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TITLE 40--PROTECTION OF ENVIRONMENT

CHAPTER I--ENVIRONMENTAL PROTECTION AGENCY--(Continued)

PART 152--PESTICIDE REGISTRATION AND CLASSIFICATION PROCEDURES

Subpart A--General Provisions

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

Subpart B--Exemptions

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

Subpart C--Registration Procedures

152.40 Who may apply.
152.42 Application for new registration.
152.43 Alternate formulations.
152.44 Application for amended registration.
152.46 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.
152.168 Advertising of restricted use products.
152.170 Criteria for restriction to use by certified applicators.

152.171 Restrictions other than those relating to use by certified applicators.
152.175 Pesticides classified for restricted use.

Subparts J--T [Reserved]

Subpart U--Registration Fees

152.400 Purpose.
152.401 Inapplicability of fee provisions to applications filed prior to October 1, 1997.
152.403 Definitions of fee categories.
152.404 Fee amounts.
152.406 Submission of supplementary data.
152.408 Special considerations.
152.410 Adjustment of fees.
152.412 Waivers and refunds.
152.414 Procedures.

Subparts V--Y [Reserved]

Subpart Z--Devices

152.500 Requirements for devices.

Authority: 7 U.S.C. 136-136y; Subpart U is also issued under 31 U.S.C. 9701.

Subpart A--General Provisions

Source: 53 FR 15975, May 4, 1988, unless otherwise noted.

Sec. 152.1 Scope.

Part 152 sets forth procedures, requirements and criteria concerning the registration and reregistration of pesticide products under FIFRA sec. 3, and for associated regulatory activities affecting registration. These latter regulatory activities include data compensation and exclusive use (subpart E), and the classification of pesticide uses (subpart I).

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

Sec. 152.3 Definitions.

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

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

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

2(a).

(c) Acute dermal LD<INF>50 means a statistically derived estimate of the single dermal dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

(d) Acute inhalation LC<INF>50 means a statistically derived estimate of the concentration of a substance that would cause 50 percent mortality to the test population under specified conditions.

(e) Acute oral LD<INF>50 means a statistically derived estimate of the single oral dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

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

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

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

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

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

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

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

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

(l) Final printed labeling means the label or labeling of the product when

[[Page 7]]

distributed or sold. Final printed labeling does not include the package of the product, unless the labeling is an integral part of the package.

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

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

(1) Hospitals and nursing homes.

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

(3) Museums and libraries.

(4) Sports facilities.

(5) Office buildings.

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) On humans or pets,

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

(3) In any preschool or day care facility.

Sec. 152.5 Pests.

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

(a) Any vertebrate animal other than man;

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

(c) Any plant growing where not wanted, including any moss, alga, liverwort, or other plant of any higher

order, and any plant part such as a root; or

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

Sec. 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 Sec. 152.5, if it is:

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

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

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

(1) A fertilizer product not containing a pesticide.

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

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

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

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

Sec. 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.

Sec. 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 Secs. 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.

Sec. 152.20 Exemptions for pesticides regulated by another Federal agency.

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

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

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

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

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

(ii) Procaryotic microorganisms, including bacteria; and

(iii) Viruses.

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

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

The pesticides or classes of pesticides listed in this section have

been determined to be of a character not requiring regulation under FIFRA, and are therefore exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified.

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

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

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

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

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

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

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

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

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

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

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

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

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

(f) 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.

(g) 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, 401 M St., SW., 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.

(ii) 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.

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

[53 FR 15977, May 4, 1988, as amended at 59 FR 2751, Jan. 19, 1994; 61 FR 8878, Mar. 6, 1996]

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

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

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

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

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

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

(i) A registered product; or

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

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

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

(2) An unregistered pesticide may be distributed or sold in

accordance with the provisions of Sec. 172.3 of this chapter, pertaining to use of a pesticide for which an experimental use permit is not required, provided the product is labeled in accordance with part 156 of this chapter.

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

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

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

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

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

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

Subpart C--Registration Procedures

Source: 53 FR 15978, May 4, 1988, unless otherwise noted.

Sec. 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.

Sec. 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 Sec. 152.50. An application for new registration must be approved by

[[Page 12]]

the Agency before the product may legally be distributed or sold, except as provided by Sec. 152.30.

Sec. 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 signficance, the formulation must have the same upper certified limit for that substance as the basic formulation;

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

(4) The analytical method required under Sec. 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.

Sec. 152.44 Application for amended registration.

(a) Except as provided by Sec. 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 Sec. 152.50, as applicable to the change requested. If an application for amended registration is required, the application must be approved by the Agency before the product, as modified, may legally be distributed or sold.

(b) In its discretion, the Agency may:

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

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

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

(4) Permit an applicant to modify a registration by notification or non-notification in accordance with Sec. 152.46.

[53 FR 15978, May 4, 1988, as amended at 61 FR 33041, June 26, 1996]

Effective Date Note: At 61 FR 33041, June 26, 1996, Sec. 152.44 was amended by adding paragraph (b)(4), effective Aug. 26, 1996.

Sec. 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

[[Page 13]]

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]

Effective Date Note: At 61 FR 33041, June 26, 1996, Sec. 152.46 was revised, effective Aug. 26, 1996. For the convenience of the user, the superseded text is set forth as follows:

Sec. 152.46 Modifications to registration not requiring amended applications.

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

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

(2) Addition or substitution of brand names.

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

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

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

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

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

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

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

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

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

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

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

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

(5) Revision of the label format, provided that the format is consistent with Agency

labeling requirements and the label text is not modified.

[53 FR 15978, May 4, 1988, as amended at 58 FR 34203, June 23, 1993]

Sec. 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 Sec. 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 Sec. 158.32 of this chapter. The summary must state that is is releasable to the public after registration in accordance with Sec. 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

[[Page 15]]

of whether studies were conducted in accordance with the Good Laboratory Practices of part 160.

(3) An applicant shall furnish with his application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on man or the environment, which would be required to be reported under FIFRA sec. 6(a)(2) if the product were registered.

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

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

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

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

Sec. 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.

Subpart D--[Reserved]

Subpart E--Procedures To Ensure Protection of Data Submitters' Rights

Source: 49 FR 30903, Aug. 1, 1984, unless otherwise noted.

Sec. 152.80 General.

This subpart E (Secs. 152.80 through 152.119)\1\ describes the information that an applicant must submit with his application for registration, amended registration, or reregistration to comply (and for the Agency to determine compliance) with the provisions of FIFRA section 3(c)(1)(D). This subpart also describes the procedures by which data submitters may challenge registration actions which allegedly failed to comply with these procedures. If the Agency determines that an applicant has failed to comply with the requirements and procedures in this subpart, the application may be denied. If the Agency determines, after registration has been issued, that an applicant failed to comply with these procedures and requirements, the Agency may issue a notice of intent to cancel the product's registration.

\1\ Editorial Note: Sections 152.116 and 152.119 were transferred to subpart F at 53 FR 15980, May 4, 1988.

[49 FR 30903, Aug. 1, 1984, as amended at 58 FR 34203, June 23, 1993]

Sec. 152.81 Applicability.

(a) Except as provided in paragraph (b) of this section, Secs. 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:

[[Page 16]]

(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;

(xvi) Any other type of amendment, if the Administrator or his designee determines, by written finding, that the Agency consideration of scientific data would not be necessary in order to approve the amendment under FIFRA section 3(c)(5); and

(xvii) Compliance with Agency Regulations, adjudicatory hearing decisions, notices, or other Agency announcements that unless the registration is amended in the manner the Agency proposes, the product's registration will be suspended or cancelled, or that a hearing will be held under FIFRA section 6. (However, this paragraph does not apply to amendments designed to avoid cancellation or suspension threatened under FIFRA section 3(c)(2)(B) or because of failure to submit data.)

Sec. 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.

Sec. 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.

Sec. 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 Secs. 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]

Sec. 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

[[Page 18]]

(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 from that person 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:

[Name of applicant] hereby offers and agrees to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA section 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act.

(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.

Sec. 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,

[[Page 19]]

use pattern, or the results of required studies, are to be listed. The applicant may demonstrate via the data gap procedures in Sec. 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 Sec. 152.91.

(2) Submission of a new valid study. Refer to Sec. 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 Sec. 152.93.

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

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

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

Sec. 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.

Sec. 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 Agency should not be resubmitted but should be cited in accordance with Sec. 152.93.

Sec. 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 Sec. 152.83(c).

Sec. 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).

Sec. 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 of 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 Sec. 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 Sec. 152.86(a) for the use the 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 Sec. 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.

Sec. 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 substantially 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 substantially 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 procuct;

(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.

Sec. 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.

(3) Each applicant not already included on the Data Submitters List for a particular active ingredient must inform the Agency at the time of submission of a relevant study whether he wishes to be included on the Data Submitters List for that pesticide.

(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 study to 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.

Sec. 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.

(a) The original data submitter must submit to the Agency a transfer document that contains the following information:

(1) The name, address and state of incorporation (if any) of the original data submitter (the transferor);

(2) The name, address and state of incorporation (if any) of the person to whom the data rights are being transferred (the transferee);

(3) Identification of each item of data transferred including:

(i) The name of the study or item of data;

(ii) Whether the study is an exclusive use study, and, if so, when the period of exclusive use protection expires;

(iii) The name of the person or laboratory that conducted the study;

(iv) The date the study was submitted to the Agency;

(v) The EPA document number assigned to the item of data (the Master Record Identification Number or Accession Number), if known. If not known, the EPA administrative number (such as the EPA Registration Number, petition number, file symbol, or permit number) with which the item of data was submitted, such that the Agency can identify the item of data.

(vi) A statement that the transferor transfers irrevocably to the transferee all rights, titles, and interest in the items of data named;

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

(viii) The names, signatures and titles of the transferor and transferee, and the date signed.

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

[[Page 23]]

(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.

Sec. 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 agreement, and shall describe how the applicant has failed to comply with the agreement.

(iii) The applicant has failed to participate in an arbitration proceeding. The petitioner shall submit evidence of such failure.

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

(2) When no offer to pay has been made, the petitioner shall state in his petition the basis for the challenge, and describe how the failure of the applicant to comply with the procedures of this subpart has deprived him of the rights accorded him under FIFRA section 3(c)(1)(D). Possible grounds for challenge include, but are not limited to, the following:

(i) The applicant has failed to list a data requirement applicable to his product, or has failed to demonstrate compliance with all applicable data requirements.

(ii) The applicant has submitted or cited a study that is not valid.

(iii) The applicant has submitted or cited a study that does not satisfy the data requirement for which it was submitted or cited.

(iv) The applicant has failed to comply with the procedure for showing that a data gap exists.

(v) The applicant has improperly certified that a data gap exists. An original data submitter who has failed without good cause to respond to an applicant's request for confirmation of a data gap may not petition the Agency for review on this basis.

(vi) The applicant has submitted or cited a study originally submitted by the petitioner, without the required authorization or offer to pay.

(b) Procedure for petition to the Agency--(1) Time for filing. A petition under paragraph (a)(1) of this section may be filed at any time that the circumstances warrant. A petition under paragraph (a)(2) of this section must be filed within one year after the Agency makes public the issuance of the registration.

(2) Notice to affected registrant. At the same time that the

petitioner files his petition with the Agency, he shall send a copy by certified mail to the affected applicant or registrant. The applicant or registrant shall have 60 days from the date of his receipt of the petition to submit written comments to the Agency.

[[Page 24]]

(c) Disposition of petitions. The Agency will consider the material submitted by the petitioner and the response, if any, by the affected applicant or registrant.

(1) If the Agency determines that the petition is without merit, it will inform the petitioner and the affected applicant or registrant that the petition is denied. Denial of a petition is a final Agency action.

(2) If the Agency determines that an applicant has acted in any way described by paragraph (a)(1) of this section, the Agency will notify the petitioner and the affected applicant or registrant that it intends to deny or cancel the registration of the product in support of which the data were cited. The affected applicant or registrant will have 15 days from the date of delivery of this notice to respond. If the Agency determines, after considering any response, that the affected applicant or registrant has acted in the ways described by paragraph (a)(1) of this section, the Agency will deny or cancel the registration without further hearing. Refer to FIFRA section 3(c)(1)(D)(ii). Denial or cancellation of a registration is a final Agency action.

(3) Except as provided in paragraph (c)(2) of this section, if the Agency determines that an applicant for registration of a product has acted in any way that deprives an original data submitter of rights under FIFRA section 3(c)(1)(D), the Agency will take steps to deny the application or cancel the registration, as appropriate. The procedures in FIFRA section 3(c)(6) or section 6(b) shall be followed. Denial or cancellation is a final Agency action.

(d) Hearing. Any hearing will be conducted in accordance with the procedures in 40 CFR part 164. The only matter for resolution at the hearing shall be whether the registrant failed to comply with the requirements and procedures of FIFRA section 3(c)(1)(D) or of this subpart, in the manner described by the petitioner. A decision following a hearing shall be final.

Subpart F--Agency Review of Applications

Source: 53 FR 15980, May 4, 1988, unless otherwise noted.

Sec. 152.100 Scope.

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

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

Sec. 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.

Sec. 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 Sec. 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).

Sec. 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.

Sec. 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 Sec. 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.

Sec. 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.

Sec. 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.

Sec. 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).

Sec. 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 Secs. 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;

[[Page 26]]

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

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

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

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

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

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

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

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

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

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

(b) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide under FIFRA sec. 3(c)(7)(A) unless the Agency has determined that the applicant's product and its proposed use are identical or substantially similar to a currently registered pesticide and use, or that the pesticide and its proposed use differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.

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

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

(2) The proposed new use involves use on a major food or feed crop, or involves use on a minor food or feed crop for which there is available an effective alternative registered pesticide which does not meet the risk criteria associated with human dietary exposure. The

determination of available and effective alternatives shall be made with the concurrence of the Secretary of Agriculture.

Sec. 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

[[Page 27]]

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 Sec. 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.

Sec. 152.115 Conditions of registration.

(a) Substantially similar products and new uses. Each registration issued under Sec. 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 Sec. 152.114 shall be conditioned upon the applicant's agreement to each of the following conditions:

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

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

registrant a Notice of Intent to Cancel under FIFRA sec. 6(e), and will specify any provisions for sale and distribution of existing stocks of the pesticide product.

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

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

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

[53 FR 15980, May 4, 1988, as amended at 60 FR 32096, June 19, 1995]

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

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

(b) Within 30 days after receipt of the Agency's notice, or of the applicant's list of data requirements, whichever is later, the exclusive use data submitter

[[Page 28]]

may challenge the issuance of the registration in accordance with the procedures in Sec. 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.

Sec. 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.

Sec. 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 Secs. 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.

Sec. 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.

Sec. 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.

Sec. 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]

Sec. 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.

Sec. 152.132 Supplemental distribution.

The registrant may distribute or sell his registered product under another person's name and address instead of (or in addition to) his own. Such distribution and sale is termed ``supplemental distribution''

and the product is referred to as a ``distributor product.'' The distributor is considered an agent of the registrant for all intents and purposes under the Act, and both the registrant and the distributor may be held liable for violations pertaining to the distributor product. Supplemental distribution is permitted upon notification to the Agency if all the following conditions are met:

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

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

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

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

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

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

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

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

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

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

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

Sec. 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 transferor;

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

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

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

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

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

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

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

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

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

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

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

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

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

(f) Rights to exclusive use of data or compensation under FIFRA sec.

3(c)(1)(D) are separate from the registration itself and may be retained by the transferor, or may be transferred independently in accordance with the provisions of Sec. 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.

Sec. 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.

Sec. 152.161 Definitions.

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

(a) Dietary LC<INF>50 means a statistically derived estimate of the concentration of a test substance in the diet that would cause 50 percent mortality to the test population under specified conditions.

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

Sec. 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.

[[Page 32]]

(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.

Sec. 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 Sec. 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 Sec. 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.

Sec. 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 the final rule unless the product bears a label or labeling which complies with paragraph (a)(1) of this section.

Sec. 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.

[[Page 33]]

(b) The requirement in paragraph (a) of this section applies to all advertisements of the product, including, but not limited, to:
(1) Brochures, pamphlets, circulars and similar material offered to purchasers at the point of sale or by direct mail.
(2) Newspapers, magazines, newsletters and other material in circulation or available to the public.
(3) Broadcast media such as radio and television.
(4) Telephone advertising.
(5) Billboards and posters.
(c) The requirement may be satisfied for printed material by inclusion of the statement ``Restricted Use Pesticide,'' or the terms of restriction, prominently in the advertisement. The requirement may be satisfied with respect to broadcast or telephone advertising by inclusion in the broadcast of the spoken words ``Restricted use pesticide,'' or a statement of the terms of restriction.
(d) The requirements of this section shall be effective:
(1) After 270 days after the effective date of restriction of a product that is currently registered, unless the Agency specifies a shorter time period;
(2) Upon the effective date of registration of a product not currently registered.

Sec. 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<INF>50 of 1.5 g/kg or less;

(ii) The pesticide, as formulated, has an acute dermal LD<INF>50 of 2000 mg/kg or less;

(iii) The pesticide, as formulated, has an acute inhalation LC<INF>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<INF>50 of 50 mg/kg or less;

(ii) The pesticide, as formulated, has an acute dermal LD<INF>50 of 200 mg/kg or less;

(iii) The pesticide, as diluted for use, has an acute dermal LD<INF>50 of 16 g/kg or less;

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

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

[[Page 34]]

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

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

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

(i) When used according to label directions, application results in residues of the pesticide, its metabolites, or its degradation products,

in the diet of exposed mammalian wildlife, immediately after application, such that:

(A) The level of such residues equals or exceeds one-fifth of the acute dietary LC<INF>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<INF>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<INF>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<INF>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<INF>50 of 50 mg/kg or less as determined by extrapolation from tests conducted with technical material or directly with the formulated product; and

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

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

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

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

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

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

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

(iv) Following directions for use would result in few or no

significant adverse effects of a delayed or indirect

[[Page 35]]

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.

Sec. 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.

Sec. 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.

[[Page 36]]

Active ingredient	Formulation	Use pattern	Classification\1\	Criteria influencing restriction
Acrolein	As sole active ingredient. No mixtures registered.	All uses	Restricted	Inhalation hazard to humans. Residue effects on avian species and aquatic organisms.
Aldicarb	As sole active ingredient.	Ornamental uses (indoor and outdoor).	...do...	Other hazards--accident history.
	No mixtures registered	Agricultural crop uses.	Under further evaluation.	
Aluminum phosphide	As sole active ingredient. No mixtures registered.	...do...	...do...	Inhalation hazard to humans.
Azinphos methyl	All liquids with a concentration greater than 13.5 pct.	...do...	...do...	Do.
	All other formulations	...do...	Under futher evaluation..	
Carbofuran	All concentrate	...do...	...do...	Acute inhalation

	suspensions and wettable powders 40% and greater.			toxicity.
	All granular formulations.	Rice.....	Under evaluation.	
	All granular and fertilizer formulations.	All uses except rice.	.....do.....	
Chloropicrin.....	All formulations greater than 2%.	All uses.....	.....do.....	Acute inhalation toxicity.
	All formulations.....	Rodent control.	.....do.....	Hazard to non-target organisms.
	All formulations 2% and less.	Outdoor uses (other than rodent control).	Unclassified.....	
Clonitralid.....	All wettable powders 70% and greater.	All uses.....	Restricted.....	Acute inhalation toxicity.
	All granulars and wettable powders.	Molluscide uses	Restricted.....	Effects on aquatic organisms.
	Pressurized sprays 0.55% and less.	Hospital antiseptics.	Unclassified.....	
Dicrotophos.....	All liquid formulations 8% and greater.	All uses.....	Restricted.....	Acute dermal toxicity; residue effects on avian species (except for tree injections).
Disulfoton.....	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 in combination with 32% fensulfothion and greater.	.....do.....	Restricted.....	Do. Acute inhalation toxicity.
	Non-aqueous solution 95% and greater.	Commercial seed treatment.	Restricted.....	Acute dermal toxicity.
	Granular formulations 10% and greater.	Indoor uses (greenhouse).	.....do.....	Acute inhalation toxicity.
Ethoprop.....	Emulsifiable concentrates 40% and greater.	Aquatic uses...	.....do.....	Acute dermal toxicity.
	All granular and fertilizer formulations.	All uses.....	Under evaluation.	
Ethyl parathion.....	All granular and dust formulations greater than 2 pct, fertilizer formulations,	.....do.....	Restricted.....	Inhalation hazard to humans. Acute dermal toxicity. Residue effects on mammalian, aquatic, avian

	wettable powders, emulsifiable concentrates, concentrated suspensions, concentrated solutions.			species.
	Smoke fumigants.....	.....do.....	.....do.....	Inhalation hazard to humans.
	Dust and granular formulations 2 pct and below.	.....do.....	.....do.....	Other hazards--accident history.
Fenamiphos.....	Emulsifiable concentrates 35% and greater.	.....do.....	.....do.....	Acute dermal toxicity.
Fonofos.....	Emulsifiable concentrates 44% and greater.	.....do.....	.....do.....	Acute dermal toxicity.
	Emulsifiable concentrates 12.6% and less with pebulate 50.3% and less.	Tobacco.....	Unclassified.....	
Methamidophos.....	Liquid formulations 40% and greater.	.....do.....	Restricted.....	Acute dermal toxicity; residue effects on avian species.
	Dust formulations 2.5% and greater.	.....do.....	.....do.....	Residue effects on avian species.

[[Page 37]]

Methidathion.....	All formulations.....	All uses except nursery stock, safflower and sunflower.	.....do.....	Do.
	All formulations.....	Nursery stock, safflower and sunflower.	Unclassified.....	
Methomyl.....	As sole active ingredient in 1 pct to 2.5 baits (except 1 pct fly bait).	Nondomestic outdoors-agricultural crops, ornamental and turf. All other registered uses.	Restricted.....	Residue effects on mammalian species.
	All concentrated solution formulations.	.....do.....	.....do.....	Other hazards-accident history.
	90 pct wettable powder formulations (not in water soluble bags).	.....do.....	.....do.....	Do.
	90 pct wettable powder formulation in water soluble bags.	.....do.....	Unclassified.....	

	All granular formulations.	.....do.....	.....do.....	
	25 pct wettable powder formulations.	.....do.....	.....do.....	
	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.	.....do.....	.....do.....	
Methyl bromide.....	All formulations in containers greater than 1.5 lb.	All uses.....	Restricted.....	Do.
	Containers with not more than 1.5 lb of methyl bromide with 0.25 pct to 2.0 pct chloropicrin as an indicator.	Single applications (nondomestic use) for soil treatment in closed systems.	Unclassified.....	
	Container with not more than 1.5 lb having no indicator.	All uses.....	Restricted.....	Do.
Methyl parathion.....	All dust and granular formulations less than 5 pct.	.....do.....	.....do.....	Other hazards-accident history. All foliar applications restricted based on residue effects on mammalian and avian species.
	Microencapsulated.....	.....do.....	.....do.....	Residue effects on avian species. Hazard to bees.
	All dust and granular formulations 5 pct and greater and all wettable powders and liquids.	.....do.....	.....do.....	Acute dermal toxicity. Residue effects on mammalian and avian species.
Nicotine (alkaloid).....	Liquid and dry formulations 14% and above.	Indoor (greenhouse).	.....do.....	Acute inhalation toxicity.
	All formulations.....	Applications to cranberries.	.....do.....	Effects on aquatic organisms.
	Liquid and dry formulations 1.5% and less.	All uses (domestic and nondomestic).	Unclassified.....	
Paraquat (dichloride) and paraquat bis(methyl sulfate).	All formulations and concentrations except those listed below.	All uses.....	Restricted.....	Other hazards. Use and accident history, human toxicological data.
	Pressurized spray formulations containing 0.44 pct	Spot weed and grass control.	.....do.....	

	Paraquat bis(methyl sulfate) and 15 pct petroleum distillates as active ingredients.			
	Liquid fertilizers containing concentrations of 0.025 pct paraquat dichloride and 0.03 percent atrazine; 0.03 pct paraquat dichloride and 0.37 pct atrazine, 0.04 pct paraquat dichloride and 0.49 pct atrazine.	All uses.....	Unclassified.....	

[[Page 38]]

Phorate.....	Liquid formulations 65% and greater.	.....do.....	Restricted.....	Acute dermal toxicity. Residue effects on avian species (applies to foliar applications only). Residue effects on mammalian species (applies to foliar application only).
	All granular formulations.	Rice.....	.....do.....	Effects on aquatic organisms.
Phosphamidon.....	Liquid formulations 75% and greater.	.....do.....	.....do.....	Acute dermal toxicity. Residue effects on mammalian species. Residue effects on avian species.
	Dust formulations 1.5% and greater.	.....do.....	.....do.....	Do. Residue effects on mammalian species.
Picloram.....	All formulations and concentrations except tordon 101 R.	.....do.....	.....do.....	Hazard to nontarget organisms (specifically nontarget plants both crop and noncrop).
	Tordon 101 R forestry herbicide containing 5.4 pct picloram and 20.9 pct 2.4-D.	Control of unwanted trees by cut surface treatment.	Unclassified.....	
Sodium cyanide\3\.....	All capsules and ball formulations.	All uses.....	Restricted.....	Inhalation hazard to humans.
Sodium fluoroacetate.....	All solutions and dry baits.	.....do.....	.....do.....	Acute oral toxicity. Hazard to nontarget organisms. Use and accident history.
Strychnine.....	All dry baits, pellets and powder	.....do.....	.....do.....	Acute oral toxicity. Hazard to nontarget

	formulations greater than 0.5 pct.			avain species. Use and accident history.
	All dry baits, pellets and powder formulations.	All uses calling for burrow builders.	.....do.....	Hazard to nontarget organisms.
	All dry baits, pellets and powder formulations 0.5 pct and below.	All uses except subsoil.	.....do.....	Do.
	.....do.....	All subsoil uses.	Unclassified.....	
Sulfotepp.....	Sprays and smoke generators.	All uses.....	Restricted.....	Inhalation hazard to humans.
Zinc Phosphide.....	All formulations 2% and less.	All domestic uses and non-domestic uses in and around buildings.	Unclassified.....	
	All dry formulations 60% and greater..	All uses.....	Restricted.....	Acute inhalation toxicity.
	All bait formulations.	Non-domestic outdoor uses (other than around buildings).	.....do.....	Hazard to non-target organisms.
	All dry formulations 10% and greater.	Domestic uses..	.....do.....	Acute oral toxicity.

\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.)

[43 FR 5790, Feb. 9, 1978, as amended at 44 FR 45132, Aug. 1, 1979; 46 FR 5698, Jan. 19, 1981. Redesignated and amended at 53 FR 15988, May 4, 1988; 60 FR 32096, June 19, 1995]

[[Page 39]]

Subparts J--T [Reserved]

Subpart U--Registration Fees

Source: 53 FR 19114, May 26, 1988, unless otherwise noted.

Sec. 152.400 Purpose.

Subpart U prescribes fees to be charged for the pesticide regulatory activities set forth in Sec. 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.

Sec. 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).

[53 FR 11923, Mar. 22, 1989]

Sec. 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 Sec. 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).

Sec. 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 Sec. 152.410. The Agency may waive or refund fees in accordance with Sec. 152.412.

Table--Registration Fees

Type of review	Fee
New chemical	$184,500
New biochemical or microbial	64,000
New use pattern	33,800
Experimental use permit	4,500
Old chemical	4,000

[[Page 40]]

Amendment	700

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

Sec. 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]

Sec. 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.

Sec. 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.

Sec. 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 Sec. 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

[[Page 41]]

lack commercial feasibility for the pesticide applicant. An applicant requesting a waiver on this basis must provide supporting information that demonstrates that anticipated revenues from the uses that are the subject of the application would be insufficient to pay back the cost of the fee. The burden of proof of the reasonableness of this estimate rests with the applicant.

(2) IR-4. Fees will be waived for registration actions that are determined to be specifically associated with tolerance petitions submitted by the Inter-Regional Research Project Number 4 (IR-4 program) when such waiver is deemed by the Agency to be in the public interest.

(3) Severe economic impact. The Agency may waive two-thirds of any

cumulative registration fee payment in a 12-month period following completion of the applicant's most recent fiscal year that exceeds 3 percent of the applicant's pesticide sales in its most recently completed fiscal year. An applicant requesting a waiver on this basis must provide documentation (e.g. copy of an annual report, or income tax forms filed with the Internal Revenue Service, or if needed, a notarized statement signed by a corporate officer regarding annual pesticide sales) demonstrating that:

(i) The company applying had less than $40 million in gross revenue (including all revenue sources) in the most recently concluded fiscal year of operation, and a single fee would constitute more than 3 percent of the applicant's gross revenue from pesticide sales in the most recently completed fiscal year of operation, or

(ii) The company applying had less than $40 million in gross revenue (including all revenue sources) in the most recently concluded fiscal year of operation, and the cumulative registration fees paid during the 12 months following the applicant's most recently completed fiscal year, including any registration fees paid for the applicant for which a waiver is requested, constitute more than 3 percent of the applicant's gross revenue from pesticide sales in the most recently concluded fiscal year of operation.

(iii) The Agency will not grant such a waiver if it determines that the entity submitting the application has been formed or manipulated to qualify for such a waiver.

(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 34203, June 23, 1993]

Sec. 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), 401 M. Street SW., 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

[[Page 42]]

360277M, Pittsburgh, PA 15251. The payments should be specifically labeled ``Registration Fees'' and should be accompanied only by a copy of the registration application form or the experimental use permit application form, as appropriate. An application will not be accepted for processing until the required fees have been submitted.

(c) Procedures for submitting application and supporting data. The application, along with supporting data, shall be forwarded within 30 days of payment to the Washington DC address set forth in paragraph (a)(1) of this section.

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

Subparts V--Y [Reserved]

Subpart Z--Devices

Sec. 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.

[53 FR 15990, May 4, 1988. Redesignated at 60 FR 32096, June 19, 1995]