitted under FIFRA sec. 7 include numerous pesticides having a large production of end use products with no corresponding reported production of a technical grade active ingredient. EPA believes that the policy which allowed producers of technical grade active ingredient to distribute and sell product under the umbrella of a "sole transferee" contract accounts for much of this discrepancy.

The sale and distribution of unregistered products is contrary to the Agency's mandate to protect human health and the environment, leaves large gaps in the Agency's knowledge about and control of such pesticides, creates competitive inequities among similar products in the marketplace, and undermines the efforts of producers of registered products to comply with FIFRA.

FIFRA provides a comprehensive regulatory scheme covering all pesticide products. Registration is the principal means of ensuring that a product is brought under the FIFRA regulatory scheme. The registrant must demonstrate to the Agency's satisfaction that the product meets the statutory criteria for registration with respect to composition, labeling, and lack of unreasonable adverse effects. The registrant must take responsibility for quality control of the product's composition and for adequate labeling describing the product, its hazards and uses. He must submit or cite data concerning the pesticide's impact on man and the environment, and must assume obligations required by section 3(c)(1)(D) with respect to data compensation. Once registered, a registrant is required under FIFRA sec. 6(a)(2) to report to EPA any factual information concerning the unreasonable adverse effects of the pesticide on the environment. A person selling an unregistered product has not complied, and is under no obligation to comply, with any of these requirements.

The producer of a pesticidal active ingredient is more likely to become aware of certain types of sec. 6(a)(2) information than a formulator who buys the active ingredient. EPA is increasingly concerned about the presence of potentially toxic impurities in pesticides, and is taking steps to reduce the levels of such impurities. For instance, EPA has recently required the reduction of DDT impurity levels in products containing technical dicofol. EPA can more effectively require and monitor compliance with such a directive if the active ingredient is registered before being distributed and sold; it would have great difficulty in ascertaining compliance for similar products that are not registered by the ingredient's producer. In a situation such as this, where the Agency has concerns about the composition of a technical grade active ingredient, the Agency cannot address its concerns by dealing only with formulators, who may not be aware of the impurities of the technical they purchase. Distribution and sale of unregistered products thus seriously impairs the Agency's ability to promote the development of safer pesticides.

By requiring registration of all products, EPA also gains the efficiency of dealing with fewer companies in matters concerning safety of active ingredients or their impurities. Rather than having to concern itself with a large number of formulators who buy and use unregistered technical pesticides, the Agency can focus on the producers of the technicals, who are both more knowledgeable about the chemicals and significantly fewer in number. Registration of these products also will reduce the potential for a registrant to abuse the data compensation scheme under FIFRA sec. 3(c)(1)(D) and 3(c)(2)(D) by stating in its registration application that it will purchase a registered product, and then instead using an unregistered product as the source of the active ingredient.

Commenters who feared that limitation of the contract manufacturing exemption from registration would increase costs or be burdensome apparently base their conclusion on the data compensation implications of requiring registration of technical products. Ideally, of course, data costs to the registrant either would be included in the purchase of a registered product or would arise under FIFRA sec. 3(c)(1)(D) because of the use of an unregistered product. However, until all products are required to be registered or reregistered, the real world situation may be that use of an unregistered product is less costly.

If all products must first be registered, the burden of data generation and compensation will tend to shift from formulators to technical producers. In turn, this will foster a more competitive market in which FIFRA regulatory requirements are not a significant influence on or determinant of cost differential.

Accordingly, in the final rule, § 152.15 requires the registration of all pesticides, including products intended for formulating use. Section 152.30(a) contains the statutory exemption provided by FIFRA sec. 3(b) for products moving between establishments operated by the same producer.

In addition, a specific exemption is needed to address contract manufacturing practices (using registered products) between facilities operated by different producers. The Agency does not intend to interfere with or curtail in any way such contract manufacturing practices relied upon by registrants. Many products are produced by a series of contract operations, involving various steps in formulation, packaging, and labeling. Since intermediate products (varying in composition, packaging, or labeling from the technical or final product that is registered) must be shipped between facilities not operated by the same producer to accomplish this, a specific exemption from the registration requirement is needed. Section 152.30(b) therefore contains an exemption allowing transfer of what technically are unregistered pesticides for contract manufacture and packaging by establishments operated by different producers. As long as the products used are registered, the final product is registered, and the transferred intermediate products are properly labeled, the Agency is confident that adequate environmental and regulatory safeguards are in place.

The Agency has already taken steps to begin the process of regulating more closely pesticides used in contract manufacturing. EPA issued a notice (PR Notice 87-7, June 3, 1987) revoking the previously-mentioned enforcement policy statement and requiring that applications for currently unregistered technical pesticides be submitted by September 30, 1987. As of the effective date of this rule, the transfer of unregistered pesticides (except as provided by § 152.30) will be a violation of FIFRA sec. 12(a)(1)(A).

VI. Registration Procedures

A. Amended Applications Not Requiring Full Review

The Agency proposed in § 152.42 to define categories of amendments to registration that did not require review or approval prior to implementation. Section 152.42(b)(1) listed amendments

to registration that could be accomplished simply by notification to the Agency, and implemented immediately after notice was given. Section 152.42(b)(2) listed amendments that could be made without notice to the Agency.

The Agency proposed that certain relatively routine amendments to registration be subject only to a notification requirement, and that others of even lesser significance be permitted without notification to the Agency. Of the 10 commenters on this proposal, 7 supported the concept that not all amendments require the same level of scrutiny by the Agency, and that some can be discretionary with the registrant.

Several commenters proposed that additional types of labeling amendments would be suitable for inclusion in the "no approval" category in § 152.42(b)(1)(ii) or the "no notification" category in § 152.42(b)(2).

Two commenters suggested that changes in label format consistent with Part 156 should require no notification, noting that the language is already approved by EPA. EPA agrees that the Agency need not review each format change that is consistent with Part 156, provided that the language of the label does not change. Accordingly, paragraph (b)(2) has been revised to specify that changes in label format for consistency may be made at the discretion of the registrant.

One of those commenters stated that advertising claims are often placed on labels. Although EPA does not prohibit advertising on pesticide labels, it cautions that advertising must not differ or detract from the approved label, and that it may not obliterate or obscure the required label language.

Two other commenters suggested that paragraph (b)(2) be revised to require only notification when a company wishes to market an already-registered product as two products, each bearing a subset of approved use. Moreover, the commenters suggested that label claims be permitted to be transferred between registrations of the same formulation. Although the commenters appear to view these two situations as identical, EPA does not and wishes to clarify its policy.

The first situation is already permitted, in EPA's opinion, and will continue to be acceptable under § 152.130(b). A company having a registered product is permitted (both by current policy and by this final rule) to market the product in a variety of ways. The product may be marketed under different brand names, each product bearing the full set of uses approved by the Agency. Or it may be marketed under the same brand name, but bearing different subsets of approved uses (for example, to distinguish primary uses for different regions of the country). Or each product may bear both a different brand name and a different subset of approved uses. In each case, the product is a single formulation having a single registration number, and no other changes in labeling are permitted (in fact, if "splitting" the uses would result in changes in precautionary labeling, the "split" is not permitted).

The second situation is somewhat different. It appears that the commenters espouse the transfer of uses (without notification to the Agency) between two separately registered products having the same formulation. This is not acceptable to the Agency. Agency records are compiled and organized based upon individual registrations. A single registration covers a specified approved set of uses, regardless of whether there are other registered products with the same composition but different approved uses. If the Agency were to permit approved uses from one registered product to be transferred to another registered product without approval, accurate recordkeeping and effective enforcement would be virtually impossible.

Three commenters noted an inconsistency between the language in § 152.46(b)(1)(v) that required notification of a change in the source of "beginning materials" (defined to include inert ingredients) and the language in § 152.46(b)(2)(i) that permitted change in the source of inert ingredients without notification to the Agency. In response, the former paragraph has been revised to exclude inert ingredients.

Two commenters noted that Agency's proposed deletion of the supplemental distributor regulations as superfluous, and, while agreeing with the Agency, suggested that the requirements be retained for completeness. The Agency agrees, and in the final rule has included supplemental distributor requirements in Subpart G (Rights and Obligations of Registrants). This location has been chosen because, strictly speaking, a distributor arrangement is not an amendment to registration, but the exercise of a right accorded to a registrant to facilitate distribution and marketing of a pesticide product.

B. Separate Applications

In the final rule, EPA has revised § 152.45 (now § 152.43) to describe more explicitly what variations in product composition require registration of a new product. This has been necessitated by comments received on the proposal, as well as the Agency's ongoing project to revise and call in the statements of formula for all products.

In the final rule, the Agency has stated that a composition variation would trigger a requirement for separate registration if:

1. The variation would result in the active ingredient's nominal concentration falling outside the certified limits for the basic product; or

2. The variation would require different dosage rates, use directions or precautionary statements on the labeling. Whenever the labeling of alternative formulations would differ because of the change in composition of the product, a separate product must be registered. This is an overriding consideration that outweighs any other permitted variations, and precludes excessive variation in the composition of any product.

For practical purposes, this means that registrants may substitute inert ingredients in a product to the extent that the total percentage of inert ingredients does not change. EPA believes that variation of inert ingredients will rarely result in a change in the formulation type of the product, but in § 152.43 EPA has reserved the right to reject an alternate formulation that is significantly different from those already registered under a single registration number. If the alternate formulation would result in a change in product type, the Agency is likely to require separate registration. The Agency anticipates that a requirement for separate registration (in lieu of an alternate formulation) will rarely be necessary.

Substitution, addition, or deletion of an active ingredient would affect the label ingredients statement and would require a separate registration. Under this policy, the registrant could vary the source of his active ingredient(s); however, changing the source of an active ingredient normally will require the submission of information concerning the new source, particularly if the new source is an unregistered product.

In all cases, a registrant seeking an alternate formulation must amend his registration by submitting an application for amendment, and an additional statement of formula for approval. EPA thus will be able to monitor alternate formulations.

C. Content of Applications

Eight commenters addressed the Agency's proposed requirements for applications for registration. Since few of the requirements were new, the

comments were limited to three particular items that were required for the first time:

1. The releasable summary of data required by § 152.50(c). Five commenters questioned the requirement for a releasable summary of the application. Two commenters remarked that the § 152.119 referenced in the proposal does not exist. This section was promulgated as part of the data compensation regulations (Subpart E of Part 152) on August 1, 1984 (49 FR 30903), and has been incorporated into Subpart F in this final rule. Two commenters stated that the Agency's rationale for this requirement was not clear, and requested additional justification for the requirement; one asserted that the requirement was significant enough to warrant reproposal. Neither commenter, however, expressed any specific objection to the requirement. Two other commenters objected to the proposed requirement that an application set forth "reasonable grounds" for approval, stating that submission of the application constituted reasonable grounds, and that an additional statement was therefore unnecessary.

The Agency agrees with this last comment, and has revised § 152.50(c) to delete the language. Section 152.50(c) now requires the submission of a list of studies submitted, with a brief summary of the results. The list required by this section will suffice as the transmittal document required by § 158.32. Moreover, because it will be a releasable summary, the Agency will be able to respond rapidly to requests for information after registration. A summary of data may obviate the need for more extensive and time-consuming clearance of an entire study and, EPA believes, may better serve the needs of the non-technical public. The Agency believes that additional justification is not necessary, that additional comment would not be useful or significant, and that reproposal would be burdensome. Accordingly, the provision, as modified, is adopted in this final rule.

2. The Good Laboratory Practices certification. Several commenters noted that the Good Laboratory Practices (GLP) requirements mentioned in § 152.50(g)(2) currently apply only to toxicological studies. The commenters are correct, and the provision has been revised to insert the words "if applicable." EPA notes that it is considering the adoption of GLP requirements for other types of studies (such as ecological effects studies), and this language will be satisfactory even if Part 160 is revised to expand the coverage of GLPs.

3. The requirement that applicants submit adverse effects data in the same manner that registrants are required by FIFRA sec. 6(a)(2) to submit such information. The Agency has considered comments in response to both the September 26, 1984, proposal, and the October 3, 1985, proposal concerning "flagging" of data.

The Agency received seven comments on its September 26 proposal. Several pointed out that FIFRA sec. 6(a)(2) applies only to registered products, and suggested that the section be deleted. Others suggested that the policy would be more appropriately dealt with in the Agency's policy statement on FIFRA sec. 6(a)(2), published in the **Federal Register** of September 20, 1985 (50 FR 38115). Two commenters suggested that the requirement be made consistent with the FIFRA 6(a)(2) policy, which requires the submission only of new information and only if not available in published literature sources.

In response to the comments suggesting that the requirement be deleted because FIFRA sec. 6(a)(2) applies only to registered products, EPA notes that the authority for this requirement is not section 6(a)(2), but section 3(c)(1), which authorizes the Agency to prescribe the data that must be submitted in support of applications for registration. The Agency has chosen to apply the same requirement to applicants that is imposed on registrants. Consequently, the final rule retains the requirement, now located as § 152.50(g)(3), addressing registration data requirements. Moreover, that paragraph now references Part 153, Subpart D, as the basis for identifying which information must be submitted. This will eliminate concerns expressed by commenters about inconsistency.

VII. Registration Procedures

In Subpart D of the proposal, the Agency prescribed the procedures it would use in processing applications for reregistration in response to issuance of a registration standard. No comments were received on these procedures; however, one commenter addressed two legal aspects of the registration standards process (that precedes the procedures proposed in Subpart D). Although not pertinent to the proposed procedures, the Agency would like to make clear its position on these points.

The commenter, an environmental group, asserted that registration standards, which the Agency develops as position documents supporting its regulatory actions under FIFRA sec. 3(g) and 6, should be considered regulations, subject to the notice and comment procedures of the Administrative Procedure Act. The commenter noted that many registration standards are given procedural treatment similar to that of regulations, and therefore should be afforded legal status as regulations. EPA disagrees.

Registration standards are support documents underlying the regulatory decisions taken by the Agency. As a licensing statute, FIFRA requires that the Agency take regulatory action on an individual product basis. Although the Agency may issue regulations governing all or a group of pesticide products, regulatory decisions generally are made legally binding on individual products through cancellation actions. EPA thus far has chose not to use the rulemaking process in carrying out the reregistration of individual products.

Second, the commenter asserted that Registration Standards are subject to the Environment Impact Statement (EIS) requirements of the National Environmental Policy Act (NEPA), since they are "major Federal actions."

Regulatory actions taken by EPA have been held by the courts not to be subject to the requirements of an EIS under NEPA. Consideration of environmental concerns is intrinsic to the decisionmaking process at EPA. FIFRA's substantive and procedural provisions for the registration of pesticides, including their reregistration, are the functional equivalent of an EIS. Under the functional equivalency doctrine, EPA is not required to prepare a specific document addressing environmental issues. The process used by the Agency in developing registration standards itself provides for the analyses which would be required in an EIS. Moreover, the courts have found that in establishing the licensing process under FIFRA, Congress recognized that compliance with NEPA's procedural requirements would not be appropriate. The Agency therefore declines to accept the comment.

VIII. Agency Response to Application

Proposed Subpart F described the procedures and criteria that the Agency would use in reviewing and approving applications for registration and amended registration. This subpart largely described the Agency's current procedures and practices and did not propose a significant departure from those procedures. Comments were received primarily from industry sources and generally reflected their knowledge of these procedures and criteria. Few commenters expressed serious concerns with the Agency proposal or suggested

that significant modifications were necessary. The majority of comments suggested clarifications.

A. Procedural Issues

One commenter noted that the Agency proposed in § 152.102 to issue for publication in the Federal Register a notice of receipt of an application for registration of a new chemical or significant new use pattern, but questioned why no notice of approval was provided for. In response, EPA has revised the section to provide for publication of a notice of final action. The commenter also suggested that the notice of receipt should include the Agency's assessment of the application. EPA does not agree with this comment. The notice of receipt is required by FIFRA sec. 3(c)(4) to be published promptly after the application is received, and cannot await the Agency's evaluation of the application. Moreover, the purpose of the notice is to obtain comment from the public and other Federal agencies, rather than to provide the Agency's conclusions regarding the application.

Two clarifications were requested with respect to the Agency's proposed treatment of incomplete applications. The Agency stated that it would not begin or continue review of incomplete applications, defined generally by § 152.104. A number of commenters argued that minor deficiencies should not hold up review of applications.

With respect to applications for so-called "me-too" products, which are substantially similar to existing products, The Agency intends to follow its current practices. The Product Manager will screen incoming applications for completeness; he may choose to telephone or write applicants to correct minor deficiencies, while continuing the review of the application, or he may choose to reject the application because it cannot be processed without correction. With such applications, the Agency normally will retain the application awaiting response from the applicant. After 75 days, however, if no response is forthcoming from the applicant, the Agency will treat the application as if it had been withdrawn. The Agency cannot afford to store pending applications indefinitely awaiting response by applicants. Administrative withdrawal and a requirement for a new application permit the Agency to clear its files of applications after a reasonable period of time for response.

On the other hand, when an application is submitted for a new chemical or the first food use of a pesticide, involving substantial amounts of data and the expenditure of greater resources and time for review, the Agency will more rigorously screen the application. The Agency has issued a notice to registrants (PR Notice 86-4, April 15, 1986), describing its screening procedures for such applications. These procedures provide for the rejection of incomplete applications without extensive review, and for the return of applications to the applicant. The Agency will not begin substantive review of such applications until they are complete and correct. In these cases, the 75-day response time will not apply, since the application will be returned to the applicant, who may reapply at his convenience.

Several commenters asked for clarification of the 75-day response time. Two suggested that it not start until receipt by the applicant of a certified letter; another believed that only "working days" should be counted.

The Agency cannot adopt the first commenter's suggestion, since Agency letters are not routinely sent by certified mail. (The Agency, as a rule of thumb, does allow a 15-day mail lag time.) Because the 75-day timeframe is not calculated by the Agency by means of certified mail receipts, the Agency declines to commit itself to the more rigorously defined "working days" suggested by the second commenter. To do so would lengthen the response time by one-third (75 working days is approximately 105 calendar days). EPA believes that 75 days is sufficient time for a registrant either to correct deficiencies or to tell EPA when they will be corrected.

Two commenters expressed concern with the Agency's policy of reviewing and approving only draft labeling rather than final printed labeling (§ 152.108). Both were concerned about the ability of the States, which enforce FIFRA requirements under cooperative agreements, to discern compliance with the Act. These same concerns were raised and have been thoroughly discussed in previous documents, including the proposed and final regulations establishing the policy, issued in the Federal Register of September 15, 1982 (47 FR 40659) and that of January 4, 1984 (49 FR 380), respectively. The Agency is not aware of serious problems that have arisen with the policy in the 3 years it has been in effect.

One of the commenters also questioned whether, given the labeling changes that are permitted by the Agency without notification by § 152.42, the States might not encounter labels in channels of trade that are significantly different from those approved by the Agency. The changes permitted by § 152.42 are those that the Agency considers minor, unlikely either to involve compliance questions by States or to be of serious consequence even if not correctly accomplished. Furthermore, the permitted changes are insignificant when compared with the changes in format that are permitted to be made between the Agency's review of draft labeling and the final printed label that actually is found in channels of trade. EPA believes that States have adapted well to the current Agency practice of approving draft labeling, and that changes permitted by § 152.42 will pose no additional problems.

In § 152.110, the Agency stated that it would review applications for registration as expeditiously as possible, but the Agency did not propose to establish binding review times. Six commenters urged the Agency to obligate itself to specific review times for applications. Suggestions ranged from 75 to 180 days, with one commenter suggesting that the Agency publish a review timetable for various types of applications.

EPA has not adopted these suggestions. FIFRA does not mandate statutory timeframes for review of applications: the language of FIFRA sec. 3(c)(3) requires that Agency's determination of registrability be made "as expeditiously as possible." The Agency agrees with the commenters that, from a policy perspective, the Agency would prefer to be able to set achievable timeframes in which to review applications and determine acceptability. However, the nature of the registration process, and the associated regulatory evaluations and decisions that accompany it, preclude the Agency from doing so. EPA cannot predict the number of applications for registration that it will receive each year, because submission of an application is largely at the discretion of persons seeking registration. Nor can the Agency determine the level of review that will be needed to evaluate the application; some applications are of greater complexity than others. The Agency does not believe it prudent to establish regulatory timeframes that it may not be able to meet consistently because of circumstances beyond its control. Therefore, the final rule does not establish Agency review times.

B. Conditional Registration

Sections 152.113 through 152.115 described the criteria for issuance of conditional registration under FIFRA sec. 3(c)(7) and the conditions attached to such registrations. One commenter

focused on these criteria and procedures, in particular those in §§ 152.114 and 152.115 relating to conditional registration of new chemicals.

The commenter objected to the Agency's issuance of conditional registration for new chemicals. Acknowledging that the statute permits such registrations, and that amendment to FIFRA itself would be necessary to remove the authority for issuance, the commenter urged that the Agency adopt a policy (which would be expressed in the final rule), of severely limiting the issuance of new chemical conditional registrations.

First, the commenter expressed the opinion that conditional registration should not be granted for any new chemical that meets or exceeds risk criteria for special review found in 40 CFR Part 154. Second, the commenter urged that the final rule provide criteria for the public interest finding that must be made before a new chemical conditional registration is granted. FIFRA sec. 3(c)(7) requires that the Agency determine that issuance is "in the public interest" before granting conditional registration for a new chemical. The commenter stated that without definitive criteria on which to base a determination of public interest, the Agency could grant conditional registrations for new chemicals very broadly and, it is feared, without adequate justification. Finally, the commenter urged that conditional registration of new chemicals should be limited to the specific period required for generation of required data, and that conditional registrations should expire automatically at the end of that time if required data are not submitted.

In response to all of these comments, the Agency notes that it has issued a policy statement in the **Federal Register** of March 5, 1986 (51 FR 7628), describing its policies for issuance of conditional registration of new chemicals. That policy statement addresses each of the commenters' concerns in an affirmative manner. It states that the Agency will not grant conditional registration for new chemicals if the available data demonstrate that special review criteria are exceeded. It further sets out in greater detail the types of information that may be necessary for the Agency to make a public interest finding in accordance with FIFRA sec. 3(c)(7)(C). Lastly, the policy statement provides that conditional registrations will expire automatically if data (or interim progress reports) are not submitted in a timely manner or if the data, when submitted, show that the pesticide would meet or exceed risk criteria for special review.

In response to these comments, § 152.114 listing the criteria for approval of conditional registration of new chemicals has been revised to clarify that the public interest determination applies only during the expected period of the conditional registration. Section 152.115(b), specifying the conditions of registration for new chemicals, has been revised more substantively. The conditions attached to registration under FIFRA sec. 3(c)(7)(C) now include an automatic expiration (in addition to Agency-initiated cancellation as provided in the proposal) if data or progress reports are not submitted. Moreover, § 152.115 now also includes the condition that the conditional registrant submit information on production of the conditionally registered product. This information is required by the Agency for its annual report to Congress under FIFRA sec. 29.

C. Denial of Applications

Proposed § 152.118 contained proposed procedures for denial of applications for registration. Three commenters noted the provision in § 152.118(e) that, upon notice of denial (by certified mail, as suggested by two commenters), an applicant would have 30 days to respond and correct the deficiencies. The commenters asserted that 30 days is insufficient time to respond properly with corrective action, and urged lengthening the time to 60 or 90 days. They believed that it is unfair to expect 30-day response from the applicant when the Agency has taken several months to review the application.

Although the Agency is sympathetic to the perceived plight of the commenters, EPA notes that FIFRA sec. 3(c)(6) requires a 30-day response to a notice of intent to deny. If the applicant fails to respond within the 30 days, that section states that the Administrator may refuse to register the pesticide. This discretionary authority permits EPA to provide additional time for correction if warranted. EPA does not expect that all corrections can be accomplished within the 30 days. EPA is seeking, at a minimum, an indication from the applicant that he intends to make the corrections within a given time period. Thus, although 30 days would seem to bind the applicant to a short time for both response and correction, EPA may permit longer for actual correction, provided that the applicant notifies the Agency within the allotted 30 days.

A second commenter noted that paragraph (d) apparently makes discretionary the Agency's publication of a notice of denial in the **Federal Register**. He cited the language stating that the Agency "may issue in the **Federal Register** a notice of denial * * *," and interpreted this to mean that publication is discretionary. The language in the final rule has been revised to clarify that it is the decision to deny that is discretionary. All notices of denial will be published in the **Federal Register**, as required by FIFRA sec. 3(c)(6).

IX. Undeliverable Mail

The Agency proposed in § 152.122 that if applicants do not keep the Agency apprised of their current name and address of record, the Agency would suspend the registrations of all products of that applicant. Two comments were received on this provision, neither objecting, but offering suggested clarifications. Since this proposal, the Agency has issued in the **Federal Register** of March 5, 1986 (51 FR 7634) a notice announcing that it will cancel such registrations, and has begun the process of purging its records of registrations whose owners cannot be located. In the final rule, the Agency has modified § 152.122 to conform to its new policy. The Agency believes that this modification in the final rule does not warrant reproposal.

X. Timeframes for Use of Labeling

Section 152.128 of proposed Subpart G established timeframes for the use of existing label stocks after the label has been amended (either on the registrant's initiative or in response to an action by the Agency). Similarly, § 152.135, (concerning voluntary cancellation) proposed a time period for disposal of existing stocks of the pesticide. Although disposal of label stocks upon amendment, and disposal of pesticide stocks after voluntary cancellation are not strictly comparable, comments addressed the two together in some cases. Consequently, this unit responds to comments on both §§ 152.128 and 152.135.

The Agency proposed a period of 1 year after amendment for the replacement of product labeling if initiated by the registrant. Eleven comments were received on this proposal, all of which took exception to the Agency's proposal; all claimed that 1 year is insufficient time to dispose of existing label stocks. The commenters offered various reasons for their objection: sales of seasonal products often extend into subsequent years; the life of returnable or reusable containers (which may be embossed or silk-screened with permanent labeling) is up

to 5 years; health or safety questions that warrant such a short time period are not generally at issue in registrant-initiated amendments; States are unable to keep pace with label transactions each year; and some States (unidentified by the commenter) provide a minimum time of 2 years for exhausting old label stocks. In short, all commenters stated that the Agency should defer to the needs of industry when no questions of health and safety are involved. On the other hand, no commenter objected to (and one supported) the idea that where health or safety concerns were raised, the Agency would specify a timeframe for replacement of labeling, which might be shorter than 1 year.

Based on these comments, the Agency has decided that it will permit 18 months instead of 12 months for disposition of existing label stocks when the amendments proposed by the registrant do not involve health or safety considerations. EPA believes that persons who are seeking label amendment can and should plan in advance for use of their label stocks, so that large number of label stocks will not remain after 18 months.

One commenter urged the Agency to delete the language referring to "physical possession" as the determinant of which products must be relabeled. He suggested that the Agency instead use the more standard term "released for shipment."

EPA agrees with the commenter and has deleted the term from the final rule. "Physical possession" is not the term used in FIFRA to define when enforcement actions may be taken. The Act uses the term "released for shipment" (FIFRA sec. 9) to define when inspections may be carried out for purposes of compliance, and the Act defines violations (FIFRA sec. 12) in terms of the "distribution and sale" of the product. The Agency's current practice in defining dates when revised labeling must appear on products has been to specify two dates: a date beyond which the registrant may not distribute or sell the product (a "released for shipment" date) and a second, later, date beyond which distributors, dealers and retailers may not distribute or sell the product (a so-called "channels of trade" date). The Agency intends to continue this method of specifying timeframes for compliance.

One commenter suggested that the voluntary cancellation procedures in proposed § 152.135 (codified as § 152.138 in the final rule) be modified to include a petition process whereby a registrant could petition for a period longer than 1 year in which to dispose of a voluntarily cancelled product. Rather than specify a specific date by which pesticide stocks must be disposed with a concomitant petition process to justify a longer period, the Agency has deleted from the final rule any specific date by which existing stocks must be disposed of. The Agency prefers the flexibility of dealing with existing stocks questions individually, and hesitates to impose a formal petition process unnecessarily. Moreover, the Agency believes that a timeframe for disposal of pesticide stocks should depend on the risks associated with that pesticide that formed the basis for the cancellation. A product that is voluntarily cancelled in the face of impending suspension or special review decisions may pose risks such that no disposition of existing stocks should be permitted. By contrast, a product that is voluntarily cancelled because a changing market no longer supports continued distribution and sale may pose no risks that justify limiting existing stocks distribution. In this latter case, the registrant probably will have only a small stock of product because he has already phased down his production and distribution volume.

Consequently, § 152.138 requires that a registrant requesting cancellation of his product propose a timeframe for disposal of existing stocks of the pesticide, taking into account the amount of material and the historical time for moving the product through channels of trade. In the notice of cancellation, the Agency will specify a timeframe for disposal of existing stocks.

XI. Agency Actions Affecting Registration

Subpart H of the proposal described in summary form various Agency actions that may affect registration—classification for restricted use, data call-in, reregistration, special review, cancellation and suspension, and required use of child-resistant packaging.

Two commenters addressed this subpart. One commenter urged that when the Agency changes the requirements for data under FIFRA sec. 3(c)(2)(B) (§ 152.142), the Agency state the reason for the new data and the status of data under the old guidelines. The Agency is not certain what the commenter is referring to when he mentions "changing" data requirements.

The overwhelming majority of data required of registrants under section 3(c)(2)(B) are not new or changed requirements, but simply the application of current data requirements contained in 40 CFR Part 158 to existing pesticides. If, however, a data requirement being imposed under section 3(c)(2)(B) is not contained in Part 158, or is required only for certain products, the Agency will state the reason for the data requirement.

The Agency's policy with respect to previously submitted data is stated in 40 CFR 158.80. That section states that EPA will evaluate a study to determine whether it was conducted in conformance with accepted scientific protocols and study designs and whether the results were reproducible. The Agency will not reject a study that is conducted in accordance with Agency recommendations, or another acceptable protocol, provided that the study fulfills the purposes for which the requirement was established, and permits sound scientific judgments.

One commenter objected to the provision in § 152.148 that the Agency may initiate cancellation proceedings if the composition, packaging or labeling of the product do not comply with the Act. The commenter was particularly concerned with labeling, stating that labeling requirements are subjective. The commenter asserted that no provision is made in the rule for negotiation, arbitration or other registrant-initiated actions.

Section 152.148 states the provisions of FIFRA sec. 6(b), which permits the Agency to initiate cancellation proceedings if a product, its packaging, or its labeling is not in compliance with the Act. Once a notice of intent to cancel is issued, however, the registrant has the right to request an administrative hearing, in which he may contest the basis for the cancellation, including the reasonableness of any labeling requirement that has not been specifically established by regulation, or its applicability to his product. During the pendency of such a hearing, the product remains registered.

XII. Restricted Use Classification

Subpart I of the proposed rule reorganized and revised the criteria and procedures for restricted use classification. The Agency proposed few changes in the procedures for classification, and only minor changes in the criteria for classification. The provisions of proposed Subpart I largely reflected the criteria in § 162.11(c) and the procedures in § 162.30. A total of 13 comments were received on Subpart I, the majority directed to the changes in criteria in § 152.170.

A. Scope of Classification

Section 152.160 of the proposal described the scope of the Agency's authority to classify products, and the overall framework of the program. The

Agency noted that it may classify products for restricted use either by regulation or on a case-by-case basis in conjunction with other regulatory actions.

Several commenters stated that the Act does not provide for an "unclassified" product, as stated in § 152.160(a), and suggested that it be deleted. The commenters are correct that FIFRA sec. 3(d) provides that a product shall be classified for either restricted use or general use. However, as a policy matter, the Agency does not now, and does not intend to, classify products for general use.

As stated in the preamble to the proposal, the thrust of the classification process is the identification of products that should be restricted—not those which do not need to be restricted. A product for which no concerns warranting restriction have been raised does not need confirmation of that fact by classifying it for general use. The Agency does not intend to devote its scarce resources to reviewing a product for the purpose of general classification—a determination which would carry with it no obligations or consequences for the registrant. Therefore, a product which has not been classified for restricted use remains unclassified in EPA's opinion. Section 152.160 of the final rule acknowledges this fact.

A second commenter to § 152.160 objected to the case-by-case determinations of classification. The commenter argued that case-by-case determinations did not permit sufficient phase-in time, provided no notice or comment opportunity under the Administrative Procedure Act, no consideration of small business impacts under the Regulatory Flexibility Act, and no judicial review.

The Act specifically provides for case-by-case classification as part of its registration process. FIFRA sec. 3(c)(1)(F) requires an applicant for registration to propose a classification at the time of application and section 3(d)(1)(A) states that classification shall occur as part of the registration. In addition, the Act provides for a discretionary process of classification by regulation, which is subject to all the administrative and judicial protections provided by the Administrative Procedure Act for other regulations. In both cases (case-by-case or by regulation), the Agency's decision is a final determination subject to judicial review. Thus the commenter is in error in assuming that there are no administrative, procedural, or judicial protections for Agency classification decisions.

B. Criteria for Classification

EPA proposed in § 152.170 criteria under which the Agency would classify products for restricted use. The criteria include determinations by the Agency that the product exceeds certain hazard criteria, that restriction would reduce the risk of adverse effects to a greater extent than it would decrease benefits from use of the product, and that labeling would not be sufficient to mitigate the identified risks.

The majority of commenters on this subpart expressed concern with the criteria for restriction for residential and institutional products contained in § 152.170(b). In general, commenters were in favor of the Agency's not restricting various types of products—e.g., residential, institutional, industrial, or antimicrobial products—or, alternatively, of considering restriction only if the products were highly toxic (Toxicity Category I). Some expressed the opinion that the requirements for child-resistant packaging (40 CFR Part 157), together with labeling, are sufficient to protect users in residential use situations.

EPA has not revised the criteria to eliminate the possibility of restricted use classification for residential/institutional/industrial products. The criteria are identical to those in existing regulations (§ 162.11(c)) for new "domestic" products). EPA has not applied those criteria to date to restrict such products. Child-resistant packaging has been the mechanism thus far used to reduce the risks of products intended for residential use. Nonetheless, the Agency does not believe it should limit its regulatory choices in the manner proposed by the commenters, such that residential, institutional, industrial, or antimicrobial products could not be classified for restricted use if circumstances warrant.

A commenter questioned the practicality of a unique and independent fish and wildlife trigger for restricted use (§ 152.170(c)). The commenter's main concern appeared to be the practicality of the fish and wildlife trigger based on dietary intake, which he stated was difficult to determine. EPA agrees that there is scientific uncertainty in calculations such as those proposed. Nonetheless, EPA has developed considerable experience in estimating dietary intake of pesticides by wildlife, and believes that the estimations are reliable indicators of hazard. EPA therefore has retained the fish and wildlife triggers based on dietary intake.

The same commenter urged that the Agency retain the human risk trigger as prerequisite to a wildlife trigger (i.e., the Agency should not consider restricted use for wildlife effects unless a human risk trigger has first been exceeded). EPA believes that a scheme in which restriction for ecological and environmental effects is only secondary to potential human effects would provide inadequate protection of the environment, and limits the Agency's regulatory options. Human, ecological, and environmental risk reduction can be equally well served by restricted use classification, which requires application by or under the supervision of a trained certified applicator.

Moreover, restricted use classification is intended to function as an alternative to cancellation of a pesticide that poses unreasonable adverse effects on man or the environment; such effects are not limited to human exposures. If confronted with a pesticide that poses strictly environmental or ecological risks, the Agency might be compelled to cancel products if restriction were not available for consideration. Additionally, the criteria for initiating a special review of a pesticide, a process that may lead to cancellation, include specific and independent criteria for ecological effects. The Agency has initiated special reviews of some pesticides based solely on ecological effects. Consequently, EPA will also retain the fish and wildlife restricted use criteria independent of human effects criteria.

Three commenters asserted that use history and accident data, proposed as criteria for potential restriction in § 152.170(d), are not appropriate as triggers for restricted use. They state that these are not indicative of the inherent hazard of the product, but are the result of misuse only, and should be deleted as considerations in restricting a product. EPA disagrees. Use history and accident data are important sources of information on hazards, particularly in the ecological effects area. Moreover, EPA can usually distinguish between accidents and misuse incidents, and information from accidents can be considered apart from obvious misuse situations. The Agency believes that the training and certification of applicators that is required for restricted use classification can significantly reduce the potential for adverse effects, whether from normal use or misuse. Thus information on misuse is an important consideration in evaluating the need for restriction.

The Agency does not contemplate restricting a product based solely on misuse or accident history, but will consider such information as supporting

data on the pesticide's potential to cause adverse human and ecological effects.

XIII. Label Improvement Program

The Agency proposed to add as Subpart J regulations implementing its Label Improvement Program (LIP) initiated in 1980. The proposal described the procedures the Agency would use in conducting an LIP, the expected responses of registrants, the timeframes for submission of responses, and the compliance times for the label changes. Twelve commenters objected to the inclusion of this program in the Agency's regulations. Their objections were varied, but commonly expressed the notions that the program was not sufficiently well defined in scope and applicability, that it has not "matured" to the point of regulation as yet, and that it could develop into a quasi-registration function not offering opportunity for input by affected or interested parties. Several commenters urged greater participation in the existing non-regulatory LIP program by industry.

Based on these comments, the Agency has decided not to promulgate regulations for the LIP program at this time. EPA believes that the LIP serves a useful function, with goals of consistency, uniformity, and clarification of labeling. However, EPA agrees with commenters that the current LIP program is still evolving and that regulations for its implementation are premature. The Agency will continue to use the LIP as it has in the past, allowing considerable flexibility in procedures and requirements as individual situations warrant. The Agency will, as requested by commenters, provide more opportunity for participation by registrants and the public before issuing LIP notices. At a future time, the Agency may propose regulations for the LIP program.

XIV. Intrastate Products

EPA proposed to update its requirements for intrastate products. Subpart L of the proposed rule required that intrastate producers submit applications for full Federal registration no later than July 31, 1988. Products shipped after December 31, 1988, would be in violation of the Act unless federally registered. In addition, the Agency could require earlier submission of applications for consistency with regulatory actions concerning federally registered products.

One commenter pointed out that no provision was made for continued sale and distribution of products if an application had been submitted by July 31, 1988, but was still pending as of December 31, 1988. The Agency agrees that a pending application should suffice to permit continued sale and distribution of the product while the Agency considers the application. Accordingly, § 152.230 has been revised to state this. The December 31, 1988, date for obtaining Federal registration is therefore irrelevant (as would be any specific date for receiving Federal registration). Instead, legal sale and distribution of the intrastate product will be governed by the application submission date of July 31, 1988.

Accordingly, by July 31, 1988, each producer of an intrastate product must submit an application for full Federal registration. If no application is filed, sale or distribution of the product will be deemed to be in violation of FIFRA sec. 12(a)(1)(A) after July 31, 1988. The Agency will deny applications for registration of intrastate products that are not complete or sufficient for review.

XV. Devices

Subpart M of the proposed rule set out, by reference to the Act and regulations, the requirements pertaining to devices, which are not required to be registered but are subject to other provisions of FIFRA. No comments were received on this subpart, and it is adopted without change. However, since devices are not subject to registration requirements, Subpart M has been moved from Part 152 to Part 153, containing policies and interpretive rules concerning registration.

XVI. Determination of Active and Inert Ingredients

For organizational purposes, the Agency proposed that the information contained in § 162.60 be relocated in Part 158. Current § 162.60 describes the general criteria applied to determine whether an ingredient is active in a pesticide product, and lists a number of substances which are deemed to be inert when used in antimicrobial products. Since this material appeared to relate primarily to the data requirements that might be imposed on such substances (depending on whether they were active or inert), the Agency proposed to include the criteria and listing in Part 158, which addresses data requirements.

Although no comments were received that specifically addressed this organizational change or raised issues requiring consideration by the Agency, it was clear from comments received on other topics (product chemistry requirements in particular) that the listing was being misconstrued. At least two commenters assumed that listing a substance in § 158.1001 as an inert ingredient was equivalent to a clearance process which relieved them of the responsibility of submitting any data on those substances. The Agency's decision to locate the material in Part 158 may have contributed to this misperception.

The purpose of the listing is to identify substances that are pesticidally inert; the listing in proposed § 158.1001 applies to substances used in antimicrobial products. The criteria of proposed § 158.27 clearly were related to pesticidal effects of the substances, not toxicological or other characteristics for which data may be required. Although the Agency has discretion to limit the types and amounts of information it will require on ingredients in pesticide products, and may discriminate between pesticidally active and inert ingredients, it should not be inferred that designation as an inert ingredient automatically has that consequence. The original need for making a determination on the listed substances arose because registrants of antimicrobial products tended to include those substances as active ingredients on their labels. The only regulatory consequence that can correctly be inferred is that a listed substance may not be designated on the label as an active ingredient, but must be included in the total of inerts.

To clarify this misperception, the Agency has revised the information and is locating it separately in Part 153, which contains policies pertaining to registration. Section 153.125 clearly describes the criteria as those for determining "pesticidal" activity. Section 153.125(b) sets out the Agency's authority to determine whether a substance is pesticidally active or inert (within the meaning of FIFRA sec. 2(m)). Paragraph (c) of that section states that designation as inert affects the labeling of the product. A new paragraph (d) has been added to ensure that registrants are aware that other requirements (including data requirements) may be imposed, even though the substances are listed as inert.

XVII. Coloration and Discoloration

In accordance with FIFRA sec. 25(c)(6), the Agency proposed to require that additional types of products be colored (or discolored). Specifically, the Agency proposed that products intended for seed treatment (with certain exceptions) contain a dye, unless instructions were included on the label to color the seeds separately at the time of seed treatment.

No comments were received on this proposal, which reflects current policy and is in conformity with similar regulations under the Food and Drug

Administration and U.S. Department of Agriculture. Accordingly, this requirement is adopted as proposed.

The Agency also proposed to require that granular products for soil application be brightly colored to contrast with soil components. EPA stated that colored granules would deter wildlife (particularly birds) from ingesting the granules, and would make application easier. Eight commenters addressed this proposal, seven objecting to the requirement for various reasons. Commenters argued that coloration will not deter birds or wildlife; that the Agency has no scientific evidence to support its proposal; that the dyed granules will be an "attractive nuisance" for children; that the addition of dyes will be costly and not always technically feasible; and that the requirement is arbitrary, being imposed without regard to potential hazard or application practices that might mitigate the hazard.

EPA has considered these comments and concludes that they raise issues needing fuller evaluation before requirements are imposed. Accordingly, the Agency has deleted the requirement for coloration of granular products from the final rule.

Finally, because the requirements for coloration and discoloration are general policy, and do not pertain distinctly to the registration process, they have been redesignated in the final rule as Subpart H of Part 153.

XVIII. Format of Data Submissions

A. Format Requirements

EPA proposed to establish, as §§ 158.32 and 158.33, format requirements for the submission of data in support of applications for registration, experimental use permits, petitions for tolerance, and other regulatory activities under FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA). Submission of data in the formats required will assist the Agency in indexing, cataloging, and reviewing the data, and will facilitate retrieval of data for review and reference purposes. Additionally, the requirements pertaining to segregation of confidential business information (CBI) will permit the Agency to respond more readily to requests under the Freedom of Information Act (FOIA) without jeopardizing the confidentiality of information protected by FIFRA sec. 10(d)(1), and without undue delay.

In proposed § 158.32, EPA described a number of general format requirements for submission of data. Studies must be submitted separately; must contain a title page with specific identifying information; and, when submitted with a number of studies, must be transmitted with a cover document describing the entire transmittal. Two commenters addressed the requirements of this section, requesting clarification of the language on several points.

Both commented that at this time the Good Laboratory Practices requirements referenced in § 158.32(b)(2) pertain only to toxicological studies. The commenters are correct. Section 160.3(m) of this chapter defines a "study" in a manner that limits its applicability to toxicology studies. However, EPA has not revised the rule to specify this policy, since this final rule is intended only to cross-reference the requirements of Part 160. If Part 160 is revised to add to or change the GLP requirements, a specific cross-reference in § 158.32 would also have to be revised. The Agency is, in fact, considering revising Part 160 to specify the types of good laboratory practices that would be appropriate for other types of studies.

Both commenters also requested that the Agency clarify whether the date of "completion" of a study is synonymous with the date of "issuance" of the study. The Agency wants to know when the study itself was completed by the performing laboratory, not the date it was sent to the submitter. Section 158.32(c) has been revised to clarify this point.

B. Confidential Business Information

Section 158.33 of the proposal described the procedures that data submitters must use in asserting a claim of CBI. First, the Agency proposed that all information claimed to be CBI within the meaning of FIFRA sec. 10(d)(1) (A), (B), and (C) be isolated in a separate attachment to the study and cross-referenced in the study itself. Second, the Agency proposed that other information for which a claim of confidentiality is asserted under FIFRA sec. 10(b) be clearly marked in the text of the study, but not physically separated.

Four commenters took exception to the Agency's establishing a system that required segregation of some information from the context of the study. They asserted that the system was cumbersome and complicated for data submitters and that it is heavily weighted toward the Freedom of Information Act (FOIA) needs of the Agency. Moreover, they believed that Agency reviewers would find a system that located FIFRA sec. 10(d) information in a separate study attachment inefficient and difficult to use. All preferred the simpler marking system required for CBI claimed under section 10(b).

EPA acknowledges that the procedures required by § 158.33 may at first be inconvenient and may initially involve slightly increased costs for data submitters who have not in the past submitted information in this manner. However, as they gain experience in compiling studies in the required format, data submitters' costs should diminish. Moreover, the costs to the Government will significantly decrease if these procedures are put in place.

The Agency has had experience with the simple marking system advocated by commenters; the difficulties encountered with this system provided the impetus for the changes proposed. As to arguments that segregation of claimed CBI will be inefficient for Agency reviewers, EPA disagrees. Agency reviewers recognize the need to protect CBI, and in drafting Agency documents are required to adhere to the same requirements. They are accustomed to the procedures and have not found the segregation of claimed CBI to be overly burdensome.

The Agency's reasons for requiring separation of claimed CBI under section 10(d)(1) were clearly stated in the preamble to the proposal. Comments from data submitters have not convinced the Agency that segregation of claimed CBI is unnecessary, nor that a marking system could accomplish the objectives equally well. EPA continues to believe that the benefits and efficiencies of the requirements to EPA more than offset the cost and inconveniences cited by commenters in objecting to the requirements.

Two commenters questioned the need for the Statement of Non-Confidentiality required by § 158.33(c). They pointed out that the Agency has stated in § 158.33(b) its policy that failure to segregate CBI properly is deemed to be a waiver of claims by the submitter. Since waiver of claims is assumed in the absence of an affirmative declaration by the data submitter, the Statement of Non-Confidentiality is redundant.

EPA views the policy and the Statement of Non-Confidentiality as complementary rather than redundant. Although Agency policy is that unmarked and unsegregated information is freely releasable under the FOIA, the Agency believes that maximum protection to data submitters (and incidentally to the Agency) is afforded by the affirmative statement required by § 158.33(c). If a study is clearly marked as non-CBI, the Agency is assured that the data submitter has given careful thought to its status, and has not

inadvertently overlooked the requirements.

Finally, two commenters asked that the final rule clarify where the Statement of Confidentiality Claims should be located, suggesting that the title page of the study is an appropriate location. The proposal did not specify a location for the required statement, nor does the final rule. The title page of a study may be prepared by the performing laboratory, while the determinations of confidentiality would ordinarily be done by the submitter of the data. The Agency prefers that the statement be included on a separate page immediately following the title page. However, there in no objection to its being located on the title page if desired by the submitter.

XIX. Flagging Criteria

EPA issued a proposal in the Federal Register of October 3, 1985 (50 FR 40408), that would require pesticide applicants and registrants to mark or "flag" certain studies at the time of submission to the Agency. The Agency cited the increased volume of data expected to be submitted in the near future and its limited resources for review of those data as reasons for its proposal. Flagging the studies would serve to alert the Agency to pesticides having potentially serious adverse effects. Earlier, the Agency had issued in the Federal Register of September 20, 1985 (50 FR 38115), an interpretive rule concerning the submission of adverse effects data under FIFRA sec. 6(a)(2). That regulation, although not requiring the flagging of studies, had requested that submitters voluntarily do so. Together, these two documents attempted to address all data submissions made by registrants or applicants.

In its October proposal, the Agency proposed a set of study types subject to the flagging requirement. The proposal covered studies of three general types: toxicological studies (subchronic and chronic); ecological effects; and environmental fate studies. For each study, the proposal contained one or more criteria which, if met, would trigger a requirement for affirmative flagging of the study. The toxicology criteria were qualitative and descriptive in nature. The environmental fate and ecological effects criteria were quantitative and objective. A study was to be flagged by signing a certification statement that the study either did or did not meet the criteria.

In response to its proposal, the Agency received comments from nine pesticide companies or trade associations and one environmental organization. In response to these comments, the Agency is at this time promulgating only the toxicology criteria and has better defined those criteria for positive flagging. The Agency is reassessing the criteria for ecological effects and environmental fate to determine their feasibility and usefulness and may in the future promulgate the proposed criteria, or propose different ones. Comments on the proposal are addressed in the following preamble subunits.

A. Need for Flagging

The Agency stated in its proposal that it would be receiving large volumes of data in response to its Data Call-In (DCI) and Registration Standards programs, and that its limited scientific resources would not permit all such data to be reviewed upon receipt. For that reason, EPA viewed flagging as a means of setting review priorities so that pesticides demonstrating potentially serious adverse effects could be given early review.

Most commenters questioned whether the Agency would accomplish its stated purpose by its proposal, and several commenters objected to the proposal. Commenters generally stated that the proposal would result in overflagging of data. Flagging, it was asserted, would not isolate pesticides having potential adverse effects; rather, the Agency would be inundated with studies that were flagged, which would defeat the purpose of flagging. Commenters attributed this to the combination of several factors: the vagueness, ambiguity, or subjective nature of the criteria, particularly in the area of oncogenicity and chronic feeding studies; the Agency's recommendation for inclusion flagging where scientific uncertainty exists; and the concern that EPA would seek penalties of an unstated nature, although the proposal did not describe such a plan. These three factors, commenters stated, would lead data submitters to be extremely conservative, with the result that most studies would be flagged. One commenter also stated that a company desiring early review of its studies might be inclined to flag them simply for that purpose (and could do so with impunity, since the criteria and penalties were not sufficiently clear that they could be held accountable for erroneous flagging). The Agency believes this latter occurrence will be infrequent.

In response to concerns about ambiguity and lack of clarity in the toxicological studies and the specific comments received, the Agency has revised the criteria (see Unit XVIII.C.) to delineate more carefully the factors that should be applied.

With respect to the penalties for failure to flag, under FIFRA sec. 3(c)(2)(B) the Agency may suspend the registration if the data submitter fails to flag the data properly. Moreover, failure to flag may be deemed to be a falsification of a required report under FIFRA sec 12(a)(2)(M).

B. Scope of the Flagging Requirement

Other commenters who objected to the proposal questioned its utility in the application review process (as opposed to the Data Call-In process, about which similar comments were not made). Their comments were directed primarily at new chemicals. Commenters stated that flagging data submitted with a new chemical application was unnecessary, i.e., that early review of the studies would achieve no environmental protection because the chemical was not being marketed. These commenters also argued that early review would have little effect upon review resources, since the entire application would still have to be reviewed (including all unflagged studies) before the registration could be granted. On the other hand, they pointed out that flagging of one study could stigmatize the chemical for a single effect which might not be significant when considered with the data as a whole.

Finally, commenters pointed out that the Agency's stated policy is to give priority review to safer new chemicals, and that giving early review to studies demonstrating potential adverse effects runs counter to this policy. A new chemical application having no flagged studies could, presumably, be relegated to a lower review priority while the Agency focused its attention on a new chemical with a flagged study. Commenters viewed this as an unintended effect of the flagging requirement and recommended that new chemical applications should not be subject to flagging.

The Agency has decided to retain the flagging requirement for applications for registration. EPA believes that flagging of data for new chemical applications, although not a means of prioritizing the review of the application, will be useful in other ways. For example, if the Agency has under review other regulatory actions on a chemical, such as a section 18 exemption request, EPA will be able to use flagged data in evaluating the request.

In the case of an application for registration of a me-too product or for a new use of an old chemical, flagging will serve the purpose of identifying the

study for early review. An application for a new use of an old chemical or for a me-too product is generally reviewed in an order determined by factors other than the type of amount of data submitted. In the case of me-too products, data that would require flagging are rarely submitted. Similarly, unless an applicant seeks a significantly expanded use requiring submission of a full battery of studies, the Agency does not expect the routine submission of the types of studies requiring flagging. In both of these cases, EPA views the flagging of data that are submitted as especially important, since the Agency normally will not alter its current review priorities for such applications unless prompted to do so by having the studies flagged.

Finally, EPA notes that the task of flagging the data is not overly time-consuming or difficult, and that the number of studies requiring flagging is relatively small. EPA believes that the burden upon registrants will be insignificant compared to the time and expense of producing the study in the first place.

C. Toxicology Criteria

The Agency proposed flagging criteria for six types of toxicological studies commonly required by the Agency. These included oncogenicity, chronic and subchronic feeding studies, reproduction, teratology, and neurotoxicity studies.

1. *Oncogenicity studies* (Criteria 1 through 4 in the final rule). A number of commenters raised similar concerns about unclear terms used in describing the criteria, particularly for oncogenicity and chronic feeding studies. They singled out terms such as "marginal," "substantial," and "decreased time," as needing better definition. They noted that unless the terms are better defined, industry compliance and enforcement would be difficult, and excessive flagging would result. Commenters suggested additional language that they believed would help clarify the criteria, including "statistically and biologically" significant increases, "concurrent and historical" controls, and "treatment-related" effects.

In response to these comments, the Agency has substantially revised the criteria for oncogenicity studies to eliminate many of the imprecise terms. Specifically, EPA has eliminated the terms "marginal" and "substantial increase." and has included language concerning "concurrent controls" and "statistically significant" increases in tumor development.

EPA, however, has not adopted language concerning "historical" controls, or "treatment-related" or "biologically significant" tumor development. The Agency recognizes the importance of the concepts such as "historical controls," "biological significance," and "treatment-related effects" in the ultimate determination concerning oncogenicity of a pesticide. However, the Agency believes that, since the purpose of the criteria is to provide a rough screen to alert the Agency of potential problems, such detailed analyses are not warranted at this level of review. The "decreased time to tumor development" language has been retained because it is a commonly recognized criterion for judging oncogenicity.

Although these revisions significantly reduce the ambiguity of the criteria, scientific judgment still must be applied to determine whether the toxicology criteria have been met, but EPA believes that this scientific interpretation is no more uncertain or ambiguous than that which normally arises in interpreting the results of any scientific study.

2. *Teratology studies* (Criterion 5). Of the six commenters on the teratology criterion, three suggested the inclusion of the same language as for the oncogenicity studies. EPA has not included language on biologically significant increases, historical controls, and treatment-related effects for the reasons explained before. EPA has included language concerning a "dose-related response." The Agency is conforming this rule to its position on teratology as expressed in previous Agency documents (Final Guidelines for the Health Assessment of Suspect Development Toxicants, September 26, 1986 (51 FR 34028); Standard Evaluation Procedure: Teratology Studies, OPP, June 1985). The concept of adverse developmental toxicity in the absence or presence of significant maternal toxicity at the same dose level will be evaluated on a case-by-case basis.

Another commenter noted that teratogencity cannot be compared on a fetus basis, only on a litter basis. The Agency agrees, and has deleted the fetus-based comparisons. A third commenter noted that the presence of teratogenicity is sufficient evidence of adverse effects; language requiring an "increase" in fetal malformations is not appropriate. EPA disagrees, and has retained the original language. In most teratology studies, the controls show a certain low background rate of teratogenic effects; therefore an "increase" when compared with controls is appropriate.

3. *Neurotoxicity studies* (Criterion 6). Commenters on the neurotoxicity criterion generally stated that the end point of concern—a "positive effect"—is too vague and undefined to be meaningful in evaluating whether a study meets the criterion. Two suggested alternative language that they believed expressed the criterion more accurately. EPA rejected language requiring "histologic evidence of adverse effect on nerves" as being too narrow. In the final rule, the Agency has accepted the suggested language of the other commenter, who proposed to base the criterion on a response "indicative of acute delayed neurotoxicity," but not requiring that a positive response be dependent upon histologic findings of nerve effects.

The Agency has not adopted language suggested by commenters concerning "historical" controls, for the reasons cited earlier. Nor has EPA based the criterion on "positive and negative controls" as suggested by another commenter. EPA's concern in evaluating neurotoxic effects focuses on whether such effects are greater than negative controls, not on whether they are as potent as positive controls.

4. *Chronic feeding studies* (Criteria 7 and 8). Commenters on these criteria focused on the Agency's use of the acceptable daily intake (ADI) which is often derived from the results of chronic feeding studies. Commenters generally requested that the Agency clarify what ADI was to be used, whether a provisional ADI (PADI) should be used, and the applicability of the criteria when there is no ADI. There was no disagreement with the 10X or 100X factors used in the translation of the NOEL to the ADI.

In applying the chronic feeding criterion, data submitters should use the latest ADI upon which a tolerance (either temporary or permanent) has been based. This may be a PADI if not based on a full complement of toxicological studies sufficient to define an ADI. If no ADI has ever been determined (no tolerances have previously been established), the data submitter should flag the first study which permits the establishment of a PADI or ADI, and thereafter apply the criterion as written.

5. *Reproduction studies* (Criterion 9). Two comments were received on this criterion. One suggested the inclusion of historical controls, which the Agency has not adopted. The other suggested that the use of the "no observed effect level" (NOEL) should be replaced with the "no observed adverse effect level" (NOAEL). The Agency views these terms as interchangeable, but in the pesticide regulation program has consistently used the term "NOEL"

rather than "NOAEL" in previous documents. Language concerning "adverse" effects would introduce greater ambiguity into the criterion. Therefore, the Agency has not changed the reproduction criterion.

6. *Subchronic feeding studies* (Criteria 11 and 12). Commenters on the subchronic criteria generally were concerned about the Agency's 200X and 2000X factors used in translating the NOEL to the ADI. They argued that the Agency should not double the factors used (in addition to the tenfold difference factor normally applied based on the use of subchronic instead of chronic studies). They urged the Agency to use a 100X factor for the cholinesterase inhibition criterion and a 1000X factor for the general (systemic) toxicity criterion. EPA agrees with these comments, and has revised the criteria for subchronic studies to reflect only a tenfold uncertainty factor.

Commenters also suggested language concerning "treatment-related" effects and the NOEL; the Agency has not adopted these suggestions for reasons given earlier.

D. Environmental Fate and Ecological Effects Criteria

Commenters on both the environmental fate and ecological effects criteria questioned whether the criteria would be effective in identifying pesticides having potential adverse effects. A typical comment was that in both the environmental fate and ecological effects areas, the flagging criteria could not be applied independently as indicators of potential adverse effects, but must be considered with other studies. Particularly, commenters noted that the environmental fate criteria are actually characteristics of the pesticide that are meaningless when considered independently.

The Agency agrees with commenters that flagging of environmental fate and ecological effects studies under the criteria as proposed would result in a large number of studies being flagged for early review. The Agency has tested the flagging criteria by applying them to a random sampling of 23 Registration Standards. Of the available studies (for a number of Standards, there were no studies which could be judged against the flagging criteria), over 80 percent of the hydrolysis and aerobic soil metabolism studies and 68 percent of the solubility studies would have been flagged. When considered together, it is clear that a large proportion, if not all, pesticides would meet one or more of the environmental fate criteria. Similarly, in the area of ecological effects, 35 to 54 percent of the studies would be flagged, depending upon study type.

By contrast, a similar comparison of toxicology studies in the Registration Standards surveyed revealed that 30 percent or less of the studies would be flagged (in the Agency's estimation), ranging from a low of 10 percent for teratology studies to 31 percent of chronic feeding studies. Based on this limited survey, and the comments received, EPA has decided not to establish flagging criteria for environmental fate studies or ecological effect studies at this time. EPA will be evaluating whether criteria can be developed that will identify or isolate effects of concern more clearly. At a future time, EPA may promulgate or propose flagging criteria for environmental fate and ecological effects studies.

E. Procedural and Miscellaneous

In addition to comments on the criteria, the Agency received a number of comments on the procedural aspects of the proposal, as well as some miscellaneous comments.

1. Does flagging apply to interim reports as well as final studies? No, the requirement applies to the study when complete. However, if the study is being conducted on a registered pesticide, under FIFRA sec. 6(a)(2) there may be an obligation to submit interim reports identified as 6(a)(2) data.

2. The Agency should issue in the Federal Register semi-annually a list of all flagged studies. EPA does not intend to do so. The purpose of flagging is to identify studies that should be given early review. Industry commenters were particularly concerned that the effect of flagging might be to stigmatize the chemical in the public perception based on less than complete information. EPA believes it would be premature and inappropriate for the Agency to publicize the submission of studies merely because they had been flagged. Until the Agency has reviewed studies to determine their significance, publication would serve only to raise public concerns and fears that might prove entirely unfounded. If, based on its review of the study, the Agency determines to take regulatory action, such as initiating a special review of the pesticide, the agency would then make public its findings and reasons for so doing.

3. EPA should use the criteria as indicators that a risk trigger for special review has been exceeded. EPA rejects this idea for the same reasons as stated above. The criteria for special review are clearly set out in 40 CFR 154.7, and entail consideration of exposure factors not encompassed in the flagging criteria. A pesticide will be placed in special review only upon Agency determination that a special review criterion has been met.

In this regard, one commenter also suggested that EPA should include flagging criteria for exposure factors. The commenter's point was that the Agency should give higher priority to a pesticide having high exposure potential, even if there are flagged studies on a low exposure chemical. EPA intends that the flagging criteria be used for a relatively rapid screening process for internal review purposes. If the criteria were encumbered with exposure factors, which would be considerably more subjective in nature, they would lose their usefulness to the Agency, and would be significantly more difficult for data submitters to interpret correctly. The effectiveness of the flagging criteria depends on mutual understanding between the Agency and data submitters of the types of scientific findings that are of concern to the Agency as indicative of potential adverse effects. EPA's objective has been to introduce greater objectivity and clarity into the flagging criteria, not greater uncertainties. As noted earlier, commenters indicated that the criteria as written (without exposure considerations) were too vague and ambiguous. However, the Agency may take exposure factors into account when determining the priority of review among similarly flagged studies. For example, it is likely that higher priority would be given to a flagged study for a chemical having high or widespread exposure than to one having limited exposure.

Moreover, another commenter questioned whether the flagging criteria would not put the data submitter in the position of having to make a judgment call that the Agency is mandated to make. This commenter raised the question whether EPA's independent assessment of the study might be compromised by the submitter's flagging of the study. Although EPA does not believe that this would happen, inclusion of exposure criteria would certainly give more credence to the commenter's concern about registrant versus Agency judgments.

4. Finally, several commenters remarked on the Agency's recently issued interpretive rule on FIFRA sec. 6(a)(2) data. This final interpretive rule included the flagging criteria, with a request that data submitters use the criteria in submitting section 6(a)(2) data. Although not directly pertinent to

this rule, which specifically excludes 6(a)(2) data from the flagging requirement, the comments indicated some confusion as to the role of the flagging criteria in identifying potential adverse effects data under FIFRA sec. 6(a)(2).

The Agency has not yet made effective its final 6(a)(2) interpretive rule, published in the Federal Register of September 20, 1985 (50 FR 38115). Before it does so, EPA intends to revise the rule in response to concerns raised by commenters and to republish the final rule. The recommended use of flagging criteria will be deleted from the final rule. The Agency agrees with commenters that flagging of 6(a)(2) data would be a redundant requirement, since 6(a)(2) adverse effects data are inherently relevent to the Agency's risk/benefit decisionmaking. The purpose of the 6(a)(2) interpretive rule is to delineate the subset of adverse effects data the Agency is most interested in reviewing. Data identified as 6(a)(2) data are already given priority review in the same manner as is intended by flagging. Therefore, flagging of only some of those data would create a "subset within a subset" situation, which could prove confusing to registrants, with no corresponding benefit to the Agency in early review priorities.

XX. Product Chemistry Data Requirements

The Agency proposed establishing a new Subpart R of Part 152, which would contain product chemistry data requirements. The proposed data requirements repeated the existing product chemistry data requirements currently contained in Part 158. In addition, Subpart R was to codify certain types of product chemistry information contained in the Pesticide Assessment Guidelines, which are referenced in Part 158 in the table of product chemistry requirements (§ 158.190), but without guidance on the types and quantity of information required to be submitted. This latter information consists of information concerning identity and composition of ingredients and impurities, descriptions of starting materials and manufacturing processes, discussions of potential impurity formation, and requirements for certified limit information and analytical methods.

Eight commenters addressed the product chemistry requirements proposed as Subpart R. All but one of these were pesticide producers or groups who expressed concern about the stringency of the requirements. The other commenter was an environmental group which strongly supported the clarified requirements.

A. Reogranization of Part 158

From an organizational standpoint, most commenters noted the redundancy of repeating the product chemistry requirements in two different codified locations (Part 152 and Part 158). The Agency's proposal of Subpart R was primarily one of convenience. In order to present the existing product chemistry requirements and integrate the new requirements into a comprehensive whole, EPA extracted the requirements from Part 158 (which was then ready for promulgation) and proposed Subpart R. Ultimately, EPA intended to consolidate all the requirements in a single location in Title 40.

The Agency agrees with commenters that the requirements should be located in Part 158, and has reorganized Part 158 to do so. Product chemistry requirements are contained in Subpart C, and the remaining data requirements (presented in tables) comprise Subpart D. Other organizational changes have been made to accommodate these revisions, but the only substantive changes involve the revision of the product chemistry requirements.

Because of the reorganization of the material, this preamble unit discusses section-by-section the requirements beging adopted by the Agency, and responds to comments on the proposal. The new organization is used in this preamble. The following table correlates the new Part 158 sections, the old Part 158 sections, and the proposed sections.

TABLE—DERIVATION AND DISTRIBUTION OF PART 158 PRODUCT CHEMISTRY DATA REQUIREMENTS

New section	Old 158 section	Proposed 152 section
158.108	158.115	None.
158.150	158.105	152.340.
158.153	158.108(c)	152.342.
158.155	158.108(b)	152.344.
158.160	None	152.346.
158.162	None	152.348.
158.165	None	152.348.
158.167	None	152.350.
158.170	158.120	152.352, 152.354.
158.175	158.110	152.352, 152.353.
158.180	158.112	152.354.
158.190	158.120	None.
158.202	158.105	None.
158.240-158.740.	158.125-158.170	None.

B. Scope and Applicability

Section 158.150 has largely been repeated from current Part 158. This section outlines the applicability of the product chemistry requirements, and discusses their purpose and use in the Agency's review scheme and regulatory decisions. A new paragraph has been added discussing the nominal concentration.

C. Definitions

Section 158.153 contains definitions pertinent to the product chemistry evaluation. The Agency received specific comments on two definitions, and has revised others for clarity and simplicity.

The current (and proposed) definition of "technical grade of active ingredient" (TGAI) defines the TGAI to include added substances necessary for synthesis or purification. Thus the intended components of the TGAI are the pesticide chemical itself, any starting materials remaining from the reaction process, or added during that process, and any substances remaining from the final purification steps.

Two commenters suggested that the definition of "technical grade of active ingredient" be revised to permit the inclusion of a preservative in the TGAI. The Agency has not adopted this suggestion. The TGAI is the test substance normally required for a number of Part 158 studies in toxicology, ecological effects, and environmental fate, and the Agency believes its integrity should be preserved as carefully as possible for test purposes.

From a strictly scientific standpoint, testing to determine the characteristics of an active ingredient should be conducted with a version of the ingredient that is as pure as possible, such as the pure active ingredient. Contaminants or impurities in the test substance are scientifically undesirable for such testing, since they complicate the test procedure and may introduce uncertainties into the evaluation of results. It would be impractical and costly, however, to require that applicants take extraordinary steps beyond normal quality assurance measures to purify the TGAI simply for the purpose of most testing. The product of such purification would not be representative of the actual TGAI that will be incorporated into other products. Therefore, the Agency ordinarily allows use of the TGAI itself, at the point at which it emerges from the reaction and purification processes, as the most practical substitute, recognizing its limitations.

Since unavoidable substances are undesirable in the TGAI, the intentional addition of substances (such as a preservative used for stabilization during shipment to formulators), is less

tolerable. Therefore, the final definition of TGAI has not been modified.

Another commenter requested clarification of the definition of "impurity associated with an active ingredient." This comment, however, was directed to the question of who was required to submit information on the impurities associated with the active ingredient. The commenter's concern was that formulators should not be required to submit such information, since it would be available from producers of the TGAI. The final rule specifies that formulators would not be required to provide information on the impurities in the TGAI, but it does not affect the definition. Consequently, the definition has not been revised.

With respect to who must submit information on the impurities associated with an active ingredient, the burden falls primarily on producers using integrated systems, that is, persons who produce the TGAI or end use product in a continuous process. A formulator who purchases a registered product is not expected to provide information on impurities in that product. Both §§ 158.155 (product composition) and 158.167 (discussion of formation of impurities) clearly state that the producer of a product by a non-integrated system is not required to provide information on the identity or amount of impurities contained in the TGAI.

The Agency has revised several definitions in other ways, in response to comments that they were unclear. Further, the Agency has also revised some definitions because of modifications in the data requirements (see later sections of this preamble unit). The following changes have been made in § 158.153:

1. Definitions for "end use product" and "manufacturing use product" has been included. These were inadvertently omitted from the proposed rule.

2. A definition of "formulation" has been added for the purpose of distinguishing the operation of blending and dilution from that of chemical reaction ordinarily involved in an integrated system. Commenters uniformly noted that data requirements pertaining to the chemical reaction process were not applicable to the formulation process.

3. The definition of "beginning material" has been clarified. First, the term has been changed to "starting material." Second, the definition has been modified to clarify that the term applies only to materials used in a reaction process resulting in a TGAI or its equivalent. Only a producer who uses an integrated system is required to provide information on starting materials.

4. The definitions of "active ingredient," "inert ingredient," and "impurity" have been modified to include groups of structurally similar substances as well as single substances. This permits the Agency to specify that certain closely related impurities, such as nitrosamines, be considered together for testing or regulatory purposes.

5. The term "inert ingredient" has been changed to delete the words "intentionally added." The term is now defined to include only substances intentionally added to the pesticide product. Any other constituent that is neither an active ingredient nor an intentionally added ingredient, such as a degradation product, reaction byproduct, or contaminant, is considered to be an "impurity" within the definition of § 158.153(c) for the purposes of product chemistry evaluation.

The Agency is aware that, under FIFRA sec. 2(m), impurities are encompassed within the definition of inert ingredient. In the final rule, EPA is modifying the definition of inert ingredient to exclude impurities. EPA believes that, for clarity and usefulness of the data requirements contained in Subpart C, the term "inert ingredient" should be defined to include only those inert ingredients that are intentionally added, and the term "impurity" should be defined to include all other substances that are not "ingredients" of the product. This does not modify the legal standing of impurities under the Act as inert ingredients. However, it significantly improves the ability of the Agency to describe its data requirements for inert ingredients and impurities, and makes the terms consistent with their historical connotation and actual usage.

6. The term "integrated formulation system" is now referred to simply as an "integrated system." The reason for this is that the term "formulation" has been defined in § 158.153(b) to include only blending and dilution operations. An integrated system may or may not include a formulation step.

D. Product Composition Information

The Agency had proposed a set of product composition information that essentially repeated that contained in Part 158. A number of commenters noted that much of the information on active ingredients could be supplied simply by citing the registration number of the source product (on the assumption that the source product is EPA-registered and that EPA will already possess the information). Another commenter noted that certain identifying information required on inert ingredients is not available to a formulator because it is proprietary or trade secret. In general, the comments suggested a need for clarification of the requirements.

EPA agrees with these comments. In order to clarify the product composition information requirements, § 158.155 has been reorganized to specify separately the information required on active ingredients, inert ingredients, toxic impurities, other impurities associated with the active ingredient, and ingredients that cannot be characterized as discrete substances. Requirements concerning impurities associated with inert ingredients have been reserved in this final rule.

Section § 158.155(a) distinguishes between an active ingredient which is derived from an EPA-registered source and one derived from an unregistered source. A formulator who uses a registered product as the source of an active ingredient in his product is required to provide simply the pertinent information on the source product, and to provide the nominal concentration and certified limits of the active ingredient in his product. If the source of active ingredient is not EPA-registered, complete chemical identification of the active ingredient is required, including chemical names, formulae, and molecular weight. For all active ingredients, the nominal concentration and upper and lower certified limits are required.

With respect to inert ingredients, § 158.155(b) specifies that the chemical identity of inert ingredients is to be provided by the applicant only to the extent that it is known to him. A formulator who uses a basic chemical in the formulation of his product, or who simply dilutes the manufacturing use product with a solvent or water, is expected to provide complete information on identity. If he uses a proprietary mixture of inert ingredient, such as a combination of emulsifiers of unknown composition, he is responsible for ensuring that the producer of that proprietary ingredient furnishes the Agency with identity information directly. Producers of proprietary inert ingredients may wish to establish with the Agency master files of the composition of their products for reference by applicants. The Agency may require an applicant or registrant to know or ascertain the identity of individual inert ingredients of toxicological concern in their products, regardless of their origin in proprietary mixtures, either for data generation or labeling purposes.

Moreover, a registrant will be held responsible for the certified limits of inert ingredients included in his product only as part of a proprietary mixture (refer to Unit XX.H. for further discussion of certified limits).

Section 158.155(c) now describes the required identification information for impurities of toxicological significance associated with the active ingredient. Section 158.155(d) describes the information required for other impurities associated with the active ingredient and present at levels greater than 0.1 percent of the TGAI. These requirements for identification and certification of impurities apply only to technical grade active ingredients and products produced by an integrated system. Finally, § 158.155(f) addresses ingredients that cannot be characterized chemically because of their complexity, or because they are substances for which extensive chemical analysis is not practicable.

Section 158.155 specifies that a person who formulates a pesticide product is required to provide only information on the active and inert ingredients. A producer of a product by an integrated system (whether it is a manufacuring use product or end use product) also is required to provide information on the impurities that may be present in the product.

E. Materials Used in Producing the Product

The Agency proposed that applicants provide certain identifying information on the materials used in producing the final product. Section 158.160 sets out requirements regarding source materials which, although they are very similar to those in § 158.155, are not the same. Section 158.112 focuses strictly on the identity and quantity of the separate chemical constituents of the final product—the active ingredient, inert ingredients, and impurities—that is offered for sale and distribution. Section 158.160, by contrast, addresses information on the actual materials used to make the product, which may be distinctly different. These are often referred to as the "recipe" ingredients of the product.

Under § 158.160, the applicant is intended to provide information on the "recipe" ingredients of his production or formulation process, including their sources and properties. The "recipe" ingredients for a technical grade active ingredient or integrated system product are the starting materials for the various chemical reactions by which a product containing the active ingredient is ultimately produced. The "recipe" ingredients for a non-integrated system product, however, are those ingredients (whose identity and composition may be proprietary) which are blended to make the final product. Section 158.160 does not address impurities, since impurities are never intentionally used in the process, but are a result of the process.

Several commenters pointed out that, with respect to inert ingredients, the Agency would receive large amounts of duplicative information, since the same inert ingredients are used in a number of products. The Agency recognizes that, if producers use the same inert ingredients, EPA will receive some information that is duplicative. On the other hand, information can be incorporated by reference if it has been previously submitted by the applicant. EPA encourages producers of inert ingredients to establish master files which will eliminate much repetitious information.

The majority of information required by §§ 158.155 and 158.160 is supplied by completing the Statement of Formula. (current EPA Form 8570–4). EPA is in the process of revising its Statement of Formula form to conform to the requirements of this subpart and other needs of the Agency. The information required by §§ 158.162 through 158.180 is not amenable to standardized forms, and must be submitted in narrative form.

A commenter noted an inconsistency in requiring such extensive information on an inert ingredient, when elsewhere in the rule (proposed § 152.42), the Agency proposed to permit a change in the source of the inert ingredient without even notifying the Agency. The Agency has now revised § 152.42 such that changing the source of an inert ingredient is an action requiring notification to the Agency (but not approval) only if the Agency originally required such information. Changing the identity of an inert ingredient (including variations in proprietary mixtures of inert ingredients) requires Agency approval.

Another commenter suggested that the Agency undertake to identify inert ingredients which are sufficiently well known that no information need be provided. The commenter sugested that ingredients listed in proposed § 158.1001 (recodified as § 153.139) be considered for this purpose. That section defined substances deemed to be inert when used in antimicrobial products. Although the suggestion of the commenter is worthwhile, the substances on the list in § 153.139 are not chemicals that could necessarily form the basis of such a listing. The commenter assumed that identification as an inert ingredient in § 153.139 establishes a presumption of knowledge about, and automatic "clearance" of, such ingredients; this is not so. The substances listed in § 153.139 should not be assumed to be "cleared" in any regulatory sense of the word; they have not been reviewed by the Agency for that purpose. Listing in § 153.139 merely identifies them as pesticidally inert for purposes of labeling.

However, the Agency has developed and published in the **Federal Register** of April 22, 1987 (52 FR 13305) an inert ingredient strategy, under which the Agency categorized pesticide inert ingredients into four "lists" based upon their potential toxicological concern. List 4, which is available from the Agency, contained inert ingredients deemed to be relatively innocuous. The Agency is currently taking no regulatory action with respect to ingredients on List 4.

F. Production or Formulation Process

The Agency proposed to required that applicants provide information on their production and formulating processes, including the substances and amounts used, the equipment and conditions of production, and quality control measures. These requirements were based on the information stated in the Pesticide Assessment Guidelines, Subdivision D.

A number of industry commenters and trade groups objected to the proposed requirements as being burdensome, needlessly detailed, and of little use to the Agency. Comments from formulators expressed concern that the requirements were appropriate only for integrated processes involving chemical reactions, not for formulating processes which are essentially blending and dilution processes. They suggested that a different process be put in place for end use products (formulated from registered products) to avoid repetitious paperwork.

Producers of manufacturing use products and TGAIs also objected. Their objections stemmed less from the burden of providing the information than from the possibility that the information will not be available at the time of application. They stated that the manufacturing process for a pesticide often is not finalized until after registration. Even large producers often contract out the initial manufacture of a new manufacturing use product, until marketing and distribution factors and level of demand justify capital expenditure for a full-scale production facility. Thus, they assert, the information the Agency is seeking may not be available at the time of

application. The Agency is willing to accept initial manufacturing process information from pilot-scale production, with full-scale process information submitted later. However, the Agency will not accept laboratory bench-scale process information.

In the final rule, the Agency has defined separately the requirements applicable to the production process (§ 158.162) and the formulation process (§ 158.165). EPA agrees that some of the requirements set out in the proposed rule pertain only to production processes involving chemical reactions and not to formulation operations that are essentially blending of ingredients not expected to react. Thus a description of the "production" process needs to be more detailed and to include more information than a description of the "formulation" process.

All applicants (whether they use an integrated system, a formulation process, or both) must describe the materials used to produce the product, the type of process being used, the equipment and physical parameters of the process, and the quality control measures (both operational and analytical) for the final product.

In addition, for an integrated system where a chemical reaction is intended to occur to produce a TGAI, the reaction process must be described fully with flow charts and chemical equations, and a description of purification procedures. If the reaction process occurs in several distinct steps, with isolated chemical substances produced at each step, § 158.162 requires that each step be treated as a separate process and documented accordingly.

G. Discussion of Formation of Impurities

The Agency proposed that each applicant provide a discussion of the potential for formation of impurities in his product, based on information available to him about the materials he uses and manufacturing process. The Agency stated that it would use the discussion to determine what impurities the applicant expects to be in his product, to evaluate the possibility of other impurities and to evaluate the reliability of other data presented by the applicant. Under the Agency's proposal, an applicant would be expected to discuss the impurities that, based on chemical theory, might be formed at levels of 0.1 percent or greater in the TGAI.

Commenters from industry uniformly objected to the requirement for a discussion. Objections focused primarily on the theoretical nature of the discussion; several commenters suggested that it be limited to "expected" reactions rather than "possible" reactions, or that it deal only with known byproducts and impurities. Producers of TGAIs and manufacturing use products asserted that, because of the complexity of the chemical reactions, it would be time-consuming to construct the discussion across the entire production process and that it would not serve the purposes intended.

The Agency disagrees with the argument that the information will not be useful. Some of the risks posed by an pesticide result from the presence of impurities or contaminants rather than (or in addition to) the active ingredients or inert ingredients. In some cases, impurities pose the more significant risks, particularly when chronic health effects are considered. For example, dibenzo-p-dioxins and dibenzofurans, which are common impurities in the manufacture of some pesticides, are known to be potent carcinogens.

The Agency cannot conduct a comprehensive risk assessment of a pesticide without considering the possibility that toxic impurities may be formed. One common outcome of current Agency reviews is the requirement that registrants analyze their products to determine the presence and levels of toxic impurities. EPA believes that an early discussion of the possibility of impurities might preclude a requirement for more inclusive analysis of products. The discussion may alleviate Agency concerns or demonstrate that, although theoretically possible, impurities are not likely to be produced in an applicant's particular production process. Thus EPA has not modified the final rule.

The final rule provides that a producer using an integrated system must address impurities that are found actually found by analysis in his product, and also those that theoretically might be present based on established chemical theory. The magnitude and depth of the theoretical discussion are not prescribed in the rule, merely the topics that should be addressed. In all cases, the discussion is limited to the applicant's knowledge; he is not expected to seek out information he could not reasonably know or have access to. A registrant is not expected to provide a sophisticated or exhaustive treatment of theoretical impurities that are not toxicologically significant. However, if an impurity has actually been found by analysis, or if an impurity of toxicological concern is postulated to be formed, the Agency will expect a significantly more comprehensive discussion.

Comments from formulators also expressed concern at the Agency's proposal. The commenters questioned the need for any discussion of impurity formation for formulated products. They stated that the formulation process is intended to produce a stable product, and asserted that chemical reactions among the components are virtually unknown. Moreover, they noted that information on the identity of impurities in they active and inert ingredients they purchase is rarely, if ever, available to them, so that the would be unable to provide the information in any case.

As stated earlier, § 158.175 of the final rule is clear on this point: the discussion is to be based on information available to the formulator. Thus, the formulator is not required to seek information on the identity or level of impurities in his source products. If provided with such information by his supplier, a formulator should consider it in his discussion. Since information on the impurities in a registered source TGAI will be available to the Agency from the registrant of that source product, duplication of the information serves no purpose.

Other elements of a discussion for a formulated product, however, are concerned with reactions that could occur in the formulation process—reactions between active and inert ingredients, reactions between the product and its packaging, and migration of contaminants into the pesticide. These are topics which only the formulator can address. If the applicant does not believe it likely that any possible sources of impurity or contamination will materialize in his formulation process, his discussion need only explain why this is so. EPA agrees with commenters that the formulation process is less likely to involve chemical reactions that result in impurities; nonetheless, the possibility cannot be dismissed or ignored. In any case, EPA does not believe that the required discussion will be a protracted, time-consuming or burdensome process for formulators, since the majority of impurities in formulated products are present as a result of carryover from the active ingredient source, of which the formulator's knowledge may be limited.

One commenter misinterpreted the discussion requirement for non-intergrated system products as requiring analysis of each product at the 0.1 percent level and stated that formulators do not have laboratory capability at that level. Formulators not using an integrated system are not required to analyze their products to determine impurities qualitatively or quantitatively.

By contrast, producers who use an integrated system are required by § 158.170 to provide the Agency with a

preliminary analysis of the TGAI to the 0.1 percent level. The producer of a TGAI or integrated system product is required to address each impurity found in that analysis at a level of 0.1 percent or greater of the TGAI. Moreover, if a producer has reason to believe that the TGAI may contain nitrosamine, dibenzodioxin or dibenzofuran impurities, he is expected to analyze below the 0.1 percent level, in accordance with the Agency's policy statement on nitrosamines (42 FR 51640, September 29, 1977) and its final rule (under the Toxic Substances Control Act) on dibenzodioxins and dibenzofurans (52 FR 21412, June 5, 1987).

H. Certification of Limits

The Agency proposed essentially the same certification of limits requirements as are contained in current § 158.110. In brief, the Agency proposed to require the certification of:

1. Upper and lower limits for active ingredients.
2. Upper limits for inert ingredients (the omission of lower limits was unintentional and has been corrected in the final rule).
3. Upper limits for impurities at any level that are determined to be toxicologically significant.
4. Upper limits for other impurities associated with the active ingredient at levels of 0.1 percent or greater. Impurities were to be certified if they were postulated to be present or if they were found by analysis of the product.

Comments on the certification requirements were received from five industry sources and one environmental group. Most commenters noted that the requirements were redundant to those in Part 158. EPA acknowledges this, but chose to reproposé the requirements for completeness and organization purposes. In the final rule, all product chemistry requirements have been consolidated into Part 158, eliminating the redundancy.

Industry commenters were unanimous in objecting to the reproposed certification requirements, even though they were unchanged from those in current Part 158. A number of commenters repeated comments made at the time of initial proposal of these requirements (in 1982). In particular, several commenters addressed the requirement for certified limits for inert ingredients, and the possibility that applicants would have to develop costly analytical methods and capability to support those limits. The Agency has not changed its position on the requirement for upper and lower certified limits for active and inert ingredients, and does not believe it necessary to reiterate its responses to those comments. Readers are referred to the preamble to the final Part 158 rule, published in the **Federal Register** of October 24, 1984 (49 FR 42862), for a discussion of comments concerning certified limits for inert ingredients, and the level of analysis required in support of those limits.

The Agency has adopted the suggestion of a commenter that standardized certified limits for active and inert ingredients be established, taking into account acceptable deviations in analytical techniques and concentration factors. An applicant would have the choice of using the Agency's standard certified limits or of proposing his own certified limits, as was required by the proposal. The commenter suggested that the guidelines established by the American Association of Pesticide Control Officials be considered as the basis for the standard limits. The Agency considered those guidelines, but has adopted different limits. Section 158.175 now provides that, for active and inert ingredients, the applicant may propose certified limits or may use the standard certified limits set out in § 158.175(b)(2).

Standard certified limits are not appropriate for impurities for which a certified upper limit is required; the applicant must propose such limits. Since impurities are not intentionally added to a product, their levels cannot be predicted to fall within standardized limits. Moreover, impurities are intended to be minimized, and the Agency does not believe it should sanction their presence at predetermined levels.

An applicant is not required to use the standard limits. They are provided as an alternative to applicant-proposed certified limits, as a convenience to applicants. If an applicant chooses not to use the standard certified limits, he may propose wider (or narrower) limits. If wider, the applicant is strongly urged to include in his application a discussion of those limits and why he has selected them. A thorough discussion of the basis for different limits may avoid the Agency's questioning the applicant's proposed limits.

With respect to impurities, current § 158.190 and the proposed rule require that upper certified limits be established for impurities that are potentially present in the TGAI (as indicated in the discussion required by § 158.167). As a result of the comments received, the Agency has reexamined its requirements for certified limits for impurities, and has made significant changes in the final rule.

First, the Agency has eliminated the requirement for an upper certified limit for impurities that are not toxicologically significant. The requirement for a statement of the nominal concentration for such impurities when associated with the active ingredient has been retained in § 158.155(d). Second, the Agency has eliminated the requirement for certified limits on theoretical impurities in the formulation. An upper certified limit for toxic impurities will routinely be required only if shown by analysis of the product to be present.

The applicant is required to sign a certification statement agreeing that he will maintain his product's composition within the certified limits approved by the Agency. The certified limits approved by the Agency will be used for enforcement purposes. Moreover, although the Agency has established standard certified limits which should be acceptable for most products, the Agency reserves the right to reject those limits for an individual product, and to require the applicant to propose new limits.

A formulator should be aware that in formulating a product and certifying its active and inert ingredient ranges, he may have to adjust his formulation process to account for the permitted variability of the active ingredient in the source products he purchases. For example, a formulator may produce a product nominally containing 45 percent active ingredient by diluting a 90 percent nominal concentration technical product on a 1:1 basis. The standard certified limits would permit the technical grade active ingredient to vary from 87.3 to 92.7 percent. The forumulated product may therefore contain only 43.7 percent active ingredient if the formulator is using source product at the lower certified limit, assuming optimal formulation conditions and manufacturing practices. If the formulator assumes the standard certified limit of 3 percent, his product (nominally at 45 percent) will just barely meet the lower certified limit, and is at risk of being in violation of FIFRA if his formulation process is less than optimal.

EPA urges formulators to be aware of the percentage of active ingredient actually contained in the source products they purchase. Each registrant will be held accountable for the certified limits of his product.

The responsibility of the registrant to adhere to the certified limits extends to individual inert ingredients. The fact that the applicant uses a proprietary mixture of substances whose composition is not known to him does not remove his responsibility for maintaining the composition of each of

those inert ingredients within its certified limits.

Although EPA encourages the free and open exchange of information between producers of inert ingredients and their customers, it recognizes that producers' concerns about trade secrecy may prevent their customers from obtaining this information. Therefore, the Agency normally will not require that an applicant know the composition of a proprietary mixture of inert ingredients in order to obtain registration; he is, however, required to ensure that the Agency is informed of the mixture's composition by its producer. If a component of the proprietary mixture is an inert ingredient of toxicological concern, the agency may require that the applicant obtain information about purchased inert ingredients, so that the product may be labeled properly. Otherwise, the Agency may have to deny or cancel registration of the product.

In addition, the Agency holds the applicant responsible for the certified limits of each inert ingredient in his product, including those that are present as part of a proprietary mixture. An applicant who does not know the composition of an inert ingredient, and cannot persuade his supplier or producer to disclose it, may certify to an upper and lower limit of the ingredient as introduced into his product as a whole. In this case, the Agency will apply the certified limits of the ingredient as a whole to the individual substances comprising the ingredient, as disclosed by the supplier directly to the Agency. The applicant is responsible for maintaining his product within those Agency-derived limits.

A formulator who is uncomfortable with the extent of responsibility implicit in this policy should take steps to decrease the uncertainties, either by gaining knowledge of the composition of inert mixtures or by assuring that the composition of the mixture he uses will not change over time. EPA believes that a contractual arrangement between formulator and supplier is the best way to ensure that the formulator can rely on the composition of the material received, short of having direct knowledge of its composition.

Two commenters questioned the lack of criteria for determining "toxicological significance" of impurities. One suggested that the Agency issue a list of toxicologically significant impurities. The consequence of identification as an impurity of toxicological significance is that, under § 158.175 of the final rule, an applicant must supply an upper certified limit for each such impurity in a TGAI or integrated system product, and, under § 158.180, an analytical method suitable for enforcement of the certified limit. Impurities not identified as being of toxicological significance must be identified at levels greater than 0.1 percent of the TGAI, and a nominal concentration must be provided, but a certified upper limit is not required.

In response to the comment, the Agency has identified in two ways impurities for which it believes that certified limits are necessary. The first is a list of specific substances or classes of substances of known toxicological concern. In some cases, the listed substances are currently or have been the subject of regulatory action against pesticide products because of the risks posed by their presence as impurities in the product. In other cases, they are identified because historically they are known to contribute significantly to the toxic profile of an active ingredient. For example, the oxygen analogs of organophosphate pesticides may be more toxic than the parent compound and must be considered in setting tolerances for the toxicologically active components of the pesticide.

The second is a set of criteria for substances which are potentially of toxicological significance; in this latter list, no specific substances are named. While substances meeting the criteria of this second list are not necessarily hazardous, nor have risks associated with their presence been quantified in any specific instance, they are typical of the types of impurities that the Agency has found to be of significance in the past.

Impurities and classes of impurities of toxicological concern

Hexachlorobenzene (HCB)
Ethylene thiourea (ETU)
Dichloro diphenyl trichloroethane (DDT) and other chlorinated diphenyl ethanes and ethylenes, such as analogs and isomers of DDT, DDD, DDE and Cl-DDT ("extrachloro DDT")
Sulfotepp
Halogenated dibenzodioxins
Halogenated dibenzofurans
Nitrosamines
Biphenyl ethers
Anilines and substituted anilines
Hydrazines
Oxygen analogs of organophosphates
Sulfoxides and sulfones of organophosphates and carbamates

Impurities having characteristics of potential toxicological significance

Any impurity that is structurally related to the parent compound and is not known to be toxicologically insignificant
Any impurity that is also an active ingredient
Any impurity that is identified in standard toxicology data bases such as Toxline as being teratogenic, oncogenic or neurotoxic

This list is not exhaustive, and EPA does not intend it to be. The list may be expanded as new information on impurities becomes available. For that reason, the list is not included in the final rule. EPA will update the list periodically, and make it available to registrants and the public, or may publish it in the **Federal Register**. EPA has reserved the right to require certified limits for other impurities on a case-by-case basis. Registrants should contact the Agency if there is a question about the status of any individual impurity not listed.

It should be emphasized that the certification of limits for impurities of toxicological significance as part of the registration or reregistration process does not imply that the Agency seeks to take regulatory action based upon the presence of the impurity or its level in a product. The certified limits will permit EPA to monitor the continued stability of the manufacturing process, and will foster improved processes to further limit the presence of toxic impurities.

On the other hand, if the Agency has not quantified the risks associated with a particular impurity, it will not take regulatory action merely because the applicant certifies the limits of that impurity in his product. In a particular active ingredient and use context, the certified limits will be used to determine the risk posed by the impurity. The Agency would then undertake its risk/benefit balancing process to determine whether that risk is unreasonable.

If any of these substances is found to be present at any level in any TGAI used in or produced by an integrated system product, the applicant must provide an upper certified limit. Certified limits are not required for impurities other than those listed or meeting the criteria; however, a nominal concentration is required for each other impurity found to be present at a level greater than 0.1 percent of the TGAI if the impurity is associated with an active ingredient. Routine requirements for certification of limits for impurities of inert ingredients are not described in this final rule, but under § 158.175(a)(4), the Agency has reserved the right to require that certified limits be set for

other ingredients in a pesticide product, including if warranted, impurities derived from inert ingredients. Such requirements are imposed on a case-by-case basis, in accordance with the inerts policy notice of April 22, 1987 (52 FR 13305).

The need to certify limits of impurities does not require that a producer analyze a product to any greater extent than he is otherwise required to do. A producer of a TGAI or an integrated system product is required by § 158.170 to analyze the TGAI in his product to the 0.1 percent level and provide the results of those analyses to the Agency. Certification of limits of identified impurities found in those analyses, and identification of the nominal concentration of other impurities found at greater than 0.1 percent are analogous reporting requirements derived from the same analyses.

I. Enforcement Analytical Method

No comments were received on the proposed requirements for an enforcement analytical method for active ingredients and other toxicologically significant ingredients. Accordingly, § 158.180 has been adopted as proposed.

J. Conforming Changes

The Agency has made two conforming changes in the final rule. First, a specific certification statement has been provided in § 158.175(d). Since certified limits are legally enforceable, the Agency believes it essential not only that product composition and certified limits be established, but also that the registrant promise that his product will conform to those limits at all times during sale and distribution.

Second, the table in § 158.190(a) has been revised to delete the requirements that are now contained in §§ 158.150 through 158.180 in narrative form. The table now includes only a listing of the physical/chemical characteristic data requirements.

XXI. Consolidated Table of Contents to Part 152

The Agency is today adding a number of new subparts to existing Part 152. Part 152 was originally promulgated on August 4, 1984 (49 FR 30903), containing only Subpart E, pertaining to data compensation procedures. As a convenience to readers, this unit provides a consolidated Table of Contents to Part 152, including the subparts being promulgated today and Subpart E. This Table of Contents will appear in the Code of Federal Regulations when next published.

Subpart A—General Provisions

Sec.
152.1 Scope.
152.3 Definitions.
152.5 Pests.
152.8 Products that are not pesticides because they are not for use against pests.
152.10 Products that are not pesticides because they are not deemed to be used for a pesticidal effect.
152.15 Pesticide products required to be registered.

Subpart B—Exemptions

152.20 Exemptions for pesticides regulated by another Federal agency.
152.25 Exemptions for pesticides of a character not requiring FIFRA regulation.
152.30 Pesticides that may be transferred, sold, or distributed without registration.

Subpart C—Registration Procedures

152.40 Who may apply.
152.42 Application for new registration.
152.43 Alternate formulations.
152.44 Application for amended registration.
152.46 Modifications to registration not requiring amended applications.
152.50 Contents of application.
152.55 Where to send applications and correspondence.

Subpart D—Reregistration Procedures

152.60 General.
152.65 Application for reregistration.
152.70 Agency response to application.

Subpart E—Procedures to Ensure Protection of Data Submitters' Rights

152.80 General.
152.81 Applicability.
152.83 Definitions.
152.84 When materials must be submitted to the Agency.
152.85 Formulators' exemption.
152.86 The cite-all method.
152.90 The selective method.
152.91 Waiver of a data requirement.
152.92 Submission of a new valid study.
152.93 Citation of a previously submitted valid study.
152.94 Citation of a public literature study or study generated at government expense.
152.95 Citation of all studies in the Agency's files pertinent to a specific data requirement.
152.96 Documentation of a data gap.
152.97 Rights and obligations of data submitters.
152.98 Procedures for transfer of exclusive use or compensation rights to another person.
152.99 Petitions to cancel registration.

Subpart F—Agency Review of Applications

152.100 Scope.
152.102 Publication.
152.104 Completeness of applications.
152.105 Incomplete applications.
152.107 Review of data.
152.108 Review of labeling.
152.110 Time for Agency review.
152.111 Choice of standards for review of applications.

Sec.
152.112 Approval of registration under FIFRA sec. 3(c)(5).
152.113 Approval of registration under FIFRA sec. 3(c)(7)—Products that do not contain a new active ingredient.
152.114 Approval of registration under FIFRA sec. 3(c)(7)—Products that contain a new active ingredient.
152.115 Conditions of registration.
152.116 Notice of intent to register to original submitters of exclusive use data.
152.117 Notification to applicant.
152.118 Denial of application.
152.119 Availability of material submitted in support of registration.

Subpart G—Obligations and Rights of Registrants

152.122 Currency of address of record and authorized agent.
152.125 Submission of information pertaining to adverse effects.
152.130 Distribution under approved labeling.
152.132 Supplemental distribution.
152.135 Transfer of registration.
152.138 Voluntary cancellation.

Subpart H—Agency Actions Affecting Registrations

152.140 Classification of pesticide products.
152.142 Submission of information to maintain registration in effect.
152.144 Reregistration.
152.146 Special review of pesticides.
152.148 Cancellation of registration.
152.150 Suspension of registration.
152.152 Child-resistant packaging.
152.159 Policies applicable to registration and registered products.

Subpart I—Classification of Pesticides

152.160 Scope.
152.161 Definitions.
152.164 Classification procedures.
152.166 Labeling of restricted use products.
152.167 Distribution and sale of restricted use products.
152.168 Advertising of restricted use products.
152.170 Criteria for restriction to use by certified applicators.
152.171 Restrictions other than those relating to use by certified applicators.
152.175 Pesticides classified for restricted use.

Subparts J and K—[Reserved]

Subpart L—Intrastate Pesticide Products

152.220 Scope.
152.225 Application for Federal registration.
152.230 Sale and distribution of unregistered intrastate pesticide products.

XXII. Statutory Requirements

In accordance with FIFRA sec. 25(a), a draft of this final rule was submitted to the Secretary of Agriculture (USDA), the Scientific Advisory Panel (SAP), and the House Committee on Agriculture and Senate Committee on Agriculture, Nutrition and Forestry for comment. The SAP waived its formal review of the final rule. The Congressional

Committees did not comment on the rule.

The Department of Agriculture, although not objecting to the use of the term "unclassified" for a pesticide that has not been restricted, believed that such pesticides are essentially classified for general use, and that a determination by the Agency to restrict the pesticide's use should be considered a change in classification for the purposes of FIFRA sec. 6. EPA disagrees. EPA does not regard the initial classification of a product or use that was previously unclassified as a change in classification.

The Agency's decision to restrict a product's use can be made and announced in a number of regulatory and non-regulatory contexts, including Special Review, issuance of a Registration Standard, or case-by-case reviews of individual products. EPA may use the procedures of FIFRA sec. 3(d)(2), under which the registrant and the public are given notice of a change in classification, or EPA may initiate a hearing or cancellation process under FIFRA sec. 6(b).

If a registrant agrees with, or does not contest, the Agency's decision to restrict the product's use(s), the restriction is implemented. However, if a registrant disagrees with the Agency's decision, EPA can compel compliance with its decision only by using the cancellation procedures of FIFRA sec. 6(b), which provides for 60-day notice to and comment by the Department of Agriculture before taking action, and hearing rights for registrants.

XXIII. Regulatory Requirements

A. Executive Order 12291

Under Executive Order (E.O.) 12291, EPA must judge whether a rule is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. The Agency determined at the time of proposal that this final rule revising and reorganizing Part 162 is not a major regulation as defined by E.O. 12291. This final rule was submitted to the Office of Management and Budget for review as required by E.O. 12291.

Regulatory Flexibility Act

This final rule was reviewed against the provisions of section 3(a) of the Regulatory Flexibility Act and it was determined that it does not contain provisions which would have a significant adverse impact on a substantial number of small entities, and I hereby certify that a separate Regulatory Flexibility Analysis is not required.

C. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this final rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq. and has assigned OMB Control Numbers 2070–0057 and 2070–0060.

List of Subjects in 40 CFR Parts 152, 153, 156, 158, and 162

Administrative practice and procedure, Data requirements, Environmental protection, Intergovernmental relations, Labeling, Pesticides and pests, Policy statements, Reporting and recordkeeping requirements.

Dated: April 18, 1988.

Lee M. Thomas,

Administrator.

Therefore, Chapter I of Title 40 is amended as follows:

PART 152—PESTICIDE REGISTRATION AND CLASSIFICATION PROCEDURES

I. In Part 152:

1. The authority citation for Part 152 continues to read as follows:

Authority: 7 U.S.C. 136–136y.

2. By adding new Subpart A to read as follows:

Subpart A—General Provisions

Sec.

Subpart A—General Provisions

§ 152.1 Scope.

Part 152 sets forth procedures, requirements and criteria concerning the registration and reregistration of pesticide products under FIFRA sec. 3, and for associated regulatory activities affecting registration. These latter regulatory activities include data compensation and exclusive use (Subpart E), and the classification of pesticide uses (Subpart I). This Part also describes the requirements applicable to intrastate products that are not federally registered (Subpart L).

§ 152.3 Definitions.

Terms used in this part have the same meaning as in the Act. In addition, the following terms have the meanings set forth in this section.

(a) "Act" or "FIFRA" means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136–136y).

(b) "Active ingredient" means any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant within the meaning of FIFRA sec. 2(a).

(c) "Acute dermal LD_{50}" means a statistically derived estimate of the single dermal dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

(d) "Acute inhalation LC_{50}" means a statistically derived estimate of the concentration of a substance that would cause 50 percent mortality to the test population under specified conditions.

(e) "Acute oral LD_{50}" means a statistically derived estimate of the single oral dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

(f) "Administrator" means the Administrator of the United States Environmental Protection Agency or his delegate.

(g) "Agency" means the United States Environmental Protection Agency (EPA), unless otherwise specified.

(h) "Applicant" means a person who applies for a registration, amended registration, or reregistration, under FIFRA sec. 3.

(i) "Biological control agent" means any living organism applied to or introduced into the environment that is intended to function as a pesticide against another organism declared to be a pest by the Administrator.

(j) "Distribute or sell" and other grammatical variations of the term such as "distributed or sold" and "distribution or sale," means the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any State.

(k) "End use product" means a pesticide product whose labeling

(1) Includes directions for use of the product (as distributed or sold, or after combination by the user with other substances) for controlling pests or

defoliating, desiccating, or regulating the growth of plants, and

(2) Does not state that the product may be used to manufacture or formulate other pesticide products.

(l) "Final printed labeling" means the label or labeling of the product when distributed or sold. Final printed labeling does not include the package of the product, unless the labeling is an integral part of the package.

(m) "Inert ingredient" means any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product.

(n) "Institutional use" means any application of a pesticide in or around any property or facility that functions to provide a service to the general public or to public or private organizations, including but not limited to:

(1) Hospitals and nursing homes.

(2) Schools other than preschools and day care facilities.

(3) Museums and libraries.

(4) Sports facilities.

(5) Office buildings.

(o) "Manufacturing use product" means any pesticide product that is not an end-use product.

(p) "New use," when used with respect to a product containing a particular active ingredient, means:

(1) Any proposed use pattern that would require the establishment of, the increase in, or the exemption from the requirement of, a tolerance or food additive regulation under section 408 or 409 of the Federal Food, Drug and Cosmetic Act;

(2) Any aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern; or

(3) Any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms.

(q) "Operated by the same producer," when used with respect to two establishments, means that each such establishment is either owned by, or leased for operation by and under the control of, the same person. The term does not include establishments owned or operated by different persons, regardless of contractural agreement between such persons.

(r) "Package" or "packaging" means the immediate container or wrapping, including any attached closure(s), in which the pesticide is contained for distribution, sale, consumption, use, or storage. The term does not include any shipping or bulk container used for transporting or delivering the pesticide unless it is the only such package.

(s) "Pesticide" means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, other than any article that:

(1) Is a new animal drug under FFDCA sec. 201(w), or

(2) Is an animal drug that has been determined by regulation of the Secretary of Health and Human Services not to be a new animal drug, or

(3) Is an animal feed under FFDCA sec. 201(x) that bears or contains any substances described by paragraph (s) (1) or (2) of this section.

(t) "Pesticide product" means a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold. The term includes any physical apparatus used to deliver or apply the pesticide if distributed or sold with the pesticide.

(u) "Residential use" means use of a pesticide directly:

(1) On humans or pets,

(2) In, on, or around any structure, vehicle, article, surface, or area associated with the household, including but not limited to areas such as non-agricultural outbuildings, non-commercial greenhouses, pleasure boats and recreational vehicles, or

(3) In any preschool or day care facility.

§ 152.5 Pests

An organism is declared to be a pest under circumstances that make it deleterious to man or the environment, if it is:

(a) Any vertebrate animal other than man;

(b) Any invertebrate animal, including but not limited to, any insect, other arthropod, nematode, or mollusk such as a slug and snail, but excluding any internal parasite of living man or other living animals;

(c) Any plant growing where not wanted, including any moss, alga, liverwort, or other plant of any higher order, and any plant part such as a root; or

(d) Any fungus, bacterium, virus, or other microorganisms, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs (as defined in FFDCA sec. 201(g)(1) and cosmetics (as defined in FFDCA sec. 201(i).

§ 152.8 Products that are not pesticides because they are not for use against pests.

A substance or article is not a pesticide, because it is not intended for use against "pests" as defined in § 152.5, if it is:

(a) A product intended for use only for the control of fungi, bacteria, viruses, or other microorganisms in or on living man or animals, and labeled accordingly.

(b) A product intended for use only for control of internal invertebrate parasites or nematodes in living man or animals, and labeled accordingly.

(c) A product of any of the following types, intended only to aid the growth of desirable plants:

(1) A fertilizer product not containing a pesticide.

(2) A plant nutrient product, consisting of one or more macronutrients or macronutrient trace elements necessary to normal growth of plants and in a form readily usable by plants.

(3) A plant inoculant product consisting of microorganisms applied to the plant or soil for the purpose of enhancing the availiability or uptake of plant nutrients through the root system.

(4) A soil amendment product containing a substance or substances added to the soil for the purpose of improving soil characteristics favorable for plant growth.

(d) A product intended to force bees from hives for the collection of honey crops.

§ 152.10 Products that are not pesticides because they are not deemed to be used for a pesticidal effect.

A product that is not intended to prevent, destroy, repel, or mitigate a pest, or to defoliate, desiccate or regulate the growth of plants, is not considered to be a pesticide. The following types of products or articles are not considered to be pesticides unless a pesticidal claim is made on their labeling or in connection with their sale and distribution:

(a) Deodorizers, bleaches, and cleaning agents;

(b) Products not containing toxicants, intended only to attract pests for survey or detection purposes, and labeled accordingly;

(c) Products that are intended to exclude pests only by providing a physical barrier against pest access, and which contain no toxicants, such as certain pruning paints to trees.

§ 152.15 Pesticide products required to be registered.

No person may distribute or sell any pesticide product that is not registered

under the Act, except as provided in §§ 152.20, 152.25, and 152.30. A pesticide is any substance (or mixture of substances) intended for a pesticidal purpose, i.e., use for the purpose of preventing, destroying, repelling, or mitigating any pest or use as a plant regulator, defoliant, or desiccant. A substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if:

(a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise):

(1) That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or

(2) That the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or

(b) The substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose (by itself or in combination with any other substance), (2) use for manufacture of a pesticide; or

(c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

3. By adding Subpart B to read as follows:

Subpart B—Exemptions

Sec.

Subpart B—Exemptions

§ 152.20 Exemptions for pesticides regulated by another Federal agency.

The pesticides or classes of pesticide listed in this section are exempt from all requirements of FIFRA. The Agency has determined, in accordance with FIFRA sec. 25(b)(1), that they are adequately regulated by another Federal agency.

(a) *Certain biological control agents.* (1) Except as provided by paragraph (a)(3) of this section, all biological control agents are exempt from FIFRA requirements.

(2) If the Agency determines that an individual biological control agent or class of biological control agents is no longer adequately regulated by another Federal agency, and that it should not otherwise be exempted from the requirements of FIFRA, the Agency will revoke this exemption by amending paragraph (a)(3) of this section.

(3) The following biological control agents are not exempt from FIFRA requirements:

(i) Eucaryotic microorganisms, including protozoa, algae and fungi;

(ii) Procaryotic microorganisms, including bacteria; and

(iii) Viruses.

(b) *Certain human drugs.* A pesticide product that is offered solely for human use and also is a new drug within the meaning of FFDCA sec. 201(p) or is an article that has been determined by the Secretary of Health and Human Services not to be a new drug by a regulation establishing conditions of use for the article, is exempt from the requirements of FIFRA. Such products are subject to regulation in accordance with the Federal Food, Drug, and Cosmetic Act and implementing regulations.

§ 152.25 Exemptions for pesticides of a character not requiring FIFRA regulation.

The pesticides or classes of pesticides listed in this section have been determined to be of a character not requiring regulation under FIFRA, and are therefore exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified.

(a) *Treated articles or substances.* An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.

(b) *Pheromones and pheromone traps.* Pheromones and identical or substantially similar compounds labeled for use only in pheromone traps (or labeled for use in a manner which the Administrator determines poses no greater risk of adverse effects on the environment than use in pheromone traps), and pheromone traps in which those compounds are the sole active ingredient(s).

(1) For the purposes of this paragraph, a pheromone is a compound produced by an arthropod which, alone or in combination with other such compounds, modifies the behavior of other individuals of the same species.

(2) For the purposes of this paragraph, a synthetically produced compound is identical to a pheromone only when their molecular structures are identical, or when the only differences between the molecular structures are between the stereochemical isomer ratios of the two compounds, except that a synthetic compound found to have toxicological properties significantly different from a pheromone is not identical.

(3) When a compound possesses many characteristics of a pheromone but does not meet the criteria in paragraph (a)(2) of this section, it may, after review by the Agency, be deemed a substantially similar compound.

(4) For the purposes of this paragraph, a pheromone trap is a device containing a pheromone or an identical or substantially similar compound used for the sole purpose of attracting, and trapping or killing, target arthropods. Pheromone traps are intended to achieve pest control by removal of target organisms from their natural environment and do not result in increased levels of pheromones or identical or substantially similar compounds over a significant fraction of the treated area.

(c) *Preservatives for biological specimens.* (1) Embalming fluids.

(2) Products used to preserve animal or animal organ specimens, in mortuaries, laboratories, hospitals, museums and institutions of learning.

(3) Products used to preserve the integrity of milk, urine, blood, or other body fluids for laboratory analysis.

(d) *Vitamin hormone products.* Vitamin hormone horticultural products consisting of mixtures of plant hormones, plant nutrients, inoculants, or soil amendments, which meet the following criteria:

(1) The product, in the undiluted package concentration at which it is distributed or sold, meets the criteria of § 156.10(h)(1) of this chapter for Toxicity Category III or IV; and

(2) The product is not intended for use on food crop sites, and is labeled accordingly.

(e) *Foods.* Products consisting of foods and containing no active ingredients, which are used to attract pests.

§ 152.30 Pesticides that may be transferred, sold, or distributed without registration.

An unregistered pesticide, or a pesticide whose registration has been cancelled or suspended, may be distributed or sold, or otherwise transferred, to the extent described by this section.

(a) *A pesticide transferred between registered establishments operated by the same producer.* An unregistered pesticide may be transferred between registered establishments operated by the same producer. The pesticide as transferred must be labeled in accordance with Part 156 of this chapter.

(b) *A pesticide transferred between registered establishments not operated*

by the same producer. An unregistered pesticide may be transferred between registered establishments not operated by the same producer if:

(1) The transfer is solely for the purpose of further formulation, packaging, or labeling into a product that is registered;

(2) Each active ingredient in the pesticide, at the time of transfer, is present as a result of incorporation into the pesticide of either:

(i) A registered product; or

(ii) A pesticide that is produced by the registrant of the final product; and

(3) The product as transferred is labeled in accordance with Part 156 of this chapter.

(c) *A pesticide distributed or sold under an experimental use permit.* (1) An unregistered pesticide may be distributed or sold in accordance with the terms of an experimental use permit issued under FIFRA sec. 5, if the product is labeled in accordance with § 172.6 of this chapter.

(2) An unregistered pesticide may be distributed or sold in accordance with the provisions of § 172.3 of this chapter, pertaining to use of a pesticide for which an experimental use permit is not required, provided the product is labeled in accordance with Part 156 of this chapter.

(d) *A pesticide transferred solely for export.* An unregistered pesticide may be transferred within the United States solely for export if it meets the following conditions:

(1) The product is prepared and packaged according to the specifications of the foreign purchaser; and

(2) The product is labeled in accordance with Part 156 of this chapter.

(e) *A pesticide distributed or sold under an emergency exemption.* An unregistered pesticide may be distrubuted or sold in accordance with the terms of an emergency exemption under FIFRA sec. 18, if the product is labeled in accordance with Part 156 of this chapter.

(f) *A pesticide transferred for purposes of disposal.* An unregistered, suspended, or cancelled pesticide may be transferred solely for disposal in accordance with FIFRA sec. 19 or an applicable Administrator's order. The product must be labeled in accordance with Part 156 of this chapter.

(g) *Existing stocks of a formerly registered product.* A cancelled or suspended pesticide may be distributed or sold to the extent and in the manner specified in an order issued by the Administrator concerning existing stocks of the pecticide.

4. By adding Subpart C to read as follows:

Subpart C—Registration Procedures

Subpart C—Registration Procedures

§ 154.40 Who may apply.

Any person may apply for new registration of a pesticide product. Any registrant may apply for amendment of the registration of his product.

§ 152.42 Application for new registration.

Any person seeking to obtain a registration for a new pesticide product must submit an application for registration, containing the information specified in § 152.50. An application for new registration must be approved by the Agency before the product may legally be distributed or sold, except as provided by § 152.30.

§ 152.43 Alternate formulations.

(a) A product proposed for registration must have a single, defined composition, except that EPA may approve a basic formulation and one or more alternate formulations for a single product.

(b) An alternate formulation must meet the criteria listed in paragraph (b)(1) through (4) of this section. The Agency may require the submission of data to determined whether the criteria have been met.

(1) The alternate formulation must have the same certified limits for each active ingredient as the basic formulation.

(2) If the alternate formulation contains an inert ingredient or impurity of toxicological signficance, the formulation must have the same upper certified limit for that substance as the basic formulation;

(3) The label text of the alternate formulation product must be identical to that of the basic formulation.

(4) The analytical method required under § 158.180 must be suitable for use on both the basic formulation and the alternate formulation.

(c) Notwithstanding the criteria in this section, the Agency may determine that an alternate formulation must be separately registered. If EPA makes this determination, the Agency will notify the applicant of its determination and its reasons. Thereafter the application for an alternate formulation will be treated as an application for new registration, and the alternate formulation will be assigned a new registration number.

§ 152.44 Application for amended registration.

(a) Except as provided by § 152.46, any modification in the composition, labeling, or packaging of a registered product must be submitted with an application for amended registration. The applicant must submit the information required by § 152.50, as applicable to the change requested. If an application for amended registration is required, the application must be approved by the Agency before the product, as modified, may legally be distributed or sold.

(b) In its discretion, the Agency may:

(1) Waive the requirement for submission of an application for amended registration;

(2) Require that the applicant certify to the Agency that he has complied with an Agency directive rather than submit an application for amended registration; or

(3) Permit an applicant to consolidate an amendment affecting a number of products into a single application.

§ 152.46 Modifications to registration not requiring amended applications.

(a) *Changes needing Agency notification, but not approval.* A registrant may modify his registration as provided in paragraph (a)(1) through (7) of this section if he notifies the Agency before the modified product is distributed or sold. The registrant need not obtain Agency approval of any such amendment, but may distribute or sell the product, as changed, as soon as he has notified the Agency of the change. Based upon a notification, the Agency may require that the registrant submit an application for amended registration. If it does so, the Agency will notify the registrant and state its reasons for requiring an application for amended registration in lieu of a notification. Thereafter, if the registrant fails to submit an application without good cause, the Agency may determine that the product is no longer in compliance with the requirements of the Act and initiate cancellation proceedings under FIFRA sec. 6. Notification under this paragraph is considered a report filed under the Act for the purposes of FIFRA sec. 12(a)(2)(M).

(1) A revision of the label language consistent with Part 156 of this chapter and involving no change in the statement of ingredients, precautionary statements of directions for use.

(2) Addition or substitution of brand names.

(3) A change in the source of any starting material used in the manufacturing process for a product produced by an integrated process, unless the applicant has reason to believe that such source change would result in:

(i) An increase in the level of any impurity of toxicological significance (but not to exceed the upper certified limit); or

(ii) The formulation of any new impurity at a level greater than 0.1% by weight of the technical grade active ingredient.

(4) A change in the source of an active ingredient if, after the change the registrant continues to be eligible for a formulator's or generic data exemption.

(5) If the Agency has previously required that the source(s) of an inert ingredient be specified, a change in the source(s) of that ingredient.

(6) A change in the nominal concentration, but not the identity or certified limits, of any inert ingredient whose chemical identity or composition is known to the registrant. Substitution of a proprietary or trade name inert ingredient whose identity or composition is unknown to the registrant does not qualify.

(7) Change in the formulation process of a product produced by a non-integrated system (as defined in § 158.153), provided that the certified limits of the active and inert ingredients would not change as a result.

(b) *Changes not needing Agency approval or notification.* The following changes may be made in a product's composition, labeling or packaging without notification to or approval by the Ageny:

(1) Correction of typographical or printing errors on the labeling.

(2) Change in the package size and label net contents, provided no change in use directions or requirement for child-resistant packaging would ensue.

(3) Revision of non-mandatory label statements, consistent with Part 156 of this chapter, including additions or changes required by other Federal statutes or regulations.

(4) Change on the label of the name or address of the registrant, except for a change resulting from transfer of ownership, which requires Agency approval in accordance with § 152.135. Section 152.122 requires, however, that a registrant keep his name and address current with the Agency.

(5) Revision of the label format, provided that the format is consistent with Agency labeling requirements and the label text is not modified.

(Approved by the Office of Management and Budget under Control Number 2070–0060.)

§ 152.50 Contents of application.

Each application for registration or amended registration must include the following information, as applicable:

(a) *Application form.* An application form must be completed and submitted to the Agency. Application forms are provided by the Agency, with instructions as to the number of copies required and proper completion.

(b) *Identity of the applicant*—(1) *Name.* The applicant must identify himself. An applicant not residing in the United States must also designate an agent in accordance with paragraph (b)(3) of this section to act on behalf of the applicant on all registration matters.

(2) *Address of record.* The applicant must provide an address in the United States for correspondence purposes. The U.S. address provided will be considered the applicant's address of record, and EPA will send all correspondence concerning the application and any subsequent registration to that address. It is the responsibility of the applicant and any registrant under § 152.122 to ensure that the Agency has a current and accurate address.

(3) *Authorized agent.* An applicant may designate a person residing in the United States to act as his agent. If an applicant wishes to designate an agent, he must send the Agency a letter stating the name and United States address of his agent. The applicant must notify the Agency if he changes his designated agent. This relationship may be terminated at any time by the applicant by notifying the Agency in writing.

(4) *Company number.* If an applicant has been assigned a company number by the Agency, the application must reference that number.

(c) *Summary of the application.* Each application must include a list of the data submitted with the application, together with a brief description of the results of the studies. The list of data submitted may be the same as the list required by § 158.32 of this chapter. The summary must state that is is releasable to the public after registration in accordance with § 152.119.

(d) *Identity of the product.* The product for which application is being submitted must be identified. The following information is required:

(1) The product name;

(2) The trade name(s) (if different); and

(3) The EPA Registration Number, if currently registered.

(e) *Draft labeling.* Each application for new registration must be accompanied by five legible copies of draft labeling (typescript or mock-up). Each application for amended registration that proposes to make any changes in the product labeling must be accompanied by five legible copies of draft labeling incorporating the proposed labeling changes. If the proposed labeling change affects only a portion of the labeling, such as the use directions, the applicant may submit five copies of that portion of the label which is the subject of the amendment. Upon request, an applicant for amended registration must submit a complete label to consolidate amendments.

(f) *Registration data requirements.* (1) An applicant must submit materials to demonstrate that he has complied with the FIFRA sec. 3(c)(1)(D) and Subpart E of this part with respect to satisfaction of data requirements, to enable the Agency to make the determination required by FIFRA sec. 3(c)(5)(B). Required items are described in Subpart E of this part.

(2) An applicant must furnish any data specified in Part 158 of this chapter which are required by the Agency to determine that the product meets the registration standards of FIFRA sec. 3(c)(5) or (7). Each study must comply with:

(i) Section 158.30 of this chapter, with respect to times for submission;

(ii) Section 158.32 of this chapter, with respect to format of submission;

(iii) Section 158.33 of this chapter, with respect to studies for which a claim of trade secret or confidential business information is made;

(iv) Section 158.34 of this chapter, with respect to flagging for potential adverse effects; and

(v) Section 160.12 of this chapter, if applicable, with respect to a statement of whether studies were conducted in accordance with the Good Laboratory Practices of Part 160.

(3) An applicant shall furnish with his application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on man or the environment, which would be required to be reported under FIFRA sec. 6(a)(2) if the product were registered. The types of information and submission requirements are described in Part 153, Subpart D of this chapter.

(g) *Certification relating to child-resistant packaging.* If the product meets the criteria for child-resistant packaging, the applicant must submit a certification that the product will be distributed or sold only in child-resistant packaging. Refer to Part 157 of this chapter for the criteria and certification requirements.

(h) *Request for classification.* If an applicant wishes to request a classification different from that established by the Agency, he must

submit a request for such classification and information supporting the request.

(i) *Statement concerning tolerances.* If the proposed labeling bears instructions for use of the pesticide on food or feed crops, or if the intended use of the pesticide results or may be expected to result, directly or indirectly, in pesticide residues in or on food or feed (including residues of any active ingredient, inert ingredient, metabolite, or degradation product), the applicant must submit a statement indicating whether such residues are authorized by a tolerance, exemption from the requirement of a tolerance, or food additive regulation issued under section 408 or 409 of the Federal Food, Drug and Cosmetic Act (FFDCA). If such residues have not been authorized, the application must be accompanied by a petition for establishment of appropriate tolerances, exemptions from the requirement of a tolerance, or food additive regulations, in accordance with Part 180 of this chapter.

(Approved by the Office of Management and Budget under Control Number 2070–0024.)

§ 152.55 Where to send applications and correspondence.

Applications and correspondence relating to registration should be mailed to the Registration Division (TS–767C), U.S. Environmental Protection Agency, Washington, DC 20460. Persons who wish to hand-deliver applications should contact the Registration Division to determine the location for delivery.

5. By adding Subpart D to read as follows:

Subpart D—Reregistration Procedures

Subpart D—Reregistration Procedures

§ 152.60 General.

FIFRA sec. 3(g) requires that all currently registered pesticide products be reregistered. To facilitate the reregistration of products, EPA has instituted a program for the review of a pesticide active ingredient, the data supporting registration of products containing that active ingredient, and its uses. This review normally culminates in the issuance of a Registration Standard. The Standard explains the Agency's position on the registrability of products containing the active ingredient(s), assesses the acceptability of existing tolerances, lists additional data or information, if any, that must be submitted to complete the reregistration review, and identifies labeling changes or use restrictions needed for the product to remain in compliance with FIFRA.

§ 152.65 Application for reregistration.

(a) When the Agency is prepared to reregister products containing a specified active ingredient or combination of ingredients, it will notify the registrant by certified mail and will inform him of the specific requirements and the timeframes for submission of an application for reregistration.

(b) After receiving notice, the registrant is required to submit an application for reregistration within the timeframes specified in the notice.

(c) The application must contain the information required by § 152.50, unless such information is already on file with the Agency and is current and accurate.

§ 152.70 Agency response to application.

(a) *Approval of application.* The Agency will approve an application for reregistration when it determines that the registrant has complied with the instructions in the Agency's notice, and that the product meets the criteria for registration stated in § 152.112.

(b) *Time for compliance after approval.* If the Agency approves the application, it will notify the registrant of such approval. The notice of approval will specify the time permitted for modification of product composition, labeling and packaging of products shipped or distributed in commerce.

(c) *Notice of intent to cancel.* If a registrant fails to submit an application within the time allowed, or submits an application that does not conform to Agency requirements, the Agency may issue a notice of intent to cancel the registration. The registration will be cancelled after 30 days, unless within the 30 days the registrant takes one of the following actions:

(1) Submits a complete and correct application.

(2) Corrects the deficiencies in his previously submitted application.

(3) Requests a hearing, in accordance with § 152.148.

6. By adding Subpart F consisting of §§ 152.100 through 152.115 and 152.117 and 152.118, and §§ 152.116 and 152.119 which are revised and transferred from Subpart E to new Subpart F. As added, Subpart F reads as follows:

Subpart F—Agency Review of Applications

Subpart F—Agency Review of Applications

§ 152.100 Scope.

(a) The Agency will follow the procedures in this subpart for all applications for registration, except an application for registration of a pesticide that has been the subject of a previous Agency cancellation or suspension notice under FIFRA sec. 6.

(b) The Agency will follow the procedures of Subpart D of Part 164 of this chapter in evaluating any application for registration of a pesticide involving use of the pesticide in a manner that is prohibited by a suspension or cancellation order, to the extent required by Subpart D of Part 164.

§ 152.102 Publication.

The Agency will issue in the **Federal Register** a notice of receipt of each application for registration of a product that contains a new active ingredient or that proposes a new use. After registration of the product, the Agency will issue in the **Federal Register** a notice of issuance. The notice of issuance will describe the new chemical or new use, summarize the Agency's regulatory conclusions, list missing data and the conditions for their submission, and respond to comments received on the notice of application.

§ 152.104 Completeness of applications.

The applicant is responsible for the accuracy and completeness of all information submitted in connection with the application. The Agency will review each application to determine whether it is complete. An application is incomplete if any pertinent item specified in § 152.50 has not been submitted, or has been incorrectly submitted (for example, data required by Part 158 of this chapter not submitted in accordance with the requirements for format, claims of confidential business information, or flagging).

§ 152.105 Incomplete applications.

The Agency will not begin or continue the review of an application that is incomplete. If the Agency determines that an application is incomplete or that further information is needed in order to complete the Agency's review, the Agency will notify the applicant of the deficiencies and allow the applicant 75 days to make corrections or additions to complete the application. If the applicant believes that the deficiencies cannot be corrected within 75 days, he must notify the Agency within those 75 days of the date on which he expects to complete the application. If, after 75 days, the applicant has not responded, or if the applicant subsequently fails to complete the application within the time scheduled for completion, the Agency will terminate any action on such application, and will treat the application as if it had been withdrawn by the applicant. Any subsequent submission relating to the same product must be submitted as a new application.

§ 152.107 Review of data.

(a) The Agency normally will review data submitted with an application that have not previously been submitted to the Agency.

(b) The Agency normally will review other data submitted or cited by an applicant only:

(1) As part of the process of reregistering currently registered products;

(2) When acting on an application for registration of a product containing a new active ingredient;

(3) If such data have been flagged in accordance with § 158.34 of this chapter; or

(4) When the Agency determines that it would otherwise serve the public interest.

(c) If the Agency finds that it needs additional data in order to determine whether the product may be registered, it will notify the applicant as early as possible in the review process.

§ 152.108 Review of labeling.

The Agency will review all draft labeling submitted with the application. If an applicant for amended registration submits only that portion of the labeling proposed for amendment, the Agency may review the entire label, as revised by the proposed changes, in deciding whether to approve the amendment. The Agency will not approve final printed labeling, but will selectively review it for compliance.

§ 152.110 Time for Agency review.

The Agency will complete its review of applications as expeditiously as possible. Applications involving new active ingredients, new uses, petitions for tolerance or exemptions, or consultation with other Federal agencies normally will take longer than applications for substantially similar products and uses.

§ 152.111 Choice of standards for review of applications.

The Agency has discretion to review applications under either the unconditional registration criteria of FIFRA sec. 3(c)(5) or the conditional registration criteria of FIFRA sec. 3(c)(7). The type of review chosen depends primarily on the extent to which the relevant data base has been reviewed for completeness and scientific validity. EPA conducts data reviews needed to support unconditional registrations on a chemical-by-chemical basis, according to an established priority list. Except for applications for registration of a new active ingredient or in special cases where it finds immediate review to be warranted, the Agency will not commence a complete review of the existing data base on a given chemical in response to receipt of an application for registration. Instead the Agency will review the application using the criteria for conditional registration in FIFRA sec. 3(c)(7) (A) and (B).

§ 152.112 Approval of registration under FIFRA sec. 3(c)(5).

EPA will approve an application under the criteria of FIFRA sec. 3(c)(5) only if:

(a) The Agency has determined that the application is complete and is accompanied by all materials required by the Act and this part, including, but not limited to, evidence of compliance with Subpart E of this part;

(b) The Agency has reviewed all relevant data in the possession of the Agency (see §§ 152.107 and 152.111);

(c) The Agency has determined that no additional data are necessary to make the determinations required by FIFRA sec. 3(c)(5) with respect to the pesticide product which is the subject of the application;

(d) The Agency has determined that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data are required to be submitted by Part 158 of this chapter for the product;

(e) The Agency has determined that the product will perform its intended function without unreasonable adverse effects on the environment, and that, when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment;

(f) The Agency has determined that the product is not misbranded as that term is defined in FIFRA sec. 2(q) and Part 156 of this chapter, and its labeling and packaging comply with the applicable requirements of the Act, this Part, and Parts 156 and 157 of this chapter;

(g) If the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues (including residues of any active or inert ingredient of the product, or of any metabolite or degradation product thereof) in or on food or animal feed, all necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCA sec. 408, sec. 409 or both; and

(h) If the product, in addition to being a pesticide, is a drug within the meaning of FFDCA sec. 201(q), the Agency has been notified by the Food and Drug Administration (FDA) that the product complies with any requirements imposed by FDA.

§ 152.113 Approval of registration under FIFRA sec. 3(c)(7)—Products that do not contain a new active ingredient.

(a) Except as provided in paragraph (b) of this section, the Agency may approve an application for registration or amended registration of a pesticide product, each of whose active ingredients is contained in one or more other registered peticide products, only if the Agency has determined that:

(1) It possesses all data necessary to make the determinations required by FIFRA sec. 3(c)(7)(A) or (B) with respect to the pesticide product which is the subject of the application (including, at a minimum, data needed to characterize any incremental risk that would result from approval of the application);

(2) Approval of the application would not significantly increase the risk of any unreasonable adverse effect on the environment; and

(3) The criteria of § 152.112(a), (d), and (f) through (h) have been satisfied.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide under FIFRA sec. 3(c)(7)(A) unless the Agency has determined that the applicant's product and its proposed use are identical or substantially similar to a currently registered pesticide and use, or that the pesticide and its proposed use

differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.

(c) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide product for a new use under FIFRA sec. 3(c)(7)(B) if:

(1) The pesticide is the subject of a special review, based on a use of the product that results in human dietary exposure; and

(2) The proposed new use involves use on a major food or feed crop, or involves use on a minor food or feed crop for which there is available an effective alternative registered pesticide which does not meet the risk criteria associated with human dietary exposure. The determination of available and effective alternatives shall be made with the concurrence of the Secretary of Agriculture.

§ 152.114 Approval of registration under FIFRA sec. 3(c)(7)—Products that contain a new active ingredient.

An application for registration of a pesticide containing an active ingredient not in any currently registered product may be conditionally approved for a period of time sufficient for the generation and submission of certain of the data necessary for a finding of registrability under FIFRA sec. 3(c)(5) if the Agency determines that:

(a) Insufficient time has elapsed since the imposition of the data requirement for those data to have been developed;

(b) All other required test data and materials have been submitted to the Agency;

(c) The criteria in § 152.112(a), (b), (d), and (f) through (h) have been satisfied;

(d) The use of the pesticide product during the period of the conditional registration will not cause any unreasonable adverse effect on the environment; and

(e) The registration of the pesticide product and its subsequent use during the period of the conditional registration are in the public interest.

§ 152.115 Conditions of registration.

(a) *Substantially similar products and new uses.* Each registration issued under § 152.113 shall be conditioned upon the submission or citation by the registrant of all data which are required for unconditional registration of his product under FIFRA sec. 3(c)(5), but which have not yet been submitted, no later than the time such data are required to be submitted for similar pesticide products already registered. If a notice requiring submission of such data has been issued under FIFRA sec. 3(c)(2)(B) prior to the date of approval of the application, the applicant must submit or cite the data described by that notice at the time specified by that notice. The applicant must agree to these conditions before the application may be approved.

(b) *New active ingredients.* Each registration issued under § 152.114 shall be conditioned upon the applicant's agreement to each of the following conditions:

(1) The applicant will submit remaining required data (and interim reports if required) in accordance with a schedule approved by the Agency.

(2) The registration will expire upon a date established by the Agency, if the registrant fails to submit data as required by the Agency. The expiration date will be established based upon the length of time necessary to generate and submit the required data. If the studies are submitted in a timely manner, the registration will be cancelled if the Agency determines, based on the data (alone, or in conjuction with other data), that the product or one or more of its uses meets or exceeds any of the risk criteria established by the Agency to initiate a special review. If the Agency so determines, it will issue to the registrant a Notice of Intent to Cancel under FIFRA sec. 6(e), and will specify any provisions for sale and distribution of existing stocks of the pesticide product.

(3) The applicant will submit an annual report of the production of the product.

(c) *Other conditions.* The Agency may establish, on a case-by-case basis, other conditions applicable to registrations to be issued under FIFRA sec. 3(c)(7).

(d) *Cancellation if condition is not satisfied.* If any condition of the registration of the product is not satisfied, or if the Agency determines that the registrant has failed to initiate or pursue appropriate action towards fulfillment of any condition, the Agency will issue a notice of intent to cancel under FIFRA sec. 6(e) and § 152.148.

§ 152.116 Notice of intent to register to original submitters of exclusive use data.

(a) Except as provided in paragraph (c) of this section, at least 30 days before registration of a product containing an active ingredient for which a previously submitted study is eligible for exclusive use under FIFRA sec. 3(c)(1)(D)(i), the Agency will notify the original submitter of the exclusive use study of the intended registration of the product. If requested by the exclusive use data submitter within 30 days, the Agency will also provide the applicant's list of data requirements and method of demonstrating compliance with each data requirement.

(b) Within 30 days after receipt of the Agency's notice, or of the applicant's list of data requirements, whichever is later, the exclusive use data submitter may challenge the issuance of the registration in accordance with the procedures in § 152.99 (b) and (c). If the Agency finds that the challenge has merit, it will issue a notice of denial of the application. The applicant may then avail himself of the hearing procedures provided by FIFRA sec. 3(c)(6). If the Agency finds that the challenge is without merit, it will deny the petition and register the applicant's product. Denial of the petition is a final Agency action.

(c) If an applicant has submitted to the Agency a certification from an exclusive use data submitter that he is aware of the applicant's application for registration, and does not object to the issuance of the registration, the Agency will not provide the 30-day notification described in paragraph (a) of this section to that exclusive use data submitter.

§ 152.117 Notification to applicant.

The Agency will notify the applicant of the approval of his application by a Notice of Registration for new registration, or by a letter in the case of an amended registration.

§ 152.118 Denial of application.

(a) *Basis for denial.* The Agency may deny an application for registration if the Agency determines that the pesticide product does not meet the criteria for registration under either FIFRA sec. 3(c)(5) or (7), as specified in §§ 152.112 through 152.114.

(b) *Notification of applicant.* If the Agency determines that an application should be denied, it will notify the applicant by certified letter. The letter will set forth the reasons and factual basis for the determination with conditions, if any, which must be fulfilled in order for the registration to be approved.

(c) *Opportunity for remedy by the applicant.* The applicant will have 30 days from the date of receipt of the certified letter to take the specified corrective action. During this time the applicant may request that his application be withdrawn.

(d) *Notice of denial.* If the applicant fails to correct the deficiencies within the 30-day period, the Agency may issue a notice of denial, which will be published in the **Federal Register**, and which will set forth the reasons and the factual basis for the denial.

(e) *Hearing rights.* Within 30 days following the publication of the notice of denial, an applicant, or any interested person with written authorization of the applicant, may request a hearing in accordance with FIFRA sec. 6(b). Hearings will be conducted in accordance with Part 164 of this chapter.

§ 152.119 Availability of material in support of registration.

(a) The information submitted to support a registration application shall be part of the official Agency file for that registration.

(b) Within 30 days after registration, the Agency will make available for public inspection, upon request, the materials required by Subpart E to be submitted with an application. Materials that will be publicly available include an applicant's list of data requirements, the method used by the applicant to demonstrate compliance for each data requirement, and the applicant's citations of specific studies in the Agency's possession if applicable.

(c) Except as provided by FIFRA sec. 10, within 30 days after registration, the data on which the Agency based its decision to register the product will be made available for public inspection, upon request, in accordance with the procedures in 40 CFR Part 2.

7. By adding Subpart G to read as follows:

Subpart G—Obligations and Rights of Registrants

Sec.

Subpart G—Obligations and Rights of Registrants

§ 152.122 Currency of address of record and authorized agent.

(a) The registrant must keep the Agency informed of his current name and address of record. If the Agency's good faith attempts to contact the registrant are not successful, the Agency will issue in the **Federal Register** a notice of intent to cancel all products of the registrant under FIFRA sec. 6(b). The registrant must respond within 30 days requesting that the registrations be maintained in effect, and providing his name and address of record. If no response is received, the cancellations will become effective at the end of 30 days without further notice to the registrant. The Agency may make provision for the sale and distribution of existing stocks of such products after the effective date of cancellation.

(b) The registrant must also notify the Agency if he changes his authorized agent.

§152.125 Submission of information pertaining to adverse effects.

If at any time the registrant receives or becomes aware of any factual information regarding unreasonable adverse effects of the pesticide on the environment that has not previously been submitted to the Agency, he shall, in accordance with FIFRA sec. 6(a)(2) and Subpart D of Part 153 of this chapter, provide such information to the Agency, clearly identified as FIFRA 6(a)(2) data.

§152.130 Distribution under approved labeling.

(a) A registrant may distribute or sell a registered product with the composition, packaging and labeling currently approved by the Agency.

(b) A registrant may distribute or sell a product under labeling bearing any subset of the approved directions for use, provided that in limiting the uses listed on the label, no changes would be necessary in precautionary statements, use classification, or packaging of the product.

(c) Normally, if the product labeling is amended on the initiative of the registrant, by submission of an application for amended registration, the registrant may distribute or sell under the previously approved labeling for a period of 18 months after approval of the revision, unless an order subsequently issued by the Agency under FIFRA sec. 6 or 13 provides otherwise. However, if paragraph (d) of this section applies to the registrant's product, the time frames established by the Agency in accordance with that paragraph shall take precedence.

(d) If a product's labeling is required to be revised as a result of the issuance of a Registration Standard, a Label Improvement Program notice, or a notice concluding a special review process, the Agency will specify in the notice to the registrant the period of time that previously approved labeling may be used. In all cases, supplemental or sticker labeling may be used as an interim compliance measure for a reasonable period of time. The Agency may establish dates as follows governing when label changes must appear on labels:

(1) The Agency may establish a date after which all product distributed or sold by the registrant must bear revised labeling.

(2) The Agency may also establish a date after which no product may be distributed or sold by any person unless it bears revised labeling. This date will provide sufficient time for product in channels of trade to be distributed or sold to users or otherwise disposed of.

§152.132 Supplemental distribution.

The registrant may distribute or sell his registered product under another person's name and address instead of (or in addition to) his own. Such distribution and sale is termed "supplemental distribution" and the product is referred to as a "distributor product." The distributor is considered an agent of the registrant for all intents and purposes under the Act, and both the registrant and the distributor may be held liable for violations pertaining to the distributor product. Supplemental distribution is permitted upon notification to the Agency if all the following conditions are met:

(a) The registrant has submitted to the Agency for each distributor product a statement signed by both the registrant and the distributor listing the names and addresses of the registrant and the distributor, the distributor's company number, the additional brand name(s) to be used, and the registration number of the registered product.

(b) The distributor product is produced, packaged and labeled in a registered establishment operated by the same producer (or under contract in accordance with § 152.30) who produces, packages, and labels the registered product.

(c) The distributor product is not repackaged (remains in the producer's unopened container).

(d) The label of the distributor product is the same as that of the registered product, except that:

(1) The product name of the distributor product may be different (but may not be misleading);

(2) The name and address of the distributor may appear instead of that of the registrant;

(3) The registration number of the registered product must be followed by a dash, followed by the distributor's company number (obtainable from the Agency upon request);

(4) The establishment number must be that of the final establishment at which the product was produced; and

(5) Specific claims may be deleted, provided that no other changes are necessary.

§152.135 Transfer of registration.

(a) A registrant may transfer the registration of a product to another

person, and the registered product may be distributed and sold without the requirement of a new application for registration by that other person, if the parties submit to the Agency the documents listed in paragraphs (b) and (c) of this section, and receive Agency approval as described in paragraph (d) of this section.

(d) Persons seeking approval of a transfer of registration must provide a document signed by the authorized representative of the registrant (the transferor) and of the person to whom the registration is transferred (the transferee) that contains the following information:

(1) The name, address and State of incorporation (if any) of the transferor;

(2) The name, address and State of incorporation of the transferee;

(3) The name(s) and EPA registration number(s) of the product(s) being transferred;

(4) A statement that the transferor transfers irrevocably to the transferee all right, title, and interest in the EPA registration(s) listed in the document;

(5) A statement that the transferred registration(s) shall not serve as collateral or otherwise secure any loan or other payment arrangement or executory promise, and that the registration(s) shall not revert to the transferor unless a new transfer agreement is submitted to and approved by the Agency;

(6) A description of the general nature of the underlying transaction, e.g., merger, spinoff, bankruptcy transfer (no financial information need be disclosed);

(7) A statement that the transferor and transferee understand that any false statement may be punishable under 18 U.S.C. 1001; and

(8) An acknowledgment by the transferee that his rights and duties concerning the registration under FIFRA and this chapter will be deemed by EPA to be the same as those of the transferor at the time the transfer is approved.

(c) In addition, the transferor must submit to the Agency a notarized statement affirming that:

(1) The person signing the transfer agreement is authorized by the registrant to bind the transferor;

(2) No court order prohibits the transfer, and that any required court approvals have been obtained; and

(3) The transfer is authorized under all relevant Federal, State and local laws and all relevant corporate charters, bylaws, partnerships, or other agreements.

(d) If the required documents are submitted, and no information available to the Agency indicates that the information is incorrect, the Agency will approve the transfer without requiring that the transferee obtain a new registration. The Agency will notify the transferor and transferee of its approval.

(e) The transfer will be effective on the date of Agency approval. Thereafter the transferee will be regarded as the registrant for all purposes under FIFRA.

(f) Rights to exclusive use of data or compensation under FIFRA sec. 3(c)(1)(D) are separate from the registration itself and may be retained by the transferor, or may be transferred independently in accordance with the provisions of § 152.98. If the registrant as the original data submitter wishes to transfer data rights at the same time as he transfers the registration, he may submit a single transfer document containing the information required by this section for both the registration and the data.

(Approved by the Office of Management and Budget under Control Number 2070–0060.)

§ 152.138 Voluntary cancellation.

(a) A registrant may request at any time that his registration be cancelled. A request for voluntary cancellation must include the registrant's name and address, the product name(s), the EPA registration number(s) involved, and the signature of the registrant or his authorized representative. In addition, if the registrant wishes to continue to distribute and sell existing stocks of the product, the request must include a proposed timeframe for disposition of such stocks.

(b) EPA will send a notice of cancellation by certified mail to the registrant. The notice will specify the effective date of cancellation, and the timeframe for disposal of existing stocks of the product.

(c) Voluntary cancellation of a product applies to the registered product and all distributor products distributed or sold under that registration number. The registrant is responsible for ensuring that distributors under his cancelled registration are notified and comply with the terms of the cancellation.

8. By adding Subpart H to read as follows:

Subpart H—Agency Actions Affecting Registrations

Sec.

Subpart H—Agency Actions Affecting Registrations

§ 152.140 Classification of pesticide products.

FIFRA sec. 3(d) authorizes the Agency, as part of the registration or reregistration of a pesticide, or by issuing a regulation, or by an order under FIFRA sec. 6, to classify a product, its uses, or a class of products or uses for restricted use, in accordance with the criteria and procedures in Subpart I of this part.

§ 152.142 Submission of information to maintain registration in effect.

(a) FIFRA sec. 3(c)(2)(B) authorizes the Agency to require that a registrant submit information necessary to maintain his registration in effect. Such information may consist of data on the chemistry, efficacy, toxicity, environmental fate, environmental effects or other characteristics of the product or its ingredients, or on the exposure of humans or other organisms to the product or its components, or any other information necessary to support the continued registration of the product.

(b) If the Agency determines that additional information is necessary in order to maintain a registration in effect, the procedures set out in FIFRA sec. 3(c)(2)(B) will be used. The Agency will notify each affected registrant, and list the information needed and the required submission date. The information, when submitted to the Agency, is subject to the requirements of §§ 158.32, 158.33, and 158.34 of this chapter.

(Approved by the Office of Management and Budget under Control Number 2070–0057.)

§ 152.144 Reregistration.

Under FIFRA sec. 3(g), the Agency must evaluate all currently registered pesticides against the standards of FIFRA sec. 3(c)(5) and reregister the products that meet those standards. The Agency has an ongoing program for the systematic review of pesticides. In that program, the Agency develops and maintains a Registration Standard for products containing a specified ingredient. The Registration Standard sets out the Agency's position with respect to regulation of products containing the ingredient, and is updated periodically as the Agency receives additional information. Based on the Registration Standard, the Agency may require a registrant to change a product's composition, labeling, packaging, or uses in order to

be reregistered and to maintain his registration in compliance with FIFRA. The procedures for reregistration are found in Subpart D of this Part.

§ 152.146 Special review of pesticides.

The Agency has established a special review process that, in its discretion, may be used to assist in identifying and evaluating pesticides that may cause unreasonable adverse effects on the environment. If the Agency determines through the special review process that the product or its uses may cause unreasonable adverse effects, or that the risks posed by the pesticide outweigh its benefits, the Agency may initiate cancellation proceedings under § 152.148. Criteria and procedures for the special review process are contained in Part 154 of this chapter.

§ 152.148 Cancellation of registration.

(a) *Grounds for cancellation.* The Agency may issue a notice of intent to cancel the registration of a product or to cancel the registration unless it is amended as specified in the notice, if the Agency determines that any of the following criteria has been met:

(1) Under FIFRA sec. 6(b), the pesticide, its labeling, or other material required to be submitted, does not comply with the Act. For example, the Agency may propose cancellation if a registrant fails to comply with a requirement that a product bear restricted use labeling, or if a registrant submits to the Agency a false statement concerning compliance of a study with the Good Laboratory Practices requirements of Part 160 of this chapter.

(2) Under FIFRA sec. 6(b), the pesticide, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment;

(3) Under FIFRA sec. 6(e), a registrant fails to initiate or pursue appropriate action toward meeting any conditions imposed on the registration;

(4) Under FIFRA sec. 6(c), a registrant fails to meet any conditions imposed on the registration;

(5) Under FIFRA sec. 3(c)(1)(D)(ii), the Agency determines, based upon a petition by an original data submitter, that a registrant has failed to comply with the requirements of Subpart E of this Part concerning compensation for use of data. Such cancellations are governed by the procedures of § 152.99, and are not subject to the procedures of this section.

(b) *Notice of intent to cancel.* The Agency will notify the registrant by certified mail at the address of record of the Agency's intent to cancel, and will state the reasons for the proposed cancellation. The Agency will also issue in the **Federal Register** a notice of its intent to cancel a registration.

(c) *Opportunity for corrections.* The registrant may, within 30 days of his receipt of the notice or publication in the **Federal Register**, whichever is later, make any corrections identified in the notice. If he does so, the cancellation action will not become final.

(d) *Hearing*—(1) *Requested by a registrant.* A registrant may, within 30 days of his receipt of a notice of intent to cancel, or publication in the **Federal Register**, whichever is later, request that a hearing be held. The registrant may request a hearing on any or all of the Agency's requirements, as stated in the Agency's notice of intent to cancel. The registrant must state in his request the specific requirements he objects to, and the reasons for his objection. He need not comply with the requirements in dispute until a final hearing decision has been issued. The registrant must, however, within the timeframes specified, comply with all other Agency requirements that are not at issue.

(2) *Requested by another person.* Any other person adversely affected by a proposed cancellation may, within 30 days of publication in the **Federal Register**, request that a hearing be held. The request must identify in what manner the person is adversely affected by the Agency's proposed cancellation.

(3) *Initiated by the Agency.* Under FIFRA sec. 6(b)(2), in lieu of issuing a notice of intent to cancel, the Agency may hold a hearing to determine whether a registration should be cancelled.

(4) *Hearing procedures.* A hearing will be conducted according to FIFRA sec. 6(d) or 6(e) and Part 164 of this chapter.

(e) *Effective date of cancellation.* (1) If a hearing request is not received in a timely manner and the registrant fails to make required corrections in a timely manner, the cancellation shall be effective at the end of 30 days from the date of publication in the **Federal Register** or receipt by the registrant, whichever is later.

(2) If a hearing is held to challenge the cancellation, and thereafter the cancellation is sustained, or if the Agency holds a hearing in which it is concluded that a registration should be cancelled, the cancellation shall be effective immediately upon issuance of the final Agency order in the proceeding.

(f) *Effect of cancellation.* After the effective date of cancellation, distribution or sale of a cancelled product, except in accordance with the terms of the notice of cancellation, will be considered a violation of FIFRA sec. 12(a)(1)(A) or 12(a)(2)(K). The Agency will specify in the order of final cancellation whether existing stocks of the product may be distributed or sold, what conditions of distribution, sale, and use (if any) have been established, and the date after which such distribution or sale will no longer be permitted.

(g) *Reinstatement of registration.* The Agency will reinstate a cancelled registration if the registrant can show that the cancellation was the result of Agency clerical or administative error.

§ 152.150 Suspension of registration.

(a) *Grounds for suspension.* The Agency may issue a notice of intent to suspend the registration of a product if:

(1) Under FIFRA sec. 6(c)(1), the Agency determines that suspension is necessary in order to prevent an imminent hazard during the time necessary for cancellation or change in classification proceedings.

(2) Under FIFRA sec. 3(c)(2)(B), a registrant has failed, within the time required by the Agency:

(i) To take appropriate steps to provide information necessary for continued registration;

(ii) To participate in a procedure for reaching agreement concerning joint development of data or in an arbitration proceeding; or

(iii) To comply with the terms of any agreement or arbitration decision.

(b) *Suspension order.* The Agency may issue a suspension order if:

(1) The registrant who has received a notice of intent to suspend fails to request a hearing in a timely manner;

(2) A hearing is held, and the suspension is sustained; or

(3) Under FIFRA sec. 6(c)(3), the Agency determines that an emergency exists which warrants immediate suspension.

(c) *Procedures of suspension.* The Agency will conduct proceedings to suspend products in accordance with the provisions of Subpart C of Part 164 of this chapter, or FIFRA sec. 3(c)(2)(B), as applicable.

(d) *Effect of suspension.* After the effective date of suspension, the distribution, sale, or use of a suspended product, except in accordance with the terms of the suspension notice, will be considered a violation of FIFRA sec. 12(a)(2)(J).

§ 152.152 Child-resistant packaging.

The Agency has established criteria, standards and recordkeeping requirements for child-resistant packaging of products that are highly toxic and are intended for residential use. Refer to Part 157 of this chapter.

§ 152.159 Policies applicable to registration and registered products.

Codified policies and interpretations pertaining to registration and registered products may be found in Part 153 of this chapter. Additional policies and interpretations may be published in the Federal Register, mailed directly to registrants, or both.

9. By adding Subpart I to read as follows:

Subpart I—Classification of Pesticides

Subpart I—Classification of Pesticides

§ 152.160 Scope.

(a) *Types of classification.* A pesticide product may be unclassified, or it may be classified for restricted use or for general use. The Agency does not normally classify products for general use; products that are not restricted remain unclassified.

(b) *Kinds of restrictions.* The Agency may restrict a product or its uses to use by a certified applicator, or by or under the direct supervision of a certified applicator, as described in FIFRA sec. 3(d)(1)(C). The Agency may also, by regulation, prescribe restrictions relating to the product's composition, labeling, packaging, uses, or distribution and sale, or to the status or qualifications of the user.

§ 152.161 Definitions.

In addition to the definitions in § 152.3, the following terms are defined for the purposes of this subpart:

(a) "Dietary LC_{50}" means a statistically derived estimate of the concentration of a test substance in the diet that would cause 50 percent mortality to the test population under specified conditions.

(b) "Outdoor use" means any pesticide application that occurs outside enclosed manmade structures or the consequences of which extend beyond enclosed manmade structures, including, but not limited to, pulp and paper mill water treatments and industrial cooling water treatments.

§ 152.164 Classification procedures.

(a) *Grouping of products for classification purposes.* In its discretion, the Agency may identify a group of products having common characteristics or uses and may classify for restricted use same or all of the products or uses included in that group. Such a group may be comprised of, but is not limited to, products that:

(1) Contain the same active ingredients.

(2) Contain the same active ingredients in a particular concentration range, formulation type, or combination of concentration range and formulation type.

(3) Have uses in common.

(4) Have other characteristics, such as toxicity, flammability, or physical properties, in common.

(b) *Classification reviews.* The Agency may conduct classification reviews and classify products at any time, if it determines that a restriction on the use of a pesticide product is necessary to avoid unreasonable adverse effects on the environment. However, classification reviews normally will be conducted and products classified only in the following circumstances:

(1) As part of the review of an application for new registration of a product containing an active ingredient not contained in any currently registered product.

(2) As part of the review of an application for a new use of a product, if existing uses of that product previously have been classified for restricted use. Review of a restricted use product at this time is for the purpose of determining whether the new use should also be classified for restricted use. Normally the Agency will not conduct initial classification reviews for existing uses of individual products in conjunction with an application for amended registration.

(3) As part of the process of developing or amending a registration standard for a pesticide. The Agency normally will conduct classification reviews of all uses of a currently registered pesticide at this time.

(4) As part of any special review of a pesticide, in accordance with the procedures of 40 CFR Part 154.

(c) *Classification procedures.* (1) If the Agency determines that a product or one or more of its uses should be classified for restricted use, the Agency initially may classify the product by regulation. In this case, within 60 days after the effective date of a final rule, each registrant of a product subject to the rule must submit to the Agency one of the following, as directed in the final rule:

(i) A copy of the amended label and any supplemental labeling to be used as an interim compliance measure.

(ii) A statement, which the Agency considers a report under the Act, that the registrant will comply with the labeling requirements prescribed by the Agency within the timeframes prescribed by the regulation.

(iii) An application for amended registration to delete the uses which have been restricted, or to "split" the registration into two registrations, one including only restricted or all uses, and the other including only uses that have not been classified.

(2) Alternatively, EPA may notify the applicant or registrant of the classification decision and require that he submit the information required by paragraph (c)(1) of this section. The Agency may deny registration or initiate cancellation proceedings if the registrant fails to comply within the timeframes established by the Agency in its notification.

§ 152.166 Labeling of restricted use products.

(a) *Products intended for end use.* A product whose labeling bears directions for end use and that has been classified for restricted use must be labeled in accordance with the requirements of § 156.10 of this chapter or other Agency instructions. The Agency will permit the use of stickers or supplemental labeling as an interim alternative to the use of an approved amended label, in accordance with § 152.167.

(b) *Products intended only for formulation.* A product whose labeling does not bear directions for end use (a product that is intended and labeled solely for further formulation into other pesticide products) is not subject to the labeling requirements of this subpart.

§ 152.167 Distribution and sale of restricted use products.

Unless modified by the Agency, the compliance dates in this section shall apply to restricted use products.

(a) *Sale by registrant or producer.* (1) No product with a use classified for restricted use may be distributed or sold by the registrant or producer after the 120th day after the effective date of such classification unless the product:

(i) Bears an approved amended label which contains the terms of restricted use imposed by the Agency and otherwise complies with Part 156 of this chapter;

(ii) Bears a sticker containing the product name, EPA registration number, and any terms of restricted use imposed by the Agency; or

(iii) Is accompanied by supplemental labeling bearing the information listed in paragraph (a)(1)(ii) of this section.

(2) If the registrant chooses to delete the restricted uses from his product label, that product may not be distributed or sold after the 180th day after the effective date of classification unless the product bears amended labeling with the restricted uses deleted.

(3) Notwithstanding paragraphs (a)(1) and (2) of this section, after the 270th day after the effective date of classification, no registrant or producer may distribute or sell a product that does not bear the approved amended label. After that date, stickers and supplemental labeling described in paragraph (a)(1)(ii) and (iii) are not longer acceptable.

(b) *Sale by retailer.* No product with a use classified for restricted use by a regulation may be distributed or sold by a retailer or other person after the 270th day after the effective date of the final rule unless the product bears a label or labeling which complies with paragraph (a)(1) of this section.

§ 152.168 Advertising of restricted use products.

(a) Any product classified for restricted use shall not be advertised unless the advertisement contains a statement of its restricted use classification.

(b) The requirement in paragraph (a) of this section applies to all advertisements of the product, including, but not limited, to:

(1) Brochures, pamphlets, circulars and similar material offered to purchasers at the point of sale or by direct mail.

(2) Newspapers, magazines, newsletters and other material in circulation or available to the public.

(3) Broadcast media such as radio and television.

(4) Telephone advertising.

(5) Billboards and posters.

(c) The requirement may be satisfied for printed material by inclusion of the statement "Restricted Use Pesticide," or the terms of restriction, prominently in the advertisement. The requirement may be satisfied with respect to broadcast or telephone advertising by inclusion in the broadcast of the spoken words "Restricted use pesticide," or a statement of the terms of restriction.

(d) The requirements of this section shall be effective:

(1) After 270 days after the effective date of restriction of a product that is currently registered, unless the Agency specifies a shorter time period;

(2) Upon the effective date of registration of a product not currently registered.

§ 152.170 Criteria for restriction to use by certified applicators.

(a) *General criteria.* An end-use product will be restricted to use by certified applicators (or persons under their direct supervision) if the Agency determines that:

(1) Its toxicity exceeds one or more of the specific hazard criteria in paragraph (b) or (c) of this section, or evidence described in paragraph (d) of this section substantiates that the product or use poses a serious hazard that may be mitigated by restricting its use;

(2) Its labeling, when considered according to the factors in paragraph (e)(2) of this section, is not adequate to mitigate these hazard(s);

(3) Restriction of the product would decrease the risk of adverse effects; and

(4) The decrease in risks of the pesticide as a result of restriction would exceed the decrease in benefits.

(b) *Criteria for human hazard*—(1) *Residential and institutional uses.* A pesticide product intended for residential or institutional use will be considered for restricted use classification if:

(i) The pesticide, as diluted for use, has an acute oral LD_{50} of 1.5 g/kg or less;

(ii) The pesticide, as formulated, has an acute dermal LD_{50} of 2000 mg/kg or less;

(iii) The pesticide, as formulated, has an acute inhalation LC_{50} of 0.5 mg/liter or less, based upon a 4-hour exposure period;

(iv) The pesticide, as formulated, is corrosive to the eye (causes irreversible destruction of ocular tissue) or results in corneal involvement or irritation persisting for more than 7 days;

(v) The pesticide, as formulated, is corrosive to the skin (causes tissue destruction into the dermis and/or scarring) or causes severe irritation (severe erythema or edema) at 72 hours; or

(vi) When used in accordance with label directions, or widespread and commonly recognized practice, the pesticide may cause significant subchronic, chronic or delayed toxic effects on man as a result of single or multiple exposures to the product ingredients or residues.

(2) *All other uses.* A pesticide product intended for uses other than residential or institutional use will be considered for restricted use classification if:

(i) The pesticide, as formulated, has an acute oral LD_{50} of 50 mg/kg or less;

(ii) The pesticide, as formulated, has an acute dermal LD_{50} of 200 mg/kg or less;

(iii) The pesticide, as diluted for use, has an acute dermal LD_{50} of 16 g/kg or less;

(iv) The pesticide, as formulated, has an acute inhalation LC_{50} of 0.05 mg/liter or less, based upon a 4-hour exposure period;

(v) The pesticide, as formulated, is corrosive to the eye or causes corneal involvement or irritation persisting for more than 21 days;

(vi) The pesticide, as formulated, is corrosive to the skin (causes tissue destruction into the dermis and/or scarring); or

(vii) When used in accordance with label directions, or widespread and commonly recognized practice, the pesticide may cause significant subchronic toxicity, chronic toxicity, or delayed toxic effects on man, as a result of single or multiple exposures to the product ingredients or residues.

(c) *Criteria for hazard to non-target species*—(1) *All products.* A pesticide product intended for outdoor use will be considered for restricted use classification if:

(i) When used according to label directions, application results in residues of the pesticide, its metabolites, or its degradation products, in the diet of exposed mammalian wildlife, immediately after application, such that:

(A) The level of such residues equals or exceeds one-fifth of the acute dietary LC_{50}; or

(B) The amount of pesticide consumed in one feeding day (mg/kg/day) equals or exceeds one-fifth of the mammalian acute oral LD_{50};

(ii) When used according to label directions, application results, immediately after application, in residues of the pesticide, its metabolites or its degradation products, in the diet of exposed birds at levels that equal or exceed one-fifth of the avian subacute dietary LC_{50};

(iii) When used according to label directions, application results in residues of the pesticide, its metabolites or its degradation products, in water that equal or exceed one-tenth of the acute LC_{50} for non-target aquatic organisms likely to be exposed; or

(iv) Under conditions of label use or widespread and commonly recognized practice, the pesticide may cause discernible adverse effects on non-target organisms, such as significant mortality or effects on the physiology, growth, population levels or reproduction rates of such organisms, resulting from direct or indirect exposure to the pesticide, its metabolites or its degradation products.

(2) *Granular products.* In addition to the criteria of paragraph (c)(1) of this

section, a pesticide intended for outdoor use and formulated as a granular product will be considered for restricted use classification if:

(i) The formulated product has an acute avian or mammalian oral LD_{50} of 50 mg/kg or less as determined by extrapolation from tests conducted with technical material or directly with the formulated product; and

(ii) It is intended to be applied in such a manner that significant exposure to birds or mammals may occur.

(d) *Other evidence.* The Agency may also consider evidence such as field studies, use history, accident data, monitoring data, or other pertinent evidence in deciding whether the product or use may pose a serious hazard to man or the environment that can reasonably be mitigated by restricted use classification.

(e) *Alternative labeling language.* (1) If the Agency determines that a product meets one or more of the criteria of paragraphs (b) or (c) of this section, or if other evidence identified in paragraph (d) of this section leads the Agency to conclude that the product should be considered for restricted use classification, the Agency will then determine if additional labeling language would be adequate to mitigate the identified hazard(s) without restricted use classification. If the labeling language meets all the criteria specified in paragraph(e)(2) of this section, the product will not be classified for restricted use.

(2) The labeling will be judged adequate if it meets all the following criteria:

(i) The user, in order to follow label directions, would not be required to perform complex operations or procedures requiring specialized training and/or experience.

(ii) The label directions do not call for specialized apparatus, protective equipment, or materials that reasonably would not be available to the general public.

(iii) Failure to follow label directions in a minor way would result in few or no significant adverse effects.

(iv) Following directions for use would result in few or no significant adverse effects of a delayed or indirect nature through bioaccumulation, persistence, or pesticide movement from the original application site.

(v) Widespread and commonly recognized practices of use would not nullify or detract from label directions such that unreasonable adverse effects on the environment might occur.

§ 152.171 Restrictions other than those relating to use by certified applicators.

The Agency may by regulation impose restrictions on a product or class of products if it determines that:

(a) Without such restrictions, the product when used in accordance with warnings, cautions and directions for use or in accordance with widespread and commonly recognized practices of use may cause unreasonable adverse effects on the environment; and

(b) The decrease in risks as a result of restricted use would exceed the decrease in benefits as a result of restricted use.

§ 162.31 [Redesignated as 152.175]

10. Section 152.175 is redesignated from § 162.31, the section heading is revised to read as set forth below, and the section is added to Subpart I.

§ 152.175 Pesticides classified for restricted use.

* * * * *

11. Part 152 is amended by adding and reserving Subparts J and K.

Subparts J and K—[Reserved]

12. By adding Subpart L, to read as follows:

Subpart L—Intrastate Pesticide Products

Sec.

Subpart L—Intrastate Pesticide Products

§ 152.220 Scope.

This subpart applies to any intrastate pesticide product defined as a product:

(a) Which is distributed and sold solely within a single State, in accordance with a registration issued to the producer by that State; and

(b) For which a proper Notice of Application for Federal Registration (EPA Form 8570–8) was filed (in accordance with regulations codified in 40 CFR 162.17(d) on July 3, 1975) by October 4, 1975 (or by a later date as allowed by the Agency).

§ 152.225 Application for Federal registration.

(a) Each current intrastate producer who has submitted a "Notice of Application for Federal Registration" must, no later than July 31, 1988, submit a full application for Federal registration complying with the requirements of this Part 152.

(b) The Agency may, at any time before that date, require the producer of an intrastate product to submit an application for Federal registration of the product. If the Agency requires the submission of an application for registration of an intrastate product prior to July 31, 1988, the Agency will notify the producer of the intrastate product in writing, and will specify a date by which the application must be submitted.

(c) The Agency will require the producer of an intrastate product to submit an application for Federal registration if the intrastate product contains the same active ingredient as, and is intended for the same or a substantially similar end use as, a federally registered product that is subject to:

(1) A notice of special review in accordance with § 154.25 of this chapter;

(2) A notice under FIFRA sec. 3(c)(2)(B) requiring the submission of data in support of Federal registration;

(3) A regulation or notice classifying the product for restricted use under FIFRA sec. 3(d)(1)(C); or

(4) A notice requiring the Federal registrant to submit an application for reregistration of his product.

§ 152.230 Sale and distribution of unregistered intrastate pesticide products.

(a) An intrastate product which is not federally registered may continue to be sold or distributed solely within a single State, provided that:

(1) Such product complies with FIFRA sec. 12(a)(1)(D) and (E), in accordance with definitions contained in:

(i) FIFRA sec. 2(q)(1)(A) through (G); and

(ii) FIFRA sec. 2(q)(2)(A), (C)(i) through (iii), and (D).

(2) The producer of such product has submitted a timely application for Federal registration of the pesticide (by July 31, 1988, or earlier if notified by the Agency to do so);

(3) The Agency has not issued in the **Federal Register** a notice of denial of an application for registration of such product under FIFRA sec. 3(c)(6);

(4) The Agency has not issued a notice of intent to cancel or suspend any federally registered pesticide products containing the same active ingredient as, and intended for the same (or substantially similar) end uses as, such intrastate product; and

(5) The pesticide product is registered under the applicable State pesticide registration law.

(b) No person may distribute or sell an intrastate product after the date specified in a notice furnished in accordance with § 152.225(b) that requires submission of a full application for Federal registration by such date.

(c) No person may distribute or sell an intrastate product after July 31, 1988, unless he has submitted an application for full Federal registration in accordance with § 152.225. Distribution or sale of any such product will be considered a violation of FIFRA sec. 12(a)(1)(A).

PART 153—REGISTRATION POLICIES AND INTERPRETATIONS

II. In Part 153:

1. The authority citation for Part 153 is revised to read as follows:

Authority: 7 U.S.C. 136–136y.

2. The Part heading is revised to read as set forth above.

3. By adding Subparts G, H, and M, to read as follows; and by adding and reserving Subparts E and F, I and J, and K and L.

Subparts E and F [Reserved]

Subpart G—Determination of Active and Inert Ingredients

Sec.

Subpart H—Coloration and Discoloration of Pesticides

Subparts I, J, K, and L [Reserved]

Subpart M—Devices

Subparts E and F [Reserved]

Subpart G—Determination of Active and Inert Ingredients

§ 153.125 Criteria for determination of pesticidal activity.

(a) An ingredient will be considered an active ingredient if it is contained in a pesticide product and:

(1) The ingredient has the capability by itself, and when used as directed at the proposed use dilution, to function as a pesticide; or

(2) The ingredient has the ability to elicit or enhance a pesticidal effect in another compound whose pesticidal activity is substantially increased due to the interaction of the compounds. Compounds which function simply to enhance or prolong the activity of an active ingredient by physical action, such as stickers and other adjuvants, are not generally considered to be active ingredients.

(b) Normally the applicant will determine and state in his application whether an ingredient is active or inert with respect to pesticidal activity. The Agency, as part of its review of an application for registration, or in conjunction with the Registration Standard or Special Review process, may require any ingredient (including those listed in § 153.139), to be designated as an active ingredient if the Agency finds that it meets the criteria in paragraph (a) of this section. Conversely, the Agency may determine that any ingredient designated as active by an applicant is an inert ingredient if it fails to meet those criteria.

(c) If an applicant or registrant submits data to the Agency which demonstrates to the Agency's satisfaction that an ingredient listed in § 153.139 is pesticidally active according to the criteria of this section, the ingredient may be deemed to be an active ingredient in that registrant's product.

(d) If an ingredient is designated as an active ingredient, it must be identified in the label ingredients statement. If an ingredient is designated as an inert ingredient, it must be included as part of the total inert ingredients in the label ingredients statement.

(e) Designation of a substance as a pesticidally inert ingredient does not relieve the applicant or registrant of other requirements of FIFRA with respect to labeling of inert ingredients or submission of data, or from the requirements of the Federal Food, Drug, and Cosmetic Act with respect to tolerances or other clearance of ingredients.

§ 153.139 Substances determined to be pesticidally inert.

(a) *Antimicrobial products.* The Agency has concluded that the following ingredients normally have no independent pesticidal activity when included in antimicrobial products for the designated uses, and thus normally are properly classified as inert ingredients of such products, within the meaning of FIFRA sec. 2(m):

Substance	Uses
Acetone	Solvent.
Alkyl* amino betaine (*46 percent C_{12}, 24 percent C_{14}, 10 percent C_{16}, 6 percent C_{10}, 7 percent C_8, 5 percent C_{18}).	Corrosion inhibitor, surfactant.
Alkyl monoethanolamide	Emulsifier.
Aluminum chloride	Detergent.
Aluminum hyroxybenzenesulfate sulfonate.	Emulsifier.
Aluminum powder	Filler.
Aluminum carbonate	Detergent.
Ammonium citrate	Sequestrant.
Ammonium lauryl sulfonate	Emulsifier.
Ammonium oleate	Detergent, emulsifier.
Ammonium oxalate	Detergent.
Amyl acetate	Diluent.
Borax	Detergent.
Butyl alcohol, tertiary	Solvent, odorant.
Carbon	Carrier, absorbent.
Castor oil	Emulsifier.
Citric acid	Sequestrant.
Diethanolamine dodecylbenzene sulfonate.	Detergent.
Sodium oleate	Emulsifier.
Dimethyl phthalate	Perfume.
Disodium monoethanolamine phosphate.	Emulsifier.
Dodecyl benzene sulfonic acid	Detergent.
Essential oils	Perfume.
Ethanol (ethyl alcohol)	Solvent, except in tinctures or where sole or major ingredient.
Ethanolamine	Emulsifier.
Ethanolamine dodecylbenzene sulfonate.	Detergent.
Ethoxylated lanolin	Ointment base.
Ethylenediamine	Emulsifier.
Ethylenediaminetetraacetic acid (including all salts and derivatives).	Sequestrant.
Fumaric acid	Sequestrant.
Gluconic acid	Buffer.
Isooctyl phenoxy polyethoxy ethanol	Surfactant.
Isopropanol (isopropyl alcohol)	Solvent, except in tinctures, or where sole or major ingredient.
Isopropyl myristate	Solvent.
Juniper tar	Odorant.
Lauryl alcohol	Detergent, odorant.
Lauryl methacrylate	Emulsifier.
Limonene	Odorant, perfume.
Magnesium chloride	Builder.
Magnesium lauryl sulfate	Detergent.
Magnesium silicate	Odor absorbent.
Menthol	Perfume.
Methanol (methyl alcohol)	Solvent, except in tinctures, or where sole or major ingredient.
Methyl ethyl ketone	Solvent.
Methyl salicylate	Perfume, odorant.
Mineral oil, mineral seal oil, or white mineral oil.	Lubricant.
Monoethanolamides of the fatty acids of coconut oil.	Emulsifier.
Monosodium phosphate	Emulsifier, buffer.
Morpholine	Corrosion inhibitor.
Nonylphenoxypolyethoxyethanol	Surfactant.
Octylphenol	Nonionic surfactant.
Oil of citronella	Perfume, odorant.
Oil of eucalyptus	Perfume.
Oil of lemongrass	Perfume.
Oleic acid	Solvent.

Substance	Uses
Petroleum distillate, oils, hydrocarbons, also paraffinic hydrocarbons, aliphatic hydrocarbons, paraffinic oil.	Lubricant, solvent.
Polyoxyethylene sorbitol, mixed ethyl ester of.	Emulsifier.
Polyvinylpyrrolidone	Emulsifier.
Potassium bisulfate	Builder.
Potassium carbonate	Detergent.
Potassium dodecylbenzenesulfonate	Anionic detergent.
Potassium laurate	Emulsifier.
Potassium myristate	Emulsifier.
Potassium *N*-(*s*-(nitroethyl)benzyl) ethylenediamine.	Emulsifier.
Potassium phosphate, tribasic	Sequestrant.
Potassium ricinoleate	Emulsifier.
Potassium toluene sulfonate	Detergent.
Potassium xylene sulfonate	Detergent.
Propanol (propyl alcohol)	Solvent, except in tinctures or where sole or major ingredient.
Soap	Detergent.
Sodium acetate	Buffer.
Sodium alkyl (100 percent C_9): benzene sulfonate.	Detergent.
Sodium bicarbonate	Detergent.
Sodium carbonate	Detergent.
Sodium chloride	Builder.
Sodium decylbenzene sulfonate	Detergent.
Sodium diacetate	Sequestrant.
Sodium dihydroxyethylglycine	Chelate, buffer.
Sodium diisopropylnaphthalene sulfonate.	Detergent.
Sodium di(monoethanolamine) phosphate.	Emulsifier.
Sodium dodecylbenzene sulfonate (may be active as a sanitizer in dishwashing formulations).	Detergent.
Sodium dodecyl diphenyl oxide sulfonate.	Perfume.
Sodium glycolate	Sequestrant.
Sodium laurate	Detergent.
Sodium *N*-lauroylsarcosinate	Detergent.
Sodium lauryl sulfate	Detergent.
Sodium metasilicate	Detergent.
Sodium *N*-methyl-*N* oleyltaurate	Emulsifier.
Sodium mono and dimethyl naphthalene sulfonate.	Detergent.
Sodium oleate	Emulsifier.
Sodium phosphate	Emulsifier, buffer.
Sodium salt of turkey red oil	Emulsifier.
Sodium sesquicarbonate	Detergent.
Sodium silicate	Detergent.
Sodium sulfate	Detergent.
Sodium sulfonated oleic acid	Emulsifier.
Sodium thiosulfate	Builder.
Sodium toluene sulfonate	Detergent.
Sodium tripolyphosphate	Sequestrant.
Sodium xylene sulfonate	Detergent.
Tetrapotassium pyrophosphate	Sequestrant.
Tetrasodium pyrophosphate	Sequestrant.
Toluene sulfonic acid	Emulsifier.
1,1,1-Trichloroethane	Diluent.
Triethanolamine	Emulsifier.
Triethanolamine dodecylbenzene sulfonate.	Detergent.
Triethanolamine laurate	Emulsifier.
Triethanolamine lauryl sulfate	Emulsifier.
Triisopropanolamine	Emulsifier.
Triisopropylamine	Emulsifier.
Trisodium phosphate	Detergent.
Turkey red oil	Emulsifier
Undecylenic acid	Perfume.
Xylene	Solvent.
Zirconium oxide	Dye.

(b) [Reserved]

(c) *Limitation.* This statement of policy does not bind decision makers in a formal adjudicatory proceeding under FIFRA sec. 3, 6, or 14. If this section becomes an issue in any such proceeding, the decision makers in that proceeding will make an independent judgment whether to adhere to it or not.

Subpart H—Coloration and Discoloration of Pesticides

§ 153.140 General.

Section 25(c)(5) of the Act authorizes the Administrator to prescribe regulations requiring coloration or discoloration of any pesticide if he determines that such requirement is feasible and necessary for the protection of health and the environment. The Munsell Manual of Color, or its equivalent, shall be used as a color standard. References in §§ 153.145 and 153.150 to hues, values, chromas and neutral lightness refer to the Munsell Manual of Color.

§ 153.142 Coloring agent.

The coloring agent must produce a uniformly colored product not subject to change beyond the minimum requirements specified in this subpart during ordinary conditions of distribution and storage and must not cause the product to be ineffective or result in adverse effects on non-target organisms when used as directed.

§ 153.145 Arsenicals and barium fluosilicate.

Standard lead arsenate, basic lead arsenate, calcium arsenate, magnesium arsenate, zinc arsenate, zinc arsenite, and barium fluosilicate shall be colored any hue, except the yellow-reds and yellows, having a value of not more than 8 and a chroma of not less than 4, or shall be discolored to a neutral lightness value not over 7.

§ 153.150 Sodium fluoride and sodium fluosilicate.

(a) Products containing sodium fluoride and sodium fluosilicate shall be colored blue or green having a value of not more than 2 and a chroma of not less than 4, or shall be discolored to a neutral lightness value not over 7.

(b) A product containing sodium fluoride shall be exempt from the requirements of this section if:

(1) It is intended and labeled for use as a fungicide solely in the manufacture or processing of rubber, glue, or leather goods.

(2) Coloration of the pesticide in accordance with these requirements will be likely to impart objectionable color characteristics to the finished goods;

(3) The pesticide will not be present in such finished goods in sufficient quantities to cause injury to any person; and

(4) The pesticide will not come into the hands of the public except after incorporation into such finished goods.

§ 153.155 Seed treatment products.

(a) Pesticide products intended for use in treating seeds must contain an EPA-approved dye to impart an unnatural color to the seed, unless appropriate tolerances or other clearances have been established under the Federal Food, Drug and Cosmetic Act for residues of the pesticide.

(b) The following products are exempt from the requirement of paragraph (a) of this section:

(1) Products intended and labeled for use solely by commercial seed treaters, provided that the label bears a statement requiring the user to add an EPA-approved dye with the pesticide during the seed treatment process.

(2) Products intended and labeled for use solely as at-planting or hopper box treatments.

(3) Products which are gaseous in form or are used as fumigants.

(c) EPA-approved dyes are those listed in § 180.1001 (c) and (d) of this chapter. Upon written request additional dyes will be considered for inclusion in this listing.

§ 153.158 Exceptions.

(a) Notwithstanding other provisions of this subpart, the Agency may exempt a product from the requirements of this subpart, or may permit other colors to be used for any particular purpose, if it determines that use of the prescribed color is not feasible for such purpose and is not necessary for the protection of health and the environment.

(b) Any pesticide product specified in this subpart which is intended solely for use by a textile manufacturer or commercial laundry, cleaner or dryer as a mothproofing agent, and which would not be suitable for such use if colored, and which will not come into the hands of the public except when incorporated into a fabric, is exempt from the requirements of this subpart.

Subparts I, J, K, and L—[Reserved]

Subpart M—Devices

§ 153.240 Requirements for devices.

(a) A device is defined as any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than a

bacterium, virus, or other microorganism on or in living man or living animals) but not including equipment used for the application of pesticides (such as tamper-resistant bait boxes for rodenticides) when sold separately therefrom.

(b) A device is not required to be registered under FIFRA sec. 3. The Agency has issued a policy statement concerning its authority and activities with respect to devices, which was published in the Federal Register of November 19, 1976 (41 FR 51065). A device is subject to the requirements set forth in:

(1) FIFRA sec. 2(q)(1) and Part 156 of this chapter, with respect to labeling;

(2) FIFRA sec. 7 and Part 167 of this chapter, with respect to establishment registration and reporting;

(3) FIFRA sec. 8 and Part 169 of this chapter, with respect to books and records;

(4) FIFRA sec. 9, with respect to inspection of establishments;

(5) FIFRA sec. 12, 13, and 14, with respect to violations, enforcement activities, and penalties;

(6) FIFRA sec. 17, with respect to import and export of devices;

(7) FIFRA sec. 25(c)(3), with respect to child-resistant packaging; and

(8) FIFRA sec. 25(c)(4), with respect to the Agency's authority to declare devices subject to certain provisions of the Act.

PART 156—LABELING REQUIREMENTS FOR PESTICIDES AND DEVICES

§ 162.10 [Redesignated as §156.10]

III. 1. Part 156, entitled Labeling Requirements for Pesticides and Devices, is added, consisting of § 156.10, which is redesignated from §162.10.

2. The authority citation for Part 156 reads as follows:

Authority: 7 U.S.C. 136–136y.

PART 158—DATA REQUIREMENTS FOR REGISTRATION

IV. In Part 158:

1. The authority citation for Part 158 is revised to read as follows:

Authority: 7 U.S.C. 136–136y.

2. By adding §§ 158.32, 158.33, and 158.34 to Subpart A to read as follows:

§ 158.32 Format of data submission.

(a) *Transmittal document.* All data submitted at the same time and for review in support of a single administrative action (e.g., an application for registration, reregistration, experimental use permit, or in response to a requirement for data under the authority of FIFRA sec. 3(c)(2)(B), must be accompanied by a single transmittal document including the following information:

(1) The identity of the submitter, or the identity of each joint submitter and of the agent for joint submitters;

(2) The date of the submission;

(3) The identification of the Agency action in support of which the data are being submitted, such as the registration number or file symbol, petition number, experimental use permit number, or registration standard review; and

(4) A bibliography of all specific documents included in the submission and covered by the transmittal.

(b) *Individual studies.* (1) All data must be submitted in the form of individual studies. Unless otherwise specified by the Agency, each study should address a single data requirement, and be listed separately in the bibliography.

(2) Each study must include the following elements in addition to the study itself:

(i) A title page, as described in paragraph (c) of this section;

(ii) A Statement of Data Confidentiality Claims and, if desired, a Supplemental Statement of Data Confidentiality Claims, in accordance with § 158.33;•

(iii) A certification with respect to Good Laboratory Practice standards, if required by § 160.12 of this chapter;

(iv) If the original study is not in the English language, a complete and accurate English translation under the same cover; and

(v) If the study is of a type listed in § 158.34(b), the statement prescribed by paragraph (c) of that section.

(3) Three identical copies of each study must be submitted. If the study is submitted in conjunction with a pending Special Review or Registration Standard under development, four copies must be submitted. Three copies must be identical and must conform to the requirements of § 158.33 with respect to claims of confidentiality. The fourth copy will be placed in the public docket and must conform to the requirements of § 154.15(c) of this chapter or 155.30(c) of this chapter with respect to claimed confidential business information.

(4) All copies must be in black ink on uniform pages of white, 8½ × 11 inch paper. Copies must have high contrast and good resolution for microfilming. Frayed or oversize pages and glued bindings are not acceptable.

(c) *Contents of title page.* Each individual study must have a title page bearing the following identifying information:

(1) The title of the study, including identification of the substance(s) tested and the test name or data requirement addressed;

(2) The author(s) of the study;

(3) The date the study was completed;

(4) If the study was performed in a laboratory, the name and address of the laboratory and any laboratory project numbers or other identifying codes;

(5) If the study is a commentary on or supplement to another previously submitted study, full identification of the other study with which it should be associated in review; and

(6) If the study is a reprint of a published document, all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and date of publication.

(d) *EPA identification number.* EPA will assign each study an EPA Master Record Identification (MRID) number, and will promptly notify the submitter of the number assigned. This number should be used in all further communications with the Agency about the study.

(e) *Reference to previously submitted data.* Data which previously have been submitted need not be resubmitted unless resubmission is specifically requested by the Agency. If an applicant or registrant wishes the Agency to consider such data in the review of an Agency action, he should cite the data by providing:

(1) The title or adequate description of the study;

(2) The transmittal information required by paragraph (a) (1), (2), and (3) of this section; and

(3) The MRID number assigned in accordance with paragraph (d) of this section.

§ 158.33 Procedures for claims of confidentiality of data.

(a) *General.* A data submitter must clearly identify any information which he claims is entitled to confidential treatment under FIFRA sec. 10. The procedures in this section must be followed to assert a claim of confidentiality.

(b) *Claims of confidentiality for information described by FIFRA sec. 10(d)(1) (A), (B), and (C).* Any information claimed to be confidential under FIFRA sec. 10(d)(1) (A) through (C) must be submitted in accordance with the following procedures:

(1) The information must be contained in a separate attachment to the study. If any information is included in the body of the study rather than in the confidential attachment, the submitter waives a claim of confidentiality for

such information under FIFRA sec. 10(d)(1) (A), (B), or (C).

(2) The attachment must have a cover page which is clearly marked to indicate that the material contained in the attachment falls within the scope of FIFRA sec. 10(d)(1) (A), (B), or (C).

(3) Each item in the attachment must be numbered. For each item, the submitter must cite the applicable portion of FIFRA sec. 10(d)(1) (A), (B), or (C) on which the claim of confidentiality is based. In addition, for each item, the submitter must provide a list of page numbers in the study where the item is cited (i.e., identified by number).

(4) Each item in the attachment must be referenced in the body of the study by its number in the attachment.

(5) The following statement must appear on the Statement of Data Confidentiality Claims:

Information claimed confidential on the basis of its falling within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

The statement must bear the name, title, and signature of the submitter or his properly designated agent, and the date of signature.

(c) *No claim of confidentiality under FIFRA sec. 10(d)(1)(A), (B), or (C).* If no claim of confidentiality is being made for information described by FIFRA sec. 10(d)(1)(A), (B), or (C), or if such information is not contained in the body of the study, the Statement of Data Confidentiality Claims must include the following statement:

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C).

This statement must bear the name, title and signature of the submitter or his properly designated agent, and the date of signature.

(d) *Claim of confidentiality for information not described by FIFRA sec. 10(d)(1) (A), (B), or (C).* Any information not described by FIFRA sec. 10(d)(1) (A), (B), or (C) for which a claim of confidentiality is made must be submitted in accordance with the following procedures:

(1) The information must be clearly marked in the body of the study as being claimed confidential.

(2) A separate Supplemental Statement of Data Confidentiality Claims must be submitted identifying by page and line number the location within the study of each item claimed confidential, and stating the basis for the claim.

(3) The Supplemental Statement of Data Confidentiality Claims must bear the name, title, and signature of the submitter or his properly designated agent, and the date of signature.

§ 158.34 Flagging of studies for potential adverse effects.

(a) Any person who submits a study of a type listed in paragraph (b) of this section to support an application for new or amended registration, or to satisfy a requirement imposed under FIFRA sec. 3(c)(2)(B), must submit with the study a statement in accordance with paragraph (c) of this section.

(b) The following table indicates that study types and the criteria to be applied to each. Column 1 lists the study types by name. Column 2 lists the associated Pesticide Assessment Guideline number. Column 3 lists the criteria applicable to each type of study. Column 4 lists the reporting code to be included in the statement specified in § 158.34(c) when any criterion is met or exceeded.

TABLE.—FLAGGING CRITERIA

Toxicity studies	Pesticide assessment guidelines No.	Criteria	Reporting code
Oncogenicity [or combined oncogenicity/chronic feeding study]	83-2	Treated animals show any of the following:	
or			
Subchronic feeding study	82-1	An incidence of neoplasms in male or female animals which increases with dose;	1
		or	
		A statistically significant ($p < 0.05$) incidence of any type of neoplasm in any test group (male or female animals at any dose level) compared to concurrent control animals of the same sex;	2
		or	
		An increase in any type of uncommon or rare neoplasms in any test group (male or female animals at any dose level) compared to concurrent control animals	3
		or	
		A decrease in the time to development of any type of neoplasms in any test group (male or female animals at any dose level) compared to concurrent control animals	4
Teratogenicity	83-3	When compared with concurrent controls, treated animals show a dose-related increase in malformations (or deaths) on a litter basis in the absence of significant maternal toxicity at the same dose levels	5
Neurotoxicity	81-7	When compared with controls, treated animals show a response indicative of acute delayed neurotoxicity	6
Chronic feeding study or combined chronic feeding/oncogenicity study	83-1	Cholinesterase inhibition NOEL less than 10 times the current existing ADI	7
		or	
		General (systemic) toxicity NOEL less than 100 times the current existing ADI	8
Reproduction study	83-4	Reproductive effects NOEL less than 100 times the current ADI	9
Subchronic feeding study	82-1	Cholinesterase inhibition NOEL less than 100 times the current existing ADI	10
		or	
		General (systemic) toxicity NOEL less than 1000 times the current existing ADI	11

(c) *Identification of studies.* For each study of a type identified in paragraph (b) of this section, the applicant (or registrant in the case of information submitted under FIFRA sec. 3(c)(2)(B)) shall include the appropriate one of the following two statements, together with the signature of the authorized representative of the company, and the date of signature:

(1) "I have applied the criteria of 40 CFR 158.34 for flagging studies for potential adverse effects to the results of the attached study. This study neither meets nor exceeds any of the applicable criteria."

(2) "I have applied the criteria of 40 CFR 158.34 for flagging studies for potential adverse effects to the results of the attached study. This study meets or exceeds the criteria numbered [insert all applicable reporting codes.]"

(Approved by the Office of Management and Budget under Control Numbers 2070–0057 and 2070–0060)

Subpart B—How to Use Data Tables

3. By revising the title of Subpart B to read as set forth above.

4. By revising paragraph (a) of § 158.100 to read as follows:

§ 158.100 How to determine registration data requirements.

* * * * *

(a) Refer to Subparts C and D (§§ 158.150 through 158.740). These subparts describe the data requirements, including data tables for each subject area. The corresponding subdivisions in the Pesticide Assessment Guidelines are listed in § 158.108.

* * * * *

§ 158.105 [Amended]

5. a. By removing and reserving paragraph (b) of § 158.105.

§ 158.105 [Redesignated as § 158.202]

b. By redesignating § 158.105 under Subpart B as § 158.202 under new Subpart D.

§§ 158.108, 158.110, 158.112, and 158.120 [Removed]

6. By removing §§ 158.108, 158.110, 158.112, and 158.120.

§ 158.115 [Redesignated as § 158.108]

7. By revising and redesignating § 158.115 as § 158.108, to read as follows:

§ 158.108 Relationship of Pesticide Assessment Guidelines to data requirements.

The Pesticide Assessment Guidelines contain the standards for conducting acceptable tests, guidance on evaluation and reporting of data, definition of terms, further guidance on when data are required, and examples of acceptable protocols. They are available through the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703–487–4650). The following Subdivisions of the Pesticide Assessment Guidelines, referenced to the appropriate sections of this part, are currently available:

Subdivision	Title	NTIS order no.	Corresponding section(s) in this part
D	Product Chemistry	PB83–153890	§§ 158.150–158.190
E	Hazard Evaluation: Wildlife and Aquatic Organisms	PB83–153908	§ 158.490
F	Hazard Evaluation: Humans and Domestic Animals	PB83–153916	§ 158.340
G	Product Performance	PB83–153924	§ 158.640
I	Experimental Use Permits	PB83–153932	§§ 158.20–158.740
J	Hazard Evaluation: Nontarget Plants	PB83–153940	§ 158.540
K	Reentry Protection	PB85–120962	§ 158.390
L	Hazard Evaluation: Nontarget Insect	PB83–153957	§ 158.590
M	Biorational Pesticides	PB83–153965	§§ 158.690–158.740
N	Environmental Fate	PB83–153973	§ 158.290
O	Residue Chemistry	PB83–153961	§ 158.240
R	Spray Drift Evaluation	PB84–189216	§ 158.440

8. By redesignating §§ 158.125, 158.130, 158.135, 158.140, 158.142, 158.145, 158.150, 158.155, 158.160, 158.165, and 158.170 under Subpart B as §§ 158.240, 158.290, 158.340, 158.390, 158.440, 158.490, 158.540, 158.590, 158.640, 158.690, and 158.740, respectively, under new Subpart D.

9. By adding new Subpart C, to read as follows:

Subpart C—Product Chemistry Data Requirements

Sec.

Subpart C—Product Chemistry Data Requirements

§ 158.150 General.

(a) *Applicability.* This subpart describes the product chemistry data that are required to support the registration of each pesticide product. The information specified in this subpart must be submitted with each application for new or amended registration or for reregistration, if it has not been submitted previously or if the previously submitted information is not complete and accurate. References in this subpart to the "applicant" include the registrant if the information is required for a registered product.

(b) *Purpose*—(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 starting materials, production or formulating process, possible formation of impurities, results of preliminary analysis of product samples, a description of analytical methods to identify and quantify ingredients and validation data for such methods. In addition, an applicant is required to certify the limits for ingredients of his product.

(ii) Product composition data are compared to the composition of materials used in required testing under Subpart D of this part. This comparison indicates which components of a pesticide product have been evaluated by a particular study, and might lead to a conclusion that another study is needed. Based on conclusions concerning the product's composition and its toxic properties, appropriate use restrictions, labeling requirements, or special packaging requirements may be imposed.

(iii) Product composition data, including certified limits of components, are used to determine whether a product is "identical or substantially similar" to

another product or "differs only in ways that do not significantly increase the risk of unreasonable adverse effects on the environment" (FIFRA sec. 3(c)(7)(A)). In nearly every case, this determination involves a comparison of the composition of an applicant's product with that of currently registered products.

(2) *Certified limits.* Certified limits required by § 158.175 are used in two ways. First, the Agency considers the certified limits in making the registration determination required by sections 3(c)(5), 3(c)(7) and 3(d) of the Act and making other regulatory decisions required by the Act. Second, the Agency may collect commercial samples of the registered products and analyze them for the active ingredient(s), inert ingredients, or impurities determined by the Agency to be toxicologically significant. If, upon analysis the composition of such a sample is found to differ from that certified, the results may be used by the Agency in regulatory actions under FIFRA sec. 12(a)(1)(C) and other pertinent sections.

(3) *Nominal concentration.* The nominal concentration required by § 158.155 is the amount of active ingredient that is most likely to be present in the product when produced. Unlike the certified limits, which are the outer limits of the range of the product's ingredients and thus are present only in a small proportion of the products, the nominal concentration is the amount that typically is expected to result from the applicant's production or formulating process. The nominal concentration together with production process information is used to gauge the acceptability of the certified limits presented by the applicant. The nominal concentration is used by the Agency as the basis for enforceable certified limits if the applicant has chosen not to specify certified limits of his own (thereby agreeing to abide by the standard limits in § 158.175).

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

(ii) Certain information (e.g., color, odor, physical state) is needed for 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 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, measures can be taken to ensure that lids, liners, seams or container sides will not be damaged and cause the contents to leak during storage, transport, handling, or use. The storage stability study provides data on change (or lack of change) in product composition over time. If certain ingredients decompose, other new chemicals are formed whose toxicity and other characteristics must be considered.

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

§ 158.153 Definitions.

The following terms are defined for the purposes of this subpart:

(a) "Active ingredient" means any substance (or group of structurally similar substances, if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant within the meaning of FIFRA sec. 2(a).

(b) "End use product" means a pesticide product whose labeling

(1) Includes directions for use of the product (as distributed or sold, or after combination by the user with other substances) for controlling pests or defoliating, desiccating or regulating growth of plants, and

(2) Does not state that the product may be used to manufacture or formulate other pesticide products.

(c) "Formulation" means

(1) The process of mixing, blending, or dilution of one or more active ingredients with one or more other active or inert ingredients, without an intended chemical reaction, to obtain a manufacturing use product or an end use product, or

(2) The repackaging of any registered product.

(d) "Impurity" means any substance (or group of structurally similar substances if specified by the Agency) in a pesticide product other than an active ingredient or an inert ingredient, including unreacted starting materials, side reaction products, contaminants, and degradation products.

(e) "Impurity associated with an active ingredient" means:

(1) Any impurity present in the technical grade of active ingredient; and

(2) Any impurity which forms in the pesticide product through reactions between the active ingredient and any other component of the product or packaging of the product.

(f) "Inert ingredient" means any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product.

(g) "Integrated system" means a process for producing a pesticide product that:

(1) Contains any active ingredient derived from a source that is not an EPA-registered product; or

(2) Contains any active ingredient that was produced or acquired in a manner that does not permit its inspection by the Agency under FIFRA sec. 9(a) prior to its use in the process.

(h) "Manufacturing use product" means any pesticide product other than an end use product. A product may consist of the technical grade of active ingredient only, or may contan inert ingredients, such as stabilizers or solvents.

(i) "Nominal concentration" means the amount of an ingredient which is expected to be present in a typical sample of a pesticide product at the time the product is produced, expressed as a percentage by weight.

(j) "Starting material" means a substance used to synthesize or purify a technical grade of active ingredient (or the practical equivalent of the technical grade ingredient if the technical grade cannot be isolated) by chemical reaction.

(k) "Technical grade of active ingredient" means a material containing an active ingredient:

(1) Which contains no inert ingredient, other than one used for purification of the active ingredient; and

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

§ 158.155 Product composition.

Information on the composition of the pesticide product must be furnished. The information required by paragraphs (a), (b) and (f) of this section must be provided for each product. In addition, if the product is produced by an integrated system, the information on impurities required by paragraphs (c) and (d) must be provided.

(a) *Active ingredient.* The following information is required for each active ingredient in the product:

(1) If the source of any active ingredient in the product is an EPA-registered product:

(i) The chemical and common name (if any) of the active ingredient, as listed on the source product.

(ii) The nominal concentration of the active ingredient in the product, based upon the nominal concentration of active ingredient in the source product.

(iii) Upper and lower certified limits of the active ingredient in the product, in accordance with § 158.175.

(2) If the source of any active ingredient in the product is not an EPA-registered product:

(i) The chemical name according to Chemical Abstracts Society nomenclature, the CAS Registry Number, and any common names.

(ii) The molecular, structural, and empirical formulae, and the molecular weight or weight range.

(iii) The nominal concentration.

(iv) Upper and lower certified limits in accordance with § 158.175.

(v) The purpose of the ingredient in the formulation.

(b) *Inert ingredients.* The following information is required for each inert ingredient (if any) in the product:

(1) The chemical name of the ingredient according to Chemical Abstracts Society nomenclature, the CAS Registry Number, and any common names (if known). If the chemical identity or chemical composition of an ingredient is not known to the applicant because it is proprietary or trade secret information, the applicant must ensure that the supplier or producer of the ingredient submits to the Agency (or has on file with the Agency) information on the identity or chemical composition of the ingredient. Generally, it is not required that an applicant know the identity of each ingredient in a mixture that he uses in his product. However, in certain circumstances, the Agency may require that the applicant know the identity of a specific ingredient in such a mixture. If the Agency requires specific knowledge of an ingredient, it will notify the applicant in writing.

(2) The nominal concentration in the product.

(3) Upper and lower certified limits in accordance with § 158.175.

(4) The purpose of the ingredient in the formulation.

(c) *Impurities of toxicological significance associated with the active ingredient.* For each impurity associated with the active ingredient that is determined to be toxicologically significant, the following information is required:

(1) Identification of the ingredient as an impurity.

(2) The chemical name of the impurity.

(3) The nominal concentration of the impurity in the product.

(4) A certified upper limit, in accordance with § 158.175.

(d) *Other impurities associated with the active ingredient.* For each other impurity associated with an active ingredient that was found to be present in any sample at a level equal to or greater than 0.1 percent by weight of the technical grade active ingredient, the following information is required:

(1) Identification of the ingredient as an impurity.

(2) Chemical name of the impurity.

(3) The nominal concentration of the impurity in the final product.

(e) *Impurities associated with an inert ingredient* [Reserved].

(f) *Ingredients that cannot be characterized.* If the identity of any ingredient or impurity cannot be specified as a discrete chemical substance (such as mixtures that cannot be characterized or isomer mixtures), the applicant must provide sufficient information to enable EPA to identify its source and qualitative composition.

§ 158.160 Description of materials used to produce the product.

The following information must be submitted on the materials used to produce the product:

(a) *Products not produced by an integrated system.*

(1) For each active ingredient that is derived from an EPA-registered product:

(i) The name of the EPA-registered product.

(ii) The EPA registration number of that product.

(2) For each inert ingredient:

(i) Each brand name, trade name, or other commercial designation of the ingredient.

(ii) All information that the applicant knows (or that is reasonably available to him) concerning the composition (and, if requested by the Agency, chemical and physical properties) of the ingredient, including a copy of technical specifications, data sheets, or other documents describing the ingredient.

(iii) If requested by the Agency, the name and address of the producer of the ingredient or, if that information is not known to the applicant, the name and address of the supplier of the ingredient.

(b) *Products produced by an integrated system.* (1) The information required by paragraph (a)(1) of this section concerning each active ingredient that is derived from an EPA-registered product (if any).

(2) The following information concerning each active ingredient that is not derived from an EPA-registered product:

(i) The name and address of the producer of the ingredient (if different from the applicant).

(ii) Information on each starting material used to produce the active ingredient, as follows:

(A) Each brand name, trade name, or other commercial designation of the starting material.

(B) The name and address of the person who produces the starting material or, if that information is not known to the applicant, the name and address of each person who supplies the starting material.

(C) All information that the applicant knows (or that is reasonably available to him) concerning the composition (and if requested by the Agency, chemical or physical properties) of the starting material, including a copy of all technical specifications, data sheets, or other documents describing it.

(3) The information required by paragraph (a)(2) of this section concerning each inert ingredient.

(c) *Additional information.* On a case-by-case basis, the Agency may require additional information on substances used in the production of the product.

§ 158.162 Description of production process.

If the product is produced by an integrated system, the applicant must submit information on the production (reaction) processes used to produce the active ingredients in the product. The applicant must also submit information on the formulation process, in accordance with § 158.165.

(a) Information must be submitted for the current production process for each active ingredient that is not derived from an EPA-registered product. If the production process is not continuous (a single reaction process from starting materials to active ingredient), but is accomplished in stages or by different

producers, the information must be provided for each such production process.

(b) The following information must be provided for each process resulting in a separately isolated substance:

(1) the name and address of the producer who uses the process, if not the same as the applicant.

(2) A general characterization of the process (e.g., whether it is a batch or continuous process).

(3) A flow chart of the chemical equations of each intended reaction occurring at each step of the process, the necessary reaction conditions, and the duration of each step and of the entire process.

(4) The identity of the materials used to produce the product, their relative amounts, and the order in which they are added.

(5) A description of the equipment used that may influence the composition of the substance produced.

(6) A description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process to affect the composition of the substance produced, and the limits that are maintained.

(7) A description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced).

(8) A description of the procedures used to assure consistent composition of the substance produced, e.g., calibration of equipment, sampling regimens, analytical methods, and other quality control methods.

§ 158.165 Description of formulation process.

The applicant must provide information on the formulation process of the product (unless the product consists solely of a technical grade of active ingredient), as required by the following sections:

(a) Section 158.162(b)(2), pertaining to characterization of the process.

(b) Section 158.162(b)(4), pertaining to ingredients used in the process.

(c) Section 158.162(b)(5), pertaining to process equipment.

(d) Section 158.162(b)(6), pertaining to the conditions of the process.

(e) Section 158.162(b)(8), pertaining to quality control measures.

§ 158.167 Discussion of formation of impurities.

The applicant must provide a discussion of the impurities that may be present in the product, and why they may be present. The discussion should be based on established chemical theory and on what the applicant knows about the starting materials, technical grade of active ingredient, inert ingredients, and production or formulation process. If the applicant has reason to believe that an impurity that EPA would consider toxicologically significant may be present, the discussion must include an expanded discussion of the possible formation of the impurity and the amounts at which it might be present. The impurities which must be discussed are the following, as applicable:

(a) *Technical grade active ingredients and products produced by an integrated system.* (1) Each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the applicant.

(2) Each other impurity which the applicant has reason to believe may be present in his product at any time before use at a level equal to or greater than 0.1 percent (1000 ppm) by weight of the technical grade of the active ingredient, based on what he knows about the following:

(i) The composition (or composition range) of each starting material used to produce his product.

(ii) The impurities which he knows are present (or believes are likely to be present) in the starting materials, and the known or presumed level (or range of levels) of those impurities.

(iii) The intended reactions and side reactions which may occur in the production of the product, and the relative amounts of byproduct impurities produced by such reactions.

(iv) The possible degradation of the ingredients in the product after its production but prior to its use.

(v) Post-production reactions between the ingredients in the product.

(vi) The possible migration of components of packaging materials into the pesticide.

(vii) The possible carryover of contaminants from use of production equipment previously used to produce other products or substances.

(viii) The process control, purification and quality control measures used to produce the product.

(b) *Products not produced by an integrated system.* Each impurity associated with the active ingredient which the applicant has reason to believe may be present in the product at any time before use at a level equal to or greater than 0.1 percent (1000 ppm) by weight of the product based on what he knows about the following:

(1) The possible carryover of impurities present in any registered product which serves as the source of any of the product's active ingredients. The identity and level of impurities in the registered source need not be discussed or quantified unless known to the formulator.

(2) The possible carryover of impurities present in the inert ingredients in the product.

(3) Possible reactions occurring during the formulation of the product between any of its active ingredients, between the active ingredients and inert ingredients, or between the active ingredients and the production equipment.

(4) Post-production reactions between any of the product's active ingredients and any other component of the product or its packaging.

(5) Possible migration of packaging materials into the product.

(6) Possible contaminants resulting from earlier use of equipment to produce other products.

(c) *Expanded discussion.* On a case-by-case basis, the Agency may require an expanded discussion of information of impurities:

(1) From other possible chemical reactions;

(2) Involving other ingredients; or

(3) At additional points in the production or formulation process.

§ 158.170 Preliminary analysis.

(a) If the product is produced by an integrated system, the applicant must provide a preliminary analysis of each technical grade of active ingredient contained in the product to identify all impurities present at 0.1 percent or greater of the TGAI. The preliminary analysis should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substance are intended.

(b) Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided. If the technical grade of active ingredient cannot be isolated, a statement of the composition of the practical equivalent of the technical grade of active ingredient must be submitted.

§ 158.175 Certified limits.

The applicant must propose certified limits for the ingredients in the product. Certified limits become legally binding limits upon approval of the application. Certified limits will apply to the product from the date of production to date of use, unless the product label bears a statement prohibiting use after a certain date, in which case the certified limits will apply only until that date.

(a) *Ingredients for which certified limits are required.* Certified limits are required on the following ingredients of a pesticide product:

(1) An upper and lower limit for each active ingredient.

(2) An upper and lower limit for each inert ingredient.

(3) If the product is a technical grade of active ingredient or is produced by an integrated system, an upper limit for each impurity of toxicological significance associated with the active ingredient and found to be present in any sample of the product.

(4) On a case-by-case basis, certified limits for other ingredients or impurities as specified by EPA.

(b) *EPA determination of certified limits for active and inert ingredients.* (1) Unless the applicant proposes different limits as provided in paragraph (c) of this section, the upper and lower certified limits for active and inert ingredients will be determined by EPA. EPA will calculate the certified limits on the basis of the nominal concentration of the ingredient in the product, according to the table in paragraph (b)(2) of this section.

(2) Table of standard certified limits.

If the nominal concentration (N) for the ingredient is:	The certified limits for that ingredient will be as follows:	
	Upper limit	Lower limit
N < 1.0%	N + 10%N	N − 10%N
1.0% < N < 20.0%	N + 5%N	N − 5%N
20.0% < N < 100.0%	N + 3%N	N − 3%N

(c) *Applicant proposed limits.* (1) The applicant may propose a certified limit for an active or inert ingredient that differs from the standard certified limit calculated according to paragraph (b)(2) of this section.

(2) If certified limits are required for impurities, the applicant must propose a certified limit. The standard certified limits may not be used for such substances.

(3) Certified limits should:

(i) Be based on a consideration of the variability of the concentration of the ingredient in the product when good manufacturing practices and normal quality control procedures are used.

(ii) Allow for all sources of variability likely to be encountered in the production process.

(iii) Take into account the stability of the ingredient in the product and the possible formation of impurities between production and sale of distribution.

(4) The applicant may include an explanation of the basis of his proposed certified limits, including how the certified limits were arrived at (e.g., sample analysis, quantitative estimate based on production process), and its accuracy and precision. This will be particularly useful if the range of the certified limit for an active or inert ingredient is greater than the standard certified limits.

(d) *Special cases.* If the Agency finds unacceptable any certified limit (either standard or applicant-proposed), the Agency will inform the applicant of its determination and will provide supporting reasons. EPA may also recommend alternative limits to the applicant. The Agency may require, on a case-by-case basis, any or all of the following:

(1) More precise limits.

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

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

(e) *Certification statement.* The applicant must certify the accuracy of the information presented, and that the certified limits of the ingredients will be maintained. The following statement, signed by the authorized representative of the company, is acceptable:

I hereby certify that, for purposes of FIFRA sec. 12(a)(1)(C), the description of the composition of [*product name*], EPA Reg. No. [*insert registration number*], refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that: (1) no ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit (if required) specified for that ingredient in a currently approved Statement of Formula (or as calculated by the Agency); and (2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

§ 158.180 Enforcement analytical method.

An analytical method suitable for enforcement purposes must be provided for each active ingredient in the product and for each other ingredient or impurity that is determined to be toxicologically significant.

§ 158.190 Physical and chemical characteristics.

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

Kind of data required	(b) Notes	All general use patterns (requirements are the same for every use pattern)	Test substance		Guidelines reference No.
			Data to support MP	Data to support EP	
Color		[R]	MP and TGAI	EP* and TGAI	63-2
Physical state		[R]	MP and TGAI	EP* and TGAI	63-3
Odor		[R]	MP and TGAI	EP* and TGAI	63-4
Melting point	(1)	[R]	TGAI	TGAI	63-5
Boiling point	(2)	[R]	TGAI	TGAI	63-6
Density, bulk density, or specific gravity		[R]	MP and TGAI	EP* and TGAI	63-7
Solubility		[R]	TGAI or PAI	TGAI or PAI	63-8
Vapor pressure		[R]	TGAI or PAI	TGAI or PAI	63-9
Dissociation constant		[R]	TGAI or PAI	TGAI or PAI	63-10
Octanol/water partition coefficient	(3)	[CR]	PAI	PAI	63-11
pH	(4)	[CR]	MP and TGAI	EP* and TGAI	63-12
Stability		[R]	TGAI	TGAI	63-13
Oxidizing or reducing action	(5)	[CR]			
Flammability	(6)	[CR]	MP	EP*	63-15
Explodability	(7)	[R]	MP	EP*	63-16
Storage stability		[R]	MP	EP*	63-17
Viscosity	(8)	[CR]	MP	EP*	63-18
Miscibility	(9)	[CR]	MP	EP*	63-19
Corrosion characteristics		[R]	MP	EP*	63-20

Kind of data required	(b) Notes	All general use patterns (requirements are the same for every use pattern)	Test substance		Guidelines reference No.
			Data to support MP	Data to support EP	
Dielectric breakdown voltage	(10)	[CR]		EP*	63-21
Other requirements: Submittal of samples	(11)	[CR]	MP, TGAI, PAI	EP*, TGAI, PAI	64-1

Key: R = Required; CR = Conditionally Required; [ ] = Brackets (i.e. [R],[CR]) indicate data requirements that apply when an experimental use permit is being sought; MP = Manufacturing Use Product, EP* = End Use Product; asterisk indicates those registrants that end-use applicants (i.e. formulators) need not satisfy, if their active ingredient(s) is (are) purchased from a registered source; TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient.

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

(1) Required if technical chemical is a solid at room temperature.
(2) Required if technical chemical is a liquid at room temparature.
(3) Required if technical chemical is organic and non-polar.
(4) Required if test substance is dispersible with water.
(5) Required if product contains an oxidizing or reducing agent.
(6) Required if product contains combustible liquids.
(7) Required if product is potentially explosive.
(8) Required if product is a liquid.
(9) Required if product is a emulsifiable liquid and is to be diluted with petroleum solvents.
(10) Required if end-use product is a liquid and is to be used around electrical equipment.
(11) Basic manufacturers are required to provide the Agency with a sample of each TGAI used to formulate a product produced by an integrated system when the new TGAI is first used as a formulating ingredient in products registered under FIFRA. A sample of the active ingredient (PAI) suitable for use as an analytical standard is also required at this time. Samples of end use products produced by an integrated system must be submitted on a case-by-case basis.

(Approved by the Office of Management and Budget under control numbers 2070–0057 and 2070–0060.)

10. By adding Subpart D, Data Requirement Tables, consisting of §§ 158.105, 158.125, 158.130, 158.135, 158.140, 158.142, 158.145, 158.150, 158.155, 158.160, 158.165, and 158.170, which are transferred from Subpart B and redesignated as §§ 158.202, 158.240, 158.290, 158.340, 158.390, 158.440, 158.490, 158.540, 158.590, 158.640, 158.690, and 158.740, respectively, under new Subpart D. The Table of Contents for Subpart D reads as follows:

Subpart D—Data Requirement Tables

Sec.

PART 162—STATE REGISTRATION OF PESTICIDE PRODUCTS

V. In Part 162:

1. The Part heading is revised to read as set forth above.

2. The authority citation for Part 162 is revised to read as follows:

Authority: 7 U.S.C. 136v, 136w.

Subparts A and E [Removed and Reserved]

3. By removing and reserving Subparts A and E, consisting of §§ 162.1 through 162.60 and 162.160 through 162.177.

[FR Doc. 88–9747 Filed 5–3–88; 8:45 am]

BILLING CODE 6560–50–M

40 CFR Parts 153, 156, 158, 162 and 163

[OPP–36132; FRL–3266–9a]

Cross References; Technical Amendments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; Technical Amendments.

SUMMARY: This document revises cross references in 40 CFR Parts 153, 156, 158, 162, and 163 to reflect changes made by the promulgation of final rules revising Parts 152, 153, 158, and 162, as published elsewhere in today's **Federal Register**. This regulation is a technical amendment which requires no opportunity for comment or public participation.

EFFECTIVE DATE: This rule will become effective after 60 days of continuous congressional session from the date of promulgation as provided in section 25(a)(4) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). After that period has elapsed, the Agency will issue for publication in the **Federal Register** a notice announcing the effective date of this rule.

FOR FURTHER INFORMATION CONTACT:

By mail: Jean M. Frane, Registration Division (TS–767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

Office location and telephone number: Rm. 1114B, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703–557–0944).

SUPPLEMENTARY INFORMATION:

List of Subjects in 40 CFR Parts 153, 156, 158, 162, and 163

Administrative practice and procedure, Data requirements, Environmental protection, Intergovernmental relations, Labeling, Pesticides and pests, Policy statements, Reporting and recordkeeping requirements.

Dated: April 12, 1988.

Lee M. Thomas,

Administrator.

Therefore, Title 40, Chapter I, Subchapter E, is amended as follows:

PART 153—[AMENDED]

I. In Part 153:

1. The authority citation for Part 153 continues to read as follows:

Authority: 7 U.S.C. 136–126y.

§ 153.62 [Amended]

2. In § 153.62(a), the reference to "Part 162" is revised to read "Part 152."

§ 153.69 [Amended]

3. In § 153.69(c)(2), the reference to "§ 162.11 of this chapter" is revised to read "Part 154 of this chapter."

§ 153.72 [Amended]

4. In § 153.72(a)(1), the reference to "§ 162.163(b)(2)" is revised to read "§ 158.640."