SUBCHAPTER E—PESTICIDE PROGRAMS

PART 150–151 [RESERVED]

PART 152—PESTICIDE REGISTRATION AND CLASSIFICATION PROCEDURES

Subpart A—General Provisions

Sec.
152.1 Scope.
152.3 Definitions.
152.5 Pests.
152.6 Substances excluded from regulation by FIFRA.
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 Notification and non-notification changes to registrations.
152.50 Contents of application.
152.55 Where to send applications and correspondence.

Subpart D [Reserved]

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.
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.

Subpart H [Reserved]

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.
§ 152.1 Scope.

Except as provided in part 174, 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). Part 152 also sets forth procedures, requirements, and criteria applicable to plant-incorporated protectants. Unless specifically superseded by part 174, the regulations in part 152 apply to plant-incorporated protectants.

[66 FR 37814, July 19, 2001]

§ 152.2 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.


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), except as provided in §174.3 of this chapter.

Acute dermal LD50 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.

Acute inhalation LC50 means a statistically derived estimate of the concentration of a substance that would cause 50 percent mortality to the test population under specified conditions.

Acute oral LD50 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.

Adverse biological effect means an effect on the established uses of a plant caused by the pesticide, resulting from the use of the pesticide.

Administrator means the Administrator of the United States Environmental Protection Agency or his delegate.

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

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

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.

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.

End use product means a pesticide product whose labeling 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.

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.

Genetic material necessary for the production means both: Genetic material that encodes a substance or leads to the production of a substance, and regulatory regions. It does not include noncoding, nonexpressed nucleotide sequences.

In a living plant means inside the living plant, on the surface of the living plant, or as an exudate from the living plant.

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, except as provided by §174.3 of this chapter.

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.

Living plant means a plant, plant organ, or plant part that is alive, viable, or dormant. Examples of plant parts include, but are not limited to, seeds, fruits, leaves, roots, stems, flowers, and pollen.

Manufacturing use product means any pesticide product that is not an end-use product.

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.

Noncoding, nonexpressed nucleotide sequences means the nucleotide sequences are not transcribed and are not involved in gene expression. Examples of noncoding, nonexpressed nucleotide sequences include, but are not limited to, linkers, adapters, homopolymers, and sequences of restriction enzyme recognition sites.

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 contractual agreement between such persons.

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.

Pesticidal substance, when referring to a plant-incorporated protectant only, means a substance that is intended to be produced and used in a living plant, or in the produce thereof, for a pesticidal purpose during any part of a plant's life cycle (e.g., in the embryo, seed, seedling, mature plant).

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
§ 152.5 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.

§ 152.6 Substances excluded from regulation by FIFRA.

Products and substances listed in this section are excluded from FIFRA regulation if they meet the specified conditions or criteria.

(a) Liquid chemical sterilants. A liquid chemical sterilant product is not a pesticide under section 2(u) of FIFRA if it meets all of the following criteria. Excluded products are regulated by the Food and Drug Administration (FDA). Products excluded are those meeting all of the following criteria:

(1) Composition. The product must be in liquid form as sold or distributed. Pressurized gases or products in dry or semi-solid form are not excluded by this provision. Ethylene oxide products are not liquid products and are not excluded by this provision.

(2) Claims. The product must bear a sterilant claim, or a sterilant plus subordinate level disinfection claim. Products that bear antimicrobial claims solely at a level less than “sterilant”...
are not excluded and are jointly regulated by EPA and FDA. “Sterilant” is defined in §156.441 of this chapter.

(3) **Use site.** (i) The product must be intended and labeled only for use on “critical or semi-critical devices.” A “critical device” is any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body. A semi-critical device is any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

(ii) Liquid chemical sterilants that bear claims solely for use on non-critical medical devices are jointly regulated by EPA and FDA.

(iii) Liquid chemical sterilants that bear claims solely for use on sites that are not medical devices, such as veterinary equipment, are not excluded and are regulated solely by EPA.

(b) **Nitrogen stabilizers.** A nitrogen stabilizer is excluded from regulation under FIFRA if it is a substance (or mixture of substances), meeting all of the following criteria:

(1) The substance prevents or hinders the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria and is distributed and sold solely for those purposes and no other pesticidal purposes. For purposes of this section, living organisms are not considered to be substances, and the actions of living organisms are not relevant to whether a substance is deemed to be a nitrogen stabilizer.

(2) The substance was in “commercial agronomic use” in the United States before January 1, 1992. EPA considers a substance to be in commercial agronomic use if it is available for sale or distribution to users for direct agronomic benefit, as opposed to limited research, experimental or demonstration use.

(3) The substance was not registered under FIFRA before January 1, 1992.

(4) Since January 1, 1992, the distributor or seller has made no claim that the product prevents or hinders the process of nitrification, denitrification, ammonia volatilization or urease production. EPA considers any of the following claims (or their equivalents) to be a claim that the product prevents or hinders nitrification, denitrification, ammonia volatilization or urease production:

(i) Improves crop utilization of applied nitrogen.

(ii) Reduces leaching of applied nitrogen or reduces groundwater nitrogen contamination.

(iii) Prevents nitrogen loss.

(iv) Increases nitrogen uptake, availability, usage, or efficiency.

(5) A product will be considered to have met the criterion of paragraph (b)(4) of this section that no nitrogen stabilization claim has been made if:

(i) The nitrogen stabilization claim, in whatever terms expressed, is made solely in compliance with a State requirement to include the claim in materials required to be submitted to a State legislative or regulatory authority, or in the labeling or other literature accompanying the product; and

(ii) The State requirement to include the claim was in effect both before the product bearing the claim was introduced into commercial agronomic use, and before the effective date of this rule.

(6) A product that meets all of the criteria of this paragraph with respect to one State is not thereby excluded from FIFRA regulation if distributed and sold in another State whose nitrogen stabilization statement requirement does not meet the requirements of paragraph (b)(5)(ii) of this section.

(c) **Human drugs.** Fungi, bacteria, viruses or other microorganisms in or on living man are not “pests” as defined in section 2(t) of FIFRA. Products intended and labeled for use against such organisms are human drugs subject to regulation by the FDA under the FFDCA.

(d) **Animal drugs.** (1) Fungi, viruses, bacteria or other microorganisms on or in living animals are not “pests” under section 2(t) of FIFRA. Products intended for use against such organisms are “animal drugs” regulated by the FDA under the FFDCA.

(2) A “new animal drug” as defined in section 201(w) of the FFDCA, or an animal drug that FDA has determined is
§ 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 fertilizer product not containing a pesticide.

(b) 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.

Subpart B—Exemptions

Source: 53 FR 15977, May 4, 1988, unless otherwise noted.

§ 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 paragraphs (a)(3) and (a)(4) 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.

(4) All living plants intended for use as biological control agents are exempt from the requirements of FIFRA. However, plant-incorporated protectants are not exempt pursuant to this section. Regulations, including exemptions, for plant-incorporated protectants are addressed in part 174 of this chapter.

(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


§ 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) Non-liquid chemical sterilants. A non-liquid chemical sterilant, except ethylene oxide, that meets the criteria of §152.6(a)(2) with respect to its claims and §152.6(a)(3) with respect to its use sites is exempted from regulation under FIFRA.
§ 152.25  

40 CFR Ch. I (7–1–02 Edition)

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.

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

(e) Natural cedar. (1) Natural cedar blocks, chips, shavings, balls, chests, drawer liners, paneling, and needles that meet all of the following criteria:

(i) The product consists totally of cedarwood or natural cedar.

(ii) The product is not treated, combined, or impregnated with any additional substance(s).

(iii) The product bears claims or directions for use solely to repel arthropods other than ticks or to retard mildew, and no additional claims are made in sale or distribution. The labeling must be limited to specific arthropods, or must exclude ticks if any general term such as "arthropods," "insects," "bugs," or any other broad inclusive term, is used. The exemption does not apply to natural cedar products claimed to repel ticks.

(2) The exemption does not apply to cedar oil, or formulated products which contain cedar oil, other cedar extracts, or ground cedar wood as part of a mixture.

(f) Minimum risk pesticides—(1) Exempted products. Products containing the following active ingredients are exempt from the requirements of FIFRA, alone or in combination with other substances listed in this paragraph, provided that all of the criteria of this section are met.

- Castor oil (U.S.P. or equivalent)
- Cedar oil
- Cinnamon and cinnamon oil
- Citric acid
- Citronella and citronella oil
- Cloves and clove oil
- Corn gluten meal
- Corn oil
- Cottonseed oil
- Dried blood
- Eugenol
- Garlic and garlic oil
- Geraniol
- Geranium oil
- Lauryl sulfate
- Lemongrass oil
- Linseed oil
- Malic acid
- Mint and mint oil
- Peppermint and peppermint oil
- 2-Phenethyl propionate (2-phenylethyl propionate)
- Potassium sorbate
- Putrescent whole egg solids
- Rosemary and rosemary oil
- Sesame (includes ground sesame plant) and sesame oil
- Sodium chloride (common salt)
- Sodium lauryl sulfate
- Soybean oil
- Thyme and thyme oil
- White pepper
- Zinc metal strips (consisting solely of zinc metal and impurities)

(2) Permitted inerts. A pesticide product exempt under paragraph (g)(1) of this section may only include inert ingredients listed in the most current List 4A. This list is updated periodically and is published in the FEDERAL REGISTER. The most current list may be obtained by writing to Registration Support Branch (4A Inerts List) Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(3) Other conditions of exemption. All of the following conditions must be met for products to be exempted under this section:

(i) Each product containing the substance must bear a label identifying the name and percentage (by weight) of each active ingredient and the name of each inert ingredient.
(i) The product must not bear claims either to control or mitigate microorganisms that pose a threat to human health, including but not limited to disease transmitting bacteria or viruses, or claims to control insects or rodents carrying specific diseases, including, but not limited to ticks that carry Lyme disease.

(ii) The product must not include any false and misleading labeling statements, including those listed in 40 CFR 156.10(a)(5)(i) through (viii).

§ 152.40 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 determine 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 significance, 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 modify a registration by notification or non-notification in accordance with §152.46.

(c) A registrant may at any time submit identical minor labeling amendments affecting a number of products as a single application if no data are required for EPA to approve the amendment (for example, a change in the wording of a storage statement for designated residential use products). A consolidated application must clearly identify the labeling modification(s) to be made (which must be identical for all products included in the application), list the registration number of each product for which the modification is requested, and provide required supporting materials (for example, labeling) for each affected product.


§ 152.46 Notification and non-notification changes to registrations.

(a) Changes permitted by notification.

(1) EPA may determine that certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment may be accomplished by notification to the Agency, without requiring that the registrant obtain Agency approval. If EPA so determines, it will issue procedures following an opportunity for public comment describing the types of modifications permitted by notification and any conditions and procedures for submitting notifications.
(2) A registrant may modify a registration consistent with paragraph (a)(1) of this section and any procedures issued thereunder and distribute or sell the modified product as soon as the Agency has received the notification. Based upon the 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. Thereafter, if the registrant fails to submit an application the Agency may determine that the product is not in compliance with the requirements of the Act. Notification under this paragraph is considered a report filed under the Act for the purposes of FIFRA section 12(a)(2)(M).

(b) Changes permitted without notification. EPA may determine that certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment may be accomplished without notification to or approval by the Agency. If EPA so determines, it will issue procedures following an opportunity for public comment describing the types of amendments permitted without notification (also known as non-notification). A registrant may distribute or sell a product changed in a manner consistent with such procedures without notification to or approval by the Agency.

(c) Effect of non-compliance. Notwithstanding any other provision of this section, if the Agency determines that a product has been modified through notification or without notification in a manner inconsistent with paragraphs (a) or (b) of this section and any procedures issued thereunder, the Agency may initiate regulatory and/or enforcement action without first providing the registrant with an opportunity to submit an application for amended registration.

[61 FR 33041, June 26, 1996]

§ 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 it 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 PIPRA sec. 8(a)(2) if the product were registered.

(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.

   (1) 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.

[53 FR 15978, May 4, 1988, as amended at 58 FR 34203, June 23, 1993; 60 FR 32096, June 19, 1995]

§ 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.
§ 152.81 Applicability.

(a) Except as provided in paragraph (b) of this section, §§152.83 through 152.119 apply to:

(1) Each application for registration of a new product;
(2) Each application for an amendment of a registration; and
(3) Each application for reregistration under FIFRA section 3(g).

(b) This subpart E does not apply to:

(1) Applications for registration submitted to States under FIFRA section 24(c);
(2) Applications for experimental use permits under FIFRA section 5;
(3) Applications for emergency exemptions under FIFRA section 18;
(4) Applications to make only one or more of the following types of amendments to existing registrations, unless the Administrator or his designee finds that Agency consideration of scientific data would be necessary in order to approve the amendment under FIFRA section 3(c)(5):
   (i) An increase or decrease in the percentage in the product of one or more of its active ingredients or deliberately added inert ingredients;
   (ii) A revision of the identity or amount of impurities present in the product;
   (iii) The addition or deletion of one or more deliberately added inert ingredients;
   (iv) The deletion of one or more active ingredients;
   (v) A change in the source of supply of one or more of the active ingredients used in the product, if the new source of the active ingredient is a product which is registered under FIFRA section 3;
   (vi) Deletion of approved uses of claims;
   (vii) Redesign of the label format involving no substantive changes, express or implied, in the directions for use, claims, representations, or precautionary statements;
   (viii) Change in the product name or addition of an additional brand name, if no additional claims, representations, or uses are expressed or implied by the changes;
   (ix) Clarification of directions for use;
   (x) Correction of typographical errors;
   (xi) Changes in the registrant's name or address;
   (xii) Adding or deleting supplemental registrants;
   (xiii) Changes in the package or container size;
   (xiv) Changes in warranty, warranty disclaimer, or liability limitation statements, or addition to or deletion of such statements;
   (xv) “Splitting” a label for the sole purpose of facilitating the marketing of a product in different geographic regions with appropriate labels, where each amended label will contain previously approved use instructions (and related label statements) appropriate to a particular geographic region;
§ 152.83 Definitions.

As used in this subpart, the following terms shall have the meanings set forth in this section:

(a) Data gap means the absence of any valid study or studies in the Agency’s files which would satisfy a specific data requirement for a particular pesticide product.

(b) Data Submitters List means the current Agency list, entitled “Pesticide Data Submitters by Chemical,” of persons who have submitted data to the Agency.

(c) Exclusive use study means a study that meets each of the following requirements:

(1) The study pertains to a new active ingredient (new chemical) or new combination of active ingredients (new combination) first registered after September 30, 1978;

(2) The study was submitted in support of, or as a condition of approval of, the application resulting in the first registration of a product containing such new chemical or new combination (first registration), or an application to amend such registration to add a new use; and

(3) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B);

Provided that, a study is an exclusive use study only during the 10-year period following the date of the first registration.

(d) Original data submitter means the person who possesses all rights to exclusive use or compensation under FIFRA section 3(c)(1)(D) in a study originally submitted in support of an application for registration, amended registration, reregistration, or experimental use permit, or to maintain an existing registration in effect. The term includes the person who originally submitted the study, any person to whom the rights under FIFRA section 3(c)(1)(D) have been transferred, or the authorized representative of a group of joint data developers.

(e) Valid study means a study that has been conducted in accordance with the Good Laboratory Practice standards of 40 CFR part 160 or generally accepted scientific methodology and that EPA has not determined to be invalid.

§ 152.84 When materials must be submitted to the Agency.

All information required by this subpart should be submitted with the application, but may be submitted at any later time prior to EPA’s approval of the application. The Agency will not approve any application until it determines either that the application is not subject to these requirements or that all required materials have been submitted and are acceptable.

§ 152.85 Formulators’ exemption.

(a) FIFRA section 3(c)(2)(D) excuses an applicant from the requirement to submit or cite data pertaining to the safety of any ingredient (or mixture of ingredients) contained in his product that is derived solely from one or more EPA-registered products which the applicant purchases from another producer.

(b) If the product contains one or more ingredients eligible for the formulators’ exemption, the applicant need not comply with the requirements of §§152.90 through 152.96 with respect to any data requirements pertaining to the safety of any such ingredient, provided that he submits to the Agency a certification statement containing the following information (a form for this purpose is available from the Agency):

(1) Identification of the applicant, and of the product by EPA registration number or file symbol;
(2) Identification of each ingredient in the pesticide that is eligible for the formulators’ exemption, and the EPA registration number of the product that is the source of that ingredient;

(3) A statement that the listed ingredients meet the requirements for the formulators’ exemption;

(4) A statement that the applicant has submitted (either previously or with the current application) a complete, accurate and current Confidential Statement of Formula; and

(5) The name, title and signature of the applicant or his authorized representative and the date of signature.

(c) An applicant for amended registration is not required to submit a new formulators’ exemption statement, if the current statement in Agency files is complete and accurate.

[49 FR 30903, Aug. 1, 1984, as amended at 58 FR 34203, June 23, 1993; 60 FR 32096, June 19, 1995]

§ 152.86 The cite-all method.

An applicant may comply with this subpart by citing all data in Agency files that are pertinent to its consideration of the requested registration under FIFRA section 3(c)(5), in accordance with the procedures in this section, as applicable.

(a) Exclusive use studies. The applicant must certify to the Agency that he has obtained, from each person listed on the Data Submitters List as an exclusive use data submitter for the chemical in question, a written authorization that contains at least the following information:

(1) Identification of the applicant to whom the authorization is granted;

(2) Authorization to the applicant to use all pertinent studies in satisfaction of data requirements for the application in question; and

(3) The signature and title of the original data submitter or his authorized representative and date of the authorization.

If the Agency identifies any exclusive use data submitter not on the Data Submitters List, the applicant will be required prior to registration to obtain the necessary written authorization from such person.

(b) Other studies. The applicant must certify to the Agency that, with respect to each other person on the Data Submitters List for the chemical in question:

(1) He has obtained a written authorization that contains the information required by paragraphs (a) (1) through (3) of this section; or

(2) He has furnished to that person:

(i) A notification of his intent to apply for registration, including the name of the proposed product, and a list of the product’s active ingredients;

(ii) An offer to pay the person compensation to the extent required by FIFRA section 3(c)(1)(D) for any data on which the application relies;

(iii) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of any study; and

(iv) His name, address and telephone number.

(c) General offer to pay statement. The applicant must submit to the Agency the following general offer to pay statement:

[Graphical representation of the statement is not provided in the text.]

(d) Acknowledgement of reliance on data. Each application filed under this section shall include an acknowledgement that for purposes of FIFRA section 3(c)(1)(D) the application relies on the following data:

(1) All data submitted with or specifically cited in the application; and

(2) Each other item of data in the Agency’s files which:

(i) Concerns the properties or effects of the applicant’s product, of any product which is identical or substantially similar to the applicant’s product, or of one or more of the active ingredients in the applicant’s product; and

(ii) Is one of the types of data that EPA would require to be submitted if the application sought the initial registration under FIFRA section 3(c)(5) of a product with composition and intended uses identical or substantially similar to the applicant’s product, under the data requirements in effect on the date EPA approves the applicant’s present application.
§ 152.90 The selective method.

An applicant may comply with this subpart by listing the specific data requirements that apply to his product, its active ingredients, and use patterns, and demonstrating his compliance for each data requirement by submitting or citing individual studies, or by demonstrating that no study has previously been submitted to the Agency. This section summarizes the procedures that an applicant must follow if he chooses the selective method of demonstrating compliance. Sections 152.91 through 152.96 contain specific procedures for citing or submitting a study or demonstrating a data gap.

(a) List of data requirements. Each applicant must submit a list of the data requirements that would apply to his pesticide, its active ingredients, and its use patterns, if the product were being proposed for registration under FIFRA section 3(c)(5) for the first time. The applicant need not list data requirements pertaining to any ingredient which qualifies for the formulator’s exemption.

(1) If a Registration Standard has been issued for any active ingredient, the applicant must list the applicable data requirements enumerated in that Standard for the active ingredient and, if end use products are covered by the Registration Standard, for such products containing that active ingredient.

(2) If a Registration Standard has not been issued, or if an issued Registration Standard does not cover all data requirements for products containing the active ingredient in question, the applicant must list the applicable requirements as prescribed by 40 CFR part 158. All required (R) studies, and any studies that could be conditionally required (CR) based upon composition, use pattern, or the results of required studies, are to be listed. The applicant may demonstrate via the data gap procedures in §152.96 that a conditional requirement need not be satisfied by the submission or citation of data at the time of application.

(b) Methods of demonstrating compliance. The applicant must state for each data requirement on the list required by paragraph (a) of this section which of the following methods of compliance with the requirement he is using, and shall provide the supporting documentation specified in the referenced section.

(1) Existence of or granting of a data waiver. Refer to §152.91.

(2) Submission of a new valid study. Refer to §152.92.

(3) Citation of a specific valid study previously submitted to the Agency by the applicant or another person, with any necessary written authorizations or offers to pay. Refer to §152.93.

(4) Citation of a public literature study. Refer to §152.94.

(5) Citation of all pertinent studies previously submitted to the Agency, with any necessary written authorizations or offers to pay. Refer to §152.95.

(6) Documentation of a data gap. Refer to §152.96.

§ 152.91 Waiver of a data requirement.

The applicant may demonstrate compliance for a data requirement by documenting the existence of a waiver in accordance with paragraph (a) of this section, or by being granted a new waiver requested in accordance with paragraph (b) of this section.

(a) Request for extension of an existing waiver. An applicant may claim that a waiver previously granted by the Agency also applies to a data requirement for his product. To document this claim, the applicant must provide a reference to the Agency record that describes the previously granted waiver, such as an Agency list of waivers or an applicable Registration Standard, and must explain why that waiver should apply to his product.

(b) Request for a new waiver. An applicant who requests a waiver to satisfy a data requirement must submit the information specified in 40 CFR 158.45.

(c) Effect of denial of waiver request. If the request for a new waiver or extension of an existing waiver is denied by the Agency, the applicant must choose another method of satisfying the data requirement.

§ 152.92 Submission of a new valid study.

An applicant may demonstrate compliance for a data requirement by submitting a valid study that has not previously been submitted to the Agency. A study previously submitted to the
§ 152.93 Citation of a previously submitted valid study.

An applicant may demonstrate compliance for a data requirement by citing a valid study previously submitted to the Agency. The study is not to be submitted to the Agency with the application.

(a) Study originally submitted by the applicant. If the applicant certifies that he is the original data submitter, no documentation other than the citation is necessary.

(b) Study previously submitted by another person. If the applicant is not the original data submitter, the applicant may cite the study only in accordance with paragraphs (b)(1) through (3) of this section.

(1) Citation with authorization of original data submitter. The applicant may cite any valid study for which he has obtained the written authorization of the original data submitter. The applicant must obtain written authorization to cite any study that is an exclusive use study. The applicant must certify that he has obtained from the original data submitter a written authorization that contains at least the following information:

(i) Identification of the applicant to whom the authorization is granted;
(ii) Identification by title, EPA Accession Number or Master Record Identification Number, and date of submission, of the study or studies for which the authorization is granted;
(iii) Authorization to the applicant to use the specified study in satisfaction of the data requirement for the application in question; and
(iv) The signature and title of the original data submitter or his authorized representative, and date of the authorization.

(2) Citation with offer to pay compensation to the original data submitter. The applicant may cite any valid study that is not subject to the exclusive use provisions of FIFRA section 3(c)(1)(D)(i) without written authorization from the original data submitter if the applicant certifies to the Agency that he has furnished to the original data submitter:

(i) A notification of the applicant’s intent to apply for registration, including the proposed product name and a list of the product’s active ingredients;
(ii) Identification of the specific data requirement involved and of the study for which the offer to pay is made (by title, EPA Accession Number or Master Record Identification Number, and date of submission, if possible);
(iii) An offer to pay the person compensation to the extent required by FIFRA section 3(c)(1)(D);
(iv) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study; and
(v) The applicant’s name, address and telephone number.

(3) Citation without authorization or offer to pay. The applicant may cite any valid study without written authorization from, or offer to pay to, the original data submitter, if:

(i) The study was originally submitted to the Agency on or before December 31, 1969; or
(ii) The study was originally submitted to the Agency on or before the date that is 15 years before the date of the application for which it is cited, and the study is not an exclusive use study, as defined in §152.83(c).

§ 152.94 Citation of a public literature study or study generated at government expense.

(a) An applicant may demonstrate compliance for a data requirement by citing, and submitting to the Agency, one of the following:

(1) A valid study from the public literature.
(2) A valid study generated by, or at the expense of, any government (Federal, State, or local) agency.

(b) In no circumstances does submission of a public literature study or government-generated study confer any rights on the data submitter to exclusive use of data or compensation under FIFRA section 3(c)(1)(D).
§ 152.95 Citation of all studies in the Agency’s files pertinent to a specific data requirement.

An applicant normally may demonstrate compliance for a data requirement by citation of all studies in the Agency’s files pertinent to that data requirement. The applicant who selects this cite-all option must submit to the Agency:

(a) A general offer to pay statement having the same wording as that specified in §152.86(c) except that the offer to pay may be limited to apply only to data pertinent to the specific data requirement(s) for which the cite-all method of support has been selected;

(b) A certification that:
   (1) For each person who is included on the Data Submitters List as an original data submitter of exclusive use data for the active ingredient in question, the applicant has obtained a written authorization containing the information required by §152.86(a) for the use any exclusive use study that would be pertinent to the applicant’s product; and
   (2) For each person included on the current Data Submitters List as an original data submitter of data that are not exclusive use for the active ingredient in question, the applicant has furnished:
      (i) A notification of the applicant’s intent to apply for registration, including the name of the proposed product, and a list of the product’s active ingredients;
      (ii) Identification of the specific data requirement(s) for which the offer to pay for data is being made;
      (iii) An offer to pay the person compensation to the extent required by FIFRA section 3(c)(1)(D);
      (iv) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for use of any study; and
      (v) The applicant’s name, address and telephone number; and
   (c) An acknowledgment having the same wording as that specified in §152.86(d), except that it may be limited to apply only to data pertinent to the specific data requirement(s) for which the cite-all method of support has been selected.

§ 152.96 Documentation of a data gap.

Except as provided in paragraph (a) of this section, an applicant may defer his obligation to satisfy an applicable data requirement until the Agency requests the data if he can demonstrate, by the procedure in this section, that no other person has previously submitted to the Agency a study that would satisfy the data requirement in question.

(a) When data gap procedures may not be used. (1) An applicant for registration of a product containing a new chemical may not defer his obligation by the procedure in this section, unless he can demonstrate to the Agency’s satisfaction that the data requirement was imposed so recently that insufficient time has elapsed for the study to have been completed and that, in the public interest, the product should be registered during the limited period of time required to complete the study. Refer to FIFRA section 3(c)(7)(C).

(2) An applicant for registration of a product under FIFRA section 3(c)(7) (A) or (B) may not defer his obligation by the procedure in this section if the Agency requires the data to determine:
   (i) Whether the product is identical or substantially similar to another currently registered product or differs only in ways that would not substantively increase the risk of unreasonable adverse effects on the environment;
   (ii) If efficacy data are required, whether the product is efficacious; or
   (iii) Whether the new use would substantively increase the risk of unreasonable adverse effects on the environment, usually required when the application involves a new use of a product which is identical or substantially similar to a currently registered product.

(b) Data gap listed in a Registration Standard. The applicant may rely on a data gap that is documented by a Registration Standard without submitting the certification required by paragraph (c) of this section. If the data gap listed in the Registration Standard has been filled since the issuance of the Standard, the Agency will notify the applicant and require him to choose another method of demonstrating compliance.

(c) Certification of a data gap. Except as provided by paragraph (b) of this...
section, an applicant who wishes to claim that a data gap exists must certify to the Agency that:

1. The applicant has furnished, by certified mail, to each original data submitter on the current Data Submitters List for the active ingredient in question, a notice containing the following information:
   (i) The name and address of the applicant;
   (ii) The name of the product, and a statement that the applicant intends to apply for registration of that product;
   (iii) The name(s) of the active ingredient(s) in the product;
   (iv) A list of the data requirements for which the applicant intends to claim under this section that a data gap exists; and
   (v) A request that the data submitter identify, within 60 days of receipt of the notice, any valid study which he has submitted to the Agency that would fulfill any of the data requirement(s) listed.

2. The applicant has, within that 60-day period, received no response, or has received a negative response, from each person notified; and

3. The applicant has no basis to believe that any data have been submitted to the Agency that would fulfill the data requirement, and is entitled to claim that a data gap exists.

(d) Requirement to obtain permission or make offer to pay. In responding to a data gap letter, the original data submitter is not deemed to have given his authorization for the applicant to cite any study which the data submitter identifies in his response. The applicant must seek and obtain specific written authorization from, or make an offer to pay to, the original data submitter to cite the identified study in order to demonstrate compliance for the data requirement. Nothing, however, precludes the applicant from requesting written authorization or making an offer to pay at the same time that he requests confirmation of a data gap.

§ 152.97 Rights and obligations of data submitters.

(a) Right to be listed on Data Submitters List. (1) Each original data submitter shall have the right to be included on the Agency’s Data Submitters List.

(2) Each original data submitter who wishes to have his name added to the current Data Submitters List must submit to the Agency the following information:
   (i) Name and current address;
   (ii) Chemical name and common name (if any) of the active ingredient(s), with respect to which he is an original data submitter;
   (iii) For each such active ingredient, the type(s) of study he has previously submitted (corresponding to Guidelines reference numbers given in tables in 40 CFR part 158, if applicable), the date of submission, and the EPA registration number, file symbol, or other identifying reference for which it was submitted.

(b) Obligation to respond to data gap letters. An applicant who chooses to defer his obligation by demonstrating the existence of a data gap must write to each original data submitter for confirmation that the data submitter has not submitted a valid study that would satisfy the requirement. The original data submitter is not required to respond to such letters. However, if he fails to respond, the applicant is entitled to assume (and the Agency will act on the assumption) that the original data submitter has not submitted a valid study that would satisfy the requirement. The data submitter may thereby limit his right to later challenge the applicant’s claim if he fails respond in writing delivered to the applicant within 60 days of receipt of the applicant’s data gap letter.

§ 152.98 Procedures for transfer of exclusive use or compensation rights to another person.

A person who possesses rights to exclusive use or compensation under FIFRA section 3(c)(1)(D) may transfer such rights to another person in accordance with this section.
§ 152.99 Petitions to cancel registration.

An original data submitter may petition the Agency to deny or cancel the registration of a product in accordance with this section if he has submitted to the Agency a valid study which, he claims, satisfies a data requirement that an applicant purportedly has failed to satisfy.

(a) Grounds for petition. (1) If an applicant has offered to pay compensation to an original data submitter of a study (either specifically or by filing a general offer to pay statement), the original data submitter may petition the Agency to deny or cancel the registration to which the offer related on any of the following grounds:

(i) The applicant has failed to participate in an agreed-upon procedure for reaching an agreement on the amount and terms of compensation. The petitioner shall submit a copy of the agreed-upon procedure and describe the applicant’s failure to participate in the procedure.

(ii) The applicant has failed to comply with the terms of an agreement on compensation. The petitioner shall submit a copy of the arbitration decision, and describe how the applicant has failed to comply with the decision.

(b) In addition, the original data submitter must submit to the Agency a notarized statement affirming that:

(1) The person signing the transfer agreement is authorized by the original data submitter to bind the data submitter;

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

(3) The transfer is authorized under Federal, State, and local law and relevant corporate charters, bylaws or partnership agreements.

(c) The Agency will acknowledge the transfer of the data by notifying both transferor and transferee, and will state the effective date of the transfer. Thereafter the transferee will be considered to be the original data submitter of the items of data transferred for all purposes under FIFRA section 3(c)(1)(D), unless a new transfer agreement is submitted to the Agency.
Environmental Protection Agency

§ 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...
§ 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 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 prac-
§ 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 conjunction 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
Environmental Protection Agency

§ 152.118 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.

Subpart G—Obligations and Rights of Registrants

SOURCE: 53 FR 15983, May 4, 1988, unless otherwise noted.

§ 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), provide such information to the Agency, clearly identified as FIFRA 6(a)(2) data.

[53 FR 15975, May 4, 1988, as amended at 60 FR 32096, June 19, 1995]

§ 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.

§152.135 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.

(b) 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 transferee;

(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 transferee transfers irrevocably to the transferor 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.

[53 FR 15983, May 4, 1988, as amended at 58 FR 34203, June 23, 1993]

Subpart H [Reserved]

Subpart I—Classification of Pesticides

SOURCE: 53 FR 15986, May 4, 1988, unless otherwise noted.

§ 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 LC50 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 no 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 classification unless the product bears amended 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 advertise-

§ 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 16 g/kg or less;
   (iii) The pesticide, as formulated, has an acute inhalation LC$_{50}$ of 0.05 mg/liter or less, based upon a 4-hour exposure period;
   (iv) The pesticide, as formulated, is corrosive to the eye or causes corneal involvement or irritation persisting for more than 21 days;
   (v) The pesticide, as formulated, is corrosive to the skin (causes tissue destruction into the dermis and/or scarring); or
   (vi) 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
§ 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.

§ 152.175 Pesticides classified for restricted use.

The following uses of pesticide products containing the active ingredients specified below have been classified for restricted use and are limited to use by or under the direct supervision of a certified applicator.

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.
<table>
<thead>
<tr>
<th>Active ingredient</th>
<th>Formulation</th>
<th>Use pattern</th>
<th>Classification ¹</th>
<th>Criteria influencing restriction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acrolein</td>
<td>As sole active ingredient. No mixtures registered.</td>
<td>All uses</td>
<td>Restricted</td>
<td>Inhalation hazard to humans. Residue effects on avian species and aquatic organisms. Other hazards—accident history.</td>
</tr>
<tr>
<td>Aldicarb</td>
<td>As sole active ingredient.</td>
<td>Ornamental uses (indoor and outdoor).</td>
<td>Restricted</td>
<td>Inhalation hazard to humans.</td>
</tr>
<tr>
<td>Aluminum phosphide</td>
<td>No mixtures registered.</td>
<td>Agricultural crop uses</td>
<td>Under further evaluation.</td>
<td>Inhalation hazard to humans.</td>
</tr>
<tr>
<td>Azinphos methyl</td>
<td>All liquids with a concentration greater than 13.5 pct.</td>
<td>All uses except rice</td>
<td>Under further evaluation.</td>
<td>Do.</td>
</tr>
<tr>
<td>Carbofuran</td>
<td>All concentrate suspensions and wettable powders 40% and greater.</td>
<td>Rice</td>
<td>Restricted</td>
<td>Acute inhalation toxicity.</td>
</tr>
<tr>
<td>Chloropicrin</td>
<td>All formulations greater than 2%</td>
<td>All uses except rice</td>
<td>Under evaluation.</td>
<td>Acute inhalation toxicity.</td>
</tr>
<tr>
<td>Clonitralid</td>
<td>All wettable powders 70% and greater</td>
<td>All uses</td>
<td>Restricted</td>
<td>Acute inhalation toxicity.</td>
</tr>
<tr>
<td>Dicrotophos</td>
<td>All liquid formulations 8% and greater</td>
<td>All uses</td>
<td>Restricted</td>
<td>Acute dermal toxicity; residue effects on avian species (except for tree injections).</td>
</tr>
<tr>
<td>Disulfoton</td>
<td>All emulsifiable concentrates 65% and greater, all emulsifiable concentrates and concentrate solutions 21% and greater with fensulfothion 43% and greater, all emulsifiable concentrates 32% and greater and in combination with 32% fensulfothion and greater.</td>
<td>Commercial seed treatment.</td>
<td>Restricted</td>
<td>Acute dermal toxicity.</td>
</tr>
<tr>
<td>Ethoprop</td>
<td>Granular formulations 10% and greater</td>
<td>Indoor uses (greenhouse)</td>
<td>Restricted</td>
<td>Acute dermal toxicity.</td>
</tr>
<tr>
<td>Ethyl parathion</td>
<td>Emulsifiable concentrates 40% and greater</td>
<td>All uses</td>
<td>Restricted</td>
<td>Inhalation hazard to humans. Acute dermal toxicity. Residue effects on mammalian, aquatic, avian species.</td>
</tr>
<tr>
<td>Methamidophos</td>
<td>Liquid formulations 40% and greater</td>
<td>Tobacco</td>
<td>Restricted</td>
<td>Acute dermal toxicity; residue effects on avian species.</td>
</tr>
</tbody>
</table>

¹ Classification: Restricted, Under further evaluation, Unclassified.
<table>
<thead>
<tr>
<th>Active ingredient</th>
<th>Formulation</th>
<th>Use pattern</th>
<th>Classification</th>
<th>Criteria influencing restriction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methidathion</td>
<td>All formulations</td>
<td>All uses except nursery stock, safflower and sunflower.</td>
<td>Unclassified.</td>
<td>Do.</td>
</tr>
<tr>
<td></td>
<td>Nursery stock, safflower and sunflower.</td>
<td>All uses except nursery stock, safflower and sunflower.</td>
<td>Unclassified.</td>
<td>Do.</td>
</tr>
<tr>
<td>Methomyl</td>
<td>As sole active ingredient in 1 pct to 2.5 baits (except 1 pct fly bait).</td>
<td>All uses except nursery stock, safflower and sunflower.</td>
<td>Unclassified.</td>
<td>Do.</td>
</tr>
<tr>
<td></td>
<td>Nondomestic outdoors-agricultural crops, ornamental and turf. All other registered uses.</td>
<td>All uses except nursery stock, safflower and sunflower.</td>
<td>Unclassified.</td>
<td>Do.</td>
</tr>
<tr>
<td></td>
<td>90 pct wettable powder formulations (not in water soluble bags).</td>
<td>All uses except nursery stock, safflower and sunflower.</td>
<td>Unclassified.</td>
<td>Do.</td>
</tr>
<tr>
<td></td>
<td>All granular formulations</td>
<td>All uses except nursery stock, safflower and sunflower.</td>
<td>Unclassified.</td>
<td>Do.</td>
</tr>
<tr>
<td></td>
<td>In 1.24 pct to 2.5 pct dusts as sole active ingredient and in mixtures with fungicides and chlorinated hydrocarbon, inorganic phosphate and biological insecticides.</td>
<td>All uses except nursery stock, safflower and sunflower.</td>
<td>Unclassified.</td>
<td>Do.</td>
</tr>
<tr>
<td>Methyl bromide</td>
<td>All formulations in containers greater than 1.5 lb.</td>
<td>All uses except nursery stock, safflower and sunflower.</td>
<td>Unclassified.</td>
<td>Do.</td>
</tr>
<tr>
<td></td>
<td>Containers with not more than 1.5 lb of methyl bromide with 0.25 pct to 2.0 pct chloropicrin as an indicator.</td>
<td>All uses except nursery stock, safflower and sunflower.</td>
<td>Unclassified.</td>
<td>Do.</td>
</tr>
<tr>
<td></td>
<td>Container with not more than 1.5 lb having no indicator.</td>
<td>All uses except nursery stock, safflower and sunflower.</td>
<td>Unclassified.</td>
<td>Do.</td>
</tr>
<tr>
<td>Methyl parathion</td>
<td>All dust and granular formulations less than 5 pct.</td>
<td>All uses except nursery stock, safflower and sunflower.</td>
<td>Unclassified.</td>
<td>Do.</td>
</tr>
<tr>
<td></td>
<td>Microencapsulated formulations.</td>
<td>All uses except nursery stock, safflower and sunflower.</td>
<td>Unclassified.</td>
<td>Do.</td>
</tr>
<tr>
<td>Nicotine (alkaloid)</td>
<td>Liquid and dry formulations 14% and above.</td>
<td>All uses except nursery stock, safflower and sunflower.</td>
<td>Unclassified.</td>
<td>Do.</td>
</tr>
<tr>
<td>Paraquat (dichloride) and paraquat bis(methyl sulfate)</td>
<td>All formulations and concentrations except those listed below.</td>
<td>All uses except nursery stock, safflower and sunflower.</td>
<td>Unclassified.</td>
<td>Do.</td>
</tr>
<tr>
<td>Chemical/Herbicide</td>
<td>Formulations</td>
<td>Uses</td>
<td>Hazard</td>
<td>Notes</td>
</tr>
<tr>
<td>-------------------</td>
<td>--------------</td>
<td>------</td>
<td>--------</td>
<td>-------</td>
</tr>
<tr>
<td>Phorate</td>
<td>Liquid formulations 65% and greater</td>
<td>All uses</td>
<td>Restricted</td>
<td>Acute dermal toxicity.</td>
</tr>
<tr>
<td>Phosphamidon</td>
<td>Liquid formulations 75% and greater</td>
<td>Rice</td>
<td>do</td>
<td>do</td>
</tr>
<tr>
<td></td>
<td>Dust formulations 1.5% and greater</td>
<td></td>
<td>do</td>
<td>do</td>
</tr>
<tr>
<td>Picloram</td>
<td>All granular formulations except Tordon 101 R</td>
<td></td>
<td>do</td>
<td>do</td>
</tr>
<tr>
<td>Sodium cyanide</td>
<td>All capsules and ball formulations</td>
<td>Rice</td>
<td>do</td>
<td>do</td>
</tr>
<tr>
<td>Sodium fluoroacetate</td>
<td>All solutions and dry baits</td>
<td>All uses</td>
<td>Restricted</td>
<td>Inhalation hazard to humans.</td>
</tr>
<tr>
<td>Strychnine</td>
<td>All dry baits, pellets and powder formulations greater than 0.5 pct.</td>
<td></td>
<td>do</td>
<td>do</td>
</tr>
<tr>
<td>Sulfotep</td>
<td>Sprays and smoke generators</td>
<td>All uses</td>
<td>Restricted</td>
<td>Inhalation hazard to humans.</td>
</tr>
<tr>
<td>Zinc Phosphide</td>
<td>All formulations 2% and less</td>
<td>All uses except soil</td>
<td>do</td>
<td>do</td>
</tr>
<tr>
<td></td>
<td>All dry formulations 60% and greater</td>
<td>All subsoil uses</td>
<td>do</td>
<td>do</td>
</tr>
<tr>
<td></td>
<td>All dry formulations 10% and greater</td>
<td>Domestic uses</td>
<td>do</td>
<td>do</td>
</tr>
</tbody>
</table>

1 "Under evaluation" means no classification decision has been made and the use/formulation in question is still under active review within EPA.
2 Percentages given are the total of dioxathion plus related compounds.
3 (NOTE—M-44 sodium cyanide capsules may only be used by certified applicators who have also taken the required additional training.)
§ 152.400 Purpose.

Subpart U prescribes fees to be charged for the pesticide regulatory activities set forth in §152.403 as performed by the Environmental Protection Agency (as authorized by 31 U.S.C. 9701 and Pub. L. 100–202) and provisions regarding their payment.

§ 152.401 Inapplicability of fee provisions to applications filed prior to October 1, 1997.

No fee required by this subpart U shall be levied with respect to any application filed during the period beginning on October 25, 1988, and ending on September 30, 1997. See FIFRA section 4(i)(7) (added to FIFRA by Pub. L. 100–532, October 25, 1988, 102 Stat. 2654).

§ 152.403 Definitions of fee categories.

(a) New chemical registration review means review of an application for registration of a pesticide product containing a chemical active ingredient which is not contained as an active ingredient in any other pesticide product that is registered under FIFRA at the time the application is made.

(b) New biochemical and microbial registration review means review of an application for registration of a biochemical or microbial pesticide product containing a biochemical or microbial active ingredient not contained in any other pesticide product that is registered under FIFRA at the time the application is made. For purposes of this subpart, the definitions of biochemical and microbial pesticides contained in §158.65 (a) and (b) of this chapter shall apply.

(c) New use pattern registration review means review of an application for registration, or for amendment of a registration entailing a major change to the use pattern of an active ingredient contained in a product registered under FIFRA or pending Agency decision on a prior application at the time of application. For purposes of this paragraph, examples of major changes include but are not limited to, changes from non-food to food use, outdoor to indoor use, ground to aerial application, terrestrial to aquatic use, and non-residential to residential use.

(d) Old chemical registration review means review of an application for registration of a new product containing active ingredients and uses which are substantially similar or identical to those currently registered or for which an application is pending Agency decision.

(e) Amendment review means review of any application requiring Agency approval to amend the registration of a currently registered product, or for which an application is pending Agency decision, not entailing a major change to the use pattern of an active ingredient.

(f) Experimental use permit review means review of an application for a permit pursuant to section 5 of FIFRA to apply a limited quantity of a pesticide in order to accumulate information necessary to register the pesticide. The application may be for a new chemical or for a new use of an old chemical. The fee applies to such experimental uses of a single unregistered active ingredient (no limit on the number of other active ingredients, in a tank mix, already registered for the crops involved) and no more than three crops. This fee does not apply to experimental use permits required for small-scale field testing of microbial pest control agents (40 CFR 172.3).

§ 152.404 Fee amounts.

The fee prescribed by the following table must be submitted with each application for registration, amended registration or experimental use permit. Fees will be adjusted annually in accordance with §152.410. The Agency may waive or refund fees in accordance with §152.412.

<table>
<thead>
<tr>
<th>Type of review</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>New chemical</td>
<td>$184,500</td>
</tr>
<tr>
<td>New biochemical or microbial</td>
<td>64,000</td>
</tr>
<tr>
<td>New use pattern</td>
<td>33,800</td>
</tr>
<tr>
<td>Experimental use permit</td>
<td>4,500</td>
</tr>
<tr>
<td>Old chemical</td>
<td>4,000</td>
</tr>
</tbody>
</table>
### TABLE—REGISTRATION FEES—Continued

<table>
<thead>
<tr>
<th>Type of review</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amendment</td>
<td>700</td>
</tr>
</tbody>
</table>

[53 FR 19114, May 26, 1988, as amended at 58 FR 34203, June 23, 1993]

§ 152.406 Submission of supplementary data.

Applicants may submit data to supplement pending applications without incurring additional charges if the proper fee was paid with submission of the original application and subsequent submissions of supplementary data do not constitute a change in the type of registration action requested.

[53 FR 19114, May 26, 1988, as amended at 58 FR 34203, June 23, 1993]

§ 152.408 Special considerations.

(a) If two or more applicants apply for a new chemical registration for products having the same active ingredient and each applicant provides a set of data in support of the registration developed independently of the other applicants’ data, then each applicant submitting an independent set of data shall be charged the full new chemical registration review fee.

(b) If two or more applicants apply for a new chemical registration for products having the same active ingredient and the applicants have jointly developed or paid for the joint development of a common set of data to support their applications for registration, then each applicant shall be charged an equal share of the total fee for review of the applications for all of the subject products. The total fee will include the sum of the new chemical registration review fee for one product and one old chemical registration review fee for each additional product.

(c) If an application is received for registration of a product that contains two or more new chemical active ingredients and a different set of generic data is required by the Agency for each new chemical for the purpose of registration, the applicant will be required to pay the full new chemical registration review fee for each active ingredient.

§ 152.410 Adjustment of fees.

(a) The fee schedule will be adjusted annually by the same percentage as the percent change in the Federal General Schedule (GS) pay scale. Such adjustments will be published in the FEDERAL REGISTER as a final rule and will be effective 30 days or more after promulgation.

(b) Processing costs and fees will be reviewed periodically and changes will be made to the schedule as necessary. Such adjustments will be published for notice and comment in the FEDERAL REGISTER.

§ 152.412 Waivers and refunds.

(a) Refunds. If an application is not accepted for processing because it is incomplete, the fee, less $1,200 for handling and initial review (or the amount of the fee, whichever is less), shall be returned. If an application is withdrawn by the applicant before significant Agency scientific review has begun, the fee, less $1,200, shall be returned. If an unacceptable or withdrawn petition is resubmitted, it shall be accompanied by the fee that would be required if it were submitted for the first time.

(b) Waiver of fees for activities initiated by the Agency. The Agency may waive fees for amended registrations where the amendment has been initiated solely by the Agency. The Agency retains sole discretion in determining when this fee will be waived. The announcement of the fee waiver will accompany the EPA request for an amendment. The Agency will not approve any individual requests for waivers of EPA-initiated activity fees.

(c) Waiver of fees for activities initiated by applicants. Upon request by an applicant, together with the supporting documentation or justification described in this paragraph, the Agency may waive or refund fees in whole or in part. A request for waiver must be submitted in accordance with §152.414(a). An application for which a waiver of fees has been requested will not be accepted for review until the waiver has been granted, or until the waiver has been denied and thereafter the proper fee has been submitted.

(1) Minor use. Fees may be waived for applications limited to minor uses that
§ 152.414 Procedures.

(a) Procedures for requesting a waiver. (1) A request for a waiver must be submitted in writing at the time the application is submitted to the Environmental Protection Agency, Office of Pesticide Programs, Registration Division (TS–767C), 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(2) A payment of $1,200 for processing the waiver or the amount of the actual fee, whichever is less, must be submitted simultaneously to the address set forth in paragraph (b) of this section. This fee will be refunded (or applied to any resulting partial fee) if the waiver is granted. Payment of fees for the registration activities, in contrast to the waiver fee, shall not be required until the Agency makes a determination on the waiver request. Since the actual fee is submitted to an address different than the one to which the waiver request is submitted, a copy of the payment document must be submitted with the waiver request that is submitted to the Washington, DC address set forth in paragraph (a)(1) of this section. No fee is required from a person who has no financial interest in the application.

(b) Procedures for payment of fees. All fees required by this section must be paid by money order, bank draft, or certified check drawn to the order of the Environmental Protection Agency. All payment of fees must be forwarded to the Environmental Protection Agency, Headquarters Accounting Operations Branch, Office of Pesticide Programs (Registration Fees), P.O. Box

(4) Public interest. The Agency, in its discretion, may waive in whole or in part any of the fees established herein in the public interest. Examples include, but are not limited to, pesticides offering unique advantages for reducing public health risks, those that significantly reduce a current environmental risk, or a product with extraordinary utility for use in Integrated Pest Management (IPM).

[53 FR 19114, May 26, 1988, as amended at 58 FR 34263, June 23, 1993]
§ 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 considered to be pesticidal activity.

(b) 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.

(c) 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.

Source: 53 FR 15989, May 4, 1988, unless otherwise noted.

PART 153—REGISTRATION POLICIES AND INTERPRETATIONS

Subparts A–F [Reserved]

Subpart G—Determination of Active and Inert Ingredients

Sec. 153.125 Criteria for determination of pesticidal activity.

PART 153—REGISTRATION POLICIES AND INTERPRETATIONS

Subparts V–Y [Reserved]

Subpart Z—Devices

§ 152.500 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.

Source: 53 FR 15989, May 4, 1988, unless otherwise noted.