7 U.S.C.
United States Code, 2023 Edition
Title 7 - AGRICULTURE
CHAPTER 6 - INSECTICIDES AND ENVIRONMENTAL PESTICIDE CONTROL
From the U.S. Government Publishing Office, www.gpo.gov

CHAPTER 6—INSECTICIDES AND ENVIRONMENTAL PESTICIDE CONTROL

SUBCHAPTER I—INSECTICIDES

Sec.

121 to 134. Repealed.

SUBCHAPTER II—ENVIRONMENTAL PESTICIDE CONTROL

135 to 135k. Omitted.
136. Definitions.
136a. Registration of pesticides.
136a–1. Reregistration of registered pesticides.
136b. Transferred.
136c. Experimental use permits.
136d. Administrative review; suspension.
136e. Registration of establishments.
136f. Books and records.
136g. Inspection of establishments, etc.
136h. Protection of trade secrets and other information.
136i. Use of restricted use pesticides; applicators.
136i–1. Pesticide recordkeeping.
136i–2. Collection of pesticide use information.
136j. Unlawful acts.
136k. Stop sale, use, removal, and seizure.
136*l*. Penalties.
136m. Indemnities.
136n. Administrative procedure; judicial review.
136*o*. Imports and exports.
136p. Exemption of Federal and State agencies.
136q. Storage, disposal, transportation, and recall.
136r. Research and monitoring.
136r–1. Integrated Pest Management.
136s. Solicitation of comments; notice of public hearings.
136t. Delegation and cooperation.
136u. State cooperation, aid, and training.
136v. Authority of States.
136w. Authority of Administrator.
136w–1. State primary enforcement responsibility.
136w–2. Failure by the State to assure enforcement of State pesticide use regulations.
136w–3. Identification of pests; cooperation with Department of Agriculture's program.
136w–4. Omitted.
136w–5. Minimum requirements for training of maintenance applicators and service technicians.
136w–6. Environmental Protection Agency minor use program.
136w–7. Department of Agriculture minor use program.

136w–8. Pesticide registration service fees.
136x. Severability.
136y. Authorization of appropriations.

SUBCHAPTER I—INSECTICIDES

§§121 to 134. Repealed. June 25, 1947, ch. 125, §16, 61 Stat. 172

Sections, act Apr. 26, 1910, ch. 191, 36 Stat. 335, formerly known as "The Insecticides Act", are covered by subchapter II of this chapter.

Statutory Notes and Related Subsidiaries

Effective Date of Repeal; Savings Provision

Act June 25, 1947, ch. 125, §16, 61 Stat. 172, repealed this subchapter effective one year after June 25, 1947, and further provided that this subchapter should be deemed to remain in full force for the purpose of sustaining any proper suit, action, or other proceeding with respect to any violations, liabilities incurred, or appeals taken prior to such date of repeal or to sales, shipments, or deliveries of insecticides and fungicides exempted by the Secretary.

SUBCHAPTER II—ENVIRONMENTAL PESTICIDE CONTROL

§§135 to 135k. Omitted

Editorial Notes

Codification

Sections 135 to 135k, acts June 25, 1947, ch. 125, §§2–13, 61 Stat. 163–172; Aug. 7, 1959, Pub. L. 86–139, §2, 73 Stat. 286; May 12, 1964, Pub. L. 88–305, §§1–6, 78 Stat. 190–193; Oct. 15, 1970, Pub. L. 91–452, title II, §204, 84 Stat. 928; Dec. 30, 1970, Pub. L. 91–601, §6(b), formerly §7(b), 84 Stat. 1673, renumbered, Aug. 13, 1981, Pub. L. 97–35, title XII, §1205(c), 95 Stat. 716, which related to economic poison control, were superseded by the amendments made to act June 25, 1947, by Pub. L. 92–516, Oct. 21, 1972, 86 Stat. 975. See section 4 of Pub. L. 92–516, set out as a note under section 136 of this title. The provisions of act June 25, 1947, as amended by Pub. L. 92–516, are set out in section 136 et seq. of this title.

Section 135 provided definitions for the purposes of this subchapter.

Section 135a related to prohibited acts.

Section 135b related to registration of economic poisons.

Section 135c related to access, inspection, and use in criminal prosecutions of books and records.

Section 135d related to rules and regulations, examination of economic poisons or devices, notification to violators, certification to United States attorney, duty of attorney, and publication of judgments.

Section 135e related to exemptions from penalties.

Section 135f provided for penalties.

Section 135g related to seizure, disposal, and award of costs against claimant.

Section 135h related to refusal of admission of imports.

Section 135i related to delegation of duties.

Section 135j related to authorization of appropriations and expenditure of funds.

Section 135k related to cooperation between departments and agencies.

§136. Definitions

For purposes of this subchapter—

(a) Active ingredient

The term "active ingredient" means—

(1) in the case of a pesticide other than a plant regulator, defoliant, desiccant, or nitrogen stabilizer, an ingredient which will prevent, destroy, repel, or mitigate any pest;

(2) in the case of a plant regulator, an ingredient which, through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof;

(3) in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant;

(4) in the case of a desiccant, an ingredient which will artificially accelerate the drying of plant tissue; and

(5) in the case of a nitrogen stabilizer, an ingredient which will prevent or hinder the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria.

(b) Administrator

The term "Administrator" means the Administrator of the Environmental Protection Agency.

(c) Adulterated

The term "adulterated" applies to any pesticide if—

(1) its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold;

(2) any substance has been substituted wholly or in part for the pesticide; or

(3) any valuable constituent of the pesticide has been wholly or in part abstracted.

(d) Animal

The term "animal" means all vertebrate and invertebrate species, including but not limited to man and other mammals, birds, fish, and shellfish.

(e) Certified applicator, etc.

(1) Certified applicator

The term "certified applicator" means any individual who is certified under section 136i of this title as authorized to use or supervise the use of any pesticide which is classified for restricted use. Any applicator who holds or applies registered pesticides, or uses dilutions of registered pesticides consistent with subsection (ee), only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served is not deemed to be a seller or distributor of pesticides under this subchapter.

(2) Private applicator

The term "private applicator" means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by the applicator or the applicator's employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

(3) Commercial applicator

The term "commercial applicator" means an applicator (whether or not the applicator is a private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by paragraph (2).

(4) Under the direct supervision of a certified applicator

Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a competent person acting under the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.

(f) Defoliant

The term "defoliant" means any substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

(g) Desiccant

The term "desiccant" means any substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

(h) Device

The term "device" means any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.

(i) District court

The term "district court" means a United States district court, the District Court of Guam, the District Court of the Virgin Islands, and the highest court of American Samoa.

(j) Environment

The term "environment" includes water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these.

(k) Fungus

The term "fungus" means any non-chlorophyll-bearing thallophyte (that is, any non-chlorophyll-bearing plant of a lower order than mosses and liverworts), as for example, rust, smut, mildew, mold, yeast, and bacteria, except those on or in living man or other animals and those on or in processed food, beverages, or pharmaceuticals.

(l) Imminent hazard

The term "imminent hazard" means a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary pursuant to the Endangered Species Act of 1973 [16 U.S.C. 1531 et seq.].

(m) Inert ingredient

The term "inert ingredient" means an ingredient which is not active.

(n) Ingredient statement

The term "ingredient statement" means a statement which contains—

(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide; and

(2) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic.

(o) Insect

The term "insect" means any of the numerous small invertebrate animals generally having the body more or less obviously segmented, for the most part belonging to the class insecta, comprising six-legged, usually winged forms, as for example, beetles, bugs, bees, flies, and to other allied classes of arthropods whose members are wingless and usually have more than six legs, as for example, spiders, mites, ticks, centipedes, and wood lice.

(p) Label and labeling

(1) Label

The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) Labeling

The term "labeling" means all labels and all other written, printed, or graphic matter—

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

(q) Misbranded

(1) A pesticide is misbranded if—

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 136e of this title to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America".

(2) A pesticide is misbranded if—

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if—

(i) the size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

(B) the labeling does not contain a statement of the use classification under which the product is registered;

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing—

(i) the name and address of the producer, registrant, or person for whom produced;

(ii) the name, brand, or trademark under which the pesticide is sold;

(iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and

(iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification; and

(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this subchapter—

(i) the skull and crossbones;

(ii) the word "poison" prominently in red on a background of distinctly contrasting color; and

(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

(r) Nematode

The term "nematode" means invertebrate animals of the phylum nemathelminthes and class nematoda, that is, unsegmented round worms with elongated, fusiform, or saclike bodies covered with cuticle, and inhabiting soil, water, plants, or plant parts; may also be called nemas or eelworms.

(s) Person

The term "person" means any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.

(t) Pest

The term "pest" means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section 136w(c)(1) of this title.

(u) Pesticide

The term "pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer, except that the term "pesticide" shall not include any article that is a "new animal drug" within the meaning of section 321(w) [1] of title 21, that has been determined by the Secretary of Health and Human Services not to be a new animal drug by a regulation establishing conditions of use for the article, or that is an animal feed within the meaning of section 321(x) [1] of title 21 bearing or containing a new animal drug. The term "pesticide" does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in section 321 of title 21. For purposes of the preceding sentence, the term "critical device" includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term "semi-critical device" includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

(v) Plant regulator

The term "plant regulator" means any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but shall not include substances to

the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Also, the term "plant regulator" shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.

(w) Producer and produce

The term "producer" means the person who manufactures, prepares, compounds, propagates, or processes any pesticide or device or active ingredient used in producing a pesticide. The term "produce" means to manufacture, prepare, compound, propagate, or process any pesticide or device or active ingredient used in producing a pesticide. The dilution by individuals of formulated pesticides for their own use and according to the directions on registered labels shall not of itself result in such individuals being included in the definition of "producer" for the purposes of this subchapter.

(x) Protect health and the environment

The terms "protect health and the environment" and "protection of health and the environment" mean protection against any unreasonable adverse effects on the environment.

(y) Registrant

The term "registrant" means a person who has registered any pesticide pursuant to the provisions of this subchapter.

(z) Registration

The term "registration" includes reregistration.

(aa) State

The term "State" means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa.

(bb) Unreasonable adverse effects on the environment

The term "unreasonable adverse effects on the environment" means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

(cc) Weed

The term "weed" means any plant which grows where not wanted.

(dd) Establishment

The term "establishment" means any place where a pesticide or device or active ingredient used in producing a pesticide is produced, or held, for distribution or sale.

(ee) To use any registered pesticide in a manner inconsistent with its labeling

The term "to use any registered pesticide in a manner inconsistent with its labeling" means to use any registered pesticide in a manner not permitted by the labeling, except that the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency, (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment, (3) employing

any method of application not prohibited by the labeling unless the labeling specifically states that the product may be applied only by the methods specified on the labeling, (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling, (5) any use of a pesticide in conformance with section 136c, 136p, or 136v of this title, or (6) any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this subchapter. After March 31, 1979, the term shall not include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in section 27(b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution.

(ff) Outstanding data requirement

(1) In general

The term "outstanding data requirement" means a requirement for any study, information, or data that is necessary to make a determination under section 136a(c)(5) of this title and which study, information, or data—

(A) has not been submitted to the Administrator; or

(B) if submitted to the Administrator, the Administrator has determined must be resubmitted because it is not valid, complete, or adequate to make a determination under section 136a(c)(5) of this title and the regulations and guidelines issued under such section.

(2) Factors

In making a determination under paragraph (1)(B) respecting a study, the Administrator shall examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

(gg) To distribute or sell

The term "to distribute or sell" means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. The term does not include the holding or application of registered pesticides or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.

(hh) Nitrogen stabilizer

The term "nitrogen stabilizer" means any substance or mixture of substances intended for preventing or hindering the process of nitrification, denitrification, ammonia volatilization, or urease production through action upon soil bacteria. Such term shall not include—

(1) dicyandiamide;

(2) ammonium thiosulfate; or

(3) any substance or mixture of substances.— [2]

(A) that was not registered pursuant to section 136a of this title prior to January 1, 1992; and

(B) that was in commercial agronomic use prior to January 1, 1992, with respect to which after January 1, 1992, the distributor or seller of the substance or mixture has made no specific claim of prevention or hindering of the process of nitrification, denitrification, ammonia volatilization [3] urease production regardless of the actual use or purpose for, or future use or purpose for, the substance or mixture.

Statements made in materials required to be submitted to any State legislative or regulatory authority, or required by such authority to be included in the labeling or other literature accompanying any such substance or mixture shall not be deemed a specific claim within the meaning of this subsection.

(jj) [4] Maintenance applicator

The term "maintenance applicator" means any individual who, in the principal course of such individual's employment, uses, or supervises the use of, a pesticide not classified for restricted use (other than a ready to use consumer products pesticide); for the purpose of providing structural pest control or lawn pest control including janitors, general maintenance personnel, sanitation personnel, and grounds maintenance personnel. The term "maintenance applicator" does not include private applicators as defined in subsection (e)(2); individuals who use antimicrobial pesticides, sanitizers or disinfectants; individuals employed by Federal, State, and local governments or any political subdivisions thereof, or individuals who use pesticides not classified for restricted use in or around their homes, boats, sod farms, nurseries, greenhouses, or other noncommercial property.

(kk) Service technician

The term "service technician" means any individual who uses or supervises the use of pesticides (other than a ready to use consumer products pesticide) for the purpose of providing structural pest control or lawn pest control on the property of another for a fee. The term "service technician" does not include individuals who use antimicrobial pesticides, sanitizers or disinfectants; or who otherwise apply ready to use consumer products pesticides.

(ll) Minor use

The term "minor use" means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where—

(1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or

(2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and—

(A) there are insufficient efficacious alternative registered pesticides available for the use;

(B) the alternatives to the pesticide use pose greater risks to the environment or human health;

(C) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(D) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The status as a minor use under this subsection shall continue as long as the Administrator has not determined that, based on existing data, such use may cause an unreasonable adverse effect on the environment and the use otherwise qualifies for such status.

(mm) Antimicrobial pesticide

(1) In general

The term "antimicrobial pesticide" means a pesticide that—

(A) is intended to—

(i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or

(ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(B) in the intended use is exempt from, or otherwise not subject to, a tolerance under section 346a of title 21 or a food additive regulation under section 348 of title 21.

(2) Excluded products

The term "antimicrobial pesticide" does not include—

(A) a wood preservative or antifouling paint product for which a claim of pesticidal activity other than or in addition to an activity described in paragraph (1) is made;

(B) an agricultural fungicide product; or
(C) an aquatic herbicide product.

(3) Included products

The term "antimicrobial pesticide" does include any other chemical sterilant product (other than liquid chemical sterilant products exempt under subsection (u)), any other disinfectant product, any other industrial microbiocide product, and any other preservative product that is not excluded by paragraph (2).

(nn) Public health pesticide

The term "public health pesticide" means any minor use pesticide product registered for use and used predominantly in public health programs for vector control or for other recognized health protection uses, including the prevention or mitigation of viruses, bacteria, or other microorganisms (other than viruses, bacteria, or other microorganisms on or in living man or other living animal) that pose a threat to public health.

(oo) Vector

The term "vector" means any organism capable of transmitting the causative agent of human disease or capable of producing human discomfort or injury, including mosquitoes, flies, fleas, cockroaches, or other insects and ticks, mites, or rats.

(June 25, 1947, ch. 125, §2, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 975; amended Pub. L. 93–205, §13(f), Dec. 28, 1973, 87 Stat. 903; Pub. L. 94–140, §9, Nov. 28, 1975, 89 Stat. 754; Pub. L. 95–396, §1, Sept. 30, 1978, 92 Stat. 819; Pub. L. 100–532, title I, §101, title VI, §601(a), title VIII, §801(a), Oct. 25, 1988, 102 Stat. 2655, 2677, 2679; Pub. L. 102–237, title X, §1006(a)(1), (2), (b)(3)(A), (B), Dec. 13, 1991, 105 Stat. 1894, 1895; Pub. L. 104–170, title I, §§105(a), 120, title II, §§210(a), 221, 230, title III, §304, Aug. 3, 1996, 110 Stat. 1490, 1492, 1493, 1502, 1508, 1512.)

Editorial Notes

References in Text

The Endangered Species Act of 1973, referred to in subsec. (l), is Pub. L. 93–205, Dec. 28, 1973, 87 Stat. 884, which is classified generally to chapter 35 (§1531 et seq.) of Title 16, Conservation. For complete classification of this Act to the Code, see Short Title note set out under section 1531 of Title 16 and Tables.

Section 321 of title 21, referred to in subsec. (u), was subsequently amended, and subsecs. (w) and (x) of section 321 no longer define the terms "new animal drug" and "animal feed", respectively. However, such terms are defined elsewhere in that section.

Section 27(b) of Federal Pesticide Act of 1978, referred to in subsec. (ee), is section 27(b) of Pub. L. 95–396, Sept. 30, 1978, 92 Stat. 841, which was formerly set out as a note under section 136w–4 of this title.

Prior Provisions

A prior section 2 of act June 25, 1947, was classified to section 135 of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

Amendments

1996—Subsec. (a)(1). Pub. L. 104–170, §105(a)(1)(A), substituted "defoliant, desiccant, or nitrogen stabilizer" for "defoliant, or desiccant".

Subsec. (a)(5). Pub. L. 104–170, §105(a)(1)(B)–(D), added par. (5).

Subsec. (u). Pub. L. 104–170, §§105(a)(2), 221(1), struck out "and" before "(2)", inserted "and (3) any nitrogen stabilizer," after "desiccant,", and inserted at end "The term 'pesticide' does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in section 321 of title 21. For purposes of the preceding sentence, the term 'critical device' includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term 'semi-critical device' includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body."

Subsec. (bb). Pub. L. 104–170, §304, which directed amendment of section 2(bb) by inserting "(1)" after "means" and adding cl. (2), without specifying the Act being amended, was executed to this subsection, which

is section 2(bb) of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress.

Pub. L. 104–170, §230(a), inserted at end "The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide."

Subsec. (hh). Pub. L. 104–170, §105(a)(3), added subsec. (hh).

Subsecs. (jj), (kk). Pub. L. 104–170, §120, added subsecs. (jj) and (kk).

Subsec. (ll). Pub. L. 104–170, §210(a), added subsec. (ll).

Subsec. (mm). Pub. L. 104–170, §221(2), added subsec. (mm).

Subsecs. (nn), (oo). Pub. L. 104–170, §230(b), added subsecs. (nn) and (oo).

1991—Subsec. (e)(1). Pub. L. 102–237, §1006(a)(1), substituted "section 136i" for "section 136b" and "uses dilutions" for "use dilutions" and made technical amendment to reference to subsection (ee) of this section involving corresponding provision of original act.

Subsec. (e)(2). Pub. L. 102–237, §1006(b)(3)(A), substituted "the applicator or the applicator's" for "him or his".

Subsec. (e)(3). Pub. L. 102–237, §1006(b)(3)(B), substituted "the applicator" for "he".

Subsec. (q)(2)(A)(i). Pub. L. 102–237, §1006(a)(2), substituted "size or form" for "size of form".

1988—Subsec. (c). Pub. L. 100–532, §801(a)(1), substituted "if—" for "if:".

Subsec. (p)(2)(B). Pub. L. 100–532, §801(a)(2), substituted "Health and Human Services" for "Health, Education, and Welfare".

Subsec. (q)(2)(A). Pub. L. 100–532, §801(a)(3), substituted "if—" for "if:".

Subsec. (q)(2)(C)(iii). Pub. L. 100–532, §801(a)(4), substituted ", except that" for ": *Provided*, That".

Subsec. (u). Pub. L. 100–532, §801(a)(5), substituted ", except that" for ": *Provided*, That", struck out "(1) (a)" after "include any article" and "or (b)" after "section 321(w) of title 21,", and substituted "Health and Human Services" for "Health, Education, and Welfare", "or that is" for "or (2) that is", and "a new animal drug" for "an article covered by clause (1) of this proviso".

Subsec. (ee). Pub. L. 100–532, §§601(a)(1), 801(a)(6), substituted ", except that" for ": *Provided*, That", inserted "unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency" and "unless the labeling specifically states that the product may be applied only by the methods specified on the labeling", substituted "labeling, (4) mixing" for "labeling, or (4) mixing", ", (5)" for ": *Provided further*, That the term also shall not include", "or (6) any use" for "or any use", and ". After" for ": *And provided further*, That after".

Subsec. (ff). Pub. L. 100–532, §101, added subsec. (ff).

Subsec. (gg). Pub. L. 100–532, §601(a)(2), added subsec. (gg).

1978—Subsec. (e)(1). Pub. L. 95–396, §1(1), inserted provision deeming an applicator not a seller or distributor of pesticides when providing a service of controlling pests.

Subsec. (e)(3). Pub. L. 95–396, §1(2), substituted "an applicator" for "a certified applicator".

Subsec. (q)(1)(H). Pub. L. 95–396, §1(3), added subpar. (H).

Subsec. (w). Pub. L. 95–396, §1(4), (5), amended definition of "producer" and "produce" to include reference to active ingredient used in producing a pesticide and inserted provision that an individual did not become a producer when there was dilution of a pesticide for personal use according to directions on registered labels.

Subsec. (dd). Pub. L. 95–396, §1(6), inserted "or active ingredient used in producing a pesticide".

Subsec. (ee). Pub. L. 95–396, §1(7), added subsec. (ee).

1975—Subsec. (u). Pub. L. 94–140 inserted proviso which excluded from term "pesticide" any article designated as "new animal drug" and any article denominated as animal feed.

1973—Subsec. (l). Pub. L. 93–205 substituted "or threatened by the Secretary pursuant to the Endangered Species Act of 1973" for "by the Secretary of the Interior under Public Law 91–135".

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Pub. L. 100–532, title IX, §901, Oct. 25, 1988, 102 Stat. 2688, provided that: "Except as otherwise provided in this Act, the amendments made by this Act [see Short Title of 1988 Amendment note below] shall take effect on the expiration of 60 days after the date of enactment of this Act [Oct. 25, 1988]."

Effective Date of 1973 Amendment

Amendment by Pub. L. 93–205 effective Dec. 28, 1973, see section 16 of Pub. L. 93–205, set out as an Effective Date note under section 1531 of Title 16, Conservation.

Effective Date

Pub. L. 92–516, §4, Oct. 21, 1972, 86 Stat. 998, as amended by Pub. L. 94–140, §4, Nov. 28, 1975, 89 Stat. 752; Pub. L. 95–396, §28, Sept. 30, 1978, 92 Stat. 842, provided that:

"(a) Except as otherwise provided in the Federal Insecticide, Fungicide, and Rodenticide Act [this subchapter], as amended by this Act and as otherwise provided by this section, the amendments made by this Act [see Short Title note set out below] shall take effect at the close of the date of the enactment of this Act [Oct. 21, 1972], provided if regulations are necessary for the implementation of any provision that becomes effective on the date of enactment, such regulations shall be promulgated and shall become effective within 90 days from the date of enactment of this Act.

"(b) The provisions of the Federal Insecticide, Fungicide, and Rodenticide Act [this subchapter] and the regulations thereunder as such existed prior to the enactment of this Act shall remain in effect until superseded by the amendments made by this Act and regulations thereunder.

"(c)(1) Two years after the enactment of this Act the Administrator shall have promulgated regulations providing for the registration and classification of pesticides under the provisions of this Act and thereafter shall register all new applications under such provisions.

"(2) Any requirements that a pesticide be registered for use only by a certified applicator shall not be effective until five years from the date of enactment of this Act.

"(3) A period of five years from date of enactment shall be provided for certification of applicators.

"(A) One year after the enactment of this Act the Administrator shall have prescribed the standards for the certification of applicators.

"(B) Each State desiring to certify applicators shall submit a State plan to the Administrator for the purpose provided by section 4(b).

"(C) As promptly as possible but in no event more than one year after submission of a State plan, the Administrator shall approve the State plan or disapprove it and indicate the reasons for disapproval. Consideration of plans resubmitted by States shall be expedited.

"(4) One year after the enactment of this Act the Administrator shall have promulgated and shall make effective regulations relating to the registration of establishments, permits for experimental use, and the keeping of books and records under the provisions of this Act.

"(d) No person shall be subject to any criminal or civil penalty imposed by the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by this Act, for any act (or failure to act) occurring before the expiration of 60 days after the Administrator has published effective regulations in the Federal Register and taken such other action as may be necessary to permit compliance with the provisions under which the penalty is to be imposed.

"(e) For purposes of determining any criminal or civil penalty or liability to any third person in respect of any act or omission occurring before the expiration of the periods referred to in this section, the Federal Insecticide, Fungicide, and Rodenticide Act shall be treated as continuing in effect as if this Act had not been enacted."

Short Title of 2022 Amendment

Pub. L. 117–328, div. HH, title VI, §701, Dec. 29, 2022, 136 Stat. 5996, provided that: "This title [amending sections 136a, 136a–1, and 136w–8 of this title and section 346a of Title 21, Food and Drugs, and enacting provisions set out as notes under sections 136a, 136a–1, and 136w of this title] may be cited as the 'Pesticide Registration Improvement Act of 2022'."

Short Title of 2019 Amendment

Pub. L. 116–8, §1(a), Mar. 8, 2019, 133 Stat. 484, provided that: "This Act [amending sections 136a–1, 136c, and 136w–8 of this title and section 346a of Title 21, Food and Drugs, and enacting provisions set out as a note under section 136w of this title] may be cited as the 'Pesticide Registration Improvement Extension Act of 2018'."

Short Title of 2012 Amendment

Pub. L. 112–177, §1, Sept. 28, 2012, 126 Stat. 1327, provided that: "This Act [amending sections 136a–1 and 136w–8 of this title and section 346a of Title 21, Food and Drugs, and enacting provisions set out as notes

under section 136a–1 of this title] may be cited as the 'Pesticide Registration Improvement Extension Act of 2012'."

Short Title of 2007 Amendment

Pub. L. 110–94, §1, Oct. 9, 2007, 121 Stat. 1000, provided that: "This Act [amending sections 136a, 136a–1, and 136w–8 of this title and section 346a of Title 21, Food and Drugs, and enacting provisions set out as a note under section 136a of this title] may be cited as the 'Pesticide Registration Improvement Renewal Act'."

Short Title of 2004 Amendment

Pub. L. 108–199, div. G, title V, §501(a), Jan. 23, 2004, 118 Stat. 419, provided that: "This section [enacting section 136w–8 of this title, amending sections 136a, 136a–1, 136x, and 136y of this title, and enacting provisions set out as notes under section 136a of this title and section 346a of Title 21, Food and Drugs] may be cited as the 'Pesticide Registration Improvement Act of 2003'."

Short Title of 1996 Amendment

Pub. L. 104–170, §1, Aug. 3, 1996, 110 Stat. 1489, provided that: "This Act [enacting sections 136i–2, 136r–1, and 136w–5 to 136w–7 of this title, amending this section, sections 136a, 136a–1, 136d, 136q, 136s, 136w, 136w–3, 136x, and 136y of this title, and sections 321, 331, 333, 342, and 346a of Title 21, Food and Drugs, and enacting provisions set out as notes under section 136i–2 of this title and sections 301 and 346a of Title 21] may be cited as the 'Food Quality Protection Act of 1996'."

[Another Food Quality Protection Act of 1996 was enacted by Pub. L. 104–170, title IV, 110 Stat. 1513, see section 401(a) of Pub. L. 104–170, set out as a note under section 301 of Title 21, Food and Drugs.]

Short Title of 1988 Amendment

Pub. L. 100–532, §1(a), Oct. 25, 1988, 102 Stat. 2654, provided that: "This Act [enacting section 136a–1 of this title, amending this section and sections 136a to 136d, 136f to 136q, 136s, 136v to 136w–2, and 136y of this title, and enacting provisions set out as notes under this section and sections 136m and 136y of this title] may be cited as the 'Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988'."

Short Title of 1978 Amendment

Pub. L. 95–396, §29, Sept. 30, 1978, 92 Stat. 842, provided that: "This Act [enacting sections 136w–1 to 136w–4 of this title, amending this section and sections 136a to 136f, 136h, 136j, 136l, 136o, 136q, 136r, 136u to 136w, 136x, and 136y of this title, enacting provisions set out as notes under sections 136a, 136o, and 136w–4 of this title, and amending provisions set out as a note under this section] may be cited as the 'Federal Pesticide Act of 1978'."

Short Title

Pub. L. 92–516, §1, Oct. 21, 1972, 86 Stat. 973, provided: "That this Act [amending this subchapter generally, enacting notes set out under this section, and amending sections 1261 and 1471 of Title 15, Commerce and Trade, and sections 321 and 346a of Title 21, Foods and Drugs] may be cited as the 'Federal Environmental Pesticide Control Act of 1972'."

Act June 25, 1947, ch. 125, §1(a), as added by Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 973, provided that: "This Act [enacting this subchapter] may be cited as the 'Federal Insecticide, Fungicide, and Rodenticide Act'."

Executive Documents

Termination of Trust Territory of the Pacific Islands

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

Federal Compliance With Pollution Control Standards

For provisions relating to the responsibility of the head of each Executive agency for compliance with applicable pollution control standards, see Ex. Ord. No. 12088, Oct. 13, 1978, 43 F.R. 47707, set out as a note under section 4321 of Title 42, The Public Health and Welfare.

[1] *See References in Text note below.*

[2] So in original. Period probably should not appear.

[3] So in original. Probably should be followed by ", or".

[4] So in original. No subsec. (ii) was enacted.

§136a. Registration of pesticides

(a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

(b) Exemptions

A pesticide which is not registered with the Administrator may be transferred if—

(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

(c) Procedure for registration

(1) Statement required

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data.

(ii) The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after August 3, 1996, and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the

Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that—

(I) there are insufficient efficacious alternative registered pesticides available for the use;

(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;

(III) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

(iii) Except as otherwise provided in clause (i), with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this subchapter, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding

two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation.

(iv) After expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under clauses (i), (ii), and (iii), the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data.

(v) The period of exclusive use provided under clause (ii) shall not take effect until 1 year after August 3, 1996, except where an applicant or registrant is applying for the registration of a pesticide containing an active ingredient not previously registered.

(vi) With respect to data submitted after August 3, 1996, by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of a pesticide, such data shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. The applicant or registrant at the time the new minor use is requested shall notify the Administrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph. If the minor use registration which is supported by data submitted pursuant to this subsection is voluntarily canceled or if such data are subsequently used to support a nonminor use, the data shall no longer be subject to the exclusive use provisions of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.

(G) If the applicant is requesting that the registration or amendment to the registration of a pesticide be expedited, an explanation of the basis for the request must be submitted, in accordance with paragraph (10) of this subsection.

(2) Data in support of registration

(A) In general

The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter the Administrator requires any additional kind of information under subparagraph (B) of this paragraph, the Administrator shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, the public health and agricultural need for such minor use, and the level and degree of potential beneficial or adverse effects on man and the environment. The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this subchapter, any field residue data from a geographic area where the pesticide will not be registered for such use. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 136h of this title, within 30 days after the Administrator registers a pesticide under this subchapter the Administrator shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the Administrator's decision.

(B) Additional data

(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing, data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iv) Notwithstanding any other provision of this subchapter, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title. The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this subchapter, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of paragraph (1)(D). Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.

(vi) Upon the request of a registrant the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under section 136a–1 of this title for the other uses of the pesticide established as of August 3, 1996, if—

(I) the data to support other uses of the pesticide on a food are being provided;

(II) the registrant, in submitting a request for such an extension, provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(III) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under section 136a–1 of this title; and

(IV) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this clause, the Administrator may take action to modify or revoke the extension under this clause if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide, in writing to the registrant, a notice revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date established by the Administrator for the submission of the data.

(vii) If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this clause in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under section 136a–1 of this title for the supported uses identified pursuant to this clause unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of this subparagraph regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding the provisions of this clause, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the

minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(viii)(I) If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant.

(II) The Administrator may enter into a cooperative agreement with a State to carry out subclause (I).

(III) Not later than 1 year after August 3, 1996, the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.

(C) Simplified procedures

Within nine months after September 30, 1978, the Administrator shall, by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

(D) Exemption

No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to—

(i) submit or cite data pertaining to such purchased product; or

(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

(E) Minor use waiver

In handling the registration of a pesticide for a minor use, the Administrator may waive otherwise applicable data requirements if the Administrator determines that the absence of such data will not prevent the Administrator from determining—

(i) the incremental risk presented by the minor use of the pesticide; and

(ii) that such risk, if any, would not be an unreasonable adverse effect on the environment.

(3) Application

(A) In general

The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of the Administrator's determination that it does not comply with the provisions of the subchapter in accordance with paragraph (6).

(B) Identical or substantially similar

(i) The Administrator shall, as expeditiously as possible, review and act on any application received by the Administrator that—

(I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or

(II) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data.

(ii) In expediting the review of an application for an action described in clause (i), the Administrator shall—

(I) review the application in accordance with section 136w–8(f)(4)(B) of this title and, if the application is found to be incomplete, reject the application;

(II) not later than the applicable decision review time established pursuant to section 136w–8(f)(4)(B) of this title, or, if no review time is established, not later than 90 days after receiving a complete application, notify the registrant if the application has been granted or denied; and

(III) if the application is denied, notify the registrant in writing of the specific reasons for the denial of the application.

(C) Minor use registration

(i) The Administrator shall, as expeditiously as possible, review and act on any complete application—

(I) that proposes the initial registration of a new pesticide active ingredient if the active ingredient is proposed to be registered solely for minor uses, or proposes a registration amendment solely for minor uses to an existing registration; or

(II) for a registration or a registration amendment that proposes significant minor uses.

(ii) For the purposes of clause (i)—

(I) the term "as expeditiously as possible" means that the Administrator shall, to the greatest extent practicable, complete a review and evaluation of all data, submitted with a complete application, within 12 months after the submission of the complete application, and the failure of the Administrator to complete such a review and evaluation under clause (i) shall not be subject to judicial review; and

(II) the term "significant minor uses" means 3 or more minor uses proposed for every nonminor use, a minor use that would, in the judgment of the Administrator, serve as a replacement for any use which has been canceled in the 5 years preceding the receipt of the application, or a minor use that in the opinion of the Administrator would avoid the reissuance of an emergency exemption under section 136p of this title for that minor use.

(D) Adequate time for submission of minor use data

If a registrant makes a request for a minor use waiver, regarding data required by the Administrator, pursuant to paragraph (2)(E), and if the Administrator denies in whole or in part such data waiver request, the registrant shall have a full-time period for providing such data. For purposes of this subparagraph, the term "full-time period" means the time period originally established by the Administrator for submission of such data, beginning with the date of receipt by the registrant of the Administrator's notice of denial.

(4) Notice of application

The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

(5) Approval of registration

The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d)—

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this subchapter;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

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

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a

pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

(6) Denial of registration

If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, the Administrator shall notify the applicant for registration of the Administrator's determination and of the Administrator's reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of the Administrator's decision and of the Administrator's reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 136d of this title.

(7) Registration under special circumstances

Notwithstanding the provisions of paragraph (5)—

(A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provisions of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations issued under this subchapter, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on such other conditions as the Administrator may prescribe. A conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

(8) Interim administrative review

Notwithstanding any other provision of this subchapter, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this subchapter, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms "validated test" and "other significant evidence" as used herein shall be published by the Administrator in the Federal Register.

(9) Labeling

(A) Additional statements

Subject to subparagraphs (B) and (C), it shall not be a violation of this subchapter for a registrant to modify the labeling of an antimicrobial pesticide product to include relevant information on product efficacy, product composition, container composition or design, or other characteristics that do not relate to any pesticidal claim or pesticidal activity.

(B) Requirements

Proposed labeling information under subparagraph (A) shall not be false or misleading, shall not conflict with or detract from any statement required by law or the Administrator as a condition of registration, and shall be substantiated on the request of the Administrator.

(C) Notification and disapproval

(i) Notification

A registration may be modified under subparagraph (A) if—

(I) the registrant notifies the Administrator in writing not later than 60 days prior to distribution or sale of a product bearing the modified labeling; and

(II) the Administrator does not disapprove of the modification under clause (ii).

(ii) Disapproval

Not later than 30 days after receipt of a notification under clause (i), the Administrator may disapprove the modification by sending the registrant notification in writing stating that the proposed language is not acceptable and stating the reasons why the Administrator finds the proposed modification unacceptable.

(iii) Restriction on sale

A registrant may not sell or distribute a product bearing a disapproved modification.

(iv) Objection

A registrant may file an objection in writing to a disapproval under clause (ii) not later than 30 days after receipt of notification of the disapproval.

(v) Final action

A decision by the Administrator following receipt and consideration of an objection filed under clause (iv) shall be considered a final agency action.

(D) Use dilution

The label or labeling required under this subchapter for an antimicrobial pesticide that is or may be diluted for use may have a different statement of caution or protective measures for use of the recommended diluted solution of the pesticide than for use of a concentrate of the pesticide if the Administrator determines that—

(i) adequate data have been submitted to support the statement proposed for the diluted solution uses; and

(ii) the label or labeling provides adequate protection for exposure to the diluted solution of the pesticide.

(10) Expedited registration of pesticides

(A) Not later than 1 year after August 3, 1996, the Administrator shall, utilizing public comment, develop procedures and guidelines, and expedite the review of an application for registration of a pesticide or an amendment to a registration that satisfies such guidelines.

(B) Any application for registration or an amendment, including biological and conventional pesticides, will be considered for expedited review under this paragraph. An application for registration or an amendment shall qualify for expedited review if use of the pesticide proposed by the application may reasonably be expected to accomplish 1 or more of the following:

(i) Reduce the risks of pesticides to human health.

(ii) Reduce the risks of pesticides to nontarget organisms.

(iii) Reduce the potential for contamination of groundwater, surface water, or other valued environmental resources.

(iv) Broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective.

(C) The Administrator, not later than 30 days after receipt of an application for expedited review, shall notify the applicant whether the application is complete. If it is found to be incomplete, the Administrator may either reject the request for expedited review or ask the applicant for additional information to satisfy the guidelines developed under subparagraph (A).

(11) Interagency working group

(A) Definition of covered agency

In this paragraph, the term "covered agency" means any of the following:

(i) The Department of Agriculture.

(ii) The Department of Commerce.

(iii) The Department of the Interior.

(iv) The Council on Environmental Quality.

(v) The Environmental Protection Agency.

(B) Establishment

The Administrator shall establish an interagency working group, to be comprised of representatives from each covered agency, to provide recommendations regarding, and to implement a strategy for improving, the consultation process required under section 7 of the Endangered Species Act of 1973 (16 U.S.C. 1536) for pesticide registration and registration review.

(C) Duties

The interagency working group established under subparagraph (B) shall—

(i) analyze relevant Federal law (including regulations) and case law for purposes of providing an outline of the legal and regulatory framework for the consultation process referred to in that subparagraph, including—

(I) requirements under this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.);

(II) Federal case law regarding the intersection of this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.); and

(III) Federal regulations relating to the pesticide consultation process;

(ii) provide advice regarding methods of—

(I) defining the scope of actions of the covered agencies that are subject to the consultation requirement referred to in subparagraph (B); and

(II) properly identifying and classifying effects of actions of the covered agencies with respect to that consultation requirement;

(iii) identify the obligations and limitations under Federal law of each covered agency for purposes of providing a legal and regulatory framework for developing the recommendations referred to in subparagraph (B);

(iv) review practices for the consultation referred to in subparagraph (B) to identify problem areas, areas for improvement, and best practices for conducting that consultation among the covered agencies;

(v) develop scientific and policy approaches to increase the accuracy and timeliness of the process for that consultation, in accordance with requirements of this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.), including—

(I) processes to efficiently share data and coordinate analyses among the Department of Agriculture, the Department of Commerce, the Department of the Interior, and the Environmental Protection Agency;

(II) a streamlined process for identifying which actions require no consultation, informal consultation, or formal consultation;

(III) an approach that will provide clarity with respect to what constitutes the best scientific and commercial data available in the fields of pesticide use and ecological risk assessment, pursuant to section 7(a)(2) of the Endangered Species Act of 1973 (16 U.S.C. 1536(a)(2)); and

(IV) approaches that enable the Environmental Protection Agency to better assist the Department of the Interior and the Department of Commerce in carrying out obligations under that section in a timely and efficient manner; and

(vi) propose and implement a strategy to implement approaches to consultations under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.) and document that strategy in a memorandum of understanding, revised regulations, or another appropriate format to promote durable cooperation among the covered agencies.

(D) Reports

(i) Progress reports

(I) In general

Not later than 18 months after December 20, 2018, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing the progress of the working group in developing the recommendations under subparagraph (B).

(II) Requirements

The report under this clause shall—

(aa) reflect the perspectives of each covered agency; and

(bb) identify areas of new consensus and continuing topics of disagreement and debate.

(ii) Results

(I) In general

Not later than 1 year after December 20, 2018, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the

House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing—

(aa) the recommendations developed under subparagraph (B); and

(bb) plans for implementation of those recommendations.

(II) Requirements

The report under this clause shall—

(aa) reflect the perspectives of each covered agency; and

(bb) identify areas of consensus and continuing topics of disagreement and debate, if any.

(iii) Implementation

Not later than 1 year after the date of submission of the report under clause (i), the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing—

(I) the implementation of the recommendations referred to in that clause;

(II) the extent to which that implementation improved the consultation process referred to in subparagraph (B); and

(III) any additional recommendations for improvements to the process described in subparagraph (B).

(iv) Other reports

Not later than the date that is 180 days after the date of submission of the report under clause (iii), and not less frequently than once every 180 days thereafter during the 5-year period beginning on that date, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing—

(I) the implementation of the recommendations referred to in that clause;

(II) the extent to which that implementation improved the consultation process referred to in subparagraph (B); and

(III) any additional recommendations for improvements to the process described in subparagraph (B).

(E) Consultation with private sector

In carrying out the duties under this paragraph, the working group shall, as appropriate—

(i) consult with, representatives of interested industry stakeholders and nongovernmental organizations; and

(ii) take into consideration factors, such as actual and potential differences in interest between, and the views of, those stakeholders and organizations.

(F) Chapter 10 of title 5

Chapter 10 of title 5 shall not apply to the working group established under this paragraph.

(G) Savings clause

Nothing in this paragraph supersedes any provision of—

(i) this subchapter; or

(ii) the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.), including the requirements under section 7 of that Act (16 U.S.C. 1536).

(d) Classification of pesticides

(1) Classification for general use, restricted use, or both

(A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use. If the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, the Administrator shall classify it for both general use and restricted

use. Pesticide uses may be classified by regulation on the initial classification, and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are classified for general use, and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses. The Administrator may require that its packaging and labeling for restricted uses shall be clearly distinguishable from its packaging and labeling for general uses.

(B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment, the Administrator will classify the pesticide, or the particular use or uses of the pesticide to which the determination applies, for general use.

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, the Administrator shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use:

(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.

(ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.

(2) Change in classification

If the Administrator determines that a change in the classification of any use of a pesticide from general use to restricted use is necessary to prevent unreasonable adverse effects on the environment, the Administrator shall notify the registrant of such pesticide of such determination at least forty-five days before making the change and shall publish the proposed change in the Federal Register. The registrant, or other interested person with the concurrence of the registrant, may seek relief from such determination under section 136d(b) of this title.

(3) Change in classification from restricted use to general use

The registrant of any pesticide with one or more uses classified for restricted use may petition the Administrator to change any such classification from restricted to general use. Such petition shall set out the basis for the registrant's position that restricted use classification is unnecessary because classification of the pesticide for general use would not cause unreasonable adverse effects on the environment. The Administrator, within sixty days after receiving such petition, shall notify the registrant whether the petition has been granted or denied. Any denial shall contain an explanation therefor and any such denial shall be subject to judicial review under section 136n of this title.

(e) Products with same formulation and claims

Products which have the same formulation, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same pesticide may be registered as a single pesticide; and additional names and labels shall be added to the registration by supplemental statements.

(f) Miscellaneous

(1) Effect of change of labeling or formulation

If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this subchapter.

(2) Registration not a defense

In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter.

(3) Authority to consult other Federal agencies

In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency.

(4) Mixtures of nitrogen stabilizers and fertilizer products

Any mixture or other combination of—

(A) 1 or more nitrogen stabilizers registered under this subchapter; and

(B) 1 or more fertilizer products,

shall not be subject to the provisions of this section or sections 136a–1, 136c, 136e, 136m, and 136o(a)(2) of this title if the mixture or other combination is accompanied by the labeling required under this subchapter for the nitrogen stabilizer contained in the mixture or other combination, the mixture or combination is mixed or combined in accordance with such labeling, and the mixture or combination does not contain any active ingredient other than the nitrogen stabilizer.

(5) Bilingual labeling

(A) Requirement

(i) In general

Subject to clause (ii), not later than the applicable deadline described in subparagraph (B), each registered pesticide product released for shipment shall include—

(I) the translation of the parts of the labeling contained in the Spanish Translation Guide described in subparagraph (G) on the product container; or

(II) a link to such translation via scannable technology or other electronic methods readily accessible on the product label.

(ii) Exceptions

Notwithstanding clause (i)—

(I) an antimicrobial pesticide product may, in lieu of including a translation or a link under clause (i), provide a link to the safety data sheets in Spanish via scannable technology or other electronic methods readily accessible on the product label; or

(II) a non-agricultural pesticide product that is not classified by the Administrator as restricted use under subsection (d)(1)(A) may, in lieu of including a translation or a link under clause (i), provide a link to the safety data sheets in Spanish via scannable technology or other electronic methods readily accessible on the product label.

(B) Deadlines for bilingual labeling

(i) Pesticide products classified as restricted use

In the case of pesticide products classified by the Administrator as restricted use under subsection (d)(1)(A), the deadline specified in this subparagraph is the date that is 3 years following December 29, 2022.

(ii) Pesticide products not classified as restricted use

In the case of pesticide products not classified by the Administrator as restricted use under subsection (d)(1)(A), the deadline specified in this subparagraph shall be as follows:

(I) Agricultural

(aa) Acute Toxicity Category I

For agricultural pesticides classified as Acute Toxicity Category I, the date that is 3 years after December 29, 2022.

(bb) Acute Toxicity Category II

For agricultural pesticides classified as Acute Toxicity Category II, the date that is 5 years after December 29, 2022.

(II) Antimicrobial and non-agricultural

(aa) Acute Toxicity Category I

For antimicrobial and non-agricultural pesticide products classified as Acute Toxicity Category I, the date that is 4 years after December 29, 2022.

(bb) Acute Toxicity Category II

For antimicrobial and non-agricultural pesticide products classified as Acute Toxicity Category II, the date that is 6 years after December 29, 2022.

(III) Other pesticide products

With respect to pesticide products not described in subclause (I) or (II), the date that is 8 years after December 29, 2022.

(C) Implementation

(i) Non-notification

(I) In general

In carrying out this paragraph, the Administrator shall allow translations of the parts of the label of a pesticide contained in the Spanish Translation Guide described in subparagraph (G) and scannable technology or other electronic methods to be added using non-notification procedures.

(II) Non-notification procedure defined

In this clause, the term "non-notification procedure" refers to a procedure under which a change may be made to a pesticide label without notifying the Administrator.

(ii) Cooperation and consultation

In carrying out this paragraph, the Administrator shall cooperate and consult with State lead agencies for pesticide regulation for the purpose of implementing bilingual labeling as provided in this paragraph as expeditiously as possible.

(iii) End use labeling

The labeling requirements of this paragraph shall apply to end use product labels.

(iv) Incorporation timeframe

After initial translation deadlines provided in subparagraph (B), updates to the Spanish Translation Guide described in subparagraph (G) shall be incorporated into labeling on the earlier of—

(I) in the case of agricultural use pesticide labels, as determined by the Administrator—

(aa) 1 year after the date of publication of the updated Spanish Label Translation Guide described in subparagraph (G); or

(bb) the released for shipment date specified on the EPA Stamped Approved Label after the pesticide label is next changed or amended following the date of publication of the updated Spanish Label Translation Guide described in subparagraph (G); and

(II) in the case of antimicrobial and non-agricultural use pesticide labels, as determined by the Administrator—

(aa) 2 years after the date of publication of the updated Spanish Label Translation Guide described in subparagraph (G); or

(bb) the released for shipment date specified on the EPA Stamped Approved Label after the pesticide label is next changed or amended following the date of publication of the updated Spanish Label Translation Guide described in subparagraph (G).

(v) Notification of updates to the Spanish Translation Guide for Pesticide Labeling

Not later than 10 days after updating the Spanish Translation Guide described in subparagraph (G), the Administrator shall notify registrants of the update to such guide.

(D) Accessibility of bilingual labeling for farm workers

Not later than 180 days after December 29, 2022, to the maximum extent practicable, the Administrator shall seek stakeholder input on ways to make bilingual labeling required under this paragraph accessible to farm workers.

(E) Plan

Not later than 3 years after December 29, 2022, the Administrator shall implement a plan to ensure that farm workers have access to the bilingual labeling required under this paragraph.

(F) Reporting

Not later than 2 years after December 29, 2022, the Administrator shall develop and implement, and make publicly available, a plan for tracking the adoption of the bilingual labeling required under this paragraph.

(G) Spanish Translation Guide described

The Spanish Translation Guide described in this subparagraph is the Spanish Translation Guide for Pesticide Labeling issued in October 2019, as in effect on December 29, 2022, and any successor guides or amendments to such guide.

(g) Registration review

(1) General rule

(A) Periodic review

(i) In general

The registrations of pesticides are to be periodically reviewed.

(ii) Regulations

In accordance with this subparagraph, the Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations.

(iii) Initial registration review

The Administrator shall complete the registration review of each pesticide or pesticide case, which may be composed of 1 or more active ingredients and the products associated with the active ingredients, not later than the later of—

(I) October 1, 2022; or

(II) the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered.

(iv) Subsequent registration review

Not later than 15 years after the date on which the initial registration review is completed under clause (iii) and each 15 years thereafter, the Administrator shall complete a subsequent registration review for each pesticide or pesticide case.

(v) Cancellation

No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 136d of this title.

(B) Docketing

(i) In general

Subject to clause (ii), after meeting with 1 or more individuals that are not government employees to discuss matters relating to a registration review, the Administrator shall place in the docket minutes of the meeting, a list of attendees, and any documents exchanged at the meeting, not later than the earlier of—

(I) the date that is 45 days after the meeting; or

(II) the date of issuance of the registration review decision.

(ii) Protected information

The Administrator shall identify, but not include in the docket, any confidential business information the disclosure of which is prohibited by section 136h of this title.

(C) Limitation

Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide pursuant to this subchapter.

(2) Data

(A) Submission required

The Administrator shall use the authority in subsection (c)(2)(B) to require the submission of data when such data are necessary for a registration review.

(B) Data submission, compensation, and exemption

For purposes of this subsection, the provisions of subsections (c)(1), (c)(2)(B), and (c)(2)(D) shall be utilized for and be applicable to any data required for registration review.

(h) Registration requirements for antimicrobial pesticides

(1) Evaluation of process

To the maximum extent practicable consistent with the degrees of risk presented by an antimicrobial pesticide and the type of review appropriate to evaluate the risks, the Administrator shall identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of August 3, 1996, for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products, including—

(A) new antimicrobial active ingredients;

(B) new antimicrobial end-use products;

(C) substantially similar or identical antimicrobial pesticides; and

(D) amendments to antimicrobial pesticide registrations.

(2) Review time period reduction goal

Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete application, consistent with the degree of risk, to a period of not more than—

(A) 540 days for a new antimicrobial active ingredient pesticide registration;

(B) 270 days for a new antimicrobial use of a registered active ingredient;

(C) 120 days for any other new antimicrobial product;

(D) 90 days for a substantially similar or identical antimicrobial product;

(E) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(F) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this paragraph.

(3) Implementation

(A) Proposed rulemaking

(i) Issuance

Not later than 270 days after August 3, 1996, the Administrator shall publish in the Federal Register proposed regulations to accelerate and improve the review of antimicrobial pesticide products designed to implement, to the extent practicable, the goals set forth in paragraph (2).

(ii) Requirements

Proposed regulations issued under clause (i) shall—

(I) define the various classes of antimicrobial use patterns, including household, industrial, and institutional disinfectants and sanitizing pesticides, preservatives, water treatment, and pulp and paper mill additives, and other such products intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime;

(II) differentiate the types of review undertaken for antimicrobial pesticides;

(III) conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this subchapter, considering the use patterns of the product, toxicity, expected exposure, and product type;

(IV) ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made; and

(V) implement effective and reliable deadlines for process management.

(iii) Comments

In developing the proposed regulations, the Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

(B) Final regulations

(i) Issuance

The Administrator shall issue final regulations not later than 240 days after the close of the comment period for the proposed regulations.

(ii) Failure to meet goal

If a goal described in paragraph (2) is not met by the final regulations, the Administrator shall identify the goal, explain why the goal was not attained, describe the element of the regulations included instead, and identify future steps to attain the goal.

(iii) Requirements

In issuing final regulations, the Administrator shall—

(I) consider the establishment of a certification process for regulatory actions involving risks that can be responsibly managed, consistent with the degree of risk, in the most cost-efficient manner;

(II) consider the establishment of a certification process by approved laboratories as an adjunct to the review process;

(III) use all appropriate and cost-effective review mechanisms, including—

(aa) expanded use of notification and non-notification procedures;

(bb) revised procedures for application review; and

(cc) allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations; and

(IV) clarify criteria for determination of the completeness of an application.

(C) Expedited review

This subsection does not affect the requirements or extend the deadlines or review periods contained in subsection (c)(3).

(D) Alternative review periods

If the final regulations to carry out this paragraph are not effective 630 days after August 3, 1996, until the final regulations become effective, the review period, beginning on the date of receipt by the Agency of a complete application, shall be—

(i) 2 years for a new antimicrobial active ingredient pesticide registration;

(ii) 1 year for a new antimicrobial use of a registered active ingredient;

(iii) 180 days for any other new antimicrobial product;

(iv) 90 days for a substantially similar or identical antimicrobial product;

(v) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(vi) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this subparagraph.

(E) Wood preservatives

An application for the registration, or for an amendment to the registration, of a wood preservative product for which a claim of pesticidal activity listed in section 136(mm) of this title is made (regardless of any other pesticidal claim that is made with respect to the product) shall be reviewed by the Administrator within the same period as that established under this paragraph for an antimicrobial pesticide product application, consistent with the degree of risk posed by the use of the wood preservative product, if the application requires the applicant to satisfy the same data requirements as are required to support an application for a wood preservative product that is an antimicrobial pesticide.

(F) Notification

(i) In general

Subject to clause (iii), the Administrator shall notify an applicant whether an application has been granted or denied not later than the final day of the appropriate review period under this paragraph, unless the applicant and the Administrator agree to a later date.

(ii) Final decision

If the Administrator fails to notify an applicant within the period of time required under clause (i), the failure shall be considered an agency action unlawfully withheld or unreasonably delayed for purposes of judicial review under chapter 7 of title 5.

(iii) Exemption

This subparagraph does not apply to an application for an antimicrobial pesticide that is filed under subsection (c)(3)(B) prior to 90 days after August 3, 1996.

(iv) Limitation

Notwithstanding clause (ii), the failure of the Administrator to notify an applicant for an amendment to a registration for an antimicrobial pesticide shall not be judicially reviewable in a Federal or State court if the amendment requires scientific review of data within—

(I) the time period specified in subparagraph (D)(vi), in the absence of a final regulation under subparagraph (B); or

(II) the time period specified in paragraph (2)(F), if adopted in a final regulation under subparagraph (B).

(4) Annual report

(A) Submission

Beginning on August 3, 1996, and ending on the date that the goals under paragraph (2) are achieved, the Administrator shall, not later than March 1 of each year, prepare and submit an annual report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(B) Requirements

A report submitted under subparagraph (A) shall include a description of—

(i) measures taken to reduce the backlog of pending registration applications;

(ii) progress toward achieving reforms under this subsection; and

(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations.

(June 25, 1947, ch. 125, §3, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 979; amended Pub. L. 94–140, §12, Nov. 28, 1975, 89 Stat. 755; Pub. L. 95–396, §§2(a), 3–8, Sept. 30, 1978, 92 Stat. 820, 824–827; Pub. L. 100–532, title I, §§102(b), 103, title VI, §601(b)(1), title VIII, §801(b), Oct. 25, 1988, 102 Stat. 2667, 2677, 2680; Pub. L. 101–624, title XIV, §1492, Nov. 28, 1990, 104 Stat. 3628; Pub. L. 102–237, title X, §1006(a)(3), (b)(1), (2), (c), Dec. 13, 1991, 105 Stat. 1894–1896; Pub. L. 104–170, title I, §§105(b), 106(b), title II, §§210(b), (c)(1), (d), (e), (f)(2), 222–224, 231, 250, Aug. 3, 1996, 110 Stat. 1491, 1494–1497, 1499, 1503, 1504, 1508, 1510; Pub. L. 108–199, div. G, title V, §501(b), Jan. 23, 2004, 118 Stat. 419; Pub. L. 110–94, §§2, 3, Oct. 9, 2007, 121 Stat. 1000; Pub. L. 115–334, title X, §10115, Dec. 20, 2018, 132 Stat. 4914; Pub. L. 117–286, §4(a)(21), Dec. 27, 2022, 136 Stat. 4307; Pub. L. 117–328, div. HH, title VI, §702, Dec. 29, 2022, 136 Stat. 5996.)

Editorial Notes

References in Text

The Endangered Species Act of 1973, referred to in subsec. (c)(11)(C)(i)(I), (II), (v), (vi), (G)(ii), is Pub. L. 93–205, Dec. 28, 1973, 87 Stat. 884, which is classified generally to chapter 35 (§1531 et seq.) of Title 16, Conservation. For complete classification of this Act to the Code, see Short Title note set out under section 1531 of Title 16 and Tables.

Prior Provisions

A prior section 3 of act June 25, 1947, was classified to section 135a of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

Amendments

2022—Subsec. (c)(11)(F). Pub. L. 117–286 substituted "Chapter 10 of title 5" for "Federal Advisory Committee Act" in heading and "Chapter 10 of title 5" for "The Federal Advisory Committee Act (5 U.S.C. App.)" in text.

Subsec. (f)(5). Pub. L. 117–328 added par. (5).

2018—Subsec. (c)(11). Pub. L. 115–334 added par. (11).

2007—Subsec. (c)(3)(B)(ii)(I). Pub. L. 110–94, §2(1), substituted "review the application in accordance with section 136w–8(f)(4)(B) of this title and," for "within 45 days after receiving the application, notify the registrant whether or not the application is complete and,".

Subsec. (c)(3)(B)(ii)(II). Pub. L. 110–94, §2(2), substituted "not later than the applicable decision review time established pursuant to section 136w–8(f)(4)(B) of this title, or, if no review time is established, not later than" for "within".

Subsec. (g)(1)(A). Pub. L. 110–94, §3(1), designated first sentence as cl. (i) and inserted heading, designated second sentence as cl. (ii), inserted heading, and substituted "In accordance with this subparagraph, the Administrator" for "The Administrator", added cls. (iii) and (iv), designated fourth sentence as cl. (v) and inserted heading, and struck out third sentence which read as follows: "The goal of these regulations shall be a review of a pesticide's registration every 15 years."

Subsec. (g)(1)(B), (C). Pub. L. 110–94, §3(2), (3), added subpar. (B) and redesignated former subpar. (B) as (C).

2004—Subsec. (h)(2)(F). Pub. L. 108–199, §501(b)(1), substituted "120 days" for "90 to 180 days".

Subsec. (h)(3)(D)(vi). Pub. L. 108–199, §501(b)(2)(A), substituted "120 days" for "240 days".

Subsec. (h)(3)(F)(iv). Pub. L. 108–199, §501(b)(2)(B), added cl. (iv).

1996—Subsec. (c)(1)(F)(ii) to (vi). Pub. L. 104–170, §210(b), added cls. (ii), (v), and (vi), redesignated former cls. (ii) and (iii) as (iii) and (iv), respectively, and in cl. (iv) substituted "(i), (ii), and (iii)" for "(i) and (ii)".

Subsec. (c)(1)(G). Pub. L. 104–170, §250(1), added subpar. (G).

Subsec. (c)(2)(A). Pub. L. 104–170, §§210(d)(1), 231, inserted heading, inserted "the public health and agricultural need for such minor use," after "pattern of use,", and substituted "potential beneficial or adverse effects on man and the environment" for "potential exposure of man and the environment to the pesticide".

Subsec. (c)(2)(B). Pub. L. 104–170, §210(d)(2), inserted heading.

Subsec. (c)(2)(B)(vi). Pub. L. 104–170, §210(c)(1), added cl. (vi).

Subsec. (c)(2)(B)(vii). Pub. L. 104–170, §210(f)(2), added cl. (vii).

Subsec. (c)(2)(B)(viii). Pub. L. 104–170, §222, added cl. (viii).

Subsec. (c)(2)(C). Pub. L. 104–170, §210(d)(3), inserted heading.

Subsec. (c)(2)(E). Pub. L. 104–170, §210(d)(4), added subpar. (E).

Subsec. (c)(3)(A), (B). Pub. L. 104–170, §210(e)(1), (2), inserted headings.

Subsec. (c)(3)(C), (D). Pub. L. 104–170, §210(e)(3), added subpars. (C) and (D).

Subsec. (c)(9). Pub. L. 104–170, §223, added par. (9).

Subsec. (c)(10). Pub. L. 104–170, §250(2), added par. (10).

Subsec. (f)(4). Pub. L. 104–170, §105(b), added par. (4).

Subsec. (g). Pub. L. 104–170, §106(b), added subsec. (g).

Subsec. (h). Pub. L. 104–170, §224, added subsec. (h).

1991—Subsec. (c)(1)(D). Pub. L. 102–237, §1006(a)(3)(B), (C), added subpar. (D) and redesignated former subpar. (D) as (F).

Subsec. (c)(1)(E). Pub. L. 102–237, §1006(a)(3)(A), (C), added subpar. (E) and struck out former subpar. (E) which read as follows: "the complete formula of the pesticide; and".

Subsec. (c)(1)(F). Pub. L. 102–237, §1006(a)(3)(A), (B), (D), redesignated former subpar. (D) as (F), in cl. (i) substituted "With" for "with" and a period for semicolon at end, in cl. (ii) substituted "Except" for "except" and a period for semicolon at end, in cl. (iii) substituted "After" for "after" and a period for semicolon at end, and struck out former subpar. (F) which read as follows: "a request that the pesticide be classified for general use, for restricted use, or for both."

Subsec. (c)(2)(A). Pub. L. 102–237, §1006(b)(1), (2), substituted "the Administrator" for "he" before "requires", "shall permit", "shall make", and "deems", and substituted "the Administrator's" for "his".

Subsec. (c)(2)(D). Pub. L. 102–237, §1006(c), clarified amendment made by Pub. L. 100–532, §102(b)(2)(A). See 1988 Amendment note below.

Subsec. (c)(3)(A). Pub. L. 102–237, §1006(b)(2), substituted "the Administrator's" for "his".

Subsec. (c)(5). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "determines".

Subsec. (c)(6). Pub. L. 102–237, §1006(b)(1), (2), substituted "the Administrator" for "he" before "shall notify" in two places and "the Administrator's" for "his" in four places.

Subsec. (d)(1). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "shall classify it for both" in subpar. (A), before "will classify" in subpar. (B), and before "shall classify" in subpar. (C).

Subsec. (d)(2). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "shall notify".

1990—Subsec. (c)(2)(A). Pub. L. 101–624 inserted after third sentence "The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this subchapter, any field residue data from a geographic area where the pesticide will not be registered for such use."

1988—Subsec. (a). Pub. L. 100–532, §601(b)(1), substituted "Requirement of registration" for "Requirement" in heading and amended text generally. Prior to amendment, text read as follows: "Except as otherwise provided by this subchapter, no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator."

Subsec. (c)(1)(D). Pub. L. 100–532, §801(b)(1)–(4), in introductory provisions, substituted "paragraph (2)(D)" for "subsection (c)(2)(D) of this section", in cl. (i), substituted "(i) with" for "(i) With" and ", except that" for ": *Provided*, That", in cl. (ii), substituted "clause (i)" for "subparagraph (D)(i) of this paragraph", and in cl. (iii), substituted "clauses (i) and (ii)" for "subparagraphs (D)(i) and (D)(ii) of this paragraph".

Subsec. (c)(2)(A). Pub. L. 100–532, §801(b)(5)(A), (B), substituted "(2) Data in support of registration.—

"(A) The"

for "(2)(A) Data in support of registration.—The", and directed that subpar. (A) be aligned with left margin of subsec. (d)(1)(A) of this section.

Subsec. (c)(2)(B). Pub. L. 100–532, §§102(b)(1), 801(b)(5)(C)–(F), substituted "(B)(i) If" for "(B) Additional data to support existing registration.—(i) If", directed that cls. (ii) to (v) be aligned with left margin of subpar. (A), in cls. (ii) and (iii), inserted "The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.", in cl. (iv), substituted "title. The only" for "title: *Provided*, that the only", and in cl. (v), substituted "paragraph (1)(D)" for "subsection (c)(1)(D) of this section".

Subsec. (c)(2)(C). Pub. L. 100–532, §801(b)(5)(G), (H), struck out "Simplified procedures" after "(C)" and directed that text be aligned with left margin of subpar. (A).

Subsec. (c)(2)(D). Pub. L. 100–532, §102(b)(2)(A), and Pub. L. 102–237, §1006(c), substituted "the pesticide that is the subject of the application" for "an end-use product".

Subsec. (c)(2)(D)(i). Pub. L. 100–532, §102(b)(2)(B), struck out "the safety of" after "data pertaining to".

Subsec. (c)(3). Pub. L. 100–532, §103, substituted "(A) The Administrator" for "The Administrator" and added subpar. (B).

Subsec. (c)(7). Pub. L. 100–532, §801(b)(6), in introductory provisions, substituted "paragraph (5)" for "subsection (c)(5) of this section", in subpars. (A) and (B), substituted "paragraph (5). If" for "subsection (c)(5) of this section: *Provided*, That, if", and in subpar. (C), substituted "prescribe. A" for "prescribe: *Provided*, that a".

Subsec. (d)(1)(A). Pub. L. 100–532, §801(b)(7), substituted "restricted use. If" for "restricted use, provided that if" and "restricted uses. The Administrator" for "restricted uses: *Provided, however*, That the Administrator".

Subsec. (f)(2). Pub. L. 100–532, §801(b)(8), substituted "this subchapter. As" for "this subchapter: *Provided*, That as".

Subsec. (g). Pub. L. 100–532, §801(b)(9), struck out subsec. (g) which read as follows: "The Administrator shall accomplish the reregistration of all pesticides in the most expeditious manner practicable: *Provided*, That, to the extent appropriate, any pesticide that results in a postharvest residue in or on food or feed crops shall be given priority in the reregistration process."

1978—Subsec. (c)(1)(D). Pub. L. 95–396, §2(a)(1), added subpar. (D), and struck out provisions which required the applicant for registration of a pesticide to file with the Administrator a statement containing "if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, except that data submitted on or after January 1, 1970, in support of an application shall not, without permission of the applicant, be considered by the Administrator in support of any other application for registration unless such other applicant shall have first offered to pay reasonable compensation for producing the test data to be relied upon and such data is not protected from disclosure by section 136h(b) of this title. This provision with regard to compensation for producing the test data to be relied upon shall apply with respect to all applications for registration or reregistration submitted on or after October 21, 1972. If the parties cannot agree on the amount and method of payment, the Administrator shall make such determination and may fix such other terms and conditions as may be reasonable under the circumstances. The Administrator's determination shall be made on the record after notice and opportunity for hearing. If either party does not agree with said determination, he may, within thirty days, take an appeal to the Federal district court for the district in which he resides with respect to either the amount of the payment or the terms of payment, or both. Registration shall not be delayed pending the determination of reasonable compensation between the applicants, by the Administrator or by the court.".

Subsec. (c)(2). Pub. L. 95–396, §§2(a)(2)(A)–(D), 3, 4, designated existing provisions as subpar. (A), inserted in second sentence "under subparagraph (B) of this paragraph" after "kind of information", struck out from introductory text of third sentence "subsection (c)(1)(D) of this section and" after "Except as provided by", and inserted provisions relating to establishment of standards for data requirements for registration of pesticides with respect to minor uses and consideration of economic factors in development of standards and cost of development, and added subpars. (B) to (D).

Subsec. (c)(5). Pub. L. 95–396, §5, provided for waiver of data requirements pertaining to efficacy.

Subsec. (c)(7), (8). Pub. L. 95–396, §6, added pars. (7) and (8).

Subsec. (d)(1)(A). Pub. L. 95–396, §7(1), authorized classification of pesticide uses by regulation on the initial classification and registered pesticides prior to reregistration.

Subsec. (d)(2). Pub. L. 95–396, §7(2), substituted "forty-five days" for "30 days".

Subsec. (d)(3). Pub. L. 95–396, §7(3), added par. (3).

Subsec. (g). Pub. L. 95–396, §8, added subsec. (g).

1975—Subsec. (c)(1)(D). Pub. L. 94–140 inserted exception relating to test data submitted on or after January 1, 1970, in support of application, inserted provision that compensation for producing test data shall apply to all applications submitted on or after October 21, 1972, and provision relating to delay of registration pending determination of reasonable compensation, struck out requirement that payment determined by court not be less than amount determined by Administrator, and substituted "If either party" for "If the owner of the test data".

Statutory Notes and Related Subsidiaries

Effective Date of 2007 Amendment

Pub. L. 110–94, §6, Oct. 9, 2007, 121 Stat. 1007, provided that: "This Act [see Short Title of 2007 Amendment note set out under section 136 of this title] and the amendments made by this Act take effect on October 1, 2007."

Effective Date of 2004 Amendment

Pub. L. 108–199, div. G, title V, §501(h), Jan. 23, 2004, 118 Stat. 434, provided that: "Except as otherwise provided in this section [enacting section 136w–8 of this title, amending this section and sections 136a–1, 136x, and 136y of this title, and enacting provisions set out as notes under sections 136 of this title and section 346a of Title 21, Food and Drugs] and the amendments made by this section, this section and the amendments made by this section take effect on the date that is 60 days after the date of enactment of this Act [Jan. 23, 2004]."

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Effective Date of 1978 Amendment

Pub. L. 95–396, §2(b), Sept. 30, 1978, 92 Stat. 824, provided that: "The amendment to section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act [subsec. (c)(1)(D) of this section] made by [subsec. (a)(1) of] this section shall apply with respect to all applications for registration approved after the date of enactment of this Act [Sept. 30, 1978]."

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

Registration Review Deadline Extension

Pub. L. 117–328, div. HH, title VI, §711, Dec. 29, 2022, 136 Stat. 6083, provided that:

"(a) In General.—Notwithstanding section 3(g)(1)(A)(iii)(I) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(g)(1)(A)(iii)(I)), the Administrator of the Environmental Protection Agency (referred to in this section as the 'Administrator') shall complete the initial registration review of each pesticide or pesticide case covered by that section not later than October 1, 2026.

"(b) Interim Registration Review Decision Requirements.—

"(1) Definition of covered interim registration review decision.—In this subsection, the term 'covered interim registration review decision' means an interim registration review decision—

"(A) that is associated with an initial registration review described in subsection (a);

"(B) that is noticed in the Federal Register during the period beginning on the date of enactment of this Act [Dec. 29, 2022] and ending on October 1, 2026; and

"(C) for which the Administrator has not, as of the date on which the decision is noticed in the Federal Register, made effects determinations or completed any necessary consultation under section 7(a)(2) of the Endangered Species Act of 1973 (16 U.S.C. 1536(a)(2)).

"(2) Requirements.—Any covered interim registration review decision shall include, where applicable, measures to reduce the effects of the applicable pesticide on—

"(A) species listed under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.); or

"(B) any designated critical habitat.

"(3) Consultation.—In developing measures described in paragraph (2), the Administrator shall take into account the input received from the Secretary of Agriculture and other members of the interagency working group established under section 3(c)(11) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(c)(11))."

Biological Pesticide Handling Study

Pub. L. 101–624, title XIV, §1498, Nov. 28, 1990, 104 Stat. 3631, provided that the National Academy of Sciences would conduct a study of the biological control programs and registration procedures utilized by the Food and Drug Administration, the Animal and Plant Health Inspection Service, and the Environmental Protection Agency, and within 1 year after completion of the study, develop and implement a common process for reviewing and approving biological control applications submitted to such agencies and offices based on the study conducted, the recommendation of the National Academy of Sciences, and other public comment.

Education, Study, and Report

Pub. L. 100–478, title I, §1010, Oct. 7, 1988, 102 Stat. 2313, provided that:

"(a) Education.—The Administrator of the Environmental Protection Agency in cooperation with the Secretary of Agriculture and the Secretary of the Interior, promptly upon enactment of this Act [Oct. 7, 1988],

shall conduct a program to inform and educate fully persons engaged in agricultural food and fiber commodity production of any proposed pesticide labeling program or requirements that may be imposed by the Administrator in compliance with the Endangered Species Act [of 1973] (16 U.S.C. 1531 et seq.). The Administrator also shall provide the public with notice of, and opportunity for comment on, the elements of any such program and requirements based on compliance with the Endangered Species Act [of 1973], including (but not limited to) an identification of any pesticides affected by the program; an explanation of the restriction or prohibition on the user or applicator of any such pesticide; an identification of those geographic areas affected by any pesticide restriction or prohibition; an identification of the effects of any restricted or prohibited pesticide on endangered or threatened species; and an identification of the endangered or threatened species along with a general description of the geographic areas in which such species are located wherein the application of a pesticide will be restricted, prohibited, or its use otherwise limited, unless the Secretary of the Interior determines that the disclosure of such information may create a substantial risk of harm to such species or its habitat.

"(b) STUDY.—The Administrator of the Environmental Protection Agency, jointly with the Secretary of Agriculture and the Secretary of the Interior, shall conduct a study to identify reasonable and prudent means available to the Administrator to implement the endangered species pesticides labeling program which would comply with the Endangered Species Act of 1973, as amended, and which would allow persons to continue production of agricultural food and fiber commodities. Such study shall include investigation by the Administrator of the best available methods to develop maps and the best available alternatives to mapping as means of identifying those circumstances in which use of pesticides may be restricted; identification of alternatives to prohibitions on pesticide use, including, but not limited to, alternative pesticides and application methods and other agricultural practices which can be used in lieu of any pesticides whose use may be restricted by the labeling program; examination of methods to improve coordination among the Environmental Protection Agency, Department of Agriculture, and Department of the Interior in administration of the labeling program; and analysis of the means of implementing the endangered species pesticides labeling program or alternatives to such a program, if any, to promote the conservation of endangered or threatened species and to minimize the impacts to persons engaged in agricultural food and fiber commodity production and other affected pesticide users and applicators.

"(c) REPORT.—The Administrator of the Environmental Protection Agency in cooperation with the Secretary of Agriculture and the Secretary of the Interior shall submit a report within one year of the date of enactment of this Act [Oct. 7, 1988], presenting the results of the study conducted pursuant to subsection (b) of this section to the Committee on Merchant Marine and Fisheries and the Committee on Agriculture of the United States House of Representatives, and the Committee on Environment and Public Works and the Committee on Agriculture, Nutrition, and Forestry of the United States Senate."

§136a–1. Reregistration of registered pesticides

(a) General rule

The Administrator shall reregister, in accordance with this section, each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984, except for any pesticide as to which the Administrator has determined, after November 1, 1984, and before the effective date of this section, that—

(1) there are no outstanding data requirements; and

(2) the requirements of section 136a(c)(5) of this title have been satisfied.

(b) Reregistration phases

Reregistrations of pesticides under this section shall be carried out in the following phases:

(1) The first phase shall include the listing under subsection (c) of the active ingredients of the pesticides that will be reregistered.

(2) The second phase shall include the submission to the Administrator under subsection (d) of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants to replace such missing or inadequate data within the applicable time period.

(3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (e).

(4) The fourth phase shall include an independent, initial review by the Administrator under subsection (f) of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requests for additional data.

(5) The fifth phase shall include the review by the Administrator under subsection (g) of data submitted for reregistration and appropriate regulatory action by the Administrator.

(c) Phase one

(1) Priority for reregistration

For purposes of the reregistration of the pesticides described in subsection (a), the Administrator shall list the active ingredients of pesticides and shall give priority to, among others, active ingredients (other than active ingredients for which registration standards have been issued before the effective date of this section) that—

(A) are in use on or in food or feed and may result in postharvest residues;

(B) may result in residues of potential toxicological concern in potable ground water, edible fish, or shellfish;

(C) have been determined by the Administrator before the effective date of this section to have significant outstanding data requirements; or

(D) are used on crops, including in greenhouses and nurseries, where worker exposure is most likely to occur.

(2) Reregistration lists

For purposes of reregistration under this section, the Administrator shall by order—

(A) not later than 70 days after the effective date of this section, list pesticide active ingredients for which registration standards have been issued before such effective date;

(B) not later than 4 months after such effective date, list the first 150 pesticide active ingredients, as determined under paragraph (1);

(C) not later than 7 months after such effective date, list the second 150 pesticide active ingredients, as determined under paragraph (1); and

(D) not later than 10 months after such effective date, list the remainder of the pesticide active ingredients, as determined under paragraph (1).

Each list shall be published in the Federal Register.

(3) Judicial review

The content of a list issued by the Administrator under paragraph (2) shall not be subject to judicial review.

(4) Notice to registrants

On the publication of a list of pesticide active ingredients under paragraph (2), the Administrator shall send by certified mail to the registrants of the pesticides containing such active ingredients a notice of the time by which the registrants are to notify the Administrator under subsection (d) whether the registrants intend to seek or not to seek reregistration of such pesticides.

(d) Phase two

(1) In general

The registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) shall submit to the Administrator, within the time period prescribed by paragraph (4), the notice described in paragraph (2) and any information, commitment, or offer described in paragraph (3).

(2) Notice of intent to seek or not to seek reregistration

(A) The registrant of a pesticide containing an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) shall notify the Administrator by certified mail whether the registrant intends to seek or does not intend to seek reregistration of the pesticide.

(B) If a registrant submits a notice under subparagraph (A) of an intention not to seek reregistration of a pesticide, the Administrator shall publish a notice in the Federal Register stating that such a notice has been submitted.

(3) Missing or inadequate data

Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) and for which the registrant submitted a notice under paragraph (2) of an intention to seek reregistration of such pesticide shall submit to the Administrator—

(A) in accordance with regulations issued by the Administrator under section 136a of this title, an identification of—

(i) all data that are required by regulation to support the registration of the pesticide with respect to such active ingredient;

(ii) data that were submitted by the registrant previously in support of the registration of the pesticide that are inadequate to meet such regulations; and

(iii) data identified under clause (i) that have not been submitted to the Administrator; and

(B) either—

(i) a commitment to replace the data identified under subparagraph (A)(ii) and submit the data identified under subparagraph (A)(iii) within the applicable time period prescribed by paragraph (4)(B); or

(ii) an offer to share in the cost to be incurred by a person who has made a commitment under clause (i) to replace or submit the data and an offer to submit to arbitration as described by section 136a(c)(2)(B) of this title with regard to such cost sharing.

For purposes of a submission by a registrant under subparagraph (A)(ii), data are inadequate if the data are derived from a study with respect to which the registrant is unable to make the certification prescribed by subsection (e)(1)(G) that the registrant possesses or has access to the raw data used in or generated by such study. For purposes of a submission by a registrant under such subparagraph, data shall be considered to be inadequate if the data are derived from a study submitted before January 1, 1970, unless it is demonstrated to the satisfaction of the Administrator that such data should be considered to support the registration of the pesticide that is to be reregistered.

(4) Time periods

(A) A submission under paragraph (2) or (3) shall be made—

(i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B), not later than 3 months after the date of publication of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C), not later than 3 months after the date of publication of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D), not later than 3 months after the date of publication of the listing of such active ingredient.

On application, the Administrator may extend a time period prescribed by this subparagraph if the Administrator determines that factors beyond the control of the registrant prevent the registrant from complying with such period.

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (3)(B) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of August 3, 1996, if—

(i) the data to support other uses of the pesticide on a food are being provided;

(ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(iii) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under this section; and

(iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 136a(c)(2)(B) of this title or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(5) Cancellation and removal

(A) If the registrant of a pesticide does not submit a notice under paragraph (2) or (3) within the time prescribed by paragraph (4)(A), the Administrator shall issue a notice of intent to cancel the registration of such registrant for such pesticide and shall publish the notice in the Federal Register and allow 60 days for the submission of comments on the notice. On expiration of such 60 days, the Administrator, by order and without a hearing, may cancel the registration or take such other action, including extension of applicable time periods, as may be necessary to enable reregistration of such pesticide by another person.

(B)(i) If—

(I) no registrant of a pesticide containing an active ingredient listed under subsection (c)(2) notifies the Administrator under paragraph (2) that the registrant intends to seek reregistration of any pesticide containing that active ingredient;

(II) no such registrant complies with paragraph (3)(A); or

(III) no such registrant makes a commitment under paragraph (3)(B) to replace or submit all data described in clauses (ii) and (iii) of paragraph (3)(A);

the Administrator shall publish in the Federal Register a notice of intent to remove the active ingredient from the list established under subsection (c)(2) and a notice of intent to cancel the registrations of all pesticides containing such active ingredient and shall provide 60 days for comment on such notice.

(ii) After the 60-day period has expired, the Administrator, by order, may cancel any such registration without hearing, except that the Administrator shall not cancel a registration under this subparagraph if—

(I) during the comment period a person acquires the rights of the registrant in that registration;

(II) during the comment period that person furnishes a notice of intent to reregister the pesticide in accordance with paragraph (2); and

(III) not later than 120 days after the publication of the notice under this subparagraph, that person has complied with paragraph (3) and the fee prescribed by this section has been paid.

(6) Suspensions and penalties

The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 136a(c)(2)(B)(iv) of this title if the Administrator determines that (A) progress is insufficient to ensure the submission of the data required for such pesticide under a commitment made under paragraph (3)(B) within the time period prescribed by paragraph (4)(B) or (B) the registrant has not submitted such data to the Administrator within such time period. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this paragraph in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under this section for the supported uses identified pursuant to this paragraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a determination the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this paragraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 136a(c)(2)(B)(iv) of this title regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(e) Phase three

(1) Information about studies

Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) who has submitted a notice under subsection (d)(2) of an intent to seek the reregistration of such pesticide shall submit, in accordance with the guidelines issued under paragraph (4), to the Administrator—

(A) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient and considered by the registrant to be adequate to meet the requirements of section 136a of this title and the regulations issued under such section;

(B) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient that may not comply with the requirements of section 136a of this title and the regulations issued under such section but which the registrant asserts should be deemed to comply with such requirements and regulations;

(C) a reformat of the data from each study summarized under subparagraph (A) or (B) by the registrant concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, teratogenicity, or residue chemistry of the active ingredient that were submitted to the Administrator before January 1, 1982;

(D) where data described in subparagraph (C) are not required for the active ingredient by regulations issued under section 136a of this title, a reformat of acute and subchronic dosing data submitted by the registrant to the Administrator before January 1, 1982, that the registrant

considers to be adequate to meet the requirements of section 136a of this title and the regulations issued under such section;

(E) an identification of data that are required to be submitted to the Administrator under section 136d(a)(2) of this title, indicating an adverse effect of the pesticide;

(F) an identification of any other information available that in the view of the registrant supports the registration;

(G) a certification that the registrant or the Administrator possesses or has access to the raw data used in or generated by the studies that the registrant summarized under subparagraph (A) or (B);

(H) either—

(i) a commitment to submit data to fill each outstanding data requirement identified by the registrant; or

(ii) an offer to share in the cost of developing such data to be incurred by a person who has made a commitment under clause (i) to submit such data, and an offer to submit to arbitration as described by section 136a(c)(2)(B) of this title with regard to such cost sharing; and

(I) evidence of compliance with section 136a(c)(1)(D)(ii) [1] of this title and regulations issued thereunder with regard to previously submitted data as if the registrant were now seeking the original registration of the pesticide.

A registrant who submits a certification under subparagraph (G) that is false shall be considered to have violated this subchapter and shall be subject to the penalties prescribed by section 136l of this title.

(2) Time periods

(A) The information required by paragraph (1) shall be submitted to the Administrator—

(i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B), not later than 12 months after the date of publication of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C), not later than 12 months after the date of publication of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D), not later than 12 months after the date of publication of the listing of such active ingredient.

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (1)(H) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment under such paragraph. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of August 3, 1996, if—

(i) the data to support other uses of the pesticide on a food are being provided;

(ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(iii) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under this section; and

(iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the

production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 136a(c)(2)(B) of this title or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(3) Cancellation

(A) If the registrant of a pesticide fails to submit the information required by paragraph (1) within the time prescribed by paragraph (2), the Administrator, by order and without hearing, shall cancel the registration of such pesticide. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this subparagraph in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under this section for the supported uses identified pursuant to this subparagraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 136a(c)(2)(B)(iv) of this title regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(B)(i) If the registrant of a pesticide submits the information required by paragraph (1) within the time prescribed by paragraph (2) and such information does not conform to the guidelines for submissions established by the Administrator, the Administrator shall determine whether the registrant made a good faith attempt to conform its submission to such guidelines.

(ii) If the Administrator determines that the registrant made a good faith attempt to conform its submission to such guidelines, the Administrator shall provide the registrant a reasonable period of time to make any necessary changes or corrections.

(iii)(I) If the Administrator determines that the registrant did not make a good faith attempt to conform its submission to such guidelines, the Administrator may issue a notice of intent to cancel the registration. Such a notice shall be sent to the registrant by certified mail.

(II) The registration shall be canceled without a hearing or further notice at the end of 30 days after receipt by the registrant of the notice unless during that time a request for a hearing is made by the registrant.

(III) If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title, except that the only matter for resolution at the hearing shall be whether the registrant made a good faith attempt to conform its submission to such guidelines. The hearing shall be held and a determination made within 75 days after receipt of a request for hearing.

(4) Guidelines

(A) Not later than 1 year after the effective date of this section, the Administrator, by order, shall issue guidelines to be followed by registrants in—

(i) summarizing studies;

(ii) reformatting studies;

(iii) identifying adverse information; and

(iv) identifying studies that have been submitted previously that may not meet the requirements of section 136a of this title or regulations issued under such section,

under paragraph (1).

(B) Guidelines issued under subparagraph (A) shall not be subject to judicial review.

(5) Monitoring

The Administrator shall monitor the progress of registrants in acquiring and submitting the data required under paragraph (1).

(f) Phase four

(1) Independent review and identification of outstanding data requirements

(A) The Administrator shall review the submissions of all registrants of pesticides containing a particular active ingredient under subsections (d)(3) and (e)(1) to determine if such submissions identified all the data that are missing or inadequate for such active ingredient. To assist the review of the Administrator under this subparagraph, the Administrator may require a registrant seeking reregistration to submit complete copies of studies summarized under subsection (e)(1).

(B) The Administrator shall independently identify and publish in the Federal Register the outstanding data requirements for each active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (c)(2) and that is contained in a pesticide to be reregistered under this section. The Administrator, at the same time, shall issue a notice under section 136a(c)(2)(B) of this title for the submission of the additional data that are required to meet such requirements.

(2) Time periods

(A) The Administrator shall take the action required by paragraph (1)—

(i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B), not later than 18 months after the date of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C), not later than 24 months after the date of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D), not later than 33 months after the date of the listing of such active ingredient.

(B) If the Administrator issues a notice to a registrant under paragraph (1)(B) for the submission of additional data, the registrant shall submit such data within a reasonable period of time, as determined by the Administrator, but not to exceed 48 months after the issuance of such notice. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of August 3, 1996, if—

(i) the data to support other uses of the pesticide on a food are being provided;

(ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(iii) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under this section; and

(iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 136a(c)(2)(B) of this title or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(3) Suspensions and penalties

The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 136a(c)(2)(B)(iv) of this title if the Administrator determines that (A) tests necessary to fill an outstanding data requirement for such pesticide have not been initiated within 1 year after the issuance of a notice under paragraph (1)(B), or (B) progress is insufficient to ensure submission of the data referred to in clause (A) within the time period prescribed by paragraph (2)(B) or the required data have not been submitted to the Administrator within such time period. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this paragraph in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under this section for the supported uses identified pursuant to this paragraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a determination the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this paragraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 136a(c)(2)(B)(iv) of this title regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in

writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(g) Phase five

(1) Data review

The Administrator shall conduct a thorough examination of all data submitted under this section concerning an active ingredient listed under subsection (c)(2) and of all other available data found by the Administrator to be relevant.

(2) Reregistration and other actions

(A) IN GENERAL.—The Administrator shall make a determination as to eligibility for reregistration—

(i) for all active ingredients subject to reregistration under this section for which tolerances or exemptions from tolerances are required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), not later than the last date for tolerance reassessment established under section 408(q)(1)(C) of that Act (21 U.S.C. 346a(q)(1)(C)); and

(ii) for all other active ingredients subject to reregistration under this section, not later than October 3, 2008.

(B) PRODUCT-SPECIFIC DATA.—

(i) IN GENERAL.—Before reregistering a pesticide, the Administrator shall obtain any needed product-specific data regarding the pesticide by use of section 136a(c)(2)(B) of this title and shall review such data within 90 days after its submission.

(ii) TIMING.—

(I) IN GENERAL.—Subject to subclause (II), the Administrator shall require that data under this subparagraph be submitted to the Administrator not later than 8 months after a determination of eligibility under subparagraph (A) has been made for each active ingredient of the pesticide, unless the Administrator determines that a longer period is required for the generation of the data.

(II) EXTRAORDINARY CIRCUMSTANCES.—In the case of extraordinary circumstances, the Administrator may provide such a longer period, of not more than 2 additional years, for submission of data to the Administrator under this subparagraph.

(C) After conducting the review required by paragraph (1) for each active ingredient of a pesticide and the review required by subparagraph (B) of this paragraph, the Administrator shall determine whether to reregister a pesticide by determining whether such pesticide meets the requirements of section 136a(c)(5) of this title. If the Administrator determines that a pesticide is eligible to be reregistered, the Administrator shall reregister such pesticide within 6 months after the submission of the data concerning such pesticide under subparagraph (B).

(D) DETERMINATION TO NOT REREGISTER.—

(i) IN GENERAL.—If after conducting a review under paragraph (1) or subparagraph (B) of this paragraph the Administrator determines that a pesticide should not be reregistered, the Administrator shall take appropriate regulatory action.

(ii) TIMING FOR REGULATORY ACTION.—Regulatory action under clause (i) shall be completed as expeditiously as possible.

(E) As soon as the Administrator has sufficient information with respect to the dietary risk of a particular active ingredient, but in any event no later than the time the Administrator makes a determination under subparagraph (C) or (D) with respect to pesticides containing a particular active ingredient, the Administrator shall—

(i) reassess each associated tolerance and exemption from the requirement for a tolerance issued under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a);

(ii) determine whether such tolerance or exemption meets the requirements of that Act [21 U.S.C. 301 et seq.];

(iii) determine whether additional tolerances or exemptions should be issued;

(iv) publish in the Federal Register a notice setting forth the determinations made under this subparagraph; and

(v) commence promptly such proceedings under this subchapter and section 408 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 346a] as are warranted by such determinations.

(h) Compensation of data submitter

If data that are submitted by a registrant under subsection (d), (e), (f), or (g) are used to support the application of another person under section 136a of this title, the registrant who submitted such data shall be entitled to compensation for the use of such data as prescribed by section 136a(c)(1)(D) [1] of this title. In determining the amount of such compensation, the fees paid by the registrant under this section shall be taken into account.

(i) Fees

(1) Maintenance fee

(A) IN GENERAL.—Subject to other provisions of this paragraph, each registrant of a pesticide shall pay an annual fee by January 15 of each year for each registration, except that no fee shall be charged for more than 200 registrations held by any registrant.

(B) In the case of a pesticide that is registered for a minor agricultural use, the Administrator may reduce or waive the payment of the fee imposed under this paragraph if the Administrator determines that the fee would significantly reduce the availability of the pesticide for the use.

(C) TOTAL AMOUNT OF FEES.—The amount of each fee prescribed under subparagraph (A) shall be adjusted by the Administrator to a level that will result in the collection under this paragraph of, to the extent practicable, an average amount of $31,000,000 for each of fiscal years 2019 through 2022, and $42,000,000 for each of fiscal years 2023 through 2027.

(D) MAXIMUM AMOUNT OF FEES FOR REGISTRANTS.—The maximum annual fee payable under this paragraph by—

(i) a registrant holding not more than 50 pesticide registrations shall be $129,400 for each of fiscal years 2019 through 2022, and $172,000 for each of fiscal years 2023 through 2027; and

(ii) a registrant holding over 50 registrations shall be $207,000 for each of fiscal years 2019 through 2022, and $277,200 for each of fiscal years 2023 through 2027.

(E) MAXIMUM AMOUNT OF FEES FOR SMALL BUSINESSES.—

(i) IN GENERAL.—For a small business, the maximum annual fee payable under this paragraph by—

(I) a registrant holding not more than 50 pesticide registrations shall be $79,100 for each of fiscal years 2019 through 2022, and $105,000 for each of fiscal years 2023 through 2027; and

(II) a registrant holding over 50 pesticide registrations shall be $136,800 for each of fiscal years 2019 through 2022, and $184,800 for each of fiscal years 2023 through 2027.

(ii) DEFINITION OF SMALL BUSINESS.—

(I) IN GENERAL.—In clause (i), the term "small business" means a corporation, partnership, or unincorporated business that—

(aa) has 500 or fewer employees; and

(bb) during the 3-year period prior to the most recent maintenance fee billing cycle, had an average annual global gross revenue from pesticides that did not exceed $60,000,000.

(II) AFFILIATES.—

(aa) IN GENERAL.—In the case of a business entity with 1 or more affiliates, the gross revenue limit under subclause (I)(bb) shall apply to the gross revenue for the entity and all of the affiliates of the entity, including parents and subsidiaries, if applicable.

(bb) AFFILIATED PERSONS.—For the purpose of item (aa), persons are affiliates of each other if, directly or indirectly, either person controls or has the power to control the other person, or a third person controls or has the power to control both persons.

(cc) INDICIA OF CONTROL.—For the purpose of item (aa), indicia of control include interlocking management or ownership, identity of interests among family members, shared facilities and equipment, and common use of employees.

(F) FEE REDUCTION FOR CERTAIN SMALL BUSINESSES.—

(i) DEFINITION.—In this subparagraph, the term "qualified small business entity" means a corporation, partnership, or unincorporated business that—

(I) has 500 or fewer employees;

(II) during the 3-year period prior to the most recent maintenance fee billing cycle, had an average annual global gross revenue from all sources that did not exceed $10,000,000; and

(III) holds not more than 5 pesticide registrations under this paragraph.

(ii) WAIVER.—Except as provided in clause (iii), the Administrator shall waive 25 percent of the fee under this paragraph applicable to the first registration of any qualified small business entity under this paragraph.

(iii) LIMITATION.—The Administrator shall not grant a waiver under clause (ii) to a qualified small business entity if the Administrator determines that the entity has been formed or manipulated primarily for the purpose of qualifying for the waiver.

(G) FARM WORKER TRAINING AND EDUCATION GRANTS.—

(i) SET-ASIDE.—In addition to amounts otherwise available, for fiscal years 2023 through 2027, the Administrator shall use not more than $7,500,000 of the amounts collected under this paragraph to provide grants to organizations described in clause (ii) for purposes of facilitating —

(I) training of farm workers;

(II) education of farm workers with respect to—

(aa) rights of farm workers relating to pesticide safety; and

(bb) the worker protection standard under part 170 of title 40, Code of Federal Regulations (or successor regulations);

(III) the development of new informational materials;

(IV) the development of training modules; and

(V) the development of innovative methods of delivery of such informational materials and training modules.

(ii) ELIGIBILITY.—To be eligible to receive a grant under this subparagraph, an organization shall have demonstrated experience in—

(I) providing training and education services for farm workers or handlers of pesticides; or

(II) developing informational materials for farm workers or handlers of pesticides.

(iii) COMMUNITY-BASED ORGANIZATIONS.—

(I) COMMUNITY-BASED NON-PROFIT FARM WORKER ORGANIZATION GRANTS.—The Administrator shall use funds available under clause (i) to provide grants to community-based non-profit farm worker organizations.

(II) APPLICATION OF FUNDS.—The Administrator shall apply the unspent balance of funds available (up to $1,800,000) under clause (i) in fiscal years 2025 through 2027 to carry out subclause (I).

(iv) INTERIM FUNDING.—In addition to amounts otherwise available, the Administrator may use not more than $1,200,000 in fiscal years 2023 and 2024 to fund existing cooperative agreements that were authorized under section 136w–8(c)(3)(B) of this title, as such section was in effect as of March 8, 2019.

(v) PARTNERSHIPS.—Organizations described in clause (ii) may apply for a grant under this subparagraph as a partnership with another organization, provided such organizations, at the

time of application, have entered into an agreement designating—

(I) a member of the partnership that will enter into the assistance agreement with the Environmental Protection Agency for the purposes of accountability for the proper expenditure of Federal funds;

(II) performance of the assistance agreement;

(III) liability for claims for recovery of unallowable costs incurred under the agreement; and

(IV) specifying roles in performing the proposed scope of work for the assistance agreement.

(H) HEALTH CARE PROVIDER TRAINING.—

(i) SET-ASIDE.—In addition to other amounts available, for the period of fiscal years 2023 through 2027, the Administrator shall use not more than $2,500,000 of the amounts collected under this paragraph to provide grants to nonprofit organizations described in clause (ii) for purposes of facilitating—

(I) technical assistance and training of health care providers relating to the recognition, treatment, and management of pesticide-related injuries and illnesses;

(II) the development of informational materials for technical assistance and training described in subclause (I); and

(III) the development of outreach and delivery methods relating to the recognition, treatment, and management of pesticide-related illnesses.

(ii) ELIGIBILITY.—To be eligible to receive a grant under this subparagraph, a nonprofit organization shall have demonstrated experience in providing technical assistance and training to health care providers who serve farm worker populations.

(iii) PARTNERSHIPS.—Organizations described in clause (ii) may apply for a grant under this subparagraph as a partnership with another organization, provided such organizations, at the time of application, have entered into an agreement designating—

(I) a member of the partnership that will enter into the assistance agreement with the Environmental Protection Agency for the purposes of accountability for the proper expenditure of Federal funds;

(II) performance of the assistance agreement;

(III) liability for claims for recovery of unallowable costs incurred under the agreement; and

(IV) roles in performing the proposed scope of work for the assistance agreement.

(I) PARTNERSHIP GRANTS.—In addition to funds otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than $500,000 of the amounts collected under this paragraph for partnership grants.

(J) PESTICIDE SAFETY EDUCATION PROGRAM.—In addition to amounts otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than $500,000 of the amounts collected under this paragraph to carry out the pesticide safety education program.

(K) TECHNICAL ASSISTANCE TO GRANTEES.—

(i) SET-ASIDE.—In addition to other amounts available, for fiscal years 2023 through 2027, the Administrator shall use not more than $1,750,000 of the amounts collected under this paragraph to provide grants to nonprofit organizations, subject to such conditions as the Administrator establishes to prevent conflicts of interest, to provide easily accessible technical assistance to grantees receiving, and potential grantees applying for, grants under subparagraphs (G) and (H).

(ii) CONSIDERATIONS.—In evaluating requests for grants under this subparagraph, the Administrator shall consider, at a minimum, the extent to which—

(I) the organization applying for the grant has experience providing technical assistance to farm worker or clinician-training organizations; and

(II) the proposed project would make specific technical assistance available to organizations seeking information and assistance concerning—

(aa) the grant application process;
(bb) the drafting of grant applications; and
(cc) compliance with grant management and reporting requirements.

(iii) NO SUITABLE ORGANIZATION.—If no suitable organization requests a grant under this subparagraph, the Administrator shall provide technical assistance described in clause (i) using the amounts made available by that clause.

(iv) STAKEHOLDER INPUT.—In formulating requests for proposals for grants under subparagraphs (G) and (H) for a fiscal year, the Administrator shall solicit and consider, in an open and transparent manner that does not provide a competitive advantage to any person or persons, input from persons who conduct farm worker education and training, or technical assistance and training of clinicians, regarding the request for proposals.

(L) The Administrator shall exempt any public health pesticide from the payment of the fee prescribed under this paragraph if, in consultation with the Secretary of Health and Human Services, the Administrator determines, based on information supplied by the registrant, that the economic return to the registrant from sales of the pesticide does not support the registration or reregistration of the pesticide.

(M) If any fee prescribed by this paragraph with respect to the registration of a pesticide is not paid by a registrant by the time prescribed, the Administrator, by order and without hearing, may cancel the registration.

(N) The authority provided under this paragraph shall terminate on September 30, 2027.

(2) Other fees

Except as provided in section 136w–8 of this title, during the period beginning on December 29, 2022, and ending on September 30, 2029, the Administrator may not levy any other fees for the registration of a pesticide under this subchapter or any other action covered under a table specified in section 136w–8(b)(3)(B) of this title, except as provided in paragraph (1).

(j) Exemption of certain registrants

The requirements of subsections (d), (e), (f), and (i) (other than subsection (i)(1)) regarding data concerning an active ingredient and fees for review of such data shall not apply to any person who is the registrant of a pesticide to the extent that, under section 136a(c)(2)(D) of this title, the person would not be required to submit or cite such data to obtain an initial registration of such pesticide.

(k) Reregistration and expedited processing fund

(1) Establishment

There shall be established in the Treasury of the United States a reregistration and expedited processing fund which shall be known as the Reregistration and Expedited Processing Fund.

(2) Source and use

(A) All moneys derived from fees collected by the Administrator under subsection (i) shall be deposited in the Reregistration and Expedited Processing Fund and shall be available to the Administrator, without fiscal year limitation, including, to the maximum extent practicable, during periods in which Environmental Protection Agency employees are on shutdown or emergency furlough as a result of a lapse in appropriations, specifically to offset the costs of reregistration and expedited processing of the applications specified in paragraph (3), to offset the costs of registration review under section 136a(g) of this title, including the costs associated with any review under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.) required as part of the registration review, to offset the costs associated with tracking and implementing registration review decisions, including registration review decisions designed to reduce risk, for the purposes specified in paragraphs (4) and (5), and to enhance the information systems capabilities to improve the tracking of pesticide registration decisions. The Administrator shall, prior to expending any such moneys derived from fees—

(i) effective October 1, 1997, adopt specific and cost accounting rules and procedures as approved by the Government Accountability Office and the Inspector General of the Environmental Protection Agency to ensure that moneys derived from fees are allocated solely for the purposes specified in the first sentence of this subparagraph;

(ii) prohibit the use of such moneys derived from fees to pay for any costs other than those necessary to achieve the purposes specified in the first sentence of this subparagraph; and

(iii) ensure that personnel and facility costs associated with the functions to be carried out under this paragraph do not exceed agency averages for comparable personnel and facility costs.

(B) The Administrator shall also—

(i) complete the review of unreviewed reregistration studies required to support the reregistration eligibility decisions scheduled for completion in accordance with subsection (l)(2); and

(ii) contract for such outside assistance as may be necessary for review of required studies, using a generally accepted competitive process for the selection of vendors of such assistance.

(3) Review of registrant submissions not covered by section 136w–8(b)(3)(B) of this title

(A) Definition of submission not covered by section 136w–8(b)(3)(B) of this title

In this paragraph, the term "submission not covered by section 136w–8(b)(3)(B) of this title" means any submission filed by a registrant with the Administrator relating to a registration that is not covered by a fee table under section 136w–8(b)(3)(B) of this title.

(B) Set-aside

(i) In general

In addition to amounts otherwise available for each of fiscal years 2023 through 2027, the Administrator shall use approximately 1/8 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in clause (ii).

(ii) Activities

In addition to amounts otherwise available, the Administrator shall use amounts made available under clause (i) to obtain sufficient personnel and resources to process submissions not covered by section 136w–8(b)(3)(B) of this title to meet the applicable deadlines described in—

(I) the notice of the Administrator entitled "Pesticide Registration Notice (PR) 98–10: Notifications, Non-Notifications and Minor Formulation Amendments" and dated October 22, 1998 (and any successor amendments to such notice); and

(II) subsections (c)(3)(B) and (h) of section 136a of this title.

(4) Development of public health performance standards for antimicrobial pesticide devices

(A) Set-aside

In addition to amounts otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than $500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

(B) Antimicrobial pesticide devices

The Administrator shall use amounts made available under subparagraph (A) to develop efficacy test methods for antimicrobial pesticide devices making public health claims.

(5) Good laboratory practices inspections

(A) Set-aside

For each of fiscal years 2023 through 2027, the Administrator shall use not more than $500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

(B) Activities

The Administrator shall use amounts made available under subparagraph (A) for enhancements to the good laboratory practices standards compliance monitoring program established under part 160 of title 40 of the Code of Federal Regulations (or successor regulations), with respect to laboratory inspections and data audits conducted in support of pesticide product registrations under this subchapter. As part of such monitoring program, the Administrator shall make available to each laboratory inspected under such program in support of such registrations a preliminary summary of inspection observations not later than 60 days after the date on which such an inspection is completed.

(6) Agency training and staff

(A) Set-aside

In addition to amounts otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than $500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

(B) Activities

The Administrator shall use amounts made available under subparagraph (A) to carry out the following activities:

(i) Training for agency employees

The Administrator shall administer training and education programs for employees of the Environmental Protection Agency, relating to the regulatory responsibilities and policies established by this Act, including programs—

(I) for improving the scientific, technical, and administrative skills of officers and employees authorized to administer programs under this subchapter;

(II) to align competencies identified by the Administrator for mission accomplishment;

(III) for addressing best practices for operational performance and improvement;

(IV) for improving administrative processes and procedures and addressing efficiency issues;

(V) to promote consistent regulatory decision-making; and

(VI) for educating registrants and regulated stakeholders on regulatory procedures.

(ii) Agreements with institutions of higher education

Not later than 1 year, to the maximum extent practicable, after December 29, 2022, the Administrator shall establish a competitive grant program to develop training curricula and programs in accordance with clause (i) through financial assistance agreements with 1 or more of the following institutions of higher education:

(I) Non-land-grant colleges of agriculture (as defined in section 3103 of this title).

(II) Land-grant colleges and universities (as defined in section 3103 of this title).

(III) 1994 Institutions (as defined in section 532 of the Equity in Educational Land-Grant Status Act of 1994 (7 U.S.C. 301 note; Public Law 103–382)).

(7) Vector expedited review vouchers

(A) Set-aside

In addition to amounts otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than $500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund to establish and carry out the Vector Expedited Review Voucher program in accordance with subparagraph (B).

(B) Vector Expedited Review Voucher program

(i) Definitions

In this subparagraph:

(I) Program

The term "program" means the Vector Expedited Review Voucher program established under clause (ii).

(II) Voucher

The term "voucher" means a voucher—

(aa) issued under the program by the Administrator to a pesticide registration applicant that entitles the holder to an expedited review described under clause (vi) of a single different pesticide registration action; and

(bb) the entitlement to which may be transferred (including by sale) by the holder of the voucher, without limitation on the number of times the voucher may be transferred, before the voucher is redeemed.

(ii) Establishment

Not later than one year after December 29, 2022, the Administrator, acting though the Office of Pesticide Programs, shall establish a program to be known as the Vector Expedited Review Voucher program.

(iii) Purpose

The purpose of the program is to incentivize the development of new insecticides to control and prevent the spread of vector borne disease by expediting reviews by decreasing decision review times provided in section 136w–8(b)(3)(B) of this title.

(iv) Issuance of vouchers

(I) In general

For each of fiscal years 2023 through 2027, the Administrator shall issue a voucher to a pesticide registration applicant for a new active ingredient if the applicant submits and has successfully registered a mosquito-control product that—

(aa) demonstrates a proven efficacy against pyrethroid or other insecticide-resistant mosquitoes;

(bb) prevents, mitigates, destroys, or repels pyrethroid or other insecticide-resistant mosquitoes, with a novel or unique mechanism or mode of action, different from other insecticides already registered by the Administrator for mosquito control;

(cc) targets mosquitoes capable of spreading such diseases as Malaria, Dengue, Zika, Chikungunya, St. Louis encephalitis, Eastern encephalitis, Western encephalitis, West Nile encephalitis, Cache Valley encephalitis, LaCrosse encephalitis, and Yellow Fever;

(dd) the registrant has submitted a global access plan that will be made publicly available for the active ingredient and that includes—

(AA) manufacturing locations, including any licensed third-party manufacturers;

(BB) distribution and procurement processes for malaria vector control programs in selected countries; and

(CC) the prices for common quantities of the product;

(ee) meets the appropriate guidelines as being effective in the primary vector control intervention areas, including insecticide-treated nets and indoor residual spray;

(ff) is made accessible for use in—

(AA) the United States, including territories or possessions of the United States; and

(BB) countries where mosquito-borne diseases, such as malaria, are prevalent;

(gg) meets registration requirements for human health and environmental effects, labeling, and presents no unreasonable adverse effects to the environment;

(hh) broadens the adoption of integrated pest management strategies, such as insecticide resistance management, or makes those strategies more effective;

(ii) is not contained in any pesticide product registered by the Administrator as of December 29, 2022; or

(jj) does not contain as attested to by the registrant, an active ingredient approved in the 2-year period preceding the date of registration by any global stringent regulatory authority for the same uses, vectors, and applications.

(II) Mosquito vector priority

For each of fiscal years 2023 through 2027, the focus of the program shall be to incentivize the development of insecticides to control and prevent the spread of mosquitoes bearing diseases described in subclause (I)(cc).

(III) Exception

If the Administrator determines that there is a significant public health benefit, an active ingredient that is registered for agricultural use that is repurposed and submitted for control of mosquitoes and that otherwise meets the requirements of subclause (I) (excluding items (bb) and (jj)) as determined necessary by the Administrator, shall be considered a mosquito control product meeting the criteria specified in such subclause.

(IV) Eligibility criteria modifications

(aa) In general

Beginning in fiscal year 2028, the Administrator shall review the program and recommend—

(AA) modifications to the requirements described in subclause (I); and

(BB) additional vectors to be included in the program, prioritizing vectors that pose the most significant population health risks.

(bb) Public involvement

In carrying out item (aa), the Administrator shall solicit the involvement of registrants, nongovernmental organizations, and governmental agencies engaged in vector-borne disease mitigation and treatment.

(v) Redemption of vouchers

To redeem a voucher, the holder shall—

(I) notify the Administrator of the intent of the holder to submit a pesticide application with a voucher for expedited review not less than 90 days before the submission of the application; and

(II) pay the applicable registration service fee under section 136w–8(b) of this title.

(vi) Expedited review

On redemption of a voucher, in furtherance of the purpose described in clause (iii), the Administrator shall expedite decision review times as follows:

(I) 6 months less than the decision review time for Category R010, New Active Ingredient, Food use.

(II) 6 months less than the decision review time for Category R020, New Active Ingredient, Food use; reduced risk.

(III) 6 months less than the decision review time for Category R060, New Active Ingredient, Non-food use; outdoor.

(IV) 6 months less than the decision review time for Category R110, New Active Ingredient, Non-food use; indoor.

(V) 4 months less than the decision review time for Category R070, New Active Ingredient, Non-food use; outdoor; reduced risk.

(VI) 2 months less than the decision review time for Category R120, New Active Ingredient, Non-food use; indoor; reduced risk.

(vii) Reports

Not later than September 30, 2025, and not later than September 30 of each year thereafter, the Administrator shall issue a report on the program, including—

(I) the number of submissions seeking a voucher;

(II) the total time in review for each such submission;

(III) the number of such vouchers awarded;
(IV) the number of such vouchers redeemed; and
(V) with respect to each such redeemed voucher—
(aa) the decision review time for the pesticide application for which the voucher was redeemed; and
(bb) the average standard decision review time for the applicable pesticide category.

(C) Unused amounts

Any unused amounts made available under this paragraph at the end of each fiscal year shall be made available to the Administrator to carry out other activities for which amounts in the Reregistration and Expedited Processing Fund are authorized to be used.

(8) Pesticide surveillance program

In addition to amounts otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than $500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund to support the interagency agreement with the National Institute for Occupational Safety and Health to support the Sentinel Event Notification System for Occupational Risk pesticides program—

(A) with a goal of increasing the number of participating States, prioritizing expansion in States with the highest numbers of agricultural workers; and
(B) to improve reporting by participating States.

(9) Unused funds

Money in the fund not currently needed to carry out this section shall be—

(A) maintained on hand or on deposit;
(B) invested in obligations of the United States or guaranteed thereby; or
(C) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

(10) Accounting and performance

The Administrator shall take all steps necessary to ensure that expenditures from fees authorized by subsection (i)(1)(C)(ii) [1] are used only for the purposes described in paragraphs (2) through (8) and to carry out the goals established under subsection (l). The Reregistration and Expedited Processing Fund shall be designated as an Environmental Protection Agency component for purposes of section 3515(c) of title 31. The annual audit required under section 3521 of such title of the financial statements of activities under this subchapter under section 3515(b) of such title shall include an audit of the fees collected under subsection (i)(1)(C) and disbursed, of the amount appropriated to match such fees, and of the Administrator's attainment of performance measures and goals established under subsection (l). Such an audit shall also include a review of the reasonableness of the overhead allocation and adequacy of disclosures of direct and indirect costs associated with carrying out the reregistration and expedited processing of the applications specified in paragraph (3), and the basis for and accuracy of all costs paid with moneys derived from such fees. The Inspector General shall conduct the annual audit and report the findings and recommendations of such audit to the Administrator and to the Committees on Agriculture of the House of Representatives and the Senate. The cost of such audit shall be paid for out of the fees collected under subsection (i)(1)(C).

(l) Performance measures and goals

The Administrator shall establish and publish annually in the Federal Register performance measures and goals. Such measures and goals shall include—

(1) the number of products reregistered, canceled, or amended, the status of reregistration, the number and type of data requests under section 136a(c)(2)(B) of this title issued to support product reregistration by active ingredient, the progress in reducing the number of unreviewed, required reregistration studies, the aggregate status of tolerances reassessed, and the number of applications for registration submitted under subsection (k)(3) that were approved or disapproved;

(2) the future schedule for reregistrations, including the projection for such schedules that will be issued under subsection (g)(2)(A) and (B) in the current fiscal year and the succeeding fiscal year; and

(3) the projected year of completion of the reregistrations under this section.

(m) Judicial review

Any failure of the Administrator to take any action required by this section shall be subject to judicial review under the procedures prescribed by section 136n(b) of this title.

(n) Authorization of funds to develop public health data

(1) "Secretary" defined

For the purposes of this section, "Secretary" means the Secretary of Health and Human Services, acting through the Public Health Service.

(2) Consultation

In the case of a pesticide registered for use in public health programs for vector control or for other uses the Administrator determines to be human health protection uses, the Administrator shall, upon timely request by the registrant or any other interested person, or on the Administrator's own initiative may, consult with the Secretary prior to taking final action to suspend registration under section 136a(c)(2)(B)(iv) of this title, or cancel a registration under section 136a–1, 136d(e), or 136d(f) of this title. In consultation with the Secretary, the Administrator shall prescribe the form and content of requests under this section.

(3) Benefits to support family

The Administrator, after consulting with the Secretary, shall make a determination whether the potential benefits of continued use of the pesticide for public health or health protection purposes are of such significance as to warrant a commitment by the Secretary to conduct or to arrange for the conduct of the studies required by the Administrator to support continued registration under section 136a of this title or reregistration under this section.

(4) Additional time

If the Administrator determines that such a commitment is warranted and in the public interest, the Administrator shall notify the Secretary and shall, to the extent necessary, amend a notice issued under section 136a(c)(2)(B) of this title to specify additional reasonable time periods for submission of the data.

(5) Arrangements

The Secretary shall make such arrangements for the conduct of required studies as the Secretary finds necessary and appropriate to permit submission of data in accordance with the time periods prescribed by the Administrator. Such arrangements may include Public Health Service intramural research activities, grants, contracts, or cooperative agreements with academic, public health, or other organizations qualified by experience and training to conduct such studies.

(6) Support

The Secretary may provide for support of the required studies using funds authorized to be appropriated under this section, the Public Health Service Act [42 U.S.C. 201 et seq.], or other appropriate authorities. After a determination is made under subsection (d), the Secretary shall notify the Committees on Appropriations of the House of Representatives and the Senate of the sums required to conduct the necessary studies.

(7) Authorization of appropriations

There is authorized to be appropriated to carry out the purposes of this section $12,000,000 for fiscal year 1997, and such sums as may be necessary for succeeding fiscal years.

(June 25, 1947, ch. 125, §4, formerly §3A, as added and renumbered §4, Pub. L. 100–532, title I, §102(a), title VIII, §801(q)(2)(A), Oct. 25, 1988, 102 Stat. 2655, 2683; amended Pub. L. 101–624, title XIV, §1493, Nov. 28, 1990, 104 Stat. 3628; Pub. L. 102–237, title X, §1006(a)(4), (e), (f), Dec. 13, 1991, 105 Stat. 1895–1897; Pub. L. 104–170, title I, §103, title II, §§210(c)(2), (f)(1), 232, 237,

title V, §501, Aug. 3, 1996, 110 Stat. 1490, 1496, 1498, 1508, 1509, 1536; Pub. L. 107–73, title III, [(1)–(4)], Nov. 26, 2001, 115 Stat. 686; Pub. L. 108–7, div. K, title III, [(1)–(4)], Feb. 20, 2003, 117 Stat. 513; Pub. L. 108–199, div. G, title V, §501(c), (d)(1), (e), Jan. 23, 2004, 118 Stat. 419, 422; Pub. L. 108–271, §8(b), July 7, 2004, 118 Stat. 814; Pub. L. 110–94, §4(a)–(d)(1), (e), Oct. 9, 2007, 121 Stat. 1001, 1002; Pub. L. 112–177, §2(a)(1), (2)(A), (4), Sept. 28, 2012, 126 Stat. 1327, 1329; Pub. L. 116–8, §§2(a), (b), 3, Mar. 8, 2019, 133 Stat. 484, 485; Pub. L. 117–328, div. HH, title VI, §§703(a), 704, Dec. 29, 2022, 136 Stat. 5999, 6002.)

Editorial Notes

References in Text

The effective date of this section, referred to in subsecs. (a), (c)(1), (2), and (e)(4)(A), is 60 days after Oct. 25, 1988. See Effective Date note below.

Section 136a(c)(1)(D) of this title, referred to in subsecs. (e)(1)(I) and (h), was redesignated section 136a(c)(1)(F) of this title by Pub. L. 102–237, title X, §1006(a)(3)(B), Dec. 13, 1991, 105 Stat. 1894.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (g)(2)(A)(1), (E)(ii), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Section 136w–8(c)(3)(B) of this title, as such section was in effect as of March 8, 2019, referred to in subsec. (i)(1)(G)(iv), means section 136w–8(c)(3)(B) of this title as amended by Pub. L. 116–8, §5(b), and prior to its repeal and reenactment by Pub. L. 117–328, §705(b)(1). See 2022 Amendment note under section 136w–8 of this title.

The Endangered Species Act of 1973, referred to in subsec. (k)(2)(A), is Pub. L. 93–205, Dec. 28, 1973, 87 Stat. 884, which is classified principally to chapter 35 (§1531 et seq.) of Title 16, Conservation. For complete classification of this Act to the Code, see Short Title note set out under section 1531 of Title 16 and Tables.

Subsection (i)(1)(C)(ii) of this section, referred to in subsec. (k)(10), was previously a reference to subsec. (i)(5)(C)(ii), which was repealed and a new subsec. (i)(5)(C)(ii) was added by Pub. L. 108–199, §501(c)(2). Subsec. (i)(5)(C) was amended by Pub. L. 110–94, §4(a), and, as so amended, related to fees but no longer contained a cl. (ii). Subsec. (i)(5) was redesignated (i)(1) by Pub. L. 112–177, §2(a)(1)(C).

The Public Health Service Act, referred to in subsec. (n)(6), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

Prior Provisions

A prior section 4 of act June 25, 1947, which was classified to section 136b of this title was transferred to section 11(a)–(c) of act June 25, 1947, which is classified to section 136i(a)–(c) of this title.

Another prior section 4 of act June 25, 1947, was classified to section 135b of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

Amendments

2022—Subsec. (i)(1)(C). Pub. L. 117–328, §703(a)(1)(A), substituted "2022, and $42,000,000 for each of fiscal years 2023 through 2027" for "2023".

Subsec. (i)(1)(D)(i). Pub. L. 117–328, §703(a)(1)(B)(i), substituted "2022, and $172,000 for each of fiscal years 2023 through 2027" for "2023".

Subsec. (i)(1)(D)(ii). Pub. L. 117–328, §703(a)(1)(B)(ii), substituted "2022, and $277,200 for each of fiscal years 2023 through 2027" for "2023".

Subsec. (i)(1)(E)(i)(I). Pub. L. 117–328, §703(a)(1)(C)(i), substituted "2022, and $105,000 for each of fiscal years 2023 through 2027" for "2023".

Subsec. (i)(1)(E)(i)(II). Pub. L. 117–328, §703(a)(1)(C)(ii), substituted "2022, and $184,800 for each of fiscal years 2023 through 2027" for "2023".

Subsec. (i)(1)(G) to (M). Pub. L. 117–328, §703(a)(1)(D), (E), added subpars. (G) to (K) and redesignated former subpars. (G) and (H) as (L) and (M), respectively. Former subpar. (I) redesignated (N).

Subsec. (i)(1)(N). Pub. L. 117–328, §703(a)(1)(D), (F), redesignated subpar. (I) as (N) and substituted "2027" for "2023".

Subsec. (i)(2). Pub. L. 117–328, §703(a)(2), substituted "December 29, 2022, and ending on September 30, 2029" for "March 8, 2019, and ending on September 30, 2025" and "section 136w–8(b)(3)(B)" for "section 136w–8(b)(3)".

Subsec. (k)(2)(A). Pub. L. 117–328, §704(1), inserted "including, to the maximum extent practicable, during periods in which Environmental Protection Agency employees are on shutdown or emergency furlough as a result of a lapse in appropriations," after "limitation,".

Subsec. (k)(3), (4). Pub. L. 117–328, §704(2), added pars. (3) and (4) and struck out former pars. (3) and (4) which related, respectively, to use of maintenance fees for review of inert ingredients and expedited processing of similar applications and to expedited rulemaking and guidance development for certain product performance data requirements.

Subsec. (k)(5)(A). Pub. L. 117–328, §704(3), substituted "2023 through 2027" for "2018 through 2023".

Subsec. (k)(6) to (9). Pub. L. 117–328, §704(4), (5), added pars. (6) to (8) and redesignated former par. (6) as (9). Former par. (7) redesignated (10).

Subsec. (k)(10). Pub. L. 117–328, §704(4), (6), redesignated par. (7) as (10) and substituted "paragraphs (2) through (8)" for "paragraphs (2), (3), (4), and (5)".

2019—Subsec. (i)(1)(C). Pub. L. 116–8, §2(a)(1), substituted "an average amount of $31,000,000 for each of fiscal years 2019 through 2023" for "an aggregate amount of $27,800,000 for each of fiscal years 2013 through 2017".

Subsec. (i)(1)(D)(i). Pub. L. 116–8, §2(a)(2)(A), substituted "$129,400 for each of fiscal years 2019 through 2023" for "$115,500 for each of fiscal years 2013 through 2017".

Subsec. (i)(1)(D)(ii). Pub. L. 116–8, §2(a)(2)(B), substituted "$207,000 for each of fiscal years 2019 through 2023" for "$184,800 for each of fiscal years 2013 through 2017".

Subsec. (i)(1)(E)(i)(I). Pub. L. 116–8, §2(a)(3)(A), substituted "$79,100 for each of fiscal years 2019 through 2023" for "$70,600 for each of fiscal years 2013 through 2017".

Subsec. (i)(1)(E)(i)(II). Pub. L. 116–8, §2(a)(3)(B), substituted "$136,800 for each of fiscal years 2019 through 2023" for "$122,100 for each of fiscal years 2013 through 2017".

Subsec. (i)(1)(I). Pub. L. 116–8, §2(a)(4), substituted "2023." for "2017.."

Subsec. (i)(2). Pub. L. 116–8, §2(b), substituted "March 8, 2019, and ending on September 30, 2025" for "October 25, 1988, and ending on September 30, 2019" and inserted "or any other action covered under a table specified in section 136w–8(b)(3) of this title," after "registration of a pesticide under this subchapter".

Subsec. (k)(2)(A). Pub. L. 116–8, §3(a)(1), (2), in introductory provisions, substituted "the Reregistration and Expedited Processing Fund" for "the fund" and "paragraph (3), to offset the costs of registration review under section 136a(g) of this title, including the costs associated with any review under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.) required as part of the registration review, to offset the costs associated with tracking and implementing registration review decisions, including registration review decisions designed to reduce risk, for the purposes specified in paragraphs (4) and (5), and to enhance the information systems capabilities to improve the tracking of pesticide registration decisions." for "paragraph (3), to enhance the information systems capabilities to improve the tracking of pesticide registration decisions, and to offset the costs of registration review under section 136a(g) of this title. Such moneys derived from fees may not be expended in any fiscal year to the extent such moneys derived from fees would exceed money appropriated for use by the Administrator and expended in such year for such costs of reregistration and expedited processing of such applications."

Subsec. (k)(2)(A)(i). Pub. L. 116–8, §3(a)(3), substituted "are allocated solely for the purposes specified in the first sentence of this subparagraph;" for "are allocated solely to offset the costs of reregistration and expedited processing of the applications specified in paragraph (3), to enhance the information systems capabilities to improve the tracking of pesticide registration decisions, and to offset the costs of registration review under section 136a(g) of this title;".

Subsec. (k)(2)(A)(ii). Pub. L. 116–8, §3(a)(4), substituted "necessary to achieve the purposes specified in the first sentence of this subparagraph;" for "necessary to achieve reregistration and expedited processing of the applications specified in paragraph (3), to enhance the information systems capabilities to improve the tracking of pesticide registration decisions, and to offset the costs of registration review under section 136a(g) of this title;".

Subsec. (k)(3)(A). Pub. L. 116–8, §3(b), in introductory provisions, substituted "For each of fiscal years 2018 through 2023, the Administrator shall use between 1/9 and 1/8 of the maintenance fees collected in such fiscal year to obtain sufficient personnel and resources—" for "The Administrator shall use for each of the fiscal years 2004 through 2006, approximately $3,300,000, and for each of fiscal years 2013 through 2017, between 1/9 and 1/8, of the maintenance fees collected in such fiscal year to obtain sufficient personnel and resources—".

Subsec. (k)(4). Pub. L. 116–8, §3(c), amended par. (4) generally. Prior to amendment, par. (4) related to enhancements of information technology systems for improvement in review of pesticide applications.

Subsec. (k)(5) to (7). Pub. L. 116–8, §3(d), added par. (5), redesignated former pars. (5) and (6) as (6) and (7), respectively, and substituted "paragraphs (2), (3), (4), and (5)" for "paragraphs (2), (3), and (4)" in par. (7).

2012—Subsec. (d)(5)(B)(ii)(III). Pub. L. 112–177, §2(a)(2)(A)(i), substituted "this section" for "subsection (i)(1)".

Subsec. (i)(1) to (4). Pub. L. 112–177, §2(a)(1)(C), (D), redesignated pars. (5) and (6) as (1) and (2), respectively, and struck out former pars. (1) to (4) which related to initial fee for food or feed use pesticide active ingredients, final fee for food or feed use pesticide active ingredients, fees for other pesticide active ingredients, and reduction or waiver of fees for minor use and other pesticides, respectively.

Subsec. (i)(5). Pub. L. 112–177, §2(a)(1)(D), redesignated par. (5) as (1).

Subsec. (i)(5)(C). Pub. L. 112–177, §2(a)(1)(A)(i), substituted "aggregate amount of $27,800,000 for each of fiscal years 2013 through 2017." for "aggregate amount of $22,000,000 for each of fiscal years 2008 through 2012".

Subsec. (i)(5)(D)(i). Pub. L. 112–177, §2(a)(1)(A)(ii)(I), substituted "shall be $115,500 for each of fiscal years 2013 through 2017;" for "shall be $71,000 for each of fiscal years 2008 through 2012;".

Subsec. (i)(5)(D)(ii). Pub. L. 112–177, §2(a)(1)(A)(ii)(II), substituted "shall be $184,800 for each of fiscal years 2013 through 2017." for "shall be $123,000 for each of fiscal years 2008 through 2012."

Subsec. (i)(5)(E)(i)(I). Pub. L. 112–177, §2(a)(1)(A)(iii)(I), substituted "shall be $70,600 for each of fiscal years 2013 through 2017;" for "shall be $50,000 for each of fiscal years 2008 through 2012;".

Subsec. (i)(5)(E)(i)(II). Pub. L. 112–177, §2(a)(1)(A)(iii)(II), substituted "shall be $122,100 for each of fiscal years 2013 through 2017." for "shall be $86,000 for each of fiscal years 2008 through 2012."

Subsec. (i)(5)(F). Pub. L. 112–177, §2(a)(1)(A)(vi), added subpar. (F). Former subpar. (F) redesignated (G).

Pub. L. 112–177, §2(a)(1)(A)(iv), substituted "this paragraph" for "paragraph (3)" and "Human" for "Humans".

Subsec. (i)(5)(G), (H). Pub. L. 112–177, §2(a)(1)(A)(v), redesignated subpars. (F) and (G) as (G) and (H), respectively.

Subsec. (i)(5)(I). Pub. L. 112–177, §2(a)(1)(A)(v), (vii), redesignated subpar. (H) as (I) and substituted "2017" for "2012".

Subsec. (i)(6). Pub. L. 112–177, §2(a)(1)(D), redesignated par. (6) as (2).

Pub. L. 112–177, §2(a)(1)(B), substituted "2019" for "2014" and "paragraph (1)" for "paragraphs (1) through (5)".

Subsec. (i)(7). Pub. L. 112–177, §2(a)(1)(C), struck out par. (7) which related to apportionment of certain fees among registrants of pesticides.

Subsec. (j). Pub. L. 112–177, §2(a)(2)(A)(ii), substituted "subsection (i)(1)" for "subsection (i)(5)".

Subsec. (k)(2)(A). Pub. L. 112–177, §2(a)(4)(A)(i), inserted ", to enhance the information systems capabilities to improve the tracking of pesticide registration decisions," after "paragraph (3)" wherever appearing.

Subsec. (k)(2)(A)(i). Pub. L. 112–177, §2(a)(4)(A)(ii), inserted "offset" before "the costs of reregistration" and struck out "in the same portion as appropriated funds" before semicolon at end.

Subsec. (k)(3)(A). Pub. L. 112–177, §2(a)(4)(B), in introductory provisions, substituted "2013 through 2017, between 1/9 and 1/8" for "2008 through 2012, between 1/8 and 1/7"; in cl. (i), struck out "new" before "inert"; and, in cl. (ii), substituted "any application that—" for "any application that—".

Subsec. (k)(4). Pub. L. 112–177, §2(a)(4)(C)(ii), added par. (4). Former par. (4) redesignated (5).

Subsec. (k)(5). Pub. L. 112–177, §2(a)(4)(C)(i), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Pub. L. 112–177, §2(a)(2)(A)(iii), substituted "subsection (i)(1)(C)(ii)" for "subsection (i)(5)(C)(ii)" and "subsection (i)(1)(C)" for "subsection (i)(5)(C)" in two places.

Subsec. (k)(6). Pub. L. 112–177, §2(a)(4)(C)(i), (iii), redesignated par. (5) as (6) and substituted "for the purposes described in paragraphs (2), (3), and (4) and to carry out the goals established under subsection (l)" for "to carry out the goals established under subsection (l)".

2007—Subsec. (i)(5)(C). Pub. L. 110–94, §4(a), which directed substitution of "amount of $22,000,000 for each of fiscal years 2008 through 2012" for "amount of" and all that follows through the end of clause (v), was executed by making the substitution for "amount of—

"(i) for fiscal year 2004, $26,000,000;

"(ii) for fiscal year 2005, $27,000,000;

"(iii) for fiscal year 2006, $27,000,000;

"(iv) for fiscal year 2007, $21,000,000; and

"(v) for fiscal year 2008, $15,000,000."

to reflect the probable intent of Congress. The words "amount of" appeared in the heading and twice in the text.

Subsec. (i)(5)(D)(i). Pub. L. 110–94, §4(b)(1)(A), substituted "shall be $71,000 for each of fiscal years 2008 through 2012; and" for "shall be—

"(I) for fiscal year 2004, $84,000;

"(II) for each of fiscal years 2005 and 2006, $87,000;

"(III) for fiscal year 2007, $68,000; and

"(IV) for fiscal year 2008, $55,000; and".

Subsec. (i)(5)(D)(ii). Pub. L. 110–94, §4(b)(1)(B), substituted "shall be $123,000 for each of fiscal years 2008 through 2012." for "shall be—

"(I) for fiscal year 2004, $145,000;

"(II) for each of fiscal years 2005 and 2006, $151,000;

"(III) for fiscal year 2007, $117,000; and

"(IV) for fiscal year 2008, $95,000."

Subsec. (i)(5)(E)(i)(I). Pub. L. 110–94, §4(b)(2)(A), substituted "shall be $50,000 for each of fiscal years 2008 through 2012; and" for "shall be—

"(aa) for fiscal year 2004, $59,000;

"(bb) for each of fiscal years 2005 and 2006, $61,000;

"(cc) for fiscal year 2007, $48,000; and

"(dd) for fiscal year 2008, $38,500; and".

Subsec. (i)(5)(E)(i)(II). Pub. L. 110–94, §4(b)(2)(B), substituted "shall be $86,000 for each of fiscal years 2008 through 2012." for "shall be—

"(aa) for fiscal year 2004, $102,000;

"(bb) for each of fiscal years 2005 and 2006, $106,000;

"(cc) for fiscal year 2007, $82,000; and

"(dd) for fiscal year 2008, $66,500."

Subsec. (i)(5)(H). Pub. L. 110–94, §4(c), substituted "2012." for "2008".

Subsec. (i)(6). Pub. L. 110–94, §4(d)(1), substituted "2014" for "2010".

Subsec. (k)(2)(A). Pub. L. 110–94, §4(e)(1), inserted "and to offset the costs of registration review under section 136a(g) of this title" after "paragraph (3)" wherever appearing.

Subsec. (k)(3)(A). Pub. L. 110–94, §4(e)(2), substituted "2008 through 2012" for "2007 and 2008".

2004—Subsec. (g)(2)(A). Pub. L. 108–199, §501(c)(5)(A), added subpar. (A) and struck out former subpar. (A) which read as follows: "Within 1 year after the submission of all data concerning an active ingredient of a pesticide under subsection (f) of this section, the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration. For extraordinary circumstances, the Administrator may extend such period for not more than 1 additional year."

Subsec. (g)(2)(B). Pub. L. 108–199, §501(c)(5)(B), inserted subpar. (B) and cl. (i) headings, designated first sentence of existing provisions as cl. (i), inserted cl. (ii) and subcl. (I) headings, designated second sentence of existing provisions as cl. (ii)(I), substituted "Subject to subclause (II), the Administrator" for "The Administrator" in subcl. (I), and added subcl. (II).

Subsec. (g)(2)(D). Pub. L. 108–199, §501(c)(5)(C), inserted subpar. (D) and cl. (i) headings, designated existing provisions as cl. (i), and added cl. (ii).

Subsec. (i)(5)(A). Pub. L. 108–199, §501(c)(1)(A), inserted subpar. (A) heading and substituted "for each registration" for "of—

"(i) $650 for the first registration; and

"(ii) $1,300 for each additional registration".

Subsec. (i)(5)(C). Pub. L. 108–199, §501(c)(2), struck out cl. (i) designation before "The amount of each", inserted subpar. (C) heading, substituted "aggregate amount of—" for "aggregate amount of $21,500,000 for fiscal year 2003.", added cls. (i) to (v), and struck out former cl. (ii), which related to collection of additional fees in fiscal years 1998, 1999, and 2000.

Subsec. (i)(5)(D). Pub. L. 108–199, §501(c)(1)(B), inserted subpar. (D) heading, substituted "shall be—" for "shall be $55,000; and" and added subcls. (I) to (IV) in cl. (i), and substituted "shall be—" for "shall be $95,000." and added subcls. (I) to (IV) in cl. (ii).

Subsec. (i)(5)(E)(i). Pub. L. 108–199, §501(c)(1)(C), inserted subpar. (E) and cl. (i) headings, realigned margins of subcls. (I) and (II), substituted "shall be—" for "shall be $38,500; and" and inserted items (aa) to (dd) in subcl. (I), and substituted "shall be—" for "shall be $66,500." and inserted items (aa) to (dd) in subcl. (II).

Subsec. (i)(5)(E)(ii). Pub. L. 108–199, §501(c)(3), inserted cl. (ii) heading, redesignated existing provisions as subcl. (I), inserted subcl. (I) heading, substituted "In" for "For purposes of" in subcl. (I), redesignated former subcls. (I) and (II) as items (aa) and (bb) respectively, and realigned margins, substituted "500" for "150" in item (aa), substituted "global gross revenue from pesticides that did not exceed $60,000,000." for "gross revenue from chemicals that did not exceed $40,000,000." in item (bb), and added subcl. (II).

Subsec. (i)(5)(H). Pub. L. 108–199, §501(c)(4), substituted "2008" for "2003".

Subsec. (i)(6). Pub. L. 108–199, §501(d)(1), substituted "Except as provided in section 136w–8 of this title, during" for "During", and substituted "2010" for "2003".

Subsec. (k)(2)(A)(i). Pub. L. 108–271 substituted "Government Accountability Office" for "General Accounting Office".

Subsec. (k)(3). Pub. L. 108–199, §501(e)(1), substituted "Review of inert ingredients; expedited" for "Expedited" in par. heading.

Subsec. (k)(3)(A). Pub. L. 108–199, §501(e)(2), substituted "2004 through 2006, approximately $3,300,000, and for each of fiscal years 2007 and 2008, between 1/8 and 1/7, of the maintenance fees" for "1997 through 2003, not more than 1/10 of the maintenance fees", substituted "resources" for "resources to assure the expedited processing and review of any application that", added cl. (i), inserted cl. (ii) designation and introductory provisions, and redesignated former cls. (i) to (iii) as subcls. (I) to (III), respectively, of cl. (ii).

2003—Pub. L. 108–7, which directed the amendment of "Section 136a–1 of title 7, U.S.C.", was executed by making the amendments to this section, which is section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress. See below.

Subsec. (i)(5)(C)(i). Pub. L. 108–7, [(1)], substituted "$21,500,000 for fiscal year 2003" for "$17,000,000 fiscal year 2002".

Subsec. (i)(5)(H). Pub. L. 108–7, [(2)], substituted "2003" for "2002".

Subsec. (i)(6). Pub. L. 108–7, [(3)], substituted "2003" for "2002".

Subsec. (k)(3)(A). Pub. L. 108–7, [(4)], substituted "2003" for "2002".

2001—Pub. L. 107–73, which directed the amendment of "Section 136a–1 of title 7, U.S.C.", was executed by making the amendments to this section, which is section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress. See below.

Subsec. (i)(5)(C)(i). Pub. L. 107–73, [(1)], substituted "$17,000,000" for "$14,000,000" and "fiscal year 2002" for "each fiscal year".

Subsec. (i)(5)(H). Pub. L. 107–73, [(2)], substituted "2002" for "2001".

Subsec. (i)(6). Pub. L. 107–73, [(3)], substituted "2002" for "2001".

Subsec. (k)(3)(A). Pub. L. 107–73, [(4)], substituted "2002" for "2001" and "1/10" for "1/7" in introductory provisions.

1996—Pub. L. 104–170, §501, which directed amendment of section 4 without specifying the name of the Act being amended, was executed to this section, which is section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress.

Subsec. (d)(4)(B). Pub. L. 104–170, §210(c)(2), inserted at end provisions authorizing extension of deadline for production of residue chemistry data in case of minor use and setting forth conditions to be met for such extension in cls. (i) to (iv).

Subsec. (d)(6). Pub. L. 104–170, §210(f)(1)(A), inserted at end provisions delaying upon written request action with regard to unsupported minor uses, authorizing refusal of request where there are health or environmental concerns, authorizing publication of notice in Federal Register and monitoring of development of data, setting forth procedures where registrant is not meeting or has not met schedule for production of data, and authorizing denial, modification, or revocation of temporary extension where use may cause adverse effect on environment and requiring notice of such revocation to registrant.

Subsec. (e)(2)(B). Pub. L. 104–170, §210(c)(2), inserted at end provisions authorizing extension of deadline for production of residue chemistry data in case of minor use and setting forth conditions to be met for such extension in cls. (i) to (iv).

Subsec. (e)(3)(A). Pub. L. 104–170, §210(f)(1)(B), inserted at end provisions delaying upon written request action with regard to unsupported minor uses, authorizing refusal of request where there are health or environmental concerns, authorizing publication of notice in Federal Register and monitoring of development of data, setting forth procedures where registrant is not meeting or has not met schedule for production of data, and authorizing denial, modification, or revocation of temporary extension where use may cause adverse effect on environment and requiring notice of such revocation to registrant.

Subsec. (f)(2)(B). Pub. L. 104–170, §210(c)(2), inserted at end provisions authorizing extension of deadline for production of residue chemistry data in case of minor use and setting forth conditions to be met for such extension in cls. (i) to (iv).

Subsec. (f)(3). Pub. L. 104–170, §210(f)(1)(A), inserted at end provisions delaying upon written request action with regard to unsupported minor uses, authorizing refusal of request where there are health or environmental concerns, authorizing publication of notice in Federal Register and monitoring of development of data, setting forth procedures where registrant is not meeting or has not met schedule for production of data, and authorizing denial, modification, or revocation of temporary extension where use may cause adverse effect on environment and requiring notice of such revocation to registrant.

Subsec. (g)(2)(E). Pub. L. 104–170, §103, added subpar. (E).

Subsec. (i)(4)(B) to (D). Pub. L. 104–170, §232(1), added subpar. (B) and redesignated former subpars. (B) and (C) as (C) and (D), respectively.

Subsec. (i)(5)(C). Pub. L. 104–170, §501(a)(2), designated existing provisions as cl. (i) and added cl. (ii).

Subsec. (i)(5)(F), (G). Pub. L. 104–170, §232(2), added subpar. (F) and redesignated former subpar. (F) as (G).

Subsec. (i)(5)(H). Pub. L. 104–170, §501(a)(1), substituted "2001" for "1997".

Pub. L. 104–170, §232(2), redesignated subpar. (G) as (H).

Subsec. (i)(6). Pub. L. 104–170, §501(a)(1), substituted "2001" for "1997".

Subsec. (i)(7)(B). Pub. L. 104–170, §232(3), substituted ", to determine the registrant's eligibility" for "or to determine the registrant's eligibility" and inserted before period at end ", or to determine the volume usage for public health pesticides".

Subsec. (k)(1). Pub. L. 104–170, §501(b), inserted "which shall be known as the Reregistration and Expedited Processing Fund" before period at end.

Subsec. (k)(2). Pub. L. 104–170, §501(c), amended heading and text of par. (2) generally. Prior to amendment, text read as follows: "All fees collected by the Administrator under subsection (i) of this section shall be deposited into the fund and shall be available to the Administrator, without fiscal year limitation, to carry out reregistration and expedited processing of similar applications."

Subsec. (k)(3)(A). Pub. L. 104–170, §501(d)(1), which directed the amendment of introductory provisions by substituting "for each of the fiscal years 1997 through 2001, not more than 1/7 of the maintenance fees collected in such fiscal year" for "for each of the fiscal years 1992, 1993, and 1994, 1/7th of the maintenance fees collected, up to 2 million each year", was executed by making the substitution for text which contained the phrase "$2 million", to reflect the probable intent of Congress.

Subsec. (k)(3)(A)(iii). Pub. L. 104–170, §232(4), added cl. (iii).

Subsec. (k)(3)(C). Pub. L. 104–170, §501(d)(2), added subpar. (C).

Subsec. (k)(5). Pub. L. 104–170, §501(e), amended heading and text of par. (5) generally. Prior to amendment, text read as follows: "The Administrator shall—

"(A) provide an annual accounting of the fees collected and disbursed from the fund; and

"(B) take all steps necessary to ensure that expenditures from such fund are used only to carry out this section."

Subsec. (l). Pub. L. 104–170, §501(f), added subsec. (l). Former subsec. (l) redesignated (m).

Subsec. (m). Pub. L. 104–170, §501(f), redesignated subsec. (l) as (m). Former subsec. (m) redesignated (n).

Pub. L. 104–170, §237, added subsec. (m).

Subsec. (n). Pub. L. 104–170, §501(f), redesignated subsec. (m) as (n).

1991—Subsec. (f)(3). Pub. L. 102–237, §1006(a)(4), realigned margin.

Subsec. (i)(5). Pub. L. 102–237, §1006(e), amended par. (5) generally, substituting, in subpar. (A), provisions relating to January 15 for provisions relating to March 1, in subpar. (A)(i), provisions relating to fee of $650 for first registration for provisions relating to fee of $425 for each registration for registrants holding not more than 50 registrations, and in subpar. (A)(ii), provisions relating to fee of $1,300 for each additional registration up to 200 registrations, with no fee thereafter, for provisions relating to fee of $425 for each registration up to 50, $100 for each registration over 50, with no fee after 200 registrations, redesignating provisions formerly set out in subpar. (A), following cl. (ii), as subpar. (B), and substituting provisions relating to fee under this par. for provisions relating to fee under this subpar., redesignating former subpar. (B) as (C), striking former subpar. (C), which set maximum annual fee for registrants under subpar. (A)(i) at $20,000, and for registrants under subpar. (A)(ii) at $35,000, adding subpars. (D) and (E), and redesignating former subpars. (D) and (E) as (F) and (G), respectively.

Subsec. (k)(3)(A). Pub. L. 102–237, §1006(f), substituted "for each of the fiscal years 1992, 1993, and 1994, 1/7th of the maintenance fees collected, up to $2 million each year" for "each fiscal year not more than $2,000,000 of the amounts in the fund".

1990—Subsec. (i)(5)(A). Pub. L. 101–624 inserted sentence at end relating to reduction or waiver of fee where pesticide is registered for minor agricultural use.

Statutory Notes and Related Subsidiaries

Effective Date of 2012 Amendment

Pub. L. 112–177, §2(c), Sept. 28, 2012, 126 Stat. 1407, provided that: "This section [amending this section, section 136w–8 of this title, and section 346a of Title 21, Food and Drugs, and enacting provisions set out as a note under this section] and the amendments made by this section take effect on October 1, 2012."

Effective Date of 2007 Amendment

Amendment by Pub. L. 110–94 effective Oct. 1, 2007, see section 6 of Pub. L. 110–94, set out as a note under section 136a of this title.

Effective Date of 2004 Amendment

Amendment by Pub. L. 108–199 effective on the date that is 60 days after Jan. 23, 2004, except as otherwise provided, see section 501(h) of Pub. L. 108–199, set out as a note under section 136a of this title.

Effective Date

Section effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as an Effective Date of 1988 Amendment note under section 136 of this title.

Implementation Dates With Respect to Fees

Pub. L. 117–328, div. HH, title VI, §708, Dec. 29, 2022, 136 Stat. 6082, provided that:

"(a) Fee Increases.—

"(1) Registration service fees.—With respect to amendments made by this title [see Short Title of 2022 Amendment note set out under section 136 of this title] to increase registration service fees specified in section 33 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w–8), such increases shall not be effective until the date that is 60 days after the date of the enactment of this title [Dec. 29, 2022], regardless of whether such section 33 specifies (as so amended) that such increases are effective for fiscal year 2023.

"(2) Maintenance fees.—With respect to amendments made by this title to increase the amount of maintenance fees to be collected under section 4(i) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a–1(i)), such increases shall be effective beginning on October 1, 2022.

"(b) Set-asides.—With respect to any set-asides specified in subsection (i) or (k) of section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a–1), such set-asides shall be effective beginning on October 1, 2022."

Extension of Limitations on Fee Amounts and Usage of Fees

Pub. L. 115–141, div. M, title IV, §401(a), Mar. 23, 2018, 132 Stat. 1049, provided that subsecs. (i)(1)(C)–(E) and (k)(3), (4) of this section and section 136w–8(c)(3)(B) of this title would continue in effect through Sept. 30, 2018.

Pub. L. 115–141, div. M, title IV, §401(b)(1), Mar. 23, 2018, 132 Stat. 1050, extended the authority under subsec. (i)(1) of this section through Sept. 30, 2018.

Relationship of Pub. L. 112–177 to Other Law

Pub. L. 112–177, §2(d), Sept. 28, 2012, 126 Stat. 1407, provided that: "In the case of any conflict between this section [amending this section, section 136w–8 of this title, and section 346a of Title 21, Food and Drugs, and enacting provisions set out as a note under this section] (including the amendments made by this section) and a joint resolution making continuing appropriations for fiscal year 2013 (including any amendments made by such a joint resolution), this section and the amendments made by this section shall control."

Adjustment of Maximum Annual Fee Payable by Pesticide Registrants

Pub. L. 108–11, title II, Apr. 16, 2003, 117 Stat. 603, provided that: "Within 30 days of enactment of this Act [Apr. 16, 2003], the Administrator of the Environmental Protection Agency shall adjust each 'maximum

annual fee payable' pursuant to 7 U.S.C. 136a–1(i)(5)(D) and (E) in a manner such that maintenance fee collections made to reach the level authorized in division K of Public Law 108–7 [see Tables for classification] shall be established in the same proportion as those maintenance fee collections authorized in Public Law 107–73 [see Tables for classification]."

[1] *See References in Text note below.*

§136b. Transferred

Editorial Notes

Codification

Section, act June 25, 1947, ch. 125, §4, as added Oct. 21, 1972, Pub. L. 92–516, §2, 86 Stat. 983; amended Nov. 28, 1975, Pub. L. 94–140, §§5, 11, 89 Stat. 753, 754; Sept. 30, 1978, Pub. L. 95–396, §9, 92 Stat. 827; Oct. 25, 1988, Pub. L. 100–532, title VIII, §801(c), (q)(1)(A), (B), 102 Stat. 2681, 2683, which related to use of restricted use pesticides and certification of applicators, was transferred to subsecs. (a) to (c) of section 11 of act June 25, 1947, by section 801(q)(1)(A) of Pub. L. 100–532 and is classified to section 136i(a) to (c) of this title.

§136c. Experimental use permits

(a) Issuance

Any person may apply to the Administrator for an experimental use permit for a pesticide. An application for an experimental use permit for a covered application under section 136w–8(b) of this title shall conform with the requirements of that section. The Administrator shall review the application. After completion of the review, but not later than one hundred and twenty days after receipt of the application and all required supporting data (or in the case of an application for an experimental use permit for a covered application under section 136w–8(b) of this title, not later than the last day of the applicable timeframe for such application specified in such section), the Administrator shall either issue the permit or notify the applicant of the Administrator's determination not to issue the permit and the reasons therefor. The applicant may correct the application or request a waiver of the conditions for such permit within thirty days of receipt by the applicant of such notification. The Administrator may issue an experimental use permit only if the Administrator determines that the applicant needs such permit in order to accumulate information necessary to register a pesticide under section 136a of this title. An application for an experimental use permit may be filed at any time.

(b) Temporary tolerance level

If the Administrator determines that the use of a pesticide may reasonably be expected to result in any residue on or in food or feed, the Administrator may establish a temporary tolerance level for the residue of the pesticide before issuing the experimental use permit.

(c) Use under permit

Use of a pesticide under an experimental use permit shall be under the supervision of the Administrator, and shall be subject to such terms and conditions and be for such period of time as the Administrator may prescribe in the permit.

(d) Studies

When any experimental use permit is issued for a pesticide containing any chemical or combination of chemicals which has not been included in any previously registered pesticide, the Administrator may specify that studies be conducted to detect whether the use of the pesticide under the permit may cause unreasonable adverse effects on the environment. All results of such studies

shall be reported to the Administrator before such pesticide may be registered under section 136a of this title.

(e) Revocation

The Administrator may revoke any experimental use permit, at any time, if the Administrator finds that its terms or conditions are being violated, or that its terms and conditions are inadequate to avoid unreasonable adverse effects on the environment.

(f) State issuance of permits

Notwithstanding the foregoing provisions of this section, the Administrator shall, under such terms and conditions as the Administrator may by regulations prescribe, authorize any State to issue an experimental use permit for a pesticide. All provisions of section 136i of this title relating to State plans shall apply with equal force to a State plan for the issuance of experimental use permits under this section.

(g) Exemption for agricultural research agencies

Notwithstanding the foregoing provisions of this section, the Administrator may issue an experimental use permit for a pesticide to any public or private agricultural research agency or educational institution which applies for such permit. Each permit shall not exceed more than a one-year period or such other specific time as the Administrator may prescribe. Such permit shall be issued under such terms and conditions restricting the use of the pesticide as the Administrator may require. Such pesticide may be used only by such research agency or educational institution for purposes of experimentation.

(June 25, 1947, ch. 125, §5, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 983; amended Pub. L. 94–140, §10, Nov. 28, 1975, 89 Stat. 754; Pub. L. 95–396, §10, Sept. 30, 1978, 92 Stat. 828; Pub. L. 100–532, title VIII, §801(d), (q)(1)(D), Oct. 25, 1988, 102 Stat. 2681, 2683; Pub. L. 102–237, title X, §1006(b)(1), Dec. 13, 1991, 105 Stat. 1895; Pub. L. 116–8, §4, Mar. 8, 2019, 133 Stat. 487.)

Editorial Notes

Prior Provisions

A prior section 5 of act June 25, 1947, was classified to section 135c of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

Amendments

2019—Subsec. (a). Pub. L. 116–8 substituted "permit for a pesticide. An application for an experimental use permit for a covered application under section 136w–8(b) of this title shall conform with the requirements of that section." for "permit for a pesticide." and inserted "(or in the case of an application for an experimental use permit for a covered application under section 136w–8(b) of this title, not later than the last day of the applicable timeframe for such application specified in such section)" after "all required supporting data".

1991—Subsecs. (b), (e), (f). Pub. L. 102–237 substituted "the Administrator" for "he" before "may" in subsec. (b), before "finds" in subsec. (e), and before "may" in subsec. (f).

1988—Subsec. (f). Pub. L. 100–532, §801(q)(1)(D), substituted "136i" for "136b".

Subsec. (g). Pub. L. 100–532, §801(d), substituted "require. Such pesticide" for "require: *Provided*, That such pesticide".

1978—Subsec. (a). Pub. L. 95–396, §10(1), provided for review of application, issuance or nonissuance of experimental use permit within prescribed period including reasons for denial, correction of application, and waiver of conditions and substituted provision for filing an application for experimental use permit at any time for prior provision for filing at the time of or before or after an application for registration is filed.

Subsec. (f). Pub. L. 95–396, §10(2), substituted in first sentence "shall" for "may" where first appearing.

1975—Subsec. (g). Pub. L. 94–140 added subsec. (g).

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136d. Administrative review; suspension

(a) Existing stocks and information

(1) Existing stocks

The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under this section, or section 136a or 136a–1 of this title, to such extent, under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter.

(2) Information

If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator.

(b) Cancellation and change in classification

If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of the Administrator's intent either—

(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the Administrator's action, or

(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

Such notice shall be sent to the registrant and made public. In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy. If the Secretary comments in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator may notify the registrant and make public the notice at any time after such 30-day period notwithstanding the foregoing 60-day time requirement. The time requirements imposed by the preceding 3 sentences may be waived or modified to the extent agreed upon by the Administrator and the Secretary. Notwithstanding any other provision of this subsection and section 136w(d) of this title, in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, then upon such a finding the Administrator may waive the requirement of notice to and consultation with the Secretary of Agriculture pursuant to this subsection and of submission to the Scientific Advisory Panel pursuant to section 136w(d) of this title and proceed in accordance with subsection (c). When a public health use is affected, the Secretary of Health and Human Services should provide available benefits and use information, or an analysis thereof, in accordance with the procedures followed and subject to the same conditions as the Secretary of Agriculture in the case of agricultural pesticides. The proposed

action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request or to the Administrator's determination under paragraph (2), a decision pertaining to registration or classification issued after completion of such hearing shall be final. In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such impact.

(c) Suspension

(1) Order

If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, the Administrator may, by order, suspend the registration of the pesticide immediately. Except as provided in paragraph (3), no order of suspension may be issued under this subsection unless the Administrator has issued, or at the same time issues, a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b). Except as provided in paragraph (3), the Administrator shall notify the registrant prior to issuing any suspension order. Such notice shall include findings pertaining to the question of "imminent hazard". The registrant shall then have an opportunity, in accordance with the provisions of paragraph (2), for an expedited hearing before the Administrator on the question of whether an imminent hazard exists.

(2) Expedite hearing

If no request for a hearing is submitted to the Administrator within five days of the registrant's receipt of the notification provided for by paragraph (1), the suspension order may be issued and shall take effect and shall not be reviewable by a court. If a hearing is requested, it shall commence within five days of the receipt of the request for such hearing unless the registrant and the Administrator agree that it shall commence at a later time. The hearing shall be held in accordance with the provisions of subchapter II of chapter 5 of title 5, except that the presiding officer need not be a certified administrative law judge. The presiding officer shall have ten days from the conclusion of the presentation of evidence to submit recommended findings and conclusions to the Administrator, who shall then have seven days to render a final order on the issue of suspension.

(3) Emergency order

Whenever the Administrator determines that an emergency exists that does not permit the Administrator to hold a hearing before suspending, the Administrator may issue a suspension order in advance of notification to the registrant. The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) and the Administrator shall proceed to issue the notice under subsection (b) within 90 days of issuing an emergency order. If the Administrator does not issue a notice under subsection (b) within 90 days of issuing an emergency order, the emergency order shall expire. In the case of an emergency order, paragraph (2) shall apply except that (A) the order of suspension shall be in effect pending the expeditious completion of the remedies provided by that paragraph and the issuance of a final order on suspension, and (B) no party other than the registrant and the Administrator shall participate except that any person adversely affected may file briefs within the time allotted by the Agency's rules. Any person so filing briefs shall be considered a party to such proceeding for the purposes of section 136n(b) of this title.

(4) Judicial review

A final order on the question of suspension following a hearing shall be reviewable in accordance with section 136n of this title, notwithstanding the fact that any related cancellation proceedings have not been completed. Any order of suspension entered prior to a hearing before the Administrator shall be subject to immediate review in an action by the registrant or other interested person with the concurrence of the registrant in an appropriate district court, solely to determine whether the order of suspension was arbitrary, capricious or an abuse of discretion, or whether the order was issued in accordance with the procedures established by law. The effect of any order of the court will be only to stay the effectiveness of the suspension order, pending the Administrator's final decision with respect to cancellation or change in classification. This action may be maintained simultaneously with any administrative review proceedings under this section. The commencement of proceedings under this paragraph shall not operate as a stay of order, unless ordered by the court.

(d) Public hearings and scientific review

In the event a hearing is requested pursuant to subsection (b) or determined upon by the Administrator pursuant to subsection (b), such hearing shall be held after due notice for the purpose of receiving evidence relevant and material to the issues raised by the objections filed by the applicant or other interested parties, or to the issues stated by the Administrator, if the hearing is called by the Administrator rather than by the filing of objections. Upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing, the Hearing Examiner shall issue a subpena to compel testimony or production of documents from any person. The Hearing Examiner shall be guided by the principles of the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, the subpena may be enforced by an appropriate United States district court in accordance with the principles stated herein. Upon the request of any party to a public hearing and when in the Hearing Examiner's judgment it is necessary or desirable, the Hearing Examiner shall at any time before the hearing record is closed refer to a Committee of the National Academy of Sciences the relevant questions of scientific fact involved in the public hearing. No member of any committee of the National Academy of Sciences established to carry out the functions of this section shall have a financial or other conflict of interest with respect to any matter considered by such committee. The Committee of the National Academy of Sciences shall report in writing to the Hearing Examiner within 60 days after such referral on these questions of scientific fact. The report shall be made public and shall be considered as part of the hearing record. The Administrator shall enter into appropriate arrangements with the National Academy of Sciences to assure an objective and competent scientific review of the questions presented to Committees of the Academy and to provide such other scientific advisory services as may be required by the Administrator for carrying out the purposes of this subchapter. As soon as practicable after completion of the hearing (including the report of the Academy) but not later than 90 days thereafter, the Administrator shall evaluate the data and reports before the Administrator and issue an order either revoking the Administrator's notice of intention issued pursuant to this section, or shall issue an order either canceling the registration, changing the classification, denying the registration, or requiring modification of the labeling or packaging of the article. Such order shall be based only on substantial evidence of record of such hearing and shall set forth detailed findings of fact upon which the order is based.

(e) Conditional registration

(1) The Administrator shall issue a notice of intent to cancel a registration issued under section 136a(c)(7) of this title if (A) the Administrator, at any time during the period provided for satisfaction of any condition imposed, determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed, or (B) at the end of the period provided for satisfaction of any condition imposed, that condition has not been met. The Administrator may permit the continued sale and use of existing stocks of a pesticide whose conditional registration has been canceled under this subsection to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent

with the purposes of this subchapter and will not have unreasonable adverse effects on the environment.

(2) A cancellation proposed under this subsection shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to cancel unless during that time a request for hearing is made by a person adversely affected by the notice. If a hearing is requested, a hearing shall be conducted under subsection (d) of this section. The only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter. A decision after completion of such hearing shall be final. Notwithstanding any other provision of this section, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing.

(f) General provisions

(1) Voluntary cancellation

(A) A registrant may, at any time, request that a pesticide registration of the registrant be canceled or amended to terminate one or more pesticide uses.

(B) Before acting on a request under subparagraph (A), the Administrator shall publish in the Federal Register a notice of the receipt of the request and provide for a 30-day period in which the public may comment.

(C) In the case of a pesticide that is registered for a minor agricultural use, if the Administrator determines that the cancellation or termination of uses would adversely affect the availability of the pesticide for use, the Administrator—

(i) shall publish in the Federal Register a notice of the receipt of the request and make reasonable efforts to inform persons who so use the pesticide of the request; and

(ii) may not approve or reject the request until the termination of the 180-day period beginning on the date of publication of the notice in the Federal Register, except that the Administrator may waive the 180-day period upon the request of the registrant or if the Administrator determines that the continued use of the pesticide would pose an unreasonable adverse effect on the environment.

(D) Subject to paragraph (3)(B), after complying with this paragraph, the Administrator may approve or deny the request.

(2) Publication of notice

A notice of denial of registration, intent to cancel, suspension, or intent to suspend issued under this subchapter or a notice issued under subsection (c)(4) or (d)(5)(A) of section 136a–1 of this title shall be published in the Federal Register and shall be sent by certified mail, return receipt requested, to the registrant's or applicant's address of record on file with the Administrator. If the mailed notice is returned to the Administrator as undeliverable at that address, if delivery is refused, or if the Administrator otherwise is unable to accomplish delivery of the notice to the registrant or applicant after making reasonable efforts to do so, the notice shall be deemed to have been received by the registrant or applicant on the date the notice was published in the Federal Register.

(3) Transfer of registration of pesticides registered for minor agricultural uses

In the case of a pesticide that is registered for a minor agricultural use:

(A) During the 180-day period referred to in paragraph (1)(C)(ii), the registrant of the pesticide may notify the Administrator of an agreement between the registrant and a person or persons (including persons who so use the pesticide) to transfer the registration of the pesticide, in lieu of canceling or amending the registration to terminate the use.

(B) An application for transfer of registration, in conformance with any regulations the Administrator may adopt with respect to the transfer of the pesticide registrations, must be submitted to the Administrator within 30 days of the date of notification provided pursuant to subparagraph (A). If such an application is submitted, the Administrator shall approve the

transfer and shall not approve the request for voluntary cancellation or amendment to terminate use unless the Administrator determines that the continued use of the pesticide would cause an unreasonable adverse effect on the environment.

(C) If the Administrator approves the transfer and the registrant transfers the registration of the pesticide, the Administrator shall not cancel or amend the registration to delete the use or rescind the transfer of the registration, during the 180-day period beginning on the date of the approval of the transfer unless the Administrator determines that the continued use of the pesticide would cause an unreasonable adverse effect on the environment.

(D) The new registrant of the pesticide shall assume the outstanding data and other requirements for the pesticide that are pending at the time of the transfer.

(4) Utilization of data for voluntarily canceled pesticide

When an application is filed with the Administrator for the registration of a pesticide for a minor use and another registrant subsequently voluntarily cancels its registration for an identical or substantially similar pesticide for an identical or substantially similar use, the Administrator shall process, review, and evaluate the pending application as if the voluntary cancellation had not yet taken place except that the Administrator shall not take such action if the Administrator determines that such minor use may cause an unreasonable adverse effect on the environment. In order to rely on this subsection, the applicant must certify that it agrees to satisfy any outstanding data requirements necessary to support the reregistration of the pesticide in accordance with the data submission schedule established by the Administrator.

(g) Notice for stored pesticides with canceled or suspended registrations

(1) In general

Any producer or exporter of pesticides, registrant of a pesticide, applicant for registration of a pesticide, applicant for or holder of an experimental use permit, commercial applicator, or any person who distributes or sells any pesticide, who possesses any pesticide which has had its registration canceled or suspended under this section shall notify the Administrator and appropriate State and local officials of—

(A) such possession,

(B) the quantity of such pesticide such person possesses, and

(C) the place at which such pesticide is stored.

(2) Copies

The Administrator shall transmit a copy of each notice submitted under this subsection to the regional office of the Environmental Protection Agency which has jurisdiction over the place of pesticide storage identified in the notice.

(h) Judicial review

Final orders of the Administrator under this section shall be subject to judicial review pursuant to section 136n of this title.

(June 25, 1947, ch. 125, §6, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 984; amended Pub. L. 94–140, §1, Nov. 28, 1975, 89 Stat. 751; Pub. L. 95–251, §2(a)(2), Mar. 27, 1978, 92 Stat. 183; Pub. L. 95–396, §§11, 12, Sept. 30, 1978, 92 Stat. 828; Pub. L. 98–620, title IV, §402(4)(A), Nov. 8, 1984, 98 Stat. 3357; Pub. L. 100–532, title II, §201, title IV, §404, title VIII, §801(e), (q)(2)(B), Oct. 25, 1988, 102 Stat. 2668, 2673, 2681, 2683; Pub. L. 101–624, title XIV, §1494, Nov. 28, 1990, 104 Stat. 3628; Pub. L. 102–237, title X, §1006(a)(5), (b)(1), (2), (3)(C)–(E), Dec. 13, 1991, 105 Stat. 1895, 1896; Pub. L. 104–170, title I, §§102, 106(a), title II, §§210(g), (h), 233, Aug. 3, 1996, 110 Stat. 1489, 1491, 1500, 1509.)

Editorial Notes

Codification

"Subchapter II of chapter 5 of title 5", referred to in subsec. (c)(2), was in the original "subchapter II of Title 5", and was editorially changed to reflect the probable intent of Congress.

Prior Provisions

A prior section 6 of act June 25, 1947, was classified to section 135d of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

Amendments

1996—Subsec. (a). Pub. L. 104–170, §106(a)(1), substituted "Existing stocks and information" for "Cancellation after five years" in heading.

Subsec. (a)(1). Pub. L. 104–170, §106(a)(2), amended heading and text generally. Prior to amendment, text read as follows: "The Administrator shall cancel the registration of any pesticide at the end of the five-year period which begins on the date of its registration (or at the end of any five year period thereafter) unless the registrant, or other interested person with the concurrence of the registrant, before the end of such period, requests in accordance with regulations prescribed by the Administrator that the registration be continued in effect. The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is canceled under this subsection or subsection (b) of this section to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter and will not have unreasonable adverse effects on the environment. The Administrator shall publish in the Federal Register, at least 30 days prior to the expiration of such five-year period, notice that the registration will be canceled if the registrant or other interested person with the concurrence of the registrant does not request that the registration be continued in effect."

Subsec. (b). Pub. L. 104–170, §233, inserted "When a public health use is affected, the Secretary of Health and Human Services should provide available benefits and use information, or an analysis thereof, in accordance with the procedures followed and subject to the same conditions as the Secretary of Agriculture in the case of agricultural pesticides." before "The proposed action shall become final".

Subsec. (c)(1). Pub. L. 104–170, §102(a), amended second sentence generally. Prior to amendment, second sentence read as follows: "No order of suspension may be issued unless the Administrator has issued or at the same time issues notice of the Administrator's intention to cancel the registration or change the classification of the pesticide."

Subsec. (c)(3). Pub. L. 104–170, §102(b), inserted after first sentence "The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) of this section and the Administrator shall proceed to issue the notice under subsection (b) of this section within 90 days of issuing an emergency order. If the Administrator does not issue a notice under subsection (b) of this section within 90 days of issuing an emergency order, the emergency order shall expire." and substituted "In the case of an emergency order" for "In that case".

Subsec. (f)(1)(C)(ii). Pub. L. 104–170, §210(g)(1), substituted "180-day" for "90-day" in two places.

Subsec. (f)(3)(A). Pub. L. 104–170, §210(g)(2), substituted "180-day" for "90-day".

Subsec. (f)(4). Pub. L. 104–170, §210(h), added par. (4).

1991—Subsec. (a)(1). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "may specify" and before "determines".

Subsec. (a)(2). Pub. L. 102–237, §1006(b)(3)(C), substituted "the registrant" for "he" before "shall".

Subsec. (b). Pub. L. 102–237, §1006(b)(1), (2), substituted "the Administrator's" for "his" in introductory provisions and par. (1), and "the Administrator" for "he" before "shall publish" in last sentence.

Subsec. (c)(1). Pub. L. 102–237, §1006(b)(1), (2), substituted "the Administrator" for "he" before "may" and "the Administrator's" for "his" before "intention".

Subsec. (c)(3). Pub. L. 102–237, §1006(b)(1), (3)(D), substituted "the Administrator" for "he" before "may" and "the Administrator" for "him" after "permit".

Subsec. (d). Pub. L. 102–237, §1006(b)(2), (3)(E), in penultimate sentence substituted "the Administrator's" for "his" and "the Administrator" for "him" before "and issue".

Subsec. (f)(3)(B). Pub. L. 102–237, §1006(a)(5), substituted "adverse effect" for "adverse affect".

1990—Subsec. (f)(1). Pub. L. 101–624, §1494(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "A registrant at any time may request that any of its pesticide registrations be canceled or be amended to delete one or more uses. Before acting on such request, the Administrator shall publish in the Federal Register a notice of the receipt of the request. Thereafter, the Administrator may approve such a request."

Subsec. (f)(3). Pub. L. 101–624, §1494(2), added par. (3).

1988—Subsec. (a)(1). Pub. L. 100–532, §801(e)(1), substituted "effect. The Administrator" for "effect: *Provided*, That the Administrator".

Subsec. (c). Pub. L. 100–532, §801(e)(2)–(4), in par. (1) directed that undesignated paragraph beginning "Except as provided" be run into sentence ending "of the pesticide." and substituted "before the Administrator" for "before the Agency", in par. (2) substituted "submitted to the Administrator" for "submitted to the Agency" and "and the Administrator" for "and the Agency", and in par. (3) substituted "(A)" for "(i)", "and the Administrator" for "and the Agency", and "(B)" for "(ii)".

Subsec. (e). Pub. L. 100–532, §801(e)(5), (6), in par. (1), substituted "met. The Administrator" for "met: *Provided*, That the Administrator", and in par. (2), substituted "section. The only" for "section: *Provided*, That the only".

Subsec. (f). Pub. L. 100–532, §201, added subsec. (f). Former subsec. (f) redesignated (h).

Subsec. (f)(2). Pub. L. 100–532, §801(q)(2)(B), made a technical amendment to the reference to section 136a–1 of this title to reflect the renumbering of the corresponding section of the original act.

Subsec. (g). Pub. L. 100–532, §404, added subsec. (g).

Subsec. (h). Pub. L. 100–532, §201, redesignated former subsec. (f) as (h).

1984—Subsec. (c)(4). Pub. L. 98–620 struck out provisions requiring petitions to review orders on the issue of suspension to be advanced on the docket of the court of appeals.

1978—Subsec. (b). Pub. L. 95–396, §11, required the Administrator, in taking any final action under subsec. (b), to consider restricting a pesticide's use or uses as an alternative to cancellation and to fully explain the reasons for the restrictions.

Subsec. (c)(2). Pub. L. 95–251 substituted "administrative law judge" for "hearing examiner".

Subsecs. (e), (f). Pub. L. 95–396, §12, added subsec. (e) and redesignated former subsec. (e) as (f).

1975—Subsec. (b). Pub. L. 94–140 established criteria which Administrator must use in determining the issuance of a suspension of registration notice and the time periods relating to such notice, set forth required procedures to be followed by Administrator prior to publication of such notice, required procedures when the Secretary elects to comment or fails to comment on suspension notice, waiver or modification of time periods in specified required procedures, required procedures for waiver of notice and consent by Secretary for suspension of registration, and established criteria for Secretary taking any final action.

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Effective Date of 1984 Amendment

Amendment by Pub. L. 98–620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98–620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136e. Registration of establishments

(a) Requirement

No person shall produce any pesticide subject to this subchapter or active ingredient used in producing a pesticide subject to this subchapter in any State unless the establishment in which it is produced is registered with the Administrator. The application for registration of any establishment shall include the name and address of the establishment and of the producer who operates such establishment.

(b) Registration

Whenever the Administrator receives an application under subsection (a), the Administrator shall register the establishment and assign it an establishment number.

(c) Information required

(1) Any producer operating an establishment registered under this section shall inform the Administrator within 30 days after it is registered of the types and amounts of pesticides and, if applicable, active ingredients used in producing pesticides—

(A) which the producer is currently producing;

(B) which the producer has produced during the past year; and

(C) which the producer has sold or distributed during the past year.

The information required by this paragraph shall be kept current and submitted to the Administrator annually as required under such regulations as the Administrator may prescribe.

(2) Any such producer shall, upon the request of the Administrator for the purpose of issuing a stop sale order pursuant to section 136k of this title, inform the Administrator of the name and address of any recipient of any pesticide produced in any registered establishment which the producer operates.

(d) Confidential records and information

Any information submitted to the Administrator pursuant to subsection (c) other than the names of the pesticides or active ingredients used in producing pesticides produced, sold, or distributed at an establishment shall be considered confidential and shall be subject to the provisions of section 136h of this title.

(June 25, 1947, ch. 125, §7, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 987; amended Pub. L. 95–396, §13, Sept. 30, 1978, 92 Stat. 829; Pub. L. 102–237, title X, §1006(b)(1), (3)(F), (G), Dec. 13, 1991, 105 Stat. 1895, 1896.)

Editorial Notes

Prior Provisions

A prior section 7 of act June 25, 1947, was classified to section 135e of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

Amendments

1991—Subsec. (b). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "shall".

Subsec. (c)(1)(A) to (C). Pub. L. 102–237, §1006(b)(3)(F), substituted "the producer" for "he".

Subsec. (c)(2). Pub. L. 102–237, §1006(b)(3)(G), substituted "the Administrator" for "him" after "inform" and "the producer" for "he".

1978—Subsec. (a). Pub. L. 95–396, §13(1), made requirement of registration applicable to production of active ingredient used in producing a pesticide subject to this subchapter.

Subsec. (c)(1). Pub. L. 95–396, §13(2), required information pertaining to types and amounts of active ingredients used in producing pesticides where applicable.

Subsec. (d). Pub. L. 95–396, §13(3), considered names of pesticides or active ingredients used in producing pesticides produced, sold, or distributed at an establishment as not being confidential information.

Statutory Notes and Related Subsidiaries

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136f. Books and records

(a) Requirements

The Administrator may prescribe regulations requiring producers, registrants, and applicants for registration to maintain such records with respect to their operations and the pesticides and devices produced as the Administrator determines are necessary for the effective enforcement of this subchapter and to make the records available for inspection and copying in the same manner as

provided in subsection (b). No records required under this subsection shall extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed).

(b) Inspection

For the purposes of enforcing the provisions of this subchapter, any producer, distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide or device subject to this subchapter, shall, upon request of any officer or employee of the Environmental Protection Agency or of any State or political subdivision, duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to, and to copy: (1) all records showing the delivery, movement, or holding of such pesticide or device, including the quantity, the date of shipment and receipt, and the name of the consignor and consignee; or (2) in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device. Any inspection with respect to any records and information referred to in this subsection shall not extend to financial data, sales data other than shipment data, pricing data, personnel data; and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed). Before undertaking an inspection under this subsection, the officer or employee must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness.

(June 25, 1947, ch. 125, §8, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 987; amended Pub. L. 95–396, §14, Sept. 30, 1978, 92 Stat. 829; Pub. L. 100–532, title III, §301, Oct. 25, 1988, 102 Stat. 2668; Pub. L. 102–237, title X, §1006(b)(1), Dec. 13, 1991, 105 Stat. 1895.)

Editorial Notes

Prior Provisions

A prior section 8 of act June 25, 1947, was classified to section 135f of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

Amendments

1991—Subsec. (a). Pub. L. 102–237 substituted "the Administrator" for "he" before "determines".

1988—Subsec. (a). Pub. L. 100–532 inserted ", registrants, and applicants for registration" after "requiring producers" and "and to make the records available for inspection and copying in the same manner as provided in subsection (b) of this section" before period at end of first sentence.

1978—Subsec. (b). Pub. L. 95–396 required, in connection with inspection of records and information, the presentation of credentials, written statement as to the reason for inspection, including statement of suspected violation, or an alternative but sufficient reason, and commencement and completion of inspection with reasonable promptness.

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136g. Inspection of establishments, etc.

(a) In general

(1) For purposes of enforcing the provisions of this subchapter, officers or employees of the Environmental Protection Agency or of any State duly designated by the Administrator are authorized to enter at reasonable times (A) any establishment or other place where pesticides or devices are held for distribution or sale for the purpose of inspecting and obtaining samples of any pesticides or devices, packaged, labeled, and released for shipment, and samples of any containers or labeling for such pesticides or devices, or (B) any place where there is being held any pesticide the registration of which has been suspended or canceled for the purpose of determining compliance with section 136q of this title.

(2) Before undertaking such inspection, the officers or employees must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness. If the officer or employee obtains any samples, prior to leaving the premises, the officer or employee shall give to the owner, operator, or agent in charge a receipt describing the samples obtained and, if requested, a portion of each such sample equal in volume or weight to the portion retained. If an analysis is made of such samples, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

(b) Warrants

For purposes of enforcing the provisions of this subchapter and upon a showing to an officer or court of competent jurisdiction that there is reason to believe that the provisions of this subchapter have been violated, officers or employees duly designated by the Administrator are empowered to obtain and to execute warrants authorizing—

(1) entry, inspection, and copying of records for purposes of this section or section 136f of this title;

(2) inspection and reproduction of all records showing the quantity, date of shipment, and the name of consignor and consignee of any pesticide or device found in the establishment which is adulterated, misbranded, not registered (in the case of a pesticide) or otherwise in violation of this subchapter and in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device; and

(3) the seizure of any pesticide or device which is in violation of this subchapter.

(c) Enforcement

(1) Certification of facts to Attorney General

The examination of pesticides or devices shall be made in the Environmental Protection Agency or elsewhere as the Administrator may designate for the purpose of determining from such examinations whether they comply with the requirements of this subchapter. If it shall appear from any such examination that they fail to comply with the requirements of this subchapter, the Administrator shall cause notice to be given to the person against whom criminal or civil proceedings are contemplated. Any person so notified shall be given an opportunity to present the person's views, either orally or in writing, with regard to such contemplated proceedings, and if in the opinion of the Administrator it appears that the provisions of this subchapter have been violated by such person, then the Administrator shall certify the facts to the Attorney General, with a copy of the results of the analysis or the examination of such pesticide for the institution of a criminal proceeding pursuant to section 136l(b) of this title or a civil proceeding under section 136l(a) of this title, when the Administrator determines that such action will be sufficient to effectuate the purposes of this subchapter.

(2) Notice not required

The notice of contemplated proceedings and opportunity to present views set forth in this subsection are not prerequisites to the institution of any proceeding by the Attorney General.

(3) Warning notices

Nothing in this subchapter shall be construed as requiring the Administrator to institute proceedings for prosecution of minor violations of this subchapter whenever the Administrator believes that the public interest will be adequately served by a suitable written notice of warning.

(June 25, 1947, ch. 125, §9, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 988; amended Pub. L. 100–532, title III, §302, Oct. 25, 1988, 102 Stat. 2669; Pub. L. 102–237, title X, §1006(b)(1), (3)(H), (I), Dec. 13, 1991, 105 Stat. 1895, 1896.)

Editorial Notes

Prior Provisions

A prior section 9 of act June 25, 1947, was classified to section 135g of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

Amendments

1991—Subsec. (a)(2). Pub. L. 102–237, §1006(b)(3)(H), substituted "the officer or employee" for "he" before "shall" in fourth sentence.

Subsec. (c)(1). Pub. L. 102–237, §1006(b)(3)(I), substituted "the person's" for "his" in third sentence.

Subsec. (c)(3). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "believes".

1988—Subsec. (a). Pub. L. 100–532, §302(a), substituted "(1) For purposes of" for "For purposes of", inserted "of the Environmental Protection Agency or of any State", substituted "at reasonable times (A)" for "at reasonable times,", added cl. (B), and substituted "(2) Before" for "Before".

Subsec. (b)(1). Pub. L. 100–532, §302(b), amended par. (1) generally, substituting "entry, inspection, and copying of records for purposes of this section or section 136f of this title" for "entry for the purpose of this section".

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136h. Protection of trade secrets and other information

(a) In general

In submitting data required by this subchapter, the applicant may (1) clearly mark any portions thereof which in the applicant's opinion are trade secrets or commercial or financial information and (2) submit such market material separately from other material required to be submitted under this subchapter.

(b) Disclosure

Notwithstanding any other provision of this subchapter and subject to the limitations in subsections (d) and (e) of this section, the Administrator shall not make public information which in the Administrator's judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this subchapter, information relating to formulas of products acquired by

authorization of this subchapter may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator.

(c) Disputes

If the Administrator proposes to release for inspection information which the applicant or registrant believes to be protected from disclosure under subsection (b), the Administrator shall notify the applicant or registrant, in writing, by certified mail. The Administrator shall not thereafter make available for inspection such data until thirty days after receipt of the notice by the applicant or registrant. During this period, the applicant or registrant may institute an action in an appropriate district court for a declaratory judgment as to whether such information is subject to protection under subsection (b).

(d) Limitations

(1) All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public. The use of such data for any registration purpose shall be governed by section 136a of this title. This paragraph does not authorize the disclosure of any information that—

(A) discloses manufacturing or quality control processes,

(B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or

(C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide,

unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

(2) Information concerning production, distribution, sale, or inventories of a pesticide that is otherwise entitled to confidential treatment under subsection (b) of this section may be publicly disclosed in connection with a public proceeding to determine whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment, if the Administrator determines that such disclosure is necessary in the public interest.

(3) If the Administrator proposes to disclose information described in clause (A), (B), or (C) of paragraph (1) or in paragraph (2) of this subsection, the Administrator shall notify by certified mail the submitter of such information of the intent to release such information. The Administrator may not release such information, without the submitter's consent, until thirty days after the submitter has been furnished such notice. Where the Administrator finds that disclosure of information described in clause (A), (B), or (C) of paragraph (1) of this subsection is necessary to avoid or lessen an imminent and substantial risk of injury to the public health, the Administrator may set such shorter period of notice (but not less than ten days) and such method of notice as the Administrator finds appropriate. During such period the data submitter may institute an action in an appropriate district court to enjoin or limit the proposed disclosure. The court may enjoin disclosure, or limit the disclosure or the parties to whom disclosure shall be made, to the extent that—

(A) in the case of information described in clause (A), (B), or (C) of paragraph (1) of this subsection, the proposed disclosure is not required to protect against an unreasonable risk of injury to health or the environment; or

(B) in the case of information described in paragraph (2) of this subsection, the public interest in availability of the information in the public proceeding does not outweigh the interests in preserving the confidentiality of the information.

(e) Disclosure to contractors

Information otherwise protected from disclosure to the public under subsection (b) of this section may be disclosed to contractors with the United States and employees of such contractors if, in the opinion of the Administrator, such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this subchapter and under such conditions as the Administrator may specify. The Administrator shall require as a condition to the disclosure of information under this subsection that the person receiving it take such security precautions respecting the information as the Administrator shall by regulation prescribe.

(f) Penalty for disclosure by Federal employees

(1) Any officer or employee of the United States or former officer or employee of the United States who, by virtue of such employment or official position, has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (b) of this section, and who, knowing that disclosure of such material is prohibited by such subsection, willfully discloses the material in any manner to any person not entitled to receive it, shall be fined not more than $10,000 or imprisoned for not more than one year, or both. Section 1905 of title 18 shall not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this subchapter. Nothing in this subchapter shall preempt any civil remedy under State or Federal law for wrongful disclosure of trade secrets.

(2) For the purposes of this section, any contractor with the United States who is furnished information as authorized by subsection (e) of this section, or any employee of any such contractor, shall be considered to be an employee of the United States.

(g) Disclosure to foreign and multinational pesticide producers

(1) The Administrator shall not knowingly disclose information submitted by an applicant or registrant under this subchapter to any employee or agent of any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or to any other person who intends to deliver such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure. The Administrator shall require an affirmation from any person who intends to inspect data that such person does not seek access to the data for purposes of delivering it or offering it for sale to any such business or entity or its agents or employees and will not purposefully deliver or negligently cause the data to be delivered to such business or entity or its agents or employees. Notwithstanding any other provision of this subsection, the Administrator may disclose information to any person in connection with a public proceeding under law or regulation, subject to restrictions on the availability of information contained elsewhere in this subchapter, which information is relevant to a determination by the Administrator with respect to whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment.

(2) The Administrator shall maintain records of the names of persons to whom data are disclosed under this subsection and the persons or organizations they represent and shall inform the applicant or registrant of the names and affiliations of such persons.

(3) Section 1001 of title 18 shall apply to any affirmation made under paragraph (1) of this subsection.

(June 25, 1947, ch. 125, §10, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 989; amended Pub. L. 95–396, §15, Sept. 30, 1978, 92 Stat. 829; Pub. L. 98–620, title IV, §402(4)(B), Nov. 8, 1984, 98 Stat. 3357; Pub. L. 100–532, title VIII, §801(f), Oct. 25, 1988, 102 Stat. 2682; Pub. L. 102–237, title X, §1006(b)(1), (2), (3)(J), Dec. 13, 1991, 105 Stat. 1895, 1896.)

Editorial Notes

Prior Provisions

A prior section 10 of act June 25, 1947, was classified to section 135h of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

Amendments

1991—Subsec. (a). Pub. L. 102–237, §1006(b)(3)(J), substituted "the applicant's" for "his".

Subsec. (b). Pub. L. 102–237, §1006(b)(2), substituted "the Administrator's" for "his".

Subsec. (c). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "shall notify".

1988—Subsec. (d). Pub. L. 100–532 in par. (1), substituted "public. The use" for "public: *Provided*, That the use" and "title. This paragraph" for "title: *Provided further*, That this paragraph", and in par. (3), "notice. Where" for "notice: *Provided*, That where".

1984—Subsec. (d)(3). Pub. L. 98–620 struck out provisions requiring the court to give expedited consideration to actions involving injunctions or limitations of proposed disclosure.

1978—Subsec. (b). Pub. L. 95–396, §15(1), made disclosure of information by the Administrator subject to the limitations of subsecs. (d) and (e) of this section.

Subsecs. (d) to (g). Pub. L. 95–396, §15(2), added subsecs. (d) to (g).

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Effective Date of 1984 Amendment

Amendment by Pub. L. 98–620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98–620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136i. Use of restricted use pesticides; applicators

(a) Certification procedure

(1) Federal certification

In any State for which a State plan for applicator certification has not been approved by the Administrator, the Administrator, in consultation with the Governor of such State, shall conduct a program for the certification of applicators of pesticides. Such program shall conform to the requirements imposed upon the States under the provisions of subsection (a)(2) of this section and shall not require private applicators to take any examination to establish competency in the use of pesticides. Prior to the implementation of the program, the Administrator shall publish in the Federal Register for review and comment a summary of the Federal plan for applicator certification and shall make generally available within the State copies of the plan. The Administrator shall hold public hearings at one or more locations within the State if so requested by the Governor of such State during the thirty days following publication of the Federal Register notice inviting comment on the Federal plan. The hearings shall be held within thirty days following receipt of the request from the Governor. In any State in which the Administrator conducts a certification program, the Administrator may require any person engaging in the commercial application, sale, offering for sale, holding for sale, or distribution of any pesticide one or more uses of which have been classified for restricted use to maintain such records and submit such reports concerning the commercial application, sale, or distribution of such pesticide as the Administrator may by regulation prescribe. Subject to paragraph (2), the Administrator shall prescribe standards for the certification of applicators of pesticides. Such standards shall provide that to be certified, an individual must be determined to be competent with respect to the use and handling of the pesticides, or to the use and handling of the pesticide or class of pesticides covered by such individual's certification. The certification standard for a private applicator shall, under a State plan submitted for approval, be deemed fulfilled by the applicator completing a certification form. The Administrator shall further assure that such form contains adequate information and affirmations to carry out the intent of this subchapter, and may include in the form an affirmation

that the private applicator has completed a training program approved by the Administrator so long as the program does not require the private applicator to take, pursuant to a requirement prescribed by the Administrator, any examination to establish competency in the use of the pesticide. The Administrator may require any pesticide dealer participating in a certification program to be licensed under a State licensing program approved by the Administrator.

(2) State certification

If any State, at any time, desires to certify applicators of pesticides, the Governor of such State shall submit a State plan for such purpose. The Administrator shall approve the plan submitted by any State, or any modification thereof, if such plan in the Administrator's judgment—

(A) designates a State agency as the agency responsible for administering the plan throughout the State;

(B) contains satisfactory assurances that such agency has or will have the legal authority and qualified personnel necessary to carry out the plan;

(C) gives satisfactory assurances that the State will devote adequate funds to the administration of the plan;

(D) provides that the State agency will make such reports to the Administrator in such form and containing such information as the Administrator may from time to time require; and

(E) contains satisfactory assurances that State standards for the certification of applicators of pesticides conform with those standards prescribed by the Administrator under paragraph (1).

Any State certification program under this section shall be maintained in accordance with the State plan approved under this section.

(b) State plans

If the Administrator rejects a plan submitted under subsection (a)(2), the Administrator shall afford the State submitting the plan due notice and opportunity for hearing before so doing. If the Administrator approves a plan submitted under subsection (a)(2), then such State shall certify applicators of pesticides with respect to such State. Whenever the Administrator determines that a State is not administering the certification program in accordance with the plan approved under this section, the Administrator shall so notify the State and provide for a hearing at the request of the State, and, if appropriate corrective action is not taken within a reasonable time, not to exceed ninety days, the Administrator shall withdraw approval of such plan.

(c) Instruction in integrated pest management techniques

Standards prescribed by the Administrator for the certification of applicators of pesticides under subsection (a), and State plans submitted to the Administrator under subsection (a), shall include provisions for making instructional materials concerning integrated pest management techniques available to individuals at their request in accordance with the provisions of section 136u(c) of this title, but such plans may not require that any individual receive instruction concerning such techniques or to be shown to be competent with respect to the use of such techniques. The Administrator and States implementing such plans shall provide that all interested individuals are notified on the availability of such instructional materials.

(d) In general

No regulations prescribed by the Administrator for carrying out the provisions of this subchapter shall require any private applicator to maintain any records or file any reports or other documents.

(e) Separate standards

When establishing or approving standards for licensing or certification, the Administrator shall establish separate standards for commercial and private applicators.

(June 25, 1947, ch. 125, §11, formerly §§4, 11, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 983, 989; amended Pub. L. 94–140, §§5, 11, Nov. 28, 1975, 89 Stat. 753, 754; Pub. L. 95–396, §9, Sept. 30, 1978, 92 Stat. 827; Pub. L. 100–532, title VIII, §801(c), (q)(1)(A)–(C), Oct. 25, 1988, 102 Stat. 2681, 2683; Pub. L. 102–237, title X, §1006(a)(6), (b)(1), (2), (3)(K), Dec. 13, 1991, 105 Stat. 1895, 1896.)

Editorial Notes

Codification

Pub. L. 100–532, §801(q)(1)(A), transferred subsecs. (a) to (c) of section 4 of act June 25, 1947, which was classified to section 136b of this title, to subsecs. (a) to (c) of this section.

Prior Provisions

A prior section 11 of act June 25, 1947, was classified to section 135i of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

Amendments

1991—Pub. L. 102–237, §1006(a)(6)(A), substituted "applicators" for "appplicators" in section catchline.

Subsec. (a)(1). Pub. L. 102–237, §1006(b)(3)(K), substituted "the applicator" for "his" in ninth sentence and "the Administrator" for "him" before period at end.

Subsec. (a)(2). Pub. L. 102–237, §1006(b)(2), substituted "the Administrator's" for "his" in introductory provisions.

Subsec. (b). Pub. L. 102–237, §1006(a)(6)(B), (b)(1), substituted "subsection (a)(2) of this section" for "this paragraph" in two places and "the Administrator" for "he" before "shall afford" and before "shall so notify".

Subsec. (c). Pub. L. 102–237, §1006(a)(6)(C), substituted "subsection (a)" for "subsections (a) and (b)" after "Administrator under".

1988—Pub. L. 100–532, §801(q)(1)(A), (C), substituted section catchline for one which read: "Standards applicable to pesticide applicators", redesignated subsecs. (a) and (b) as (d) and (e), respectively, and transferred subsecs. (a) to (c) of section 136b of this title to subsecs. (a) to (c), respectively, of this section.

Subsec. (a)(1). Pub. L. 100–532, §801(c), substituted "pesticides. Such program" for "pesticides: *Provided*, That such program" and "certification. The certification" for "certification: *Provided, however*, That the certification".

1978—Subsec. (a)(1). Pub. L. 95–396 required that, in any State without a State plan for applicator certification approved by the Administrator, the Administrator, in consultation with the Governor of the State, shall conduct a program for the certification of applicators of pesticides under a Federal plan for applicator certification, and also that in such a State records be maintained and reports submitted by persons engaged in commercial application, sale or distribution of pesticides classified for restricted use.

1975—Subsec. (a)(1). Pub. L. 94–140, §5, inserted proviso relating to Administrator's powers and duties with respect to the certification forms and requirement for pesticide dealers participating in certification program.

Subsec. (c). Pub. L. 94–140, §11, added subsec. (c).

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136i–1. Pesticide recordkeeping

(a) Requirements

(1) The Secretary of Agriculture, in consultation with the Administrator of the Environmental Protection Agency, shall require certified applicators of restricted use pesticides (of the type described under section 136a(d)(1)(C) of this title) to maintain records comparable to records maintained by commercial applicators of pesticides in each State. If there is no State requirement for the maintenance of records, such applicator shall maintain records that contain the product name,

amount, approximate date of application, and location of application of each such pesticide used for a 2-year period after such use.

(2) Within 30 days of a pesticide application, a commercial certified applicator shall provide a copy of records maintained under paragraph (1) to the person for whom such application was provided.

(b) Access

Records maintained under subsection (a) shall be made available to any Federal or State agency that deals with pesticide use or any health or environmental issue related to the use of pesticides, on the request of such agency. Each such Federal agency shall conduct surveys and record the data from individual applicators to facilitate statistical analysis for environmental and agronomic purposes, but in no case may a government agency release data, including the location from which the data was derived, that would directly or indirectly reveal the identity of individual producers. In the case of Federal agencies, such access to records maintained under subsection (a) shall be through the Secretary of Agriculture, or the Secretary's designee. State agency requests for access to records maintained under subsection (a) shall be through the lead State agency so designated by the State.

(c) Health care personnel

When a health professional determines that pesticide information maintained under this section is necessary to provide medical treatment or first aid to an individual who may have been exposed to pesticides for which the information is maintained, upon request persons required to maintain records under subsection (a) shall promptly provide record and available label information to that health professional. In the case of an emergency, such record information shall be provided immediately.

(d) Penalty

The Secretary of Agriculture shall be responsible for the enforcement of subsections (a), (b), and (c). A violation of such subsection shall—

(1) in the case of the first offense, be subject to a fine of not more than $500; and

(2) in the case of subsequent offenses, be subject to a fine of not less than $1,000 for each violation, except that the penalty shall be less than $1,000 if the Secretary determines that the person made a good faith effort to comply with such subsection.

(e) Federal or State provisions

The requirements of this section shall not affect provisions of other Federal or State laws.

(f) Surveys and reports

The Secretary of Agriculture and the Administrator of the Environmental Protection Agency, shall survey the records maintained under subsection (a) to develop and maintain a data base that is sufficient to enable the Secretary and the Administrator to publish annual comprehensive reports concerning agricultural and nonagricultural pesticide use. The Secretary and Administrator shall enter into a memorandum of understanding to define their respective responsibilities under this subsection in order to avoid duplication of effort. Such reports shall be transmitted to Congress not later than April 1 of each year.

(g) Regulations

The Secretary of Agriculture and the Administrator of the Environmental Protection Agency shall promulgate regulations on their respective areas of responsibility implementing this section within 180 days after November 28, 1990.

(Pub. L. 101–624, title XIV, §1491, Nov. 28, 1990, 104 Stat. 3627; Pub. L. 102–237, title X, §1006(d), Dec. 13, 1991, 105 Stat. 1896.)

Editorial Notes

Codification

Section was enacted as part of the Conservation Program Improvements Act, and also as part of the Food, Agriculture, Conservation, and Trade Act of 1990, and not as part of the Federal Insecticide, Fungicide, and

Rodenticide Act which comprises this subchapter.

Amendments

1991—Subsec. (a)(1). Pub. L. 102–237, §1006(d)(1), inserted closing parenthesis after "section 136a(d)(1)(C) of this title".

Subsec. (d)(1). Pub. L. 102–237, §1006(d)(2), inserted "of" after "fine".

§136i–2. Collection of pesticide use information

(a) In general

The Secretary of Agriculture shall collect data of statewide or regional significance on the use of pesticides to control pests and diseases of major crops and crops of dietary significance, including fruits and vegetables.

(b) Collection

The data shall be collected by surveys of farmers or from other sources offering statistically reliable data.

(c) Coordination

The Secretary of Agriculture shall, as appropriate, coordinate with the Administrator of the Environmental Protection Agency in the design of the surveys and make available to the Administrator the aggregate results of the surveys to assist the Administrator.

(Pub. L. 104–170, title III, §302, Aug. 3, 1996, 110 Stat. 1512.)

Editorial Notes

Codification

Section was enacted as part of the Food Quality Protection Act of 1996, and not as part of the Federal Insecticide, Fungicide, and Rodenticide Act which comprises this subchapter.

Statutory Notes and Related Subsidiaries

Pesticide Use Information Study

Pub. L. 104–170, title III, §305, Aug. 3, 1996, 110 Stat. 1512, required the Secretary of Agriculture, in consultation with the Administrator of the Environmental Protection Agency, to prepare a report to Congress evaluating the current status and potential improvements in Federal pesticide use information gathering activities and to submit the report not later than 1 year following Aug. 3, 1996.

§136j. Unlawful acts

(a) In general

(1) Except as provided by subsection (b), it shall be unlawful for any person in any State to distribute or sell to any person—

(A) any pesticide that is not registered under section 136a of this title or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this subchapter;

(B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 136a of this title;

(C) any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under section 136a of this title;

(D) any pesticide which has not been colored or discolored pursuant to the provisions of section 136w(c)(5) of this title;

(E) any pesticide which is adulterated or misbranded; or

(F) any device which is misbranded.

(2) It shall be unlawful for any person—

(A) to detach, alter, deface, or destroy, in whole or in part, any labeling required under this subchapter;

(B) to refuse to—

(i) prepare, maintain, or submit any records required by or under section 136c, 136e, 136f, 136i, or 136q of this title;

(ii) submit any reports required by or under section 136c, 136d, 136e, 136f, 136i, or 136q of this title; or

(iii) allow any entry, inspection, copying of records, or sampling authorized by this subchapter;

(C) to give a guaranty or undertaking provided for in subsection (b) which is false in any particular, except that a person who receives and relies upon a guaranty authorized under subsection (b) may give a guaranty to the same effect, which guaranty shall contain, in addition to the person's own name and address, the name and address of the person residing in the United States from whom the person received the guaranty or undertaking;

(D) to use for the person's own advantage or to reveal, other than to the Administrator, or officials or employees of the Environmental Protection Agency or other Federal executive agencies, or to the courts, or to physicians, pharmacists, and other qualified persons, needing such information for the performance of their duties, in accordance with such directions as the Administrator may prescribe, any information acquired by authority of this subchapter which is confidential under this subchapter;

(E) who is a registrant, wholesaler, dealer, retailer, or other distributor to advertise a product registered under this subchapter for restricted use without giving the classification of the product assigned to it under section 136a of this title;

(F) to distribute or sell, or to make available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accordance with section 136a(d) of this title and any regulations thereunder, except that it shall not be unlawful to sell, under regulations issued by the Administrator, a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator;

(G) to use any registered pesticide in a manner inconsistent with its labeling;

(H) to use any pesticide which is under an experimental use permit contrary to the provisions of such permit;

(I) to violate any order issued under section 136k of this title;

(J) to violate any suspension order issued under section 136a(c)(2)(B), 136a–1, or 136d of this title;

(K) to violate any cancellation order issued under this subchapter or to fail to submit a notice in accordance with section 136d(g) of this title;

(L) who is a producer to violate any of the provisions of section 136e of this title;

(M) to knowingly falsify all or part of any application for registration, application for experimental use permit, any information submitted to the Administrator pursuant to section 136e of this title, any records required to be maintained pursuant to this subchapter, any report filed under this subchapter, or any information marked as confidential and submitted to the Administrator under any provision of this subchapter;

(N) who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by this subchapter;

(O) to add any substance to, or take any substance from, any pesticide in a manner that may defeat the purpose of this subchapter;

(P) to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test;

(Q) to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this subchapter;

(R) to submit to the Administrator data known to be false in support of a registration; or

(S) to violate any regulation issued under section 136a(a) or 136q of this title.

(b) Exemptions

The penalties provided for a violation of paragraph (1) of subsection (a) shall not apply to—

(1) any person who establishes a guaranty signed by, and containing the name and address of, the registrant or person residing in the United States from whom the person purchased or received in good faith the pesticide in the same unbroken package, to the effect that the pesticide was lawfully registered at the time of sale and delivery to the person, and that it complies with the other requirements of this subchapter, and in such case the guarantor shall be subject to the penalties which would otherwise attach to the person holding the guaranty under the provisions of this subchapter;

(2) any carrier while lawfully shipping, transporting, or delivering for shipment any pesticide or device, if such carrier upon request of any officer or employee duly designated by the Administrator shall permit such officer or employee to copy all of its records concerning such pesticide or device;

(3) any public official while engaged in the performance of the official duties of the public official;

(4) any person using or possessing any pesticide as provided by an experimental use permit in effect with respect to such pesticide and such use or possession; or

(5) any person who ships a substance or mixture of substances being put through tests in which the purpose is only to determine its value for pesticide purposes or to determine its toxicity or other properties and from which the user does not expect to receive any benefit in pest control from its use.

(June 25, 1947, ch. 125, §12, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 989; amended Pub. L. 95–396, §16, Sept. 30, 1978, 92 Stat. 832; Pub. L. 100–532, title VI, §§601(b)(2), 603, title VIII, §801(g), (q)(2)(B), Oct. 25, 1988, 102 Stat. 2677, 2678, 2682, 2683; Pub. L. 102–237, title X, §1006(a)(7), (b)(3)(L)–(O), Dec. 13, 1991, 105 Stat. 1895, 1896.)

Editorial Notes

Prior Provisions

A prior section 12 of act June 25, 1947, was classified to section 135j of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

Amendments

1991—Subsec. (a)(2)(C). Pub. L. 102–237, §1006(b)(3)(L), substituted "the person's" for "his" and "the person" for "he" before "received".

Subsec. (a)(2)(D). Pub. L. 102–237, §1006(b)(3)(M), substituted "the person's" for "his".

Subsec. (a)(2)(F). Pub. L. 102–237, §1006(a)(7)(A), substituted "thereunder, except that it" for "thereunder. It".

Subsec. (a)(2)(O). Pub. L. 102–237, §1006(a)(7)(B), struck out "or" after semicolon at end.

Subsec. (a)(2)(P). Pub. L. 102–237, §1006(a)(7)(C), substituted a semicolon for period at end.

Subsec. (b)(1). Pub. L. 102–237, §1006(b)(3)(N), substituted "the person" for "he" after "from whom" and for "him" after "delivery to".

Subsec. (b)(3). Pub. L. 102–237, §1006(b)(3)(O), substituted "the official duties of the public official" for "his official duties".

1988—Subsec. (a)(1). Pub. L. 100–532, §601(b)(2)(A), in introductory provisions, substituted "distribute or sell to any person" for "distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person".

Subsec. (a)(1)(A). Pub. L. 100–532, §603(1), added subpar. (A) and struck out former subpar. (A) which read as follows: "any pesticide which is not registered under section 136a of this title, except as provided by section 136d(a)(1) of this title;".

Subsec. (a)(2)(B). Pub. L. 100–532, §603(2)(A), added subpar. (B) and struck out former subpar. (B) which read as follows: "to refuse to keep any records required pursuant to section 136f of this title, or to refuse to allow inspection of any records or establishment pursuant to section 136f or 136g of this title, or to refuse to allow an officer or employee of the Environmental Protection Agency to take a sample of any pesticide pursuant to section 136g of this title;".

Subsec. (a)(2)(F). Pub. L. 100–532, §§601(b)(2)(B), 801(g), substituted "to distribute or sell, or to make" for "to make" and "thereunder, It" for "thereunder: *Provided*, That it".

Subsec. (a)(2)(J). Pub. L. 100–532, §801(q)(2)(B), made a technical amendment to the reference to section 136a–1 of this title to reflect the renumbering of the corresponding section of the original act.

Pub. L. 100–532, §603(2)(B), added subpar. (J) and struck out former subpar. (J) which read as follows: "to violate any suspension order issued under section 136d of this title;".

Subsec. (a)(2)(K). Pub. L. 100–532, §603(2)(B), added subpar. (K) and struck out former subpar. (K) which read as follows: "to violate any cancellation of registration of a pesticide under section 136d of this title, except as provided by section 136d(a)(1) of this title;".

Subsec. (a)(2)(M). Pub. L. 100–532, §603(2)(C), substituted "this subchapter" for "section 136f of this title".

Subsec. (a)(2)(Q), (R), (S). Pub. L. 100–532, §603(2)(D), added subpars. (Q), (R), and (S).

1978—Subsec. (a)(2)(F). Pub. L. 95–396 inserted proviso exempting from prohibition the sale, under regulations issued by the Administrator, of a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator.

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136k. Stop sale, use, removal, and seizure

(a) Stop sale, etc., orders

Whenever any pesticide or device is found by the Administrator in any State and there is reason to believe on the basis of inspection or tests that such pesticide or device is in violation of any of the provisions of this subchapter, or that such pesticide or device has been or is intended to be distributed or sold in violation of any such provisions, or when the registration of the pesticide has been canceled by a final order or has been suspended, the Administrator may issue a written or printed "stop sale, use, or removal" order to any person who owns, controls, or has custody of such pesticide or device, and after receipt of such order no person shall sell, use, or remove the pesticide or device described in the order except in accordance with the provisions of the order.

(b) Seizure

Any pesticide or device that is being transported or, having been transported, remains unsold or in original unbroken packages, or that is sold or offered for sale in any State, or that is imported from a

foreign country, shall be liable to be proceeded against in any district court in the district where it is found and seized for confiscation by a process in rem for condemnation if—

(1) in the case of a pesticide—

(A) it is adulterated or misbranded;

(B) it is not registered pursuant to the provisions of section 136a of this title;

(C) its labeling fails to bear the information required by this subchapter;

(D) it is not colored or discolored and such coloring or discoloring is required under this subchapter; or

(E) any of the claims made for it or any of the directions for its use differ in substance from the representations made in connection with its registration;

(2) in the case of a device, it is misbranded; or

(3) in the case of a pesticide or device, when used in accordance with the requirements imposed under this subchapter and as directed by the labeling, it nevertheless causes unreasonable adverse effects on the environment.

In the case of a plant regulator, defoliant, or desiccant, used in accordance with the label claims and recommendations, physical or physiological effects on plants or parts thereof shall not be deemed to be injury, when such effects are the purpose for which the plant regulator, defoliant, or desiccant was applied.

(c) Disposition after condemnation

If the pesticide or device is condemned it shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs, shall be paid into the Treasury of the United States, but the pesticide or device shall not be sold contrary to the provisions of this subchapter or the laws of the jurisdiction in which it is sold. On payment of the costs of the condemnation proceedings and the execution and delivery of a good and sufficient bond conditioned that the pesticide or device shall not be sold or otherwise disposed of contrary to the provisions of the subchapter or the laws of any jurisdiction in which sold, the court may direct that such pesticide or device be delivered to the owner thereof. The proceedings of such condemnation cases shall conform, as near as may be to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

(d) Court costs, etc.

When a decree of condemnation is entered against the pesticide or device, court costs and fees, storage, and other proper expenses shall be awarded against the person, if any, intervening as claimant of the pesticide or device.

(June 25, 1947, ch. 125, §13, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 991; amended Pub. L. 100–532, title VIII, §801(h), Oct. 25, 1988, 102 Stat. 2682.)

Editorial Notes

Prior Provisions

A prior section 13 of act June 25, 1947, was classified to section 135k of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

Amendments

1988—Subsec. (b). Pub. L. 100–532, §801(h)(1), directed that sentence beginning "In the case of" be moved from par. (3) and become a full measure sentence after par. (3).

Subsec. (c). Pub. L. 100–532, §801(h)(2), substituted "sold. On" for "sold: *Provided*, That upon".

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136*l*. Penalties

(a) Civil penalties

(1) In general

Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of this subchapter may be assessed a civil penalty by the Administrator of not more than $5,000 for each offense.

(2) Private applicator

Any private applicator or other person not included in paragraph (1) who violates any provision of this subchapter subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, may be assessed a civil penalty by the Administrator of not more than $1,000 for each offense, except that any applicator not included under paragraph (1) of this subsection who holds or applies registered pesticides, or uses dilutions of registered pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and who violates any provision of this subchapter may be assessed a civil penalty by the Administrator of not more than $500 for the first offense nor more than $1,000 for each subsequent offense.

(3) Hearing

No civil penalty shall be assessed unless the person charged shall have been given notice and opportunity for a hearing on such charge in the county, parish, or incorporated city of the residence of the person charged.

(4) Determination of penalty

In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. Whenever the Administrator finds that the violation occurred despite the exercise of due care or did not cause significant harm to health or the environment, the Administrator may issue a warning in lieu of assessing a penalty.

(5) References to Attorney General

In case of inability to collect such civil penalty or failure of any person to pay all, or such portion of such civil penalty as the Administrator may determine, the Administrator shall refer the matter to the Attorney General, who shall recover such amount by action in the appropriate United States district court.

(b) Criminal penalties

(1) In general

(A) Any registrant, applicant for a registration, or producer who knowingly violates any provision of this subchapter shall be fined not more than $50,000 or imprisoned for not more than 1 year, or both.

(B) Any commercial applicator of a restricted use pesticide, or any other person not described in subparagraph (A) who distributes or sells pesticides or devices, who knowingly violates any provision of this subchapter shall be fined not more than $25,000 or imprisoned for not more than 1 year, or both.

(2) Private applicator

Any private applicator or other person not included in paragraph (1) who knowingly violates any provision of this subchapter shall be guilty of a misdemeanor and shall on conviction be fined not more than $1,000, or imprisoned for not more than 30 days, or both.

(3) Disclosure of information

Any person, who, with intent to defraud, uses or reveals information relative to formulas of products acquired under the authority of section 136a of this title, shall be fined not more than $10,000, or imprisoned for not more than three years, or both.

(4) Acts of officers, agents, etc.

When construing and enforcing the provisions of this subchapter, the act, omission, or failure of any officer, agent, or other person acting for or employed by any person shall in every case be also deemed to be the act, omission, or failure of such person as well as that of the person employed.

(June 25, 1947, ch. 125, §14, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 992; amended Pub. L. 95–396, §17, Sept. 30, 1978, 92 Stat. 832; Pub. L. 100–532, title VI, §604, Oct. 25, 1988, 102 Stat. 2678; Pub. L. 102–237, title X, §1006(a)(8), Dec. 13, 1991, 105 Stat. 1895.)

Editorial Notes

Amendments

1991—Subsec. (a)(2). Pub. L. 102–237 substituted ", except that" for ": *Provided*, That" and "uses" for "use".

1988—Subsec. (b)(1). Pub. L. 100–532 amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who knowingly violates any provision of this subchapter shall be guilty of a misdemeanor and shall on conviction be fined not more than $25,000, or imprisoned for not more than one year, or both."

1978—Subsec. (a)(2). Pub. L. 95–396, §17(1), authorized assessment of a civil penalty of not more than $500 for a first offense and not more than $1,000 for each subsequent offense against any applicator providing a service of controlling pests for violations of this subchapter.

Subsec. (a)(3). Pub. L. 95–396, §17(2), struck out provision respecting certain considerations when determining amount of penalty, now covered in par. (4).

Subsec. (a)(4). Pub. L. 95–396, §17(4), reenacted second sentence of par. (3) as par. (4) and authorized Administrator to issue a warning in lieu of assessing a penalty. Former par. (4) redesignated (5).

Subsec. (a)(5). Pub. L. 95–396, §17(3), redesignated former par. (4) as (5).

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136m. Indemnities

(a) General indemnification

(1) In general

Except as otherwise provided in this section, if—

(A) the Administrator notifies a registrant under section 136d(c)(1) of this title that the Administrator intends to suspend a registration or that an emergency order of suspension of a registration under section 136d(c)(3) of this title has been issued;

(B) the registration in question is suspended under section 136d(c) of this title, and thereafter is canceled under section 136d(b), 136d(d), or 136d(f) of this title; and

(C) any person who owned any quantity of the pesticide immediately before the notice to the registrant under subparagraph (A) suffered losses by reason of suspension or cancellation of the registration;

the Administrator shall make an indemnity payment to the person.

(2) Exception

Paragraph (1) shall not apply if the Administrator finds that the person—

(A) had knowledge of facts that, in themselves, would have shown that the pesticide did not meet the requirements of section 136a(c)(5) of this title for registration; and

(B) continued thereafter to produce the pesticide without giving timely notice of such facts to the Administrator.

(3) Report

If the Administrator takes an action under paragraph (1) that requires the payment of indemnification, the Administrator shall report to the Committee on Agriculture of the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry of the Senate, and the Committees on Appropriations of the House of Representatives and the Senate on—

(A) the action taken that requires the payment of indemnification;

(B) the reasons for taking the action;

(C) the estimated cost of the payment; and

(D) a request for the appropriation of funds for the payment.

(4) Appropriation

The Administrator may not make a payment of indemnification under paragraph (1) unless a specific line item appropriation of funds has been made in advance for the payment.

(b) Indemnification of end users, dealers, and distributors

(1) End users

If—

(A) the Administrator notifies a registrant under section 136d(c)(1) of this title that the Administrator intends to suspend a registration or that an emergency order of suspension of a registration under section 136d(c)(3) of this title has been issued;

(B) the registration in question is suspended under section 136d(c) of this title, and thereafter is canceled under section 136d(b), 136d(d), or 136d(f) of this title; and

(C) any person who, immediately before the notice to the registrant under subparagraph (A), owned any quantity of the pesticide for purposes of applying or using the pesticide as an end user, rather than for purposes of distributing or selling it or further processing it for distribution or sale, suffered a loss by reason of the suspension or cancellation of the pesticide;

the person shall be entitled to an indemnity payment under this subsection for such quantity of the pesticide.

(2) Dealers and distributors

(A) Any registrant, wholesaler, dealer, or other distributor (hereinafter in this paragraph referred to as a "seller") of a registered pesticide who distributes or sells the pesticide directly to any person not described as an end user in paragraph (1)(C) shall, with respect to any quantity of the pesticide that such person cannot use or resell as a result of the suspension or cancellation of the pesticide, reimburse such person for the cost of first acquiring the pesticide from the seller (other than the cost of transportation, if any), unless the seller provided to the person at the time of distribution or sale a notice, in writing, that the pesticide is not subject to reimbursement by the seller.

(B) If—

(i) the Administrator notifies a registrant under section 136d(c)(1) of this title that the Administrator intends to suspend a registration or that an emergency order of suspension of a

registration under section 136d(c)(3) of this title has been issued;

(ii) the registration in question is suspended under section 136d(c) of this title, and thereafter is canceled under section 136d(b), 136d(d), or 136d(f) of this title;

(iii) any person who, immediately before the notice to the registrant under clause (i)—

(I) had not been notified in writing by the seller, as provided under subparagraph (A), that any quantity of the pesticide owned by such person is not subject to reimbursement by the seller in the event of suspension or cancellation of the pesticide; and

(II) owned any quantity of the pesticide for purposes of—

(aa) distributing or selling it; or

(bb) further processing it for distribution or sale directly to an end user;

suffered a loss by reason of the suspension or cancellation of the pesticide; and

(iv) the Administrator determines on the basis of a claim of loss submitted to the Administrator by the person, that the seller—

(I) did not provide the notice specified in subparagraph (A) to such person; and

(II) is and will continue to be unable to provide reimbursement to such person, as provided under subparagraph (A), for the loss referred to in clause (iii), as a result of the insolvency or bankruptcy of the seller and the seller's resulting inability to provide such reimbursement;

the person shall be entitled to an indemnity payment under this subsection for such quantity of the pesticide.

(C) If an indemnity payment is made by the United States under this paragraph, the United States shall be subrogated to any right that would otherwise be held under this paragraph by a seller who is unable to make a reimbursement in accordance with this paragraph with regard to reimbursements that otherwise would have been made by the seller.

(3) Source

Any payment required to be made under paragraph (1) or (2) shall be made from the appropriation provided under section 1304 of title 31.

(4) Administrative settlement

An administrative settlement of a claim for such indemnity may be made in accordance with the third paragraph of section 2414 of title 28 and shall be regarded as if it were made under that section for purposes of section 1304 of title 31.

(c) Amount of payment

(1) In general

The amount of an indemnity payment under subsection (a) or (b) to any person shall be determined on the basis of the cost of the pesticide owned by the person (other than the cost of transportation, if any) immediately before the issuance of the notice to the registrant referred to in subsection (a)(1)(A), (b)(1)(A), or (b)(2)(B)(i), except that in no event shall an indemnity payment to any person exceed the fair market value of the pesticide owned by the person immediately before the issuance of the notice.

(2) Special rule

Notwithstanding any other provision of this subchapter, the Administrator may provide a reasonable time for use or other disposal of the pesticide. In determining the quantity of any pesticide for which indemnity shall be paid under this section, proper adjustment shall be made for any pesticide used or otherwise disposed of by the owner.

(June 25, 1947, ch. 125, §15, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 993; amended Pub. L. 100–532, title V, §501(a), Oct. 25, 1988, 102 Stat. 2674.)

EDITORIAL NOTES

AMENDMENTS

1988—Pub. L. 100–532 amended section generally, in subsec. (a), substituting provisions relating to general indemnification for provisions relating to requirements for payment, adding subsec. (b), and redesignating provisions of former subsec. (b), with further amendment, as subsec. (c).

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Pub. L. 100–532, title V, §501(a), Oct. 25, 1988, 102 Stat. 2674, provided that amendment made by Pub. L. 100–532 is effective 180 days after Oct. 25, 1988.

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

Interim Payments

Pub. L. 100–532, title V, §501(b), Oct. 25, 1988, 102 Stat. 2676, provided that:

"(1) Source.—Any obligation of the Administrator to pay an indemnity arising under section 15 [this section], as it existed prior to the effective date of the amendment made by this section [see Effective Date of 1988 Amendment note above], shall be made from the appropriation provided under section 1304 of title 31, United States Code.

"(2) Administrative settlement.—An administrative settlement of a claim for such indemnity may be made in accordance with the third paragraph of section 2414 of title 28, United States Code, and shall be regarded as if it were made under that section for purposes of section 1304 of title 31, United States Code."

§136n. Administrative procedure; judicial review

(a) District court review

Except as otherwise provided in this subchapter, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States.

(b) Review by court of appeals

In the case of actual controversy as to the validity of any order issued by the Administrator following a public hearing, any person who will be adversely affected by such order and who had been a party to the proceedings may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has a place of business, within 60 days after the entry of such order, a petition praying that the order be set aside in whole or in part. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the Administrator's order, as provided in section 2112 of title 28. Upon the filing of such petition the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The court shall consider all evidence of record. The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole. The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

(c) Jurisdiction of district courts

The district courts of the United States are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this subchapter.

(d) Notice of judgments

The Administrator shall, by publication in such manner as the Administrator may prescribe, give notice of all judgments entered in actions instituted under the authority of this subchapter.

(June 25, 1947, ch. 125, §16, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 994; amended Pub. L. 98–620, title IV, §402(4)(C), Nov. 8, 1984, 98 Stat. 3357; Pub. L. 100–532, title VIII, §801(i), Oct. 25, 1988, 102 Stat. 2682; Pub. L. 102–237, title X, §1006(b)(1), (2), (3)(P), Dec. 13, 1991, 105 Stat. 1895, 1896.)

Editorial Notes

Amendments

1991—Subsec. (b). Pub. L. 102–237, §1006(b)(1), (2), (3)(P), substituted "the Administrator" for "he" before "based", "the Administrator's" for "his", and "the Administrator" for "him" after "designated by".

Subsec. (d). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "may".

1988—Subsec. (a). Pub. L. 100–532 amended subsec. (a) generally. Prior to amendment, subsec. (a) read as follows: "Except as is otherwise provided in this subchapter, Agency refusals to cancel or suspend registrations or change classifications not following a hearing and other final Agency actions not committed to Agency discretion by law are judicially reviewable in the district courts."

1984—Subsec. (b). Pub. L. 98–620 struck out provisions requiring the court to advance on the docket and expedite the disposition of all cases filed pursuant to this section.

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Effective Date of 1984 Amendment

Amendment by Pub. L. 98–620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98–620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136*o*. Imports and exports

(a) Pesticides and devices intended for export

Notwithstanding any other provision of this subchapter, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this subchapter—

(1) when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 136(p), 136(q)(1)(A), (C), (D), (E), (G), and (H), 136(q)(2)(A), (B), (C)(i) and (iii), and (D), 136e, and 136f of this title; and

(2) in the case of any pesticide other than a pesticide registered under section 136a or sold under section 136d(a)(1) of this title, if, prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this subchapter.

A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

(b) Cancellation notices furnished to foreign governments

Whenever a registration, or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies. Such notification shall, upon request, include all information related to the cancellation or suspension of the registration of the pesticide and information concerning other pesticides that are registered under section 136a of this title and that could be used in lieu of such pesticide.

(c) Importation of pesticides and devices

(1) In general

The Secretary of the Treasury shall notify the Administrator of the arrival of pesticides and devices and shall deliver to the Administrator, upon the Administrator's request, samples of pesticides or devices which are being imported into the United States, giving notice to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. If it appears from the examination of a sample that it is adulterated, or misbranded or otherwise violates the provisions set forth in this subchapter, or is otherwise injurious to health or the environment, the pesticide or device may be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any pesticide or device refused delivery which shall not be exported by the consignee within 90 days from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe. The Secretary of the Treasury may deliver to the consignee such pesticide or device pending examination and decision in the matter on execution of bond for the amount of the full invoice value of such pesticide or device, together with the duty thereon, and on refusal to return such pesticide or device for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of said bond. All charges for storage, cartage, and labor on pesticides or devices which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

(2) Importation of seed

Notwithstanding any other provision of law, no person is required to notify the Administrator of the arrival of a plant-incorporated protectant (as defined in section 174.3 of title 40, Code of Federal Regulations (or any successor regulation)) that is contained in a seed, if—

(A) that plant-incorporated protectant is registered under section 136a of this title;

(B) the Administrator has issued an experimental use permit for that plant-incorporated protectant under section 136c of this title; or

(C) the seed is covered by a permit (as defined in part 340 of title 7, Code of Federal Regulations (or any successor regulation)) or a notification.

(3) Cooperation

(A) In general

In response to a request from the Administrator, the Secretary of Agriculture shall provide to the Administrator a list of seed containing plant-incorporated protectants (as defined in section 174.3 of title 40, Code of Federal Regulations (or any successor regulation)) if the importation of that seed into the United States has been approved under a permit or notification referred to in paragraph (2).

(B) Contents

The list under subparagraph (A) shall be provided in a form and at such intervals as may be agreed to by the Secretary and the Administrator.

(4) Applicability

Nothing in this subsection precludes or limits the authority of the Secretary of Agriculture with respect to the importation or movement of plants, plant products, or seeds under—

(A) the Plant Protection Act (7 U.S.C. 7701 et seq.); and

(B) the Federal Seed Act (7 U.S.C. 1551 et seq.).

(d) Cooperation in international efforts

(1) In general

The Administrator shall, in cooperation with the Department of State and any other appropriate Federal agency, participate and cooperate in any international efforts to develop improved pesticide research and regulations.

(2) Department of State expenses

Any expenses incurred by an employee of the Environmental Protection Agency who participates in any international technical, economic, or policy review board, committee, or other official body that is meeting in relation to an international treaty shall be paid by the Department of State.

(e) Regulations

The Secretary of the Treasury, in consultation with the Administrator, shall prescribe regulations for the enforcement of subsection (c) of this section.

(June 25, 1947, ch. 125, §17, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 995; amended Pub. L. 95–396, §18(a), Sept. 30, 1978, 92 Stat. 833; Pub. L. 100–532, title VIII, §801(j), Oct. 25, 1988, 102 Stat. 2682; Pub. L. 102–237, title X, §1006(a)(9), (b)(2), Dec. 13, 1991, 105 Stat. 1895; Pub. L. 110–234, title XIV, §14209(a), May 22, 2008, 122 Stat. 1463; Pub. L. 110–246, §4(a), title XIV, §14209(a), June 18, 2008, 122 Stat. 1664, 2225; Pub. L. 113–79, title X, §10008, Feb. 7, 2014, 128 Stat. 948.)

Editorial Notes

References in Text

The Plant Protection Act, referred to in subsec. (c)(4)(A), is title IV of Pub. L. 106–224, June 20, 2000, 114 Stat. 438, which is classified principally to chapter 104 (§7701 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 7701 of this title and Tables.

The Federal Seed Act, referred to in subsec. (c)(4)(B), is act Aug. 9, 1939, ch. 615, 53 Stat. 1275, which is classified generally to chapter 37 (§1551 et seq.) of this title. For complete classification of this Act to the Code, see section 1551 of this title and Tables.

Codification

Pub. L. 110–234 and Pub. L. 110–246 made identical amendments to this section. The amendments by Pub. L. 110–234 were repealed by section 4(a) of Pub. L. 110–246.

Amendments

2014—Subsec. (c). Pub. L. 113–79 designated existing provisions as par. (1), inserted heading, and added pars. (2) to (4).

2008—Subsec. (d). Pub. L. 110–246, §14209(a), designated existing provisions as par. (1), inserted heading, and added par. (2).

1991—Subsec. (a). Pub. L. 102–237, §1006(a)(9), removed last sentence from par. (2) and placed it as a full measure sentence under par. (2).

Subsec. (c). Pub. L. 102–237, §1006(b)(2), substituted "the Administrator's" for "his".

1988—Subsec. (c). Pub. L. 100–532 substituted "prescribe. The Secretary" for "prescribe: *Provided*, That the Secretary" and "bond. All" for "bond: *And provided further*, That all".

1978—Subsec. (a). Pub. L. 95–396, §18(a)(1), amended subsec. (a) generally.

Subsec. (b). Pub. L. 95–396, §18(a)(2), inserted sentence at end relating to information to be included in notification.

Statutory Notes and Related Subsidiaries

Effective Date of 2008 Amendment

Amendment of this section and repeal of Pub. L. 110–234 by Pub. L. 110–246 effective May 22, 2008, the date of enactment of Pub. L. 110–234, see section 4 of Pub. L. 110–246, set out as an Effective Date note under section 8701 of this title.

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Effective Date of 1978 Amendment

Pub. L. 95–396, §18(b), Sept. 30, 1978, 92 Stat. 833, provided that: "The amendment made by subsection (a)(1) of this section [amending this section] shall become effective one hundred and eighty days after the date of enactment of this Act [Sept. 30, 1978]."

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136p. Exemption of Federal and State agencies

The Administrator may, at the Administrator's discretion, exempt any Federal or State agency from any provision of this subchapter if the Administrator determines that emergency conditions exist which require such exemption. The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination.

(June 25, 1947, ch. 125, §18, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 995; amended Pub. L. 94–140, §8, Nov. 28, 1975, 89 Stat. 754; Pub. L. 100–532, title VIII, §801(k), Oct. 25, 1988, 102 Stat. 2682; Pub. L. 102–237, title X, §1006(b)(1), (2), Dec. 13, 1991, 105 Stat. 1895.)

Editorial Notes

Amendments

1991—Pub. L. 102–237 substituted "the Administrator" for "he" before "determines" and "the Administrator's" for "his".

1988—Pub. L. 100–532 substituted "and" for "or" in section catchline, and directed that sentence beginning "The Administrator, in" be run in after first sentence beginning "The Administrator may".

1975—Pub. L. 94–140 inserted provision requiring Administrator to consult with Secretary of Agriculture and Governor of State concerned in determining whether an emergency situation exists.

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Statutory Notes and Related Subsidiaries

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136q. Storage, disposal, transportation, and recall

(a) Storage, disposal, and transportation

(1) Data requirements and registration of pesticides

The Administrator may require under section 136a or 136d of this title that—

(A) the registrant or applicant for registration of a pesticide submit or cite data or information regarding methods for the safe storage and disposal of excess quantities of the pesticide to support the registration or continued registration of a pesticide;

(B) the labeling of a pesticide contain requirements and procedures for the transportation, storage, and disposal of the pesticide, any container of the pesticide, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide; and

(C) the registrant of a pesticide provide evidence of sufficient financial and other resources to carry out a recall plan under subsection (b), and provide for the disposition of the pesticide, in the event of suspension and cancellation of the pesticide.

(2) Pesticides

The Administrator may by regulation, or as part of an order issued under section 136d of this title or an amendment to such an order—

(A) issue requirements and procedures to be followed by any person who stores or transports a pesticide the registration of which has been suspended or canceled;

(B) issue requirements and procedures to be followed by any person who disposes of stocks of a pesticide the registration of which has been suspended; and

(C) issue requirements and procedures for the disposal of any pesticide the registration of which has been canceled.

(3) Containers, rinsates, and other materials

The Administrator may by regulation, or as part of an order issued under section 136d of this title or an amendment to such an order—

(A) issue requirements and procedures to be followed by any person who stores or transports any container of a pesticide the registration of which has been suspended or canceled, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide;

(B) issue requirements and procedures to be followed by any person who disposes of stocks of any container of a pesticide the registration of which has been suspended, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide; and

(C) issue requirements and procedures for the disposal of any container of a pesticide the registration of which has been canceled, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide.

(4) Container recycling

The Secretary may promulgate a regulation for the return and recycling of disposable pesticide containers used for the distribution or sale of registered pesticide products in interstate commerce. Any such regulation requiring recycling of disposable pesticide containers shall not apply to antimicrobial pesticides (as defined in section 136 of this title) or other pesticide products intended for non-agricultural uses.

(b) Recalls

(1) In general

If the registration of a pesticide has been suspended and canceled under section 136d of this title, and if the Administrator finds that recall of the pesticide is necessary to protect health or the environment, the Administrator shall order a recall of the pesticide in accordance with this subsection.

(2) Voluntary recall

If, after determining under paragraph (1) that a recall is necessary, the Administrator finds that voluntary recall by the registrant and others in the chain of distribution may be as safe and effective as a mandatory recall, the Administrator shall request the registrant of the pesticide to submit, within 60 days of the request, a plan for the voluntary recall of the pesticide. If such a plan is requested and submitted, the Administrator shall approve the plan and order the registrant to

conduct the recall in accordance with the plan unless the Administrator determines, after an informal hearing, that the plan is inadequate to protect health or the environment.

(3) Mandatory recall

If, after determining under paragraph (1) that a recall is necessary, the Administrator does not request the submission of a plan under paragraph (2) or finds such a plan to be inadequate, the Administrator shall issue a regulation that prescribes a plan for the recall of the pesticide. A regulation issued under this paragraph may apply to any person who is or was a registrant, distributor, or seller of the pesticide, or any successor in interest to such a person.

(4) Recall procedure

A regulation issued under this subsection may require any person that is subject to the regulation to—

(A) arrange to make available one or more storage facilities to receive and store the pesticide to which the recall program applies, and inform the Administrator of the location of each such facility;

(B) accept and store at such a facility those existing stocks of such pesticide that are tendered by any other person who obtained the pesticide directly or indirectly from the person that is subject to such regulation;

(C) on the request of a person making such a tender, provide for proper transportation of the pesticide to a storage facility; and

(D) take such reasonable steps as the regulation may prescribe to inform persons who may be holders of the pesticide of the terms of the recall regulation and how those persons may tender the pesticide and arrange for transportation of the pesticide to a storage facility.

(5) Contents of recall plan

A recall plan established under this subsection shall include—

(A) the level in the distribution chain to which the recall is to extend, and a schedule for recall; and

(B) the means to be used to verify the effectiveness of the recall.

(6) Requirements or procedures

No requirement or procedure imposed in accordance with paragraph (2) of subsection (a) may require the recall of existing stocks of the pesticide except as provided by this subsection.

(c) Storage costs

(1) Submission of plan

A registrant who wishes to become eligible for reimbursement of storage costs incurred as a result of a recall prescribed under subsection (b) for a pesticide whose registration has been suspended and canceled shall, as soon as practicable after the suspension of the registration of the pesticide, submit to the Administrator a plan for the storage and disposal of the pesticide that meets criteria established by the Administrator by regulation.

(2) Reimbursement

Within a reasonable period of time after such storage costs are incurred and paid by the registrant, the Administrator shall reimburse the registrant, on request, for—

(A) none of the costs incurred by the registrant before the date of submission of the plan referred to in paragraph (1) to the Administrator;

(B) 100 percent of the costs incurred by the registrant after the date of submission of the plan to the Administrator or the date of cancellation of the registration of the pesticide, whichever is later, but before the approval of the plan by the Administrator;

(C) 50 percent of the costs incurred by the registrant during the 1-year period beginning on the date of the approval of the plan by the Administrator or the date of cancellation of the registration of the pesticide, whichever is later;

(D) none of the costs incurred by the registrant during the 3-year period beginning on the 366th day following approval of the plan by the Administrator or the date of cancellation of the

registration of the pesticide, whichever is later; and

(E) 25 percent of the costs incurred by the registrant during the period beginning on the first day of the 5th year following the date of the approval of the plan by the Administrator or the date of cancellation of the registration of the pesticide, whichever is later, and ending on the date that a disposal permit for the pesticide is issued by a State or an alternative plan for disposal of the pesticide in accordance with applicable law has been developed.

(d) Administration of storage, disposal, transportation, and recall programs

(1) Voluntary agreements

Nothing in this section shall be construed as preventing or making unlawful any agreement between a seller and a buyer of any pesticide or other substance regarding the ultimate allocation of the costs of storage, transportation, or disposal of a pesticide.

(2) Rule and regulation review

Section 136w(a)(4) of this title shall not apply to any regulation issued under subsection (a)(2) or (b).

(3) Limitations

No registrant shall be responsible under this section for a pesticide the registration of which is held by another person. No distributor or seller shall be responsible under this section for a pesticide that the distributor or seller did not hold or sell.

(4) Seizure and penalties

If the Administrator finds that a person who is subject to a regulation or order under subsection (a)(2) or (b) has failed substantially to comply with that regulation or order, the Administrator may take action under section 136k or 136l of this title or obtain injunctive relief under section 136n(c) of this title against such person or any successor in interest of any such person.

(e) Container design

(1) Procedures

(A) Not later than 3 years after the effective date of this subsection, the Administrator shall, in consultation with the heads of other interested Federal agencies, promulgate regulations for the design of pesticide containers that will promote the safe storage and disposal of pesticides.

(B) The regulations shall ensure, to the fullest extent practicable, that the containers—

(i) accommodate procedures used for the removal of pesticides from the containers and the rinsing of the containers;

(ii) facilitate the safe use of the containers, including elimination of splash and leakage of pesticides from the containers;

(iii) facilitate the safe disposal of the containers; and

(iv) facilitate the safe refill and reuse of the containers.

(2) Compliance

The Administrator shall require compliance with the regulations referred to in paragraph (1) not later than 5 years after the effective date of this subsection.

(f) Pesticide residue removal

(1) Procedures

(A) Not later than 3 years after the effective date of this subsection, the Administrator shall, in consultation with the heads of other interested Federal agencies, promulgate regulations prescribing procedures and standards for the removal of pesticides from containers prior to disposal.

(B) The regulations may—

(i) specify, for each major type of pesticide container, procedures and standards providing for, at a minimum, triple rinsing or the equivalent degree of pesticide removal;

(ii) specify procedures that can be implemented promptly and easily in various circumstances and conditions;

(iii) provide for reuse, whenever practicable, or disposal of rinse water and residue; and

(iv) be coordinated with requirements for the rinsing of containers imposed under the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.).

(C) The Administrator may, at the discretion of the Administrator, exempt products intended solely for household use from the requirements of this subsection.

(2) Compliance

Effective beginning 5 years after the effective date of this subsection, a State may not exercise primary enforcement responsibility under section 136w–1 of this title, or certify an applicator under section 136i of this title, unless the Administrator determines that the State is carrying out an adequate program to ensure compliance with this subsection.

(3) Solid Waste Disposal Act

Nothing in this subsection shall affect the authorities or requirements concerning pesticide containers under the Solid Waste Disposal Act (42 U.S.C. 6901).

(g) Pesticide container study

(1) Study

(A) The Administrator shall conduct a study of options to encourage or require—

(i) the return, refill, and reuse of pesticide containers;

(ii) the development and use of pesticide formulations that facilitate the removal of pesticide residues from containers; and

(iii) the use of bulk storage facilities to reduce the number of pesticide containers requiring disposal.

(B) In conducting the study, the Administrator shall—

(i) consult with the heads of other interested Federal agencies, State agencies, industry groups, and environmental organizations; and

(ii) assess the feasibility, costs, and environmental benefits of encouraging or requiring various measures or actions.

(2) Report

Not later than 2 years after the effective date of this subsection, the Administrator shall submit to Congress a report describing the results of the study required under paragraph (1).

(h) Relationship to Solid Waste Disposal Act

(1) In general

Nothing in this section shall diminish the authorities or requirements of the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.).

(2) Antimicrobial products

A household, industrial, or institutional antimicrobial product that is not subject to regulation under the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.) shall not be subject to the provisions of subsections (a), (e), and (f), unless the Administrator determines that such product must be subject to such provisions to prevent an unreasonable adverse effect on the environment.

(June 25, 1947, ch. 125, §19, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 995; amended Pub. L. 95–396, §19, Sept. 30, 1978, 92 Stat. 833; Pub. L. 100–532, title IV, §§401–403, title VIII, §801(q)(1)(D), Oct. 25, 1988, 102 Stat. 2669, 2672, 2683; Pub. L. 104–170, title II, §225, Aug. 3, 1996, 110 Stat. 1507; Pub. L. 110–234, title XIV, §14209(b), May 22, 2008, 122 Stat. 1463; Pub. L. 110–246, §4(a), title XIV, §14209(b), June 18, 2008, 122 Stat. 1664, 2225.)

Editorial Notes

References in Text

The effective date of this subsection, referred to in subsecs. (e), (f)(1)(A), (2), and (g)(2), is 60 days after Oct. 25, 1988, the effective date of Pub. L. 100–532. See Effective Date of 1988 Amendment note below.

The Solid Waste Disposal Act, referred to in subsecs. (f)(1)(B)(iv), (3) and (h), is title II of Pub. L. 89–272, Oct. 20, 1965, 79 Stat. 997, as amended generally by Pub. L. 94–580, §2, Oct. 21, 1976, 90 Stat. 2795, which is classified generally to chapter 82 (§6901 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 6901 of Title 42 and Tables.

Codification

Pub. L. 110–234 and Pub. L. 110–246 made identical amendments to this section. The amendments by Pub. L. 110–234 were repealed by section 4(a) of Pub. L. 110–246.

Amendments

2008—Subsec. (a)(4). Pub. L. 110–246, §14209(b), added par. (4).

1996—Subsec. (h). Pub. L. 104–170 designated existing provisions as par. (1), inserted heading, and added par. (2).

1988—Pub. L. 100–532, §401, amended section generally, in subsec. (a) substituting provisions which related to storage, disposal, and transportation, for provisions which directed Secretary to establish procedures for disposal or storage, in subsec. (b) substituting provisions which related to recalls, for provisions which directed Administrator to provide advice to Secretary of Transportation, in subsec. (c) substituting provisions which related to storage costs, for provisions which related to disposal of unused quantities, and adding subsec. (d).

Subsec. (a)(3). Pub. L. 100–532, §402, added par. (3).

Subsecs. (e), (f). Pub. L. 100–532, §403, added subsecs. (e) and (f).

Subsec. (f)(2). Pub. L. 100–532, §801(q)(1)(D), substituted "136i" for "136b".

Subsecs. (g), (h). Pub. L. 100–532, §403, added subsecs. (g) and (h).

1978—Subsec. (c). Pub. L. 95–396 added subsec. (c).

Statutory Notes and Related Subsidiaries

Effective Date of 2008 Amendment

Amendment of this section and repeal of Pub. L. 110–234 by Pub. L. 110–246 effective May 22, 2008, the date of enactment of Pub. L. 110–234, see section 4 of Pub. L. 110–246, set out as an Effective Date note under section 8701 of this title.

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136r. Research and monitoring

(a) Research

The Administrator shall undertake research including research by grant or contract with other Federal agencies, universities, or others as may be necessary to carry out the purposes of this subchapter, and the Administrator shall conduct research into integrated pest management in coordination with the Secretary of Agriculture. The Administrator shall also take care to ensure that such research does not duplicate research being undertaken by any other Federal agency.

(b) National monitoring plan

The Administrator shall formulate and periodically revise, in cooperation with other Federal, State, or local agencies, a national plan for monitoring pesticides.

(c) Monitoring

The Administrator shall undertake such monitoring activities, including, but not limited to monitoring in air, soil, water, man, plants, and animals, as may be necessary for the implementation of this subchapter and of the national pesticide monitoring plan. The Administrator shall establish procedures for the monitoring of man and animals and their environment for incidential [1] pesticide exposure, including, but not limited to, the quantification of incidental human and environmental pesticide pollution and the secular trends thereof, and identification of the sources of contamination and their relationship to human and environmental effects. Such activities shall be carried out in cooperation with other Federal, State, and local agencies.

(June 25, 1947, ch. 125, §20, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 996; amended Pub. L. 95–396, §20, Sept. 30, 1978, 92 Stat. 834; Pub. L. 102–237, title X, §1006(a)(10), (b)(1), Dec. 13, 1991, 105 Stat. 1895.)

Editorial Notes

Amendments

1991—Subsec. (a). Pub. L. 102–237 substituted "ensure" for "insure" and "the Administrator" for "he" before "shall conduct".

1978—Subsec. (a). Pub. L. 95–396, §20(1), substituted in first sentence "shall conduct research into integrated pest management in coordination with the Secretary of Agriculture" for "shall give priority to research to develop biologically integrated alternatives for pest control".

Subsec. (c). Pub. L. 95–396, §20(2), inserted provision requiring establishment of monitoring procedures and the carrying out of the activities in cooperation with other Federal, State, and local agencies.

Statutory Notes and Related Subsidiaries

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

Availability of Grants

Pub. L. 106–74, title III, Oct. 20, 1999, 113 Stat. 1081, provided in part: "That notwithstanding 7 U.S.C. 136r and 15 U.S.C. 2609, beginning in fiscal year 2000 and thereafter, grants awarded under section 20 of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136r], as amended, and section 10 of the Toxic Substances Control Act [15 U.S.C. 2609], as amended, shall be available for research, development, monitoring, public education, training, demonstrations, and studies".

[1] *So in original. Probably should be "incidental".*

§136r–1. Integrated Pest Management

The Secretary of Agriculture, in cooperation with the Administrator, shall implement research, demonstration, and education programs to support adoption of Integrated Pest Management. Integrated Pest Management is a sustainable approach to managing pests by combining biological, cultural, physical, and chemical tools in a way that minimizes economic, health, and environmental risks. The Secretary of Agriculture and the Administrator shall make information on Integrated Pest Management widely available to pesticide users, including Federal agencies. Federal agencies shall use Integrated Pest Management techniques in carrying out pest management activities and shall promote Integrated Pest Management through procurement and regulatory policies, and other activities.

(Pub. L. 104–170, title III, §303, Aug. 3, 1996, 110 Stat. 1512.)

Editorial Notes

Codification

Section was enacted as part of the Food Quality Protection Act of 1996, and not as part of the Federal Insecticide, Fungicide, and Rodenticide Act which comprises this subchapter.

§136s. Solicitation of comments; notice of public hearings

(a) Secretary of Agriculture

The Administrator, before publishing regulations under this subchapter, shall solicit the views of the Secretary of Agriculture in accordance with the procedure described in section 136w(a) of this title.

(b) Secretary of Health and Human Services

The Administrator, before publishing regulations under this subchapter for any public health pesticide, shall solicit the views of the Secretary of Health and Human Services in the same manner as the views of the Secretary of Agriculture are solicited under section 136w(a)(2) of this title.

(c) Views

In addition to any other authority relating to public hearings and solicitation of views, in connection with the suspension or cancellation of a pesticide registration or any other actions authorized under this subchapter, the Administrator may, at the Administrator's discretion, solicit the views of all interested persons, either orally or in writing, and seek such advice from scientists, farmers, farm organizations, and other qualified persons as the Administrator deems proper.

(d) Notice

In connection with all public hearings under this subchapter the Administrator shall publish timely notice of such hearings in the Federal Register.

(June 25, 1947, ch. 125, §21, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 996; amended Pub. L. 94–140, §2(b), Nov. 28, 1975, 89 Stat. 752; Pub. L. 100–532, title VIII, §801(l), Oct. 25, 1988, 102 Stat. 2682; Pub. L. 102–237, title X, §1006(b)(1), (2), Dec. 13, 1991, 105 Stat. 1895; Pub. L. 104–170, title II, §234, Aug. 3, 1996, 110 Stat. 1509.)

Editorial Notes

Amendments

1996—Subsecs. (b) to (d). Pub. L. 104–170 added subsec. (b) and redesignated former subsecs. (b) and (c) as (c) and (d), respectively.

1991—Subsec. (b). Pub. L. 102–237 substituted "the Administrator" for "he" before "deems" and "the Administrator's" for "his".

1988—Pub. L. 100–532, §801(l), inserted headings for subsecs. (a) to (c).

1975—Subsec. (a). Pub. L. 94–140 inserted "in accordance with the procedure described in section 136w(a) of this title" after "Secretary of Agriculture".

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136t. Delegation and cooperation

(a) Delegation

All authority vested in the Administrator by virtue of the provisions of this subchapter may with like force and effect be executed by such employees of the Environmental Protection Agency as the Administrator may designate for the purpose.

(b) Cooperation

The Administrator shall cooperate with Department of Agriculture, any other Federal agency, and any appropriate agency of any State or any political subdivision thereof, in carrying out the provisions of this subchapter, and in securing uniformity of regulations.

(June 25, 1947, ch. 125, §22, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 996.)

Statutory Notes and Related Subsidiaries

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136u. State cooperation, aid, and training

(a) Cooperative agreements

The Administrator may enter into cooperative agreements with States and Indian tribes—

(1) to delegate to any State or Indian tribe the authority to cooperate in the enforcement of this subchapter through the use of its personnel or facilities, to train personnel of the State or Indian tribe to cooperate in the enforcement of this subchapter, and to assist States and Indian tribes in implementing cooperative enforcement programs through grants-in-aid; and

(2) to assist States in developing and administering State programs, and Indian tribes that enter into cooperative agreements, to train and certify applicators consistent with the standards the Administrator prescribes.

Effective with the fiscal year beginning October 1, 1978, there are authorized to be appropriated annually such funds as may be necessary for the Administrator to provide through cooperative agreements an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed to under such cooperative agreements, of conducting training and certification programs during such fiscal year. If funds sufficient to pay 50 percent of the costs for any year are not appropriated, the share of each State and Indian tribe shall be reduced in a like proportion in allocating available funds.

(b) Contracts for training

In addition, the Administrator may enter into contracts with Federal, State, or Indian tribal agencies for the purpose of encouraging the training of certified applicators.

(c) Information and education

The Administrator shall, in cooperation with the Secretary of Agriculture, use the services of the cooperative State extension services to inform and educate pesticide users about accepted uses and other regulations made under this subchapter.

(June 25, 1947, ch. 125, §23, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 996; amended Pub. L. 95–396, §21, Sept. 30, 1978, 92 Stat. 834.)

Editorial Notes

Amendments

1978—Subsec. (a). Pub. L. 95–396 extended provisions to Indian tribes, authorized annual appropriation of funds for training and certification programs, and required proportionate reduction of shares in the allocation of available funds when appropriations do not cover 50 percent of the annual costs.

Subsec. (b). Pub. L. 95–396 authorized contracts with Indian tribal agencies.

Subsec. (c). Pub. L. 95–396 substituted "shall" for "may", substituted "use" for "utilize", and "to inform and educate pesticide users about accepted uses and other regulations" for "for informing farmers of accepted uses and other regulations".

Statutory Notes and Related Subsidiaries

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

Availability of Grants for Pesticide Program Development and Implementation

Pub. L. 105–276, title III, Oct. 21, 1998, 112 Stat. 2499, provided in part: "That beginning in fiscal year 1999 and thereafter, pesticide program implementation grants under section 23(a)(1) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended [7 U.S.C. 136u(a)(1)], shall be available for pesticide program development and implementation, including enforcement and compliance activities".

§136v. Authority of States

(a) In general

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

(b) Uniformity

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

(c) Additional uses

(1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under section 136a of this title for all purposes of this subchapter, but shall authorize distribution and use only within such State.

(2) A registration issued by a State under this subsection shall not be effective for more than ninety days if disapproved by the Administrator within that period. Prior to disapproval, the Administrator shall, except as provided in paragraph (3) of this subsection, advise the State of the Administrator's intention to disapprove and the reasons therefor, and provide the State time to respond. The Administrator shall not prohibit or disapprove a registration issued by a State under this subsection (A) on the basis of lack of essentiality of a pesticide or (B) except as provided in paragraph (3) of this subsection, if its composition and use patterns are similar to those of a federally registered pesticide.

(3) In no instance may a State issue a registration for a food or feed use unless there exists a tolerance or exemption under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] that permits the residues of the pesticides on the food or feed. If the Administrator determines that a registration issued by a State is inconsistent with the Federal Food, Drug, and Cosmetic Act, or the use of, a pesticide under a registration issued by a State constitutes an imminent hazard, the Administrator may immediately disapprove the registration.

(4) If the Administrator finds, in accordance with standards set forth in regulations issued under section 136w of this title, that a State is not capable of exercising adequate controls to assure that State registration under this section will be in accord with the purposes of this subchapter or has failed to exercise adequate controls, the Administrator may suspend the authority of the State to register pesticides until such time as the Administrator is satisfied that the State can and will exercise adequate controls. Prior to any such suspension, the Administrator shall advise the State of the Administrator's intention to suspend and the reasons therefor and provide the State time to respond.

(June 25, 1947, ch. 125, §24, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 997; amended Pub. L. 95–396, §22, Sept. 30, 1978, 92 Stat. 835; Pub. L. 100–532, title VIII, §801(m), Oct. 25, 1988, 102 Stat. 2682.)

Editorial Notes

References in Text

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (c)(3), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Amendments

1988—Pub. L. 100–532, §801(m), inserted headings for subsecs. (a) to (c) and realigned margins of pars. (1) to (4) of subsec. (c).

1978—Subsec. (a). Pub. L. 95–396 inserted "federally registered" before "pesticide or device".

Subsec. (b). Pub. L. 95–396 substituted "labeling or packaging" and "required under" for "labeling and packaging" and "required pursuant to", respectively.

Subsec. (c)(1). Pub. L. 95–396 incorporated existing text in provisions designated par. (1) and substituted "registration for additional uses of federally registered pesticides" for "registration for pesticides".

Subsec. (c)(2). Pub. L. 95–396 incorporated existing text in provisions designated par. (2), conditioned disapproval of registration on communication of intention to disapprove and reasons for disapproval and provision for time to respond, and restricted authority of Administrator to prohibit or disapprove a State registration.

Subsec. (c)(3). Pub. L. 95–396 added par. (3).

Subsec. (c)(4). Pub. L. 95–396 incorporated existing text in provisions designated par. (4) and authorized suspension of registration authority of the State based on findings of inability or failure to exercise adequate controls following an indication of intention to suspend and reasons for the suspension and provision for time to respond.

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136w. Authority of Administrator

(a) In general

(1) Regulations

The Administrator is authorized, in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of this subchapter. Such regulations shall take into account the difference in concept and usage between various classes of pesticides, including public health pesticides, and differences in environmental risk and the appropriate data for evaluating such risk between agricultural, nonagricultural, and public health pesticides.

(2) Procedure

(A) Proposed regulations

At least 60 days prior to signing any proposed regulation for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such

regulation within 30 days after receiving it, the Administrator shall publish in the Federal Register (with the proposed regulation) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 30 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register any time after such 30-day period notwithstanding the foregoing 60-day time requirement.

(B) Final regulations

At least 30 days prior to signing any regulation in final form for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such final regulation within 15 days after receiving it, the Administrator shall publish in the Federal Register (with the final regulation) the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 15 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register at any time after such 15-day period notwithstanding the foregoing 30-day time requirement. In taking any final action under this subsection, the Administrator shall include among those factors to be taken into account the effect of the regulation on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such effect.

(C) Time requirements

The time requirements imposed by subparagraphs (A) and (B) may be waived or modified to the extent agreed upon by the Administrator and the Secretary.

(D) Publication in the Federal Register

The Administrator shall, simultaneously with any notification to the Secretary of Agriculture under this paragraph prior to the issuance of any proposed or final regulation, publish such notification in the Federal Register.

(3) Congressional committees

At such time as the Administrator is required under paragraph (2) of this subsection to provide the Secretary of Agriculture with a copy of proposed regulations and a copy of the final form of regulations, the Administrator shall also furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(4) Congressional review of regulations

Simultaneously with the promulgation of any rule or regulation under this subchapter, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted.

(b) Exemption of pesticides

The Administrator may exempt from the requirements of this subchapter by regulation any pesticide which the Administrator determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this subchapter in order to carry out the purposes of this subchapter.

(c) Other authority

The Administrator, after notice and opportunity for hearing, is authorized—

(1) to declare a pest any form of plant or animal life (other than man and other than bacteria, virus, and other micro-organisms on or in living man or other living animals) which is injurious to health or the environment;

(2) to determine any pesticide which contains any substance or substances in quantities highly toxic to man;

(3) to establish standards (which shall be consistent with those established under the authority of the Poison Prevention Packaging Act (Public Law 91–601) [15 U.S.C. 1471 et seq.]) with respect to the package, container, or wrapping in which a pesticide or device is enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by this subchapter as well as to accomplish the other purposes of this subchapter;

(4) to specify those classes of devices which shall be subject to any provision of section 136(q)(1) or section 136e of this title upon the Administrator's determination that application of such provision is necessary to effectuate the purposes of this subchapter;

(5) to prescribe regulations requiring any pesticide to be colored or discolored if the Administrator determines that such requirement is feasible and is necessary for the protection of health and the environment; and

(6) to determine and establish suitable names to be used in the ingredient statement.

(d) Scientific advisory panel

(1) In general

The Administrator shall submit to an advisory panel for comment as to the impact on health and the environment of the action proposed in notices of intent issued under section 136d(b) of this title and of the proposed and final form of regulations issued under subsection (a) within the same time periods as provided for the comments of the Secretary of Agriculture under such section 136d(b) and subsection (a) of this section. The time requirements for notices of intent and proposed and final forms of regulation may not be modified or waived unless in addition to meeting the requirements of section 136d(b) of this title or subsection (a) of this section, as applicable, the advisory panel has failed to comment on the proposed action within the prescribed time period or has agreed to the modification or waiver. The Administrator shall also solicit from the advisory panel comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out the provisions of this subchapter. The comments, evaluations, and recommendations of the advisory panel submitted under this subsection and the response of the Administrator shall be published in the Federal Register in the same manner as provided for publication of the comments of the Secretary of Agriculture under such sections. The chairman of the advisory panel, after consultation with the Administrator, may create temporary subpanels on specific projects to assist the full advisory panel in expediting and preparing its evaluations, comments, and recommendations. The subpanels may be composed of scientists other than members of the advisory panel, as deemed necessary for the purpose of evaluating scientific studies relied upon by the Administrator with respect to proposed action. Such additional scientists shall be selected by the advisory panel. The panel referred to in this subsection shall consist of 7 members appointed by the Administrator from a list of 12 nominees, 6 nominated by the National Institutes of Health and 6 by the National Science Foundation, utilizing a system of staggered terms of appointment. Members of the panel shall be selected on the basis of their professional qualifications to assess the effects of the impact of pesticides on health and the environment. To the extent feasible to insure multidisciplinary representation, the panel membership shall include representation from the disciplines of toxicology, pathology, environmental biology, and related sciences. If a vacancy occurs on the panel due to expiration of a term, resignation, or any other reason, each replacement shall be selected by the Administrator from a group of 4 nominees, 2 submitted by each of the nominating entities named in this subsection. The Administrator may extend the term of a panel member until the new member is appointed to fill the vacancy. If a vacancy occurs due to resignation, or reason other than expiration of a term, the Administrator shall appoint a member to serve during the unexpired term utilizing the nomination process set forth in this subsection. Should the list of nominees provided under this subsection be unsatisfactory, the Administrator may request an additional set of nominees from the nominating entities. The Administrator may require such information from the nominees to the advisory panel as the Administrator deems necessary, and the Administrator shall publish in the Federal Register the name, address, and

professional affiliations of each nominee. Each member of the panel shall receive per diem compensation at a rate not in excess of that fixed for GS–18 of the General Schedule as may be determined by the Administrator, except that any such member who holds another office or position under the Federal Government the compensation for which exceeds such rate may elect to receive compensation at the rate provided for such other office or position in lieu of the compensation provided by this subsection. In order to assure the objectivity of the advisory panel, the Administrator shall promulgate regulations regarding conflicts of interest with respect to the members of the panel. The advisory panel established under this section shall be permanent. In performing the functions assigned by this subchapter, the panel shall consult and coordinate its activities with the Science Advisory Board established under the Environmental Research, Development, and Demonstration Authorization Act of 1978 [42 U.S.C. 4365]. Whenever the Administrator exercises authority under section 136d(c) of this title to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly submit to the advisory panel for comment, as to the impact on health and the environment, the action taken to suspend the registration of such pesticide.

(2) Science Review Board

There is established a Science Review Board to consist of 60 scientists who shall be available to the Scientific Advisory Panel to assist in reviews conducted by the Panel. Members of the Board shall be selected in the same manner as members of temporary subpanels created under paragraph (1). Members of the Board shall be compensated in the same manner as members of the Panel.

(e) Peer review

The Administrator shall, by written procedures, provide for peer review with respect to the design, protocols, and conduct of major scientific studies conducted under this subchapter by the Environmental Protection Agency or by any other Federal agency, any State or political subdivision thereof, or any institution or individual under grant, contract, or cooperative agreement from or with the Environmental Protection Agency. In such procedures, the Administrator shall also provide for peer review, using the advisory panel established under subsection (d) of this section or appropriate experts appointed by the Administrator from a current list of nominees maintained by such panel, with respect to the results of any such scientific studies relied upon by the Administrator with respect to actions the Administrator may take relating to the change in classification, suspension, or cancellation of a pesticide. Whenever the Administrator determines that circumstances do not permit the peer review of the results of any such scientific study prior to the Administrator's exercising authority under section 136d(c) of this title to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly thereafter provide for the conduct of peer review as provided in this sentence. The evaluations and relevant documentation constituting the peer review that relate to the proposed scientific studies and the results of the completed scientific studies shall be included in the submission for comment forwarded by the Administrator to the advisory panel as provided in subsection (d). As used in this subsection, the term "peer review" shall mean an independent evaluation by scientific experts, either within or outside the Environmental Protection Agency, in the appropriate disciplines.

(June 25, 1947, ch. 125, §25, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 997; amended Pub. L. 94–140, §§2(a), 6, 7, Nov. 28, 1975, 89 Stat. 751, 753; Pub. L. 95–396, §23, Sept. 30, 1978, 92 Stat. 836; Pub. L. 96–539, §§1, 2(a), 4, Dec. 17, 1980, 94 Stat. 3194, 3195; Pub. L. 98–201, §1, Dec. 2, 1983, 97 Stat. 1379; Pub. L. 98–620, title IV, §402(4)(D), Nov. 8, 1984, 98 Stat. 3357; Pub. L. 100–352, §6(i), June 27, 1988, 102 Stat. 664; Pub. L. 100–532, title VI, §§602, 605, title VIII, §801(n), Oct. 25, 1988, 102 Stat. 2678, 2679, 2683; Pub. L. 102–237, title X, §1006(b)(1), (2), Dec. 13, 1991, 105 Stat. 1895; Pub. L. 104–170, title I, §104, title II, §235, Aug. 3, 1996, 110 Stat. 1490, 1509.)

Editorial Notes

References in Text

The Poison Prevention Packaging Act, referred to in subsec. (c)(3), probably means the Poison Prevention Packaging Act of 1970, Pub. L. 91–601, Dec. 30, 1970, 84 Stat. 1670, which is classified principally to chapter 39A (§1471 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 1471 of Title 15, and Tables.

References in subsec. (c)(4) to "section 136(q)(1)" was, in the original, a reference to "paragraph 2(q)(1)" and has been editorially translated as "section 136(q)(1)" as the probable intent of Congress.

The Environmental Research, Development, and Demonstration Authorization Act of 1978, referred to in subsec. (d), is Pub. L. 95–155, Nov. 8, 1977, 91 Stat. 1257. Provisions of the Act establishing the Science Advisory Board are classified to section 4365 of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Tables.

AMENDMENTS

1996—Subsec. (a)(1). Pub. L. 104–170, §235, inserted ", including public health pesticides," after "various classes of pesticides" and substituted ", nonagricultural, and public health pesticides" for "and nonagricultural pesticides".

Subsec. (d). Pub. L. 104–170, §104, designated existing text as par. (1), inserted heading, and added par. (2).

1991—Subsec. (a)(3). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "shall".

Subsec. (b). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "determines".

Subsec. (c)(4). Pub. L. 102–237, §1006(b)(2), substituted "the Administrator's" for "his".

Subsec. (c)(5). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "determines".

Subsec. (d). Pub. L. 102–237, §1006(b)(1), substituted "the Administrator" for "he" before "deems necessary" and before "shall publish".

1988—Subsec. (a). Pub. L. 100–532, §801(n)(1), amended heading and directed that pars. (1) to (3) be aligned at left margin with subsec. (c)(1), and that subpars. (A) to (D) of par. (2) be indented, and in par. (3) substituted "Committee on Agriculture, Nutrition, and Forestry" for "Committee on Agriculture and Forestry".

Subsec. (a)(4). Pub. L. 100–532, §605, amended par. (4) generally, substituting single unlettered par. (4) for former subpars. (A) to (E).

Pub. L. 100–352, in subpar. (E), struck out "(i)" before "Any interested" and struck out cl. (ii) which provided that notwithstanding any other provision of law, any decision on a matter certified under cl. (i) of this subparagraph be reviewable by appeal directly to the Supreme Court of the United States, with such appeal to be brought not later than 20 days after the decision of the court of appeals.

Subsec. (d). Pub. L. 100–532, §602, substituted "section shall be permanent" for "subsection shall terminate September 30, 1987".

Subsec. (e). Pub. L. 100–532, §801(n)(2), substituted "pesticide. Whenever" for "pesticide: *Provided*, That whenever".

1984—Subsec. (a)(4)(E)(iii). Pub. L. 98–620 struck out cl. (iii) requiring the court of appeals and the Supreme Court to advance on the docket and expedite the disposition of any matter certified under cl. (i) of this subparagraph.

1983—Subsec. (d). Pub. L. 98–201 in fourth sentence, inserted "under this subsection" after "submitted"; in eighth sentence, provided for utilization of a system of staggered terms of appointment and substituted "7" and "6" for "seven" and "six", respectively, and inserted ninth through fourteenth sentences respecting basis for selection of members, multidisciplinary representation, appointments to fill vacancies, extension of term pending filling of vacancies, appointment for unexpired term, and request for additional set of nominees from nominating entities; and in present eighteenth, formerly twelfth sentence, extended termination date to Sept. 30, 1987, from Sept. 30, 1981.

1980—Subsec. (a)(4). Pub. L. 96–539, §4, added par. (4).

Subsec. (d). Pub. L. 96–539, §1, inserted provisions relating to composition of subpanels and submissions to advisory panels respecting registration suspensions.

Subsec. (e). Pub. L. 96–539, §2(a), added subsec. (e).

1978—Subsec. (a)(1). Pub. L. 95–396, §23(1), required regulations to take into account differences in environmental risk and appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.

Subsec. (a)(2)(B). Pub. L. 95–396, §23(2), required the Administrator, before taking any final action, to consider certain factors bearing on the agricultural economy and to publish an analysis of the effect in the Federal Register.

Subsec. (d). Pub. L. 95–396, §23(3), (4), required the Administrator to solicit operating guidelines from the scientific advisory panel to improve scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out this subchapter; extended requirement of publication in the Federal Register to evaluations and recommendations of the advisory panel; authorized creation of temporary subpanels on specific projects to assist in accelerating the work of the advisory panel; set forth Sept. 30, 1981, as the termination date of the advisory panel; and required the panel to consult and coordinate its activities with the Science Advisory Board established under section 4365 of title 42.

1975—Subsec. (a)(1). Pub. L. 94–140, §2(a)(1), (2), redesignated existing provision as subsec. (a)(1) and inserted ", in accordance with the procedure described in paragraph (2)," after "is authorized".

Subsec. (a)(2). Pub. L. 94–140, §2(a)(3), added par. (2).

Subsec. (a)(3). Pub. L. 94–140, §6, added par. (3).

Subsec. (d). Pub. L. 94–140, §7, added subsec. (d).

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Amendment by Pub. L. 100–352 effective ninety days after June 27, 1988, except that such amendment not to apply to cases pending in Supreme Court on such effective date or affect right to review or manner of reviewing judgment or decree of court which was entered before such effective date, see section 7 of Pub. L. 100–352, set out as a note under section 1254 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1984 Amendment

Amendment by Pub. L. 98–620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98–620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1980 Amendment

Pub. L. 96–539, §2(b), Dec. 17, 1980, 94 Stat. 3195, provided that: "The provisions of this section [amending this section] shall become effective upon publication in the Federal Register of final procedures for peer review as provided in this section, but in no event shall such provisions become effective later than one year after the date of enactment of this Act [Dec. 17, 1980]."

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

References in Other Laws to GS–16, 17, or 18 Pay Rates

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

Information

Pub. L. 117–328, div. HH, title VI, §707, Dec. 29, 2022, 136 Stat. 6082, provided that: "Not later than 180 days after the date of enactment of this title [Dec. 29, 2022], the Administrator of the Environmental Protection Agency shall post on a single webpage of the website of the Environmental Protection Agency aggregated information on pesticide regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), including—

"(1) all guidance relating to risk assessment, risk mitigation, benefits assessments, and cost-benefit balancing;

"(2) hyperlinks to resources, including the Department of Agriculture's 'national list of allowed and prohibited substances' for organic crop and livestock production;

"(3) biopesticides and pesticides exempt pursuant to section 25(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w(b)); and

"(4) integrated pest management principles developed under section 28(c) of such Act (7 U.S.C. 136w–3(c)), including technical assistance for implementation of those principles."

Agricultural Worker Protection Standard; Certification of Pesticide Applicators

Pub. L. 116–8, §7(a), (b), Mar. 8, 2019, 133 Stat. 578, provided that:

"(a) In General.—Except as provided in subsection (b), during the period beginning on the date of enactment of this Act [Mar. 8, 2019] and ending not earlier than October 1, 2021, the Administrator of the Environmental Protection Agency (referred to in this section as the 'Administrator')—

"(1) shall carry out—

"(A) the final rule of the Administrator entitled 'Pesticides; Agricultural Worker Protection Standard Revisions' (80 Fed. Reg. 67496 (November 2, 2015)); and

"(B) the final rule of the Administrator entitled 'Pesticides; Certification of Pesticide Applicators' (82 Fed. Reg. 952 (January 4, 2017)); and

"(2) shall not revise or develop revisions to the rules described in subparagraphs (A) and (B) of paragraph (1).

"(b) Exceptions.—Prior to October 1, 2021, the Administrator may propose, and after a notice and public comment period of not less than 90 days, promulgate revisions to the final rule described in subsection (a)(1)(A) addressing application exclusion zones under part 170 of title 40, Code of Federal Regulations, consistent with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.)."

User Fees

Pub. L. 101–508, title I, §1204(e), Nov. 5, 1990, 104 Stat. 1388–11, provided that: "Notwithstanding any provision of the Omnibus Budget Reconciliation Act of 1990 [Pub. L. 101–508, see Tables for classification], nothing in this title or the other provisions of this Act shall be construed to require or authorize the Administrator of the Environmental Protection Agency to assess or collect any fees or charges for services and activities authorized under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.)."

§136w–1. State primary enforcement responsibility

(a) In general

For the purposes of this subchapter, a State shall have primary enforcement responsibility for pesticide use violations during any period for which the Administrator determines that such State—

(1) has adopted adequate pesticide use laws and regulations, except that the Administrator may not require a State to have pesticide use laws that are more stringent than this subchapter;

(2) has adopted and is implementing adequate procedures for the enforcement of such State laws and regulations; and

(3) will keep such records and make such reports showing compliance with paragraphs (1) and (2) of this subsection as the Administrator may require by regulation.

(b) Special rules

Notwithstanding the provisions of subsection (a) of this section, any State that enters into a cooperative agreement with the Administrator under section 136u of this title for the enforcement of pesticide use restrictions shall have the primary enforcement responsibility for pesticide use violations. Any State that has a plan approved by the Administrator in accordance with the requirements of section 136i of this title that the Administrator determines meets the criteria set out in subsection (a) of this section shall have the primary enforcement responsibility for pesticide use violations. The Administrator shall make such determinations with respect to State plans under section 136i of this title in effect on September 30, 1978, not later than six months after that date.

(c) Administrator

The Administrator shall have primary enforcement responsibility for those States that do not have primary enforcement responsibility under this subchapter. Notwithstanding the provisions of section 136(e)(1) of this title, during any period when the Administrator has such enforcement responsibility, section 136f(b) of this title shall apply to the books and records of commercial applicators and to any applicator who holds or applies pesticides, or uses dilutions of pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and section 136g(a) of this title shall apply to the establishment or other place where pesticides or devices are held for application by such persons with respect to pesticides or devices held for such application.

(June 25, 1947, ch. 125, §26, as added Pub. L. 95–396, §24(2), Sept. 30, 1978, 92 Stat. 836; amended Pub. L. 100–532, title VIII, §801(o), (q)(1)(D), Oct. 25, 1988, 102 Stat. 2683; Pub. L. 102–237, title X, §1006(a)(11), Dec. 13, 1991, 105 Stat. 1895.)

Editorial Notes

Prior Provisions

A prior section 26 of act June 25, 1947, ch. 125, was renumbered section 34 and is classified to section 136x of this title.

Amendments

1991—Subsec. (c). Pub. L. 102–237 substituted "uses" for "use".

1988—Subsec. (a). Pub. L. 100–532, §801(o)(1), (2), inserted heading and substituted "regulations. The Administrator" for "regulations; *Provided*, That the Administrator" in par. (1).

Subsec. (b). Pub. L. 100–532, §801(o)(3), (q)(1)(D), inserted heading and substituted "136i" for "136b" in two places.

Subsec. (c). Pub. L. 100–532, §801(o)(4), inserted heading.

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

§136w–2. Failure by the State to assure enforcement of State pesticide use regulations

(a) Referral

Upon receipt of any complaint or other information alleging or indicating a significant violation of the pesticide use provisions of this subchapter, the Administrator shall refer the matter to the appropriate State officials for their investigation of the matter consistent with the requirements of this subchapter. If, within thirty days, the State has not commenced appropriate enforcement action, the Administrator may act upon the complaint or information to the extent authorized under this subchapter.

(b) Notice

Whenever the Administrator determines that a State having primary enforcement responsibility for pesticide use violations is not carrying out (or cannot carry out due to the lack of adequate legal authority) such responsibility, the Administrator shall notify the State. Such notice shall specify those aspects of the administration of the State program that are determined to be inadequate. The State shall have ninety days after receipt of the notice to correct any deficiencies. If after that time the Administrator determines that the State program remains inadequate, the Administrator may rescind, in whole or in part, the State's primary enforcement responsibility for pesticide use violations.

(c) Construction

Neither section 136w–1 of this title nor this section shall limit the authority of the Administrator to enforce this subchapter, where the Administrator determines that emergency conditions exist that require immediate action on the part of the Administrator and the State authority is unwilling or unable adequately to respond to the emergency.

(June 25, 1947, ch. 125, §27, as added Pub. L. 95–396, §24(2), Sept. 30, 1978, 92 Stat. 837; amended Pub. L. 100–532, title VIII, §801(p), Oct. 25, 1988, 102 Stat. 2683.)

Editorial Notes

Prior Provisions

A prior section 27 of act June 25, 1947, ch. 125, was renumbered section 35 and is classified to section 136y of this title.

Amendments

1988—Pub. L. 100–532 inserted headings for subsecs. (a) to (c).

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

§136w–3. Identification of pests; cooperation with Department of Agriculture's program

(a) In general

The Administrator, in coordination with the Secretary of Agriculture, shall identify those pests that must be brought under control. The Administrator shall also coordinate and cooperate with the Secretary of Agriculture's research and implementation programs to develop and improve the safe use and effectiveness of chemical, biological, and alternative methods to combat and control pests that reduce the quality and economical production and distribution of agricultural products to domestic and foreign consumers.

(b) Pest control availability

(1) In general

The Administrator, in cooperation with the Secretary of Agriculture, shall identify—

(A) available methods of pest control by crop or animal;

(B) minor pest control problems, both in minor crops and minor or localized problems in major crops; and

(C) factors limiting the availability of specific pest control methods, such as resistance to control methods and regulatory actions limiting the availability of control methods.

(2) Report

The Secretary of Agriculture shall, not later than 180 days after November 28, 1990, and annually thereafter, prepare a report and send the report to the Administrator. The report shall—

(A) contain the information described in paragraph (1);

(B) identify the crucial pest control needs where a shortage of control methods is indicated by the information described in paragraph (1); and

(C) describe in detail research and extension efforts designed to address the needs identified in subparagraph (B).

(c) Integrated pest management

The Administrator, in cooperation with the Secretary of Agriculture, shall develop approaches to the control of pests based on integrated pest management that respond to the needs of producers, with a special emphasis on minor pests.

(d) Public health pests

The Administrator, in coordination with the Secretary of Agriculture and the Secretary of Health and Human Services, shall identify pests of significant public health importance and, in coordination with the Public Health Service, develop and implement programs to improve and facilitate the safe and necessary use of chemical, biological, and other methods to combat and control such pests of public health importance.

(June 25, 1947, ch. 125, §28, as added Pub. L. 95–396, §24(2), Sept. 30, 1978, 92 Stat. 838; amended Pub. L. 101–624, title XIV, §1495, Nov. 28, 1990, 104 Stat. 3629; Pub. L. 104–127, title VIII, §862(b)(1), Apr. 4, 1996, 110 Stat. 1174; Pub. L. 104–170, title II, §236, Aug. 3, 1996, 110 Stat. 1509.)

Editorial Notes

Amendments

1996—Subsec. (b)(2)(A). Pub. L. 104–127 struck out "and the information required by section 5882 of this title" after "paragraph (1)".

Subsec. (d). Pub. L. 104–170 added subsec. (d).

1990—Pub. L. 101–624 designated existing provisions as subsec. (a) and added subsecs. (b) and (c).

§136w–4. Omitted

Editorial Notes

Codification

Section, act June 25, 1947, ch. 125, §29, as added Pub. L. 95–396, §24(2), Sept. 30, 1978, 92 Stat. 838, which required the Administrator of the Environmental Protection Agency to submit an annual report to Congress relating to applications filed for conditional registration under section 136a(c)(7)(B), (C) of this title, terminated, effective May 15, 2000, pursuant to section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance. See, also, page 164 of House Document No. 103–7.

§136w–5. Minimum requirements for training of maintenance applicators and service technicians

Each State may establish minimum requirements for training of maintenance applicators and service technicians. Such training may include instruction in the safe and effective handling and use of pesticides in accordance with the Environmental Protection Agency approved labeling, and instruction in integrated pest management techniques. The authority of the Administrator with respect to minimum requirements for training of maintenance applicators and service technicians shall be limited to ensuring that each State understands the provisions of this section.

(June 25, 1947, ch. 125, §30, as added Pub. L. 104–170, title I, §121(2), Aug. 3, 1996, 110 Stat. 1492.)

Editorial Notes

Prior Provisions

A prior section 30 of act June 25, 1947, ch. 125, was renumbered section 34 and is classified to section 136x of this title.

§136w–6. Environmental Protection Agency minor use program

(a) The Administrator shall assure coordination of minor use issues through the establishment of a minor use program within the Office of Pesticide Programs. Such office shall be responsible for coordinating the development of minor use programs and policies and consulting with growers regarding minor use issues and registrations and amendments which are submitted to the Environmental Protection Agency.

(b) The Office of Pesticide Programs shall prepare a public report concerning the progress made on the registration of minor uses, including implementation of the exclusive use as an incentive for

registering new minor uses, within 3 years of the passage of the Food Quality Protection Act of 1996.

(June 25, 1947, ch. 125, §31, as added Pub. L. 104–170, title II, §210(i), Aug. 3, 1996, 110 Stat. 1500.)

Editorial Notes

References in Text

The passage of the Food Quality Protection Act of 1996, referred to in subsec. (b), probably means the date of enactment of Pub. L. 104–170, which was approved Aug. 3, 1996.

Prior Provisions

A prior section 31 of act June 25, 1947, ch. 125, was renumbered section 35 and is classified to section 136y of this title.

§136w–7. Department of Agriculture minor use program

(a) In general

The Secretary of Agriculture (hereinafter in this section referred to as the "Secretary") shall assure the coordination of the responsibilities of the Department of Agriculture related to minor uses of pesticides, including—

(1) carrying out the Inter-Regional Project Number 4 (IR–4) as described in section 2 of Public Law 89–106 (7 U.S.C. 450i(e)) [1] and the national pesticide resistance monitoring program established under section 1651 [1] of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5882);

(2) supporting integrated pest management research;

(3) consulting with growers to develop data for minor uses; and

(4) providing assistance for minor use registrations, tolerances, and reregistrations with the Environmental Protection Agency.

(b) Minor use pesticide data and revolving fund

(1) Minor use pesticide data

(A) Grant authority

The Secretary, in consultation with the Administrator, shall establish a program to make grants for the development of data to support minor use pesticide registrations and reregistrations. The amount of any such grant shall not exceed ½ of the cost of the project for which the grant is made.

(B) Applicants

Any person who wants to develop data to support minor use pesticide registrations and reregistrations may apply for a grant under subparagraph (A). Priority shall be given to an applicant for such a grant who does not directly receive funds from the sale of pesticides registered for minor uses.

(C) Data ownership

Any data that is developed under a grant under subparagraph (A) shall be jointly owned by the Department of Agriculture and the person who received the grant. Such a person shall enter into an agreement with the Secretary under which such person shall share any fee paid to such person under section 136a(c)(1)(F) of this title.

(2) Minor Use Pesticide Data Revolving Fund

(A) Establishment

There is established in the Treasury of the United States a revolving fund to be known as the Minor Use Pesticide Data Revolving Fund. The Fund shall be available without fiscal year

limitation to carry out the authorized purposes of this subsection.

(B) Contents of the Fund

There shall be deposited in the Fund—

(i) such amounts as may be appropriated to support the purposes of this subsection; and

(ii) fees collected by the Secretary for any data developed under a grant under paragraph (1)(A).

(C) Authorizations of appropriations

There are authorized to be appropriated for each fiscal year to carry out the purposes of this subsection $10,000,000 to remain available until expended.

(June 25, 1947, ch. 125, §32, as added Pub. L. 104–170, title II, §210(j), Aug. 3, 1996, 110 Stat. 1501.)

Editorial Notes

References in Text

Section 2 of Public Law 89–106, referred to in subsec. (a)(1), was formerly classified to secton 450i of this title prior to editorial reclassification and renumbering as section 3157 of this title.

Section 1651 of the Food, Agriculture, Conservation, and Trade Act of 1990, referred to in subsec. (a)(1), was classified to section 5882 of this title prior to repeal by Pub. L. 104–127, title VIII, §862(a), Apr. 4, 1996, 110 Stat. 1174.

[1] *See References in Text note below.*

§136w–8. Pesticide registration service fees

(a) Definition of costs

In this section, the term "costs", when used with respect to review and decisionmaking pertaining to an application for which registration service fees are paid under this section, means—

(1) costs to the extent that—

(A) officers and employees provide direct support for the review and decisionmaking for covered pesticide applications, associated tolerances, and corresponding risk and benefits information and analyses;

(B) persons and organizations under contract with the Administrator engage in the review of the applications, and corresponding risk and benefits information and assessments; and

(C) advisory committees and other accredited persons or organizations, on the request of the Administrator, engage in the peer review of risk or benefits information associated with covered pesticide applications;

(2) costs of management of information, and the acquisition, maintenance, and repair of computer and telecommunication resources (including software), used to support review of pesticide applications, associated tolerances, and corresponding risk and benefits information and analyses; and

(3) costs of collecting registration service fees under subsections (b) and (c) and reporting, auditing, and accounting under this section.

(b) Fees

(1) In general

Effective beginning on the effective date of the Pesticide Registration Improvement Act of 2003, the Administrator shall assess and collect covered pesticide registration service fees in accordance with this section.

(2) Covered applications

(A) In general

An application for the registration of a pesticide covered by this subchapter that is received by the Administrator on or after the effective date of the Pesticide Registration Improvement Act of 2003 or for any other action covered by a table specified in paragraph (3)(B) shall be subject to a registration service fee under this section.

(B) Existing applications

(i) In general

Subject to clause (ii), an application for the registration of a pesticide that was submitted to the Administrator before the effective date of the Pesticide Registration Improvement Act of 2003 and is pending on that effective date shall be subject to a service fee under this section if the application is for the registration of a new active ingredient that is not listed in the Registration Division 2003 Work Plan of the Office of Pesticide Programs of the Environmental Protection Agency.

(ii) Tolerance or exemption fees

The amount of any fee otherwise payable for an application described in clause (i) under this section shall be reduced by the amount of any fees paid to support the related petition for a pesticide tolerance or exemption under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(C) Documentation

An application subject to a registration service fee under this section shall be submitted with documentation certifying—

(i) payment of the registration service fee; or

(ii) payment of at least 25 percent of the registration service fee and a request for a waiver from or reduction of the remaining amount of the registration service fee.

(D) Payment

The registration service fee required under this subsection shall be due upon submission of the application.

(E) Applications subject to additional fees

An application may be subject to additional fees if—

(i) the applicant identified the incorrect registration service fee and decision review period;

(ii) after review of a waiver request, the Administrator denies the waiver request; or

(iii) on completion of, where appropriate, the initial screening of the contents of the application or the preliminary technical screening of the application, the Administrator determines that a different registration service fee and decision review period apply to the application.

(F) Effect of failure to pay fees

The Administrator shall reject any application submitted without the required registration service fee.

(G) Non-refundable portion of fees

(i) In general

The Administrator shall retain 25 percent of the applicable registration service fee.

(ii) Limitation

Any waiver, refund, credit or other reduction in the registration service fee shall not exceed 75 percent of the registration service fee.

(H) Collection of unpaid fees

In any case in which the Administrator does not receive payment of a registration service fee (or applicable portion of the registration service fee) by the date that is 30 days after the fee is

due, the fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

(3) Schedule of covered applications and other actions and their registration service fees

(A) Data evaluation records

At the decision review time under a fee table specified in subparagraph (B) or as agreed upon under subsection (f)(5), for each covered application under a fee table specified in such subparagraph (B), the Administrator shall—

(i) complete data evaluation records for studies submitted by the applicant in support of the application; and

(ii) release those data evaluation records to the applicant, using appropriate protections for confidential business information.

(B) Schedule, actions, and fees

Subject to paragraph (6), the schedule of registration applications and other covered actions and their corresponding registration service fees shall be as follows:

TABLE 1. — REGISTRATION DIVISION (RD) — NEW ACTIVE INGREDIENTS

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R010	1	New Active Ingredient, Food use. (2)(3)	36	1,079,356
R020	2	New Active Ingredient, Food use; reduced risk. (2)(3)	27	899,464
R040	3	New Active Ingredient, Food use; Experimental Use Permit application; establish temporary tolerance; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)(4)	18	662,883
R060	4	New Active Ingredient, Non-food use; outdoor. (2)(3)	30	749,886
R070	5	New Active Ingredient, Non-food use; outdoor; reduced risk. (2)(3)	24	624,905
R090	6	New Active Ingredient, Non-food use; outdoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)(4)	16	463,930
R110	7	New Active Ingredient, Non-food use; indoor. (2)(3)(4)	20	417,069
R120	8	New Active Ingredient, Non-food use; indoor; reduced risk. (2)(3)(4)	14	347,556
R121	9	New Active Ingredient, Non-food use; indoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)(4)	18	261,322
R122	10	Enriched isomer(s) of registered mixed-isomer active ingredient. (2)(3)	27	454,526
R123	11	New Active Ingredient, Seed treatment only; includes agricultural and non-agricultural seeds; non-food use, not requiring a tolerance. (2)(3)	27	676,296
R126 (new)	12	New Active Ingredient, Seed treatment only; limited uptake into raw agricultural commodities; use requiring a	31	743,925

		tolerance. (2)(3)		
R125	13	New Active Ingredient, Seed treatment; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)(4)	16	463,930

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 2. — REGISTRATION DIVISION (RD) — NEW USES

EPA No.	New CR No.	Action	Decision Review Time	Registration Service Fee ($)

			(Months) (1)	
R130	14	First food use; indoor; food/food handling. (2)(3)(5)	23	274,388
R140	15	Additional food use; Indoor; food/food handling. (3)(4)(5)	17	64,028
R150	16	First food use. (2)(3)(5)	23	454,490
R155	17	First food use, Experimental Use Permit application; active ingredient registered for non-food use. (3)(4)(5)	21	378,742
R160	18	First food use; reduced risk. (2)(3)(5)	18	378,742
R170	19	Additional food use. (3)(4)(5)	17	113,728
R175	20	Additional food uses covered within a crop group resulting from the conversion of existing approved crop group(s) to one or more revised crop groups. (3)(4)(5)	14	94,774
R180	21	Additional food use; reduced risk. (3)(4)(5)	12	94,774
R190	22	Additional food uses; 6 or more submitted in one application. (3)(4)(5)	17	682,357
R200	23	Additional Food Use; 6 or more submitted in one application; Reduced Risk. (3)(4)(5)	12	568,632
R210	24	Additional food use; Experimental Use Permit application; establish temporary tolerance; no credit toward new use registration. (3)(4)(5)	12	70,210
R220	25	Additional food use; Experimental Use Permit application; crop destruct basis; no credit toward new use registration. (3)(4)(5)	6	28,434
R230	26	Additional use; non-food; outdoor. (3)(4)(5)	16	45,453
R240	27	Additional use; non-food; outdoor; reduced risk. (3)(4)(5)	10	37,878
R250	28	Additional use; non-food; outdoor; Experimental Use Permit application; no credit toward new use registration. (3)(4)(5)	6	28,434
R251	29	Experimental Use Permit application which requires no changes to the tolerance(s); non-crop destruct basis. (3)(5)	8	28,434
R260	30	New use; non-food; indoor. (3)(4)(5)	12	21,954
R270	31	New use; non-food; indoor; reduced risk. (3)(4)(5)	9	18,296
R271	32	New use; non-food; indoor; Experimental Use Permit application; no credit toward new use registration. (3)(4)(5)	6	13,940
R273	33	Additional use; seed treatment only; use not requiring a new tolerance; includes crops with established tolerances (e.g., for soil or foliar application). (3)(4)(5)	12	72,302
R274	34	Additional use; seed treatment only; 6 or more submitted in one application; uses not requiring new tolerances; includes crops with established tolerances (e.g., for soil or foliar application). (3)(4)(5)	12	433,793
R276 (new)	35	Additional use, seed treatment only; limited uptake into raw agricultural commodities; use requiring a tolerance. (3)(4)(5)	14	79,560
R277 (new)	36	Additional use, seed treatment only; 6 or more submitted in one application; limited uptake into raw agricultural commodities; use requiring a tolerance. (3)(4)(5)	14	477,360

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

(5) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 3. — REGISTRATION DIVISION (RD) — IMPORT AND OTHER TOLERANCES

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R280	37	Establish tolerances for residues in imported commodities; new active ingredient or first food use. (2)	22	457,311
R290	38	Establish tolerances for residues in imported commodities; Additional new food use.	16	91,465
R291	39	Establish tolerances for residues in imported commodities; additional food uses; 6 or more crops submitted in one petition.	16	548,773
R292	40	Amend an established tolerance (e.g., decrease or increase) and/or harmonize established tolerances with Codex Maximum Residue Limits; domestic or import; applicant-initiated.	12	64,987
R293	41	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated.	13	76,656
R294	42	Establish tolerances for inadvertent residues; 6 or more crops submitted in one application; applicant-initiated.	13	459,922
R295	43	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; submission of corresponding label amendments which specify the necessary plant-back restrictions; applicant-initiated. (3)(4)	16	94,774
R296	44	Establish tolerances for residues in rotational crops in response to a specific rotational crop petition; 6 or more crops submitted in one application; submission of corresponding label amendments which specify the necessary plant-back restrictions; applicant-initiated. (3)(4)	16	568,632
R297	45	Amend 6 or more established tolerances (e.g., decrease or increase) in one petition; domestic or import; applicant-initiated.	12	389,897
R298	46	Amend an established tolerance (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3)(4)	14	83,940
R299	47	Amend 6 or more established tolerances (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3)(4)	14	408,853
R281 (new)	48	Establish tolerances for residues in imported commodities; additional new food use; submission of residue chemistry	12	68,599

		data review conducted by Codex or other competent national regulatory authority.		
R282 (new)	49	Establish tolerances for residues in imported commodities; additional new food uses; 6 or more crops submitted in one petition; submission of residue chemistry data review conducted by Codex or other competent national regulatory authority.	12	411,580

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) Amendment applications to add the revised use pattern(s) to registered product labels are covered by the base fee for the category. All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the amendment application package is subject to the registration service fee for a new product or a new inert approval. However, if an amendment application only proposes to register the amendment for a new product and there are no amendments in the application, then review of one new product application is covered by the base fee. All such associated applications that are submitted together will be subject to the category decision review time.

TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R300	50	New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; no data review on acute toxicity, efficacy or child-resistant packaging — only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix. (2)(3)	4	2,270
R301	51	New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy (identical data citation and claims to cited product(s)), where applicant does not own all required data and does not have a specific authorization letter from data owner. (2)(3)	4	2,720
R310	52	New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: 1. product chemistry and/or 2. acute toxicity and/or 4.[sic] Child-resistant packaging and/or 4. pest(s) requiring efficacy – for up to 3 target pests. (2)(3)(4)	7	10,466
R314	53	New end-use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. pest(s) requiring efficacy (4) for up to 3 target pests. (2)(3)	8	12,364

R319	54	New end-use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. pest(s) requiring efficacy (4) - for 4 to 7 target pests. (2)(3)	10	18,097
R318	55	New end-use product containing four or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. pest(s) requiring efficacy – for up to 3 target pests. (2)(3)(4)	9	18,994
R321	56	New end-use product containing four or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. pest(s) requiring efficacy (4) - for 4 to 7 target pests. (2)(3)	11	24,727
R315	57	New end-use on-animal product, registered source of active ingredient(s) with submission of data and/or waivers for only: 1. animal safety and 2. pest(s) requiring efficacy and/or 3. product chemistry and/or 4. acute toxicity and/or 5. child resistant packaging. (2)(3)(4)	9	14,075
R316	58	New end-use or manufacturing-use product with registered source(s) of active ingredient(s) including products containing two or more registered active ingredients	9	16,199

		previously combined in other registered products; excludes products requiring or citing an animal safety study; and requires review of data and/or waivers for only: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. pest(s) requiring efficacy - for 4 to 7 target pests. (2)(3)(4)		
R317	59	New end-use or manufacturing-use product with registered source(s) of active ingredient(s) including products containing two or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; and requires review of data and/or waivers for only: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. Pest(s) requiring efficacy - for greater than 7 target pests, (2)(3)(4)	10	21,932
R320	60	New product; new physical form; requires data review in science divisions. (2)(3)(5)	12	18,958
R331	61	New product; repack of identical registered end-use product as a manufacturing-use product; same registered uses only. (2)(3)	3	3,627
R332	62	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of completely new generic data package; registered uses only; requires review in RD and science divisions. (2)(3)	24	405,919
R333	63	New product; manufacturing-use product or end-use product with unregistered source of active ingredient; requires science data review; new physical form; etc. Cite-all or selective data citation where applicant owns all required data. (2)(3)	11	28,434
R334	64	New product; manufacturing-use product or end-use product with unregistered source of the active ingredient; requires science data review; new physical form; etc. Selective data citation. (2)(3)	12	33,108
R361 (new)	65	New end-use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: 1. product chemistry and/or 2. acute toxicity and/or 3. Child resistant packaging and/or 4. pest(s) requiring efficacy – for more than 7 target pests. (2)(3)(4)	12	23,400

R362 (new)	66	New end-use product containing four or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: 1. product chemistry and/or 2. acute toxicity and/or 3. Child resistant packaging and/or 4. pest(s) requiring efficacy – for more than 7 target pests. (2)(3)(4)	13	25,350
R363 (new)	67	New product; repack of identical registered manufacturing-use product as an end-use product; same registered uses only, with no additional data. (2)(3)	6	7,800

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) For the purposes of classifying proposed registration actions into PRIA categories, "pest(s) requiring efficacy" are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, subpart R of part 158 of title 40, Code of Federal Regulations. This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in the Pesticide Registration Notice 2002-1. To determine the number of pests for the PRIA categories, pest groups, subgroups, and pest specific claims as listed in part 158 of title 40, Code of Federal Regulations, should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, etc.), each group will count as 1. If seeking a claim against a pest subgroup (e.g., small biting flies, filth flies, etc.) or specific pests (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each subgroup or specific pest will count as 1.

(5) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon

written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 5. — REGISTRATION DIVISION (RD) — AMENDMENTS

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R340	68	Amendment requiring data review within RD (e.g., changes to precautionary label statements); includes adding/modifying pest(s) claims for up to 2 target pests; excludes products requiring or citing an animal safety study. (2)(3)	4	7,150
R341	69	Amendment requiring data review within RD (e.g., changes to precautionary label statements), includes adding/modifying pest(s) claims for greater than 2 target pests; excludes products requiring or citing an animal safety study. (2)(3)	6	8,584
R345	70	Amending on-animal products previously registered, with the submission of data and/or waivers for only: 1. animal safety and 2. pest(s) requiring efficacy and/or 3. product chemistry and/or 4. acute toxicity and/or 5. child resistant packaging. (2)(3)(4)	7	12,643
R350	71	Amendment requiring data review in science divisions (e.g., changes to Restricted Entry Interval, or Personal Protective Equipment, or Preharvest Interval, or use rate, or number of applications; or add aerial application; or modify Ground Water/Surface Water advisory statement). (2)(3)(5)	9	18,958
R351	72	Amendment adding a new unregistered source of active ingredient. (2)(3)	8	18,958
R352	73	Amendment adding already approved uses; selective method of support; does not apply if the applicant owns all cited data. (2)(3)	8	18,958
R371	74	Amendment to Experimental Use Permit; (does not include extending a permit's time period). (3)	6	14,463

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) For the purposes of classifying proposed registration actions into PRIA categories, "pest(s) requiring efficacy" are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, subpart R of part 158 of title 40, Code of Federal Regulations. This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in the Pesticide Registration Notice 2002-1. To determine the number of pests for the PRIA categories, pest groups, subgroups, and pest specific claims as listed in part 158 of title 40, Code of Federal Regulations, should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, etc.), each group will count as 1. If seeking a claim against a pest subgroup (e.g., small biting flies, filth flies, etc.) or specific pests (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each subgroup or specific pest will count as 1.

(5) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 6. — REGISTRATION DIVISION (RD) — OTHER ACTIONS

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R124	75	Conditional Ruling on Pre-application Study Waivers; applicant-initiated.	6	3,627
R272	76	Review of Study Protocol applicant-initiated; excludes Data Analysis Reporting Tool, pre-registration conference, Rapid Response review, developmental neurotoxicity protocol review, protocol needing Human Studies Review Board review, companion animal safety protocol.	3	3,627
R275	77	Rebuttal of Agency reviewed protocol, applicant initiated.	3	3,627
R278 (new)	78	Review of Protocol for companion animal safety study.	5	4,927
R279 (new)	79	Comparative product determination for reduced risk submission, applicant initiated; submitted before	3	5,200

	application for reduced risk new active ingredient or reduced risk new use.

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

TABLE 7. — ANTIMICROBIAL DIVISION (AD) — NEW ACTIVE INGREDIENTS

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
A380	80	New Active Ingredient; Indirect Food use; establish tolerance or tolerance exemption if required. (2)(3)(4)	26	227,957
A390	81	New Active Ingredient; Direct Food use; establish tolerance or tolerance exemption if required. (2)(3)(4)	26	329,265
A410	82	New Active Ingredient Non-food use. (2)(3)(4)	23	278,659
A431	83	New Active Ingredient, Non-food use; low-risk. (2)(3)(4)	14	114,984

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a),

including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 8. — ANTIMICROBIAL DIVISION (AD) — NEW USES

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
A440	84	New Use, Indirect Food Use, establish tolerance or tolerance exemption. (2)(3)(4)(6)	23	45,737
A441	85	Additional Indirect food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application. (3)(4)(5)(6)	23	164,639
A450	86	New use, Direct food use, establish tolerance or tolerance exemption. (2)(3)(4)(6)	23	137,198
A451	87	Additional Direct food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application. (3)(4)(5)(6)	22	261,333
A500	88	New use, non-food. (4)(5)(6)	15	45,737
A501	89	New use, non-food; 6 or more submitted in one application. (4)(5)(6)	17	109,764

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) If EPA data rules are amended to newly require clearance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.

(4) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(5) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

(6) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
A530	90	New product, identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite all data	4	1,833

		citation or selective data citation where applicant owns all required data; or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix. (2)(3)		
A531	91	New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient: selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner. (2)(3)	4	2,616
A532	92	New product; identical or substantially similar in composition and use to a registered product; registered active ingredient; unregistered source of active ingredient; cite-all data citation except for product chemistry; product chemistry data submitted. (2)(3)	5	7,322
A550	93	New end-use product; uses other than FIFRA §2(mm); non-FQPA product. (2)(3)(5)	9	18,958
A560	94	New manufacturing-use product; registered active ingredient; selective data citation. (2)(3)	6	18,054
A565	95	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of new generic data package; registered uses only; requires science review. (2)(3)	18	26,135
A572	96	New Product or amendment requiring data review for risk assessment by Science Branch (e.g., changes to Restricted Entry Interval, or Personal Protective Equipment, or use rate). (2)(3)(4)(7)	9	18,958
A460 (new)	97	New end-use product; FIFRA §2(mm) uses only; 0 to 10 public health organisms. (2)(3)(5)(6)	5	7,322
A461 (new)	98	New end-use product; FIFRA §2(mm) uses only; 11 to 20 public health organisms. (2)(3)(5)(6)	6	10,158
A462 (new)	99	New end-use product; FIFRA §2(mm) uses only; 21 to 30 public health organisms. (2)(3)(5)(6)	7	12,995
A463 (new)	100	New end-use product; FIFRA §2(mm) uses only; 31 to 40 public health organisms. (2)(3)(5)(6)	9	15,831
A464 (new)	101	New end-use product; FIFRA §2(mm) uses only; 41 to 50 public health organisms. (2)(3)(5)(6)	10	18,668
A465 (new)	102	New end-use product; FIFRA §2(mm) uses only; 51 or more public health organisms. (2)(3)(5)(6)	11	21,505
A470 (new)	103	Label amendment requiring data review; 0 to 10 public health organisms. (3)(4)(5)(6)	4	5,493
A471 (new)	104	Label amendment requiring data review; 11 to 20 public health organisms. (3)(4)(5)(6)	5	8,506
A472 (new)	105	Label amendment requiring data review; 21 to 30 public health organisms. (3)(4)(5)(6)	6	10,219
A473 (new)	106	Label amendment requiring data review; 31 to 40 public health organisms. (3)(4)(5)(6)	7	11,933

A474 (new)	107	Label amendment requiring data review; 41 to 50 public health organisms. (3)(4)(5)(6)	8	13,646
A475 (new)	108	Label amendment requiring data review; 51 or more public health organisms. (3)(4)(5)(6)	9	15,766

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

(5) The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements.

(6) Once an application for an amendment or a new product with public health organisms has been submitted and classified into any of categories A460 through A465 or A470 through A475, additional organisms submitted for the same product before the first application is granted will result in combination and reclassification of both the original and subsequent submissions into the appropriate new category based on the sum of the number of organisms in both submissions. Submission of additional organisms would result in a new PRIA start date and may require additional fees to meet the fee of a new category.

(7) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 10. — ANTIMICROBIAL DIVISION (AD) — EXPERIMENTAL USE PERMITS AND OTHER ACTIONS

EPA No.	New CR No.	Action	Decision Review Time	Registration Service Fee

			(Months) (1)	($)
A520	109	Experimental Use Permit application, non-food use. (2)(3)	9	9,151
A521	110	Review of public health efficacy study protocol within AD, per AD Internal Guidance for the Efficacy Protocol Review Process; Code will also include review of public health efficacy study protocol; applicant-initiated; Tier 1.	6	6,776
A522	111	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; Code will also include review of public health efficacy study protocol; applicant-initiated; Tier 2.	12	17,424
A537	112	New Active Ingredient/New Use, Experimental Use Permit application; Direct food use; Establish tolerance or tolerance exemption if required. Credit 45% of fee toward new active ingredient/new use application that follows. (3)	18	219,512
A538	113	New Active Ingredient/New Use, Experimental Use Permit application; Indirect food use; Establish tolerance or tolerance exemption if required Credit 45% of fee toward new active ingredient/new use application that follows. (3)	18	137,198
A539	114	New Active Ingredient/New Use, Experimental Use Permit application; Nonfood use. Credit 45% of fee toward new active ingredient/new use application that follows. (3)	15	132,094
A529	115	Amendment to Experimental Use Permit; requires data review or risk assessment. (2)(3)	9	16,383
A523	116	Review of protocol other than a public health efficacy study (i.e., Toxicology or Exposure Protocols).	9	17,424
A571	117	Science reassessment: refined ecological risk, and/or endangered species; applicant-initiated. (3)	18	137,198
A533	118	Exemption from the requirement of an Experimental Use Permit. (2)	4	3,559
A534	119	Rebuttal of Agency reviewed protocol, applicant initiated.	4	6,776
A535	120	Conditional ruling on pre-application study waiver or data bridging argument; applicant-initiated.	6	3,454
A536	121	Conditional ruling on pre-application direct food, indirect food, nonfood use determination; applicant-initiated.	4	3,559
A575	122 (new)	Efficacy similarity determination; if two products can be bridged or if confirmatory efficacy data are needed.	4	3,389

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent

resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

3) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 11. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW ACTIVE INGREDIENTS

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B580	123	New active ingredient; petition to establish a tolerance. (2)(3)(4)	22	73,173
B590	124	New active ingredient; petition to establish a tolerance exemption. (2)(3)(4)	20	45,737
B600	125	New active ingredient; no change to a permanent tolerance or tolerance exemption (includes non-food uses). (2)(3)(4)	15	27,443
B610	126	New active ingredient; Experimental Use Permit application; petition to establish a permanent or temporary tolerance or temporary tolerance exemption. (3)(4)	12	18,296
B620	127	New active ingredient; Experimental Use Permit application; non-food use (includes crop destruct). (3)(4)	9	9,151

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the

applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 12. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW USES

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B630	128	First food use; petition to establish/amend a tolerance exemption. (2)(4)(5)	13	18,296
B640	129	First food use; petition to establish/amend a tolerance. (2)(4)(5)	19	27,443
B644	130	New use, no change to an established tolerance or tolerance exemption (includes non-food uses). (3)(4)(5)	8	18,296
B645	131	New use; Experimental Use Permit; petition to establish a permanent or temporary tolerance or tolerance exemption. (4)(5)	12	18,296
B646	132	New use; Experimental Use Permit; non-food use (includes crop destruct). (4)(5)	7	9,151

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new

product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screen, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

(4) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(5) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW PRODUCTS

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B660	133	New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption; no data submission or data matrix (or submission of product chemistry data only). (2)(3)	6	1,833
B670	134	New product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption; (including non-food); Must address Product-Specific Data Requirements. (2)(3)	9	7,322
B672	135	New product; unregistered source of at least one active ingredient (or registered source with new generic data package); no change in an established tolerance or tolerance exemption (including non-food); must address Product-Specific and Generic Data Requirements. (2)(3)	15	13,069
B673	136	New product; unregistered source of active ingredient(s); citation of Technical Grade Active Ingredient (TGAI) data previously reviewed and accepted by the Agency; requires an Agency determination that the cited data support the new product. (2)(3)	12	7,322
B674	137	New product; repack of identical registered end-use product or repack of an end-use product as a manufacturing-use product; same registered uses only. (2)(3)	4	1,833
B677	138	New end-use non-food animal product with submission of two or more target animal safety studies; includes data and/or waivers of data for only: 1. product chemistry and/or 2. acute toxicity and/or 3. public health pest efficacy and/or 4. animal safety studies and/or 5. child resistant packaging. (2)(3)	12	12,643

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a),

including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

TABLE 14. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — AMENDMENTS

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B621	139	Amendment; Experimental Use Permit; no change to an established temporary or permanent tolerance or tolerance exemption. (3) (4)	7	7,322
B622	140	Amendment; Experimental Use Permit; petition to amend a permanent or temporary tolerance or tolerance exemption. (3)(4)	11	18,296
B641	141	Amendment; changes to an established tolerance or tolerance exemption. (4)	13	18,296
B680	142	Amendment; registered sources of active ingredient(s); no new use(s); no changes to an established tolerance or tolerance exemption; requires data submission. (2)(3)	5	7,322
B681	143	Amendment; unregistered source of active ingredient(s); no change to an established tolerance or tolerance exemption; requires data submission. (2)(3)	7	8,714
B683	144	Amendment; no change to an established tolerance or tolerance exemption; requires review/update of previous risk assessment(s) without data submission (e.g., labeling changes to Restricted Entry Interval, Personal Protective Equipment, Preharvest Interval). (2)(3)	6	7,322
B684	145	Amending non-food animal product that includes submission of target animal safety data; previously registered. (2)(3)	8	12,643
B685	146	Amendment; add a new biochemical unregistered source of active ingredient or a new microbial production site; requires submission of analysis of samples data and source/production site-specific manufacturing process description. (3)	5	7,322

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any

changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 15. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — STRAIGHT-CHAIN LEPIDOPTERAN PHEROMONES (SCLP)

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B690	147	SCLP; new active ingredient; food or non-food use. (2)(6)(7)	7	3,662
B700	148	SCLP; Experimental Use Permit application; new active ingredient or new use. (6)(7)	7	1,833
B701	149	SCLP; Extend or amend Experimental Use Permit. (6)(7)	4	1,833
B710	150	SCLP; new product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption; no data submission or data matrix (or only product chemistry data); (Includes 100% re-pack; repack of registered end-use product as a manufacturing-use product). (3)(6)	4	1,833
B720	151	SCLP; new product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption (including non-food); Must address Product-Specific Data Requirements. (3)(6)	5	1,833
B721	152	SCLP: new product; unregistered source of active ingredient; no change in an established tolerance or tolerance exemption (including non-food); must address Product-Specific and Generic Data Requirements. (3)(6)	7	3,836
B722	153	SCLP; new use and/or amendment; petition to establish a tolerance or tolerance exemption. (4)(5)(6)(7)	7	3,552
B730	154	SCLP; amendment requiring data submission. (4)(6)	5	1,833

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(4) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

(5) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

(6) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of

the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(7) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 16. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — OTHER ACTIONS

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B614	155	Pre-application; Conditional Ruling on rationales for addressing a data requirement in lieu of data; applicant-initiated; applies to one (1) rationale at a time.	3	3,627
B682	156	Protocol review; applicant initiated; excludes time for Human Studies Review Board review (Includes rebuttal of protocol review).	3	3,487
B616	157 (new)	Pre-application; Conditional Ruling on a non-food use determination.	5	4,715
B617	158 (new)	Pre-application; biochemical classification determination.	5	4,715

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B740	159	Experimental Use Permit application; no petition for tolerance/tolerance exemption; includes: 1. non-food/feed use(s) for a new (2) or registered (3) PIP (12); 2. food/feed use(s) for a new or registered PIP with crop destruct; 3. food/feed use(s) for a new or registered PIP in which an established tolerance/tolerance exemption exists for the intended use(s). (4)(5)(12)	9	137,198

B750	160	Experimental Use Permit application; with a petition to establish a temporary or permanent tolerance/tolerance exemption for the active ingredient. Includes new food/feed use for a registered (3) PIP. (4)(12)	12	182,927
B771	161	Experimental Use Permit application; new (2) PIP; with petition to establish a temporary tolerance/tolerance exemption for the active ingredient; credit 75% of B771 fee toward registration application for a new active ingredient that follows. (5)(12)	13	182,927
B772	162	Application to amend or extend a PIP Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active ingredient is unaffected. (12)	3	18,296
B773	163	Application to amend or extend a PIP Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient. (12)	9	45,737
B780	164	Registration application; new (2) PIP; non-food/feed or food/feed without tolerance petition based on an existing permanent tolerance exemption. (5)(12)(14)	16	228,657
B800	165	Registration application; new (2) PIP; with petition to establish permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. (5)(12)(14)	17	246,949
B820	166	Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient. (5)(12)(14)	19	292,682
B851	167	Registration application; new event of a previously registered PIP active ingredient(s); no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s). (12)	9	182,927
B870	168	Registration application; registered (3) PIP; new product; new use; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (4)(12)(14)	9	54,881
B880	169	Registration application; registered (3) PIP; new product or new terms of registration; additional data submitted; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (5)(6)(7)(12)(14)	9	45,737
B883	170	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. (5)(8)(12)(14)	13	182,927
B884	171	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient. (5)(8)(12)(14)	19	228,657
B885	172	Registration application; registered (2) PIP, seed increase; breeding stack of previously approved PIPs, same crop; no	6	45,737

		petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (9)(12)		
B890	173	Application to amend a seed increase registration; converts registration to commercial registration; no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s). (5)(12)(14)	9	91,465
B900	174	Application to amend a registration, including actions such as modifying an IRM plan, or adding an insect to be controlled. (5)(10)(11)(12)	6	18,296
B902	175	PIP Protocol review.	3	9,151
B903	176	Inert ingredient permanent tolerance exemption; e.g., a marker such as NPT II; reviewed in BPPD.	12	91,465
B904	177	Import tolerance or tolerance exemption; processed commodities/food only (inert or active ingredient).	12	182,927
B905	178	FIFRA Scientific Advisory Panel Review.	6	91,465
B906	179	Petition to establish a temporary tolerance/tolerance exemption for one or more active ingredients.	9	45,733
B907	180	Petition to establish a permanent tolerance/tolerance exemption for one or more active ingredients based on an existing temporary tolerance/tolerance exemption.	9	18,296
B909	181 (new)	PIP tolerance exemption determination; applicant-initiated; request to determine if an existing tolerance exemption applies to a PIP.	6	18,296
B910	182 (new)	Biotechnology Notification for small-scale field testing of genetically engineered microbes.	3	9,151
B921	183 (new)	Experimental Use Permit application; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); non-food/feed. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. Credit 75% of B921 fee toward registration application for the new active ingredient that follows (B922). (5)(12)(13)	12	182,927
B922	184 (new)	Registration application; new active ingredient; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); non-food/feed. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. (5)(12)(13)(14)	16	228,657
B923	185 (new)	Experimental Use Permit application; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); with petition to establish a temporary or permanent tolerance/tolerance exemption of an active ingredient. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. Credit 75% of B923 fee toward registration application for the new active ingredient that follows (B924). (5)(12)(13)(14)	15	228,658

B924 (new)	186	Registration application; new active ingredient; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); with petition to establish a permanent tolerance/tolerance exemption of an active ingredient. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. (5)(12)(13)(14)	19	292,682
B925 (new)	187	Experimental Use Permit application; exogenous applications of RNA to elicit the RNA interference pathway in pests; non-food/feed; credit 75% of B925 fee toward registration application for the new active ingredient that follows (B926). (5)(12)	11	27,452
B926 (new)	188	Registration application; new active ingredient; exogenous applications of RNA to elicit the RNA interference pathway in pests; non-food/feed. (5)(12)(14)	17	82,329
B927 (new)	189	Experimental Use Permit application; exogenous applications of RNA to elicit the RNA interference pathway in pests; with petition to establish a temporary or permanent tolerance/tolerance exemption of an active ingredient; credit 75% of B927 fee toward registration application for the new active ingredient that follows (B928). (5)(12)	14	54,889
B928 (new)	190	Registration application; new active ingredient; exogenous applications of RNA to elicit the RNA interference pathway in pests; with petition to establish a permanent tolerance/tolerance exemption of an active ingredient. (5)(12)(14)	22	137,210
B929 (new)	191	Registration application; new product, registered active ingredient; exogenous applications of RNA to elicit the RNA interference pathway in pests; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (5)(12)	10	7,322
B930 (new)	192	Application to amend or extend a non-PIP Emerging Technologies Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active ingredient is unaffected. (12)	3	18,296
B931 (new)	193	Application to amend or extend a non-PIP Emerging Technologies Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient. (12)	9	45,737
B932 (new)	194	Amendment; application to amend a non-PIP Emerging Technologies registration. (4)(5)(12)	6	18,296

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) "New PIP" means a PIP with an active ingredient that has not been registered.

(3) "Registered PIP" means a PIP with an active ingredient that is currently registered.

(4) Transfer registered PIP through conventional breeding for new food/feed use, such as from field corn to sweet corn.

(5) If, during review of the application, it is determined that review by the FIFRA Scientific Advisory Panel (SAP) is needed, the applicant will submit an application for category B905, which will be processed concurrently, and the decision review time for both applications will be the longer of the two associated applications. The scientific data involved in this category are complex. EPA often seeks technical advice from the SAP on risks that pesticides pose to wildlife, farm workers, pesticide applicators, non-target species, insect resistance, and novel scientific issues surrounding new technologies. The scientists of the SAP neither make nor recommend policy decisions. They provide advice on the science used to make these decisions. Their advice is invaluable to the EPA as it strives to protect humans and the environment from risks posed by pesticides. Due to the time it takes to schedule and prepare for meetings with the SAP, additional time and costs are needed.

(6) Registered PIPs stacked through conventional breeding.

(7) Deployment of a registered PIP with a different Insecticide Resistance Management (IRM) plan (e.g., seed blend).

(8) The negotiated acreage cap will depend upon EPA's determination of the potential environmental exposure, risk(s) to non-target organisms, and the risk of targeted pest developing resistance to the pesticidal substance. The uncertainty of these risks may reduce the allowable acreage, based upon the quantity and type of non-target organism data submitted and the lack of insect resistance management data, which is usually not required for seed-increase registrations. Registrants are encouraged to consult with EPA prior to submission of a registration application in this category.

(9) Application can be submitted prior to or concurrently with an application for commercial registration.

(10) For example, IRM plan modifications that are applicant-initiated.

(11) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

(12) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(13) This category does not include genetic modifications in animals not intended for use as a pesticide, e.g., genetic modifications in animals intended for food use or animals intended for use as companion animals.

(14) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 18. — INERT INGREDIENTS

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
I001	195	Approval of new food use inert ingredient. (2)(3)	15	38,698
I002	196	Amend currently approved inert ingredient tolerance or exemption from tolerance; new data. (2)	13	10,750
I003	197	Amend currently approved inert ingredient tolerance or exemption from tolerance; no new data. (2)	11	4,742
I004	198	Approval of new non-food use inert ingredient. (2)	6	15,803
I005	199	Amend currently approved non-food use inert ingredient with new use pattern; new data. (2)	6	7,903
I006	200	Amend currently approved non-food use inert ingredient with new use pattern; no new data. (2)	4	4,742
I007	201	Approval of substantially similar non-food use inert ingredients when original inert is compositionally similar with similar use pattern. (2)	5	2,371
I008	202	Approval of new or amended polymer inert ingredient, food use. (2)	7	5,374
I009	203	Approval of new or amended polymer inert ingredient, non-food use. (2)	4	4,427
I010	204	Petition to amend a single tolerance exemption descriptor, or single non-food use descriptor, to add ≤ 10 CASRNs; no new data. (2)	7	2,371
I011	205	Approval of new food use safener with tolerance or exemption from tolerance. (2)	26	856,631
I012	206	Approval of new non-food use safener. (2)	21	595,147
I013	207	Approval of additional food use for previously approved safener with tolerance or exemption from tolerance. (2)	17	90,260
I014	208	Approval of additional non-food use for previously approved safener. (2)	15	36,074
I015	209	Approval of new generic data for previously approved food use safener. (2)	26	386,589
I016	210	Approval of amendment(s) to tolerance and label for previously approved safener. (2)	15	79,942
I017	211 (new)	Add new source of previously approved safener.	8	18,958
I018	212 (new)	Petition to add one approved inert ingredient (CASRN) to the Commodity Inert Ingredient List; no data. (4)	3	2,371

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) If another covered application is submitted that depends upon an application to approve an inert ingredient, each application will be subject to its respective registration service fee. The decision review time for both submissions will be the longest of the associated applications. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.

(3) If EPA data rules are amended to newly require clearance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.

(4) Due to low fee and short time frame this category is not eligible for small business waivers.

TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
M001	213	Study protocol requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of a currently registered active ingredient.	14	11,378
M002	214	Completed study requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of an active ingredient. (2)	14	11,378
M003	215	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of less than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA §25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active .ingredients. (3)	12	91,651
M004	216	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of greater than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA §25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (3)	18	91,651
M005	217	New Product: Combination, Contains a combination of active ingredients from a registered and/or unregistered source; conventional, antimicrobial and/or biopesticide. Requires coordination with other regulatory divisions to conduct review of data, label and/or verify the validity of existing data as cited. Only existing uses for each active ingredient in the combination product. (4)(5)(6)	9	31,604
M006	218	Request for up to 5 letters of certification (Gold Seal) for one actively registered product (excludes distributor products). (7)	1	398
M007	219	Request to extend Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(ii).	12	7,903
M008	220	Request to grant Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(vi) for a minor use, when a FIFRA Section 2(ll)(2) determination is required.	15	2,371
M009	221	Non-FIFRA Regulated Determination; applicant-initiated, per product.	6	3,389

M010	222	Conditional ruling on pre-application, product substantial similarity.	4	3,389
M011	223	Label amendment to add the DfE logo; requires data review; no other label changes. (8)	4	5,230
M012	224 (new)	Request for up to 5 letters of certification (Certificate of Establishment) for one actively registered product or one product produced for export (excludes distributor products). (7)	1	398
M013	225 (new)	Cancer reassessment; applicant-initiated.	18	284,144
M014	227 (new)	Pre-application nano-particle determination.	8	17,424

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) Any other covered application that is associated with and dependent on the review by the Human Studies Review Board will be subject to its separate registration service fee. The decision review times for the associated actions run concurrently, but will end at the date of the latest review time.

(3) Any other covered application that is associated with and dependent on the FIFRA Scientific Advisory Panel review will be subject to its separate registration service fee. The decision review time for the associated action will be extended by the decision review time for the SAP review.

(4) If another covered application is submitted that depends upon an application to approve an inert ingredient, each application will be subject to its respective registration service fee. The decision review time for both submissions will be the longest of the associated applications. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.

(5) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(6) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(7) Due to low fee and short time frame this category is not eligible for small business waivers.

(8) This category includes amendments the sole purpose of which is to add "Design for the Environment" (DfE) (or equivalent terms that do not use "safe" or derivatives of "safe") logos to a label. DfE is a voluntary program. A label bearing a DfE logo is not considered an Agency endorsement because the ingredients in the qualifying product must meet objective, scientific criteria established and widely publicized by EPA.

(4) Pending pesticide registration applications

(A) In general

An applicant that submitted a registration application to the Administrator before the effective date of the Pesticide Registration Improvement Act of 2003, but that is not required to pay a registration service fee under paragraph (2)(B), may, on a voluntary basis, pay a registration service fee in accordance with paragraph (2)(B).

(B) Voluntary fee

The Administrator may not compel payment of a registration service fee for an application described in subparagraph (A).

(C) Documentation

An application for which a voluntary registration service fee is paid under this paragraph shall be submitted with documentation certifying—

(i) payment of the registration service fee; or

(ii) a request for a waiver from or reduction of the registration service fee.

(5) Resubmission of covered applications

If a covered application is submitted by a person that paid the fee for the application under paragraph (2), is determined by the Administrator to be complete, and is not approved or is withdrawn (without a waiver or refund), the submission of the same covered application by the same person (or a licensee, assignee, or successor of the person) shall not be subject to a fee under paragraph (2).

(6) Fee adjustment

(A) In general

Subject to the following sentence, effective for a covered application received during the period beginning on October 1, 2024, and ending on September 30, 2026, the Administrator may increase by 5 percent the registration service fee payable for the application under paragraph (3).[1] No adjustment may be made under the preceding sentence until the date on which the Administrator begins to implement clauses (i) and (ii) of subsection (k)(2)(A).

(B) Additional adjustment

Subject to the following sentence, effective for a covered application received on or after October 1, 2026, the Administrator may increase by an additional 5 percent the registration service fee in effect as of September 30, 2026. No adjustment may be made under the preceding sentence until the date on which the Administrator begins to implement any recommendations for process improvements contained in the report under subsection (c)(4), as appropriate.

(C) Publication

The Administrator shall publish in the Federal Register the service fee schedules revised pursuant to this paragraph.

(7) Waivers and reductions

(A) In general

An applicant for a covered application may request the Administrator to waive or reduce the amount of a registration service fee payable under this section under the circumstances described in subparagraphs (D) through (G), except that no waiver or fee reduction shall be provided in connection with a request for a letter of certification (including a Gold Seal letter and a Certificate of Establishment).

(B) Documentation

(i) In general

A request for a waiver from or reduction of the registration service fee shall be accompanied by appropriate documentation demonstrating the basis for the waiver or reduction.

(ii) Certification

The applicant shall provide to the Administrator a written certification, signed by a responsible officer, that the documentation submitted to support the waiver or reduction request is accurate.

(iii) Inaccurate documentation

An application shall be subject to the applicable registration service fee payable under paragraph (3)(B) if, at any time, the Administrator determines that—

(I) the documentation supporting the waiver or reduction request is not accurate; or

(II) based on the documentation or any other information, the waiver or reduction should not have been granted or should not be granted.

(C) Determination to grant or deny request

As soon as practicable, but not later than 60 days, after the date on which the Administrator receives a request for a waiver or reduction of a registration service fee under this paragraph, the Administrator shall—

(i) determine whether to grant or deny the request; and

(ii) notify the applicant of the determination.

(D) Minor uses

(i) In general

The Administrator may exempt from, or waive a portion of, the registration service fee for an application for minor uses for a pesticide.

(ii) Supporting documentation

An applicant requesting a waiver or exemption under this subparagraph shall provide supporting documentation that demonstrates, to the satisfaction of the Administrator, that anticipated revenues from the uses that are the subject of the application would be insufficient to justify imposition of the full application fee.

(E) IR–4 exemption

The Administrator shall exempt an application from the registration service fee if the Administrator determines that—

(i) the application is solely associated with a tolerance petition submitted in connection with the Inter-Regional Project Number 4 (IR–4) as described in section 2 of Public Law 89–106 (7 U.S.C. 450i(e)); [1] and

(ii) the exemption is in the public interest.

(F) Small businesses

(i) In general

The Administrator shall waive 50 percent of the registration service fees payable by an entity for a covered application under this section if the entity is a small business (as defined in section 136a–1(i)(1)(E)(ii) of this title) at the time of application.

(ii) Waiver of fees

The Administrator shall waive 75 percent of the registration service fees payable by an entity under this section if the entity—

(I) is a small business (as defined in section 136a–1(i)(1)(E)(ii) of this title) at the time of application; and

(II) has average annual global gross revenues described in section 136a–1(i)(1)(E)(ii)(I)(bb) of this title that does not exceed $10,000,000, at the time of application.

(iii) Formation for waiver

The Administrator shall not grant a waiver under this subparagraph if the Administrator determines that the entity submitting the application has been formed or manipulated primarily for the purpose of qualifying for the waiver.

(iv) Documentation

An entity requesting a waiver under this subparagraph shall provide to the Administrator—

(I) documentation demonstrating that the entity is a small business (as defined in section 136a–1(i)(1)(E)(ii) of this title) at the time of application; and

(II) if the entity is requesting a waiver of 75 percent of the applicable registration service fees payable under this section, documentation demonstrating that the entity has an average annual global gross revenue described in section 136a–1(i)(1)(E)(ii)(I)(bb) of this title that does not exceed $10,000,000, at the time of application.

(G) Federal and State agency exemptions

An agency of the Federal Government or a State government shall be exempt from covered registration service fees under this section.

(8) Refunds

(A) Early withdrawals

If, during the first 60 days after the beginning of the applicable decision time review period under subsection (f)(3), a covered application is withdrawn by the applicant, the Administrator shall refund all but 25 percent.[2] of the total registration service fee payable under paragraph (3)(B) for the application.

(B) Withdrawals after the first 60 days of decision review time period

(i) In general

If a covered application is withdrawn after the first 60 days of the applicable decision time review period, the Administrator shall determine what portion, if any, of the total registration service fee payable under paragraph (3)(B) for the application may be refunded based on the proportion of the work completed at the time of withdrawal.

(ii) Timing

The Administrator shall—

(I) make the determination described in clause (i) not later than 90 days after the date the application is withdrawn; and

(II) provide any refund as soon as practicable after the determination.

(C) Discretionary refunds

(i) In general

In the case of a covered application that has been filed with the Administrator and has not been withdrawn by the applicant, but for which the Administrator has not yet made a final determination, the Administrator may refund a portion of a covered registration service fee if the Administrator determines that the refund is justified.

(ii) Basis

The Administrator may provide a refund for an application under this subparagraph—

(I) on the basis that, in reviewing the application, the Administrator has considered data submitted in support of another covered application;

(II) on the basis that the Administrator completed portions of the review of the application before the effective date of this section; or

(III) on the basis that the Administrator rejected the application under subsection (f)(4)(B).

(D) Credited fees

In determining whether to grant a refund under this paragraph, the Administrator shall take into account any portion of the registration service fees credited under paragraph (2) or (4).

(c) Pesticide Registration Fund

(1) Establishment

There is established in the Treasury of the United States a Pesticide Registration Fund to be used in carrying out this section (referred to in this section as the "Fund"), consisting of—

(A) such amounts as are deposited in the Fund under paragraph (2);
(B) any interest earned on investment of amounts in the Fund under paragraph (5); and
(C) any proceeds from the sale or redemption of investments held in the Fund.

(2) Deposits in Fund

Subject to paragraph (4), the Administrator shall deposit fees collected under this section in the Fund.

(3) Expenditures from Fund

(A) In general

Subject to subparagraphs (B) and (C) and paragraph (4), the Administrator may make expenditures from the Fund—

(i) to cover the costs associated with the review and decisionmaking pertaining to all applications for which registration service fees have been paid under this section; and
(ii) to otherwise carry out this section.

(B) Endangered species review of outdoor use of pesticide products

(i) In general

The Administrator shall use the amounts made available in the Fund to develop, receive comments with respect to, and finalize, guidance to registrants regarding analysis necessary to support the review of outdoor uses of pesticide products under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.).

(ii) Deadlines for guidance

The Administrator shall issue final guidance required by clause (i) in accordance with the following:

(I) With respect to new active ingredients or any registration review decision proposed for 1 or more outdoor uses, not later than 9 months after December 29, 2022.
(II) With respect to new outdoor uses of a registered pesticide, not later than 1 year after December 29, 2022.
(III) With respect to antimicrobial pesticide products, not later than 3 years after December 29, 2022.

(C) Independent third party assessments

(i) In general

The Administrator shall use the amounts made available in the Fund to carry out the activities described in clauses (ii) and (iii).

(ii) Workforce assessment

(I) In general

The Administrator shall procure a competitive contract with a qualified, independent contractor with expertise in assessing public sector workforce data analysis and reporting to conduct an assessment of current methodologies and data or metrics available to represent the workforce implementing the Pesticide Registration Improvement Act of 2022 and the amendments made by that Act, including an assessment of filled and vacant positions and full-time equivalent employees relating to that implementation.

(II) Report

Not later than 2 years after December 29, 2022—
(aa) the contractor selected under subclause (I) shall submit to the Administrator a report describing—
(AA) the findings from the assessment under that subclause; and
(BB) recommendations for improved methodologies to represent full-time equivalent resources described in that subclause; and

(bb) the Administrator shall publish the report submitted under item (aa) on the website of the Environmental Protection Agency.

(iii) Process assessment

(I) In general

(aa) Contracts

Within 1 year of December 29, 2022, to the extent practicable, the Administrator shall issue a competitive contract to a private, independent consulting firm—

(AA) to conduct the assessment described in subclause (II); and

(BB) to submit to the Administrator a report describing the findings of the assessment and the processes and performance of the Environmental Protection Agency relating to the implementation of the Pesticide Registration Improvement Act of 2022 and the amendments made by that Act.

(bb) Eligibility

The firm described in item (aa) shall be capable of performing the technical analysis, management assessment, and program evaluation tasks required to address the scope of the assessment under subclause (II).

(II) Assessment

(aa) In general

The Administrator, applicants, and registrants shall participate in a targeted assessment of the process for the review of applications submitted under this subchapter.

(bb) Consultation

The firm selected under subclause (I) shall consult with the Administrator and applicants at the start of the assessment under item (aa) and prior to submission of the report under subclause (I)(aa)(BB).

(cc) Requirements

The assessment under item (aa) shall evaluate and make recommendations regarding —

(AA) the initial content screen;

(BB) the preliminary technical screen;

(CC) performance, processes, and progress toward reducing renegotiation rates and the average length of renegotiations;

(DD) performance, processes, and progress toward eliminating the backlog of registrant submissions not covered by subsection (b)(3);

(EE) performance, processes, and progress toward ensuring that all registrant submissions not covered by subsection (b)(3) are completed by the applicable deadlines described in the notice of the Administrator entitled "Pesticide Registration Notice (PR) 98–10: Notifications, Non-Notifications and Minor Formulation Amendments" and dated October 22, 1998 (and any successor amendments to that notice) and described in subsections (c)(3)(B) and (h) of section 136a of this title;

(FF) compliance with the provisions of this subchapter relating to renegotiations and registrant submissions not covered by subsection (b)(3);

(GG) information technology systems;

(HH) recommended improvements to employee training;

(II) performance, progress, and processes in completing registration review; and

(JJ) other appropriate issues, such as submissions by inert suppliers and fast-track amendments under subsections (c)(3)(B) and (h) of section 136a of this title.

(III) Report to Congress

Not later than 1 year after the receipt of an assessment required under this section, the Administrator shall submit to the Committee on Agriculture, Nutrition, and Forestry of the Senate and the Committee on Agriculture of the House of Representatives—

(aa) a copy of each such assessment; and

(bb) the Administrator's evaluation of the findings and recommendations contained in each such assessment.

(IV) Recommendations

The Administrator shall include with the report submitted under subclause (III) a classification of each recommendation described in the report as—

(aa) can be implemented through administrative action of the Administrator; or

(bb) requires a statutory change.

(4) Collections and appropriations Acts

The fees authorized by this section and amounts deposited in the Fund—

(A) shall be collected and made available for obligation only to the extent provided in advance in appropriations Acts;

(B) shall be available during periods in which Environmental Protection Agency employees are on shutdown or emergency furlough as a result of a lapse in appropriations; and

(C) shall be available without fiscal year limitation.

(5) Unused funds

(A) In general

Amounts in the Fund not currently needed to carry out this section shall be—

(i) maintained readily available or on deposit;

(ii) invested in obligations of the United States or guaranteed by the United States; or

(iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

(B) Use of investment income

After consultation with the Secretary of the Treasury, the Administrator may use income from investments described in clauses (ii) and (iii) of subparagraph (A) to carry out this section.

(d) Assessment of fees

(1) Definition of covered functions

In this subsection, the term "covered functions" means functions of the Office of Pesticide Programs of the Environmental Protection Agency, as identified in key programs and projects of the final operating plan for the Environmental Protection Agency submitted as part of the budget process for fiscal year 2002, regardless of any subsequent transfer of 1 or more of the functions to another office or agency or the subsequent transfer of a new function to the Office of Pesticide Programs.

(2) Minimum amount of appropriations

Registration service fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, contracts, and expenses for the functions of the Office of Pesticide Programs of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than $166,000,000.

(3) Use of fees

Registration service fees authorized by this section shall be available, in the aggregate, only to defray increases in the costs associated with the review and decisionmaking for the review of pesticide registration applications and associated tolerances (including increases in the number of full-time equivalent positions in the Environmental Protection Agency engaged in those activities) over the costs for fiscal year 2002, excluding costs paid from fees appropriated for the fiscal year.

(4) Subsequent authority

If the Administrator does not assess registration service fees under subsection (b) during any portion of a fiscal year as the result of paragraph (2) and is subsequently permitted to assess the fees under subsection (b) during the fiscal year, the Administrator shall assess and collect the fees, without any modification in rate, at any time during the fiscal year, notwithstanding any provisions of subsection (b) relating to the date fees are to be paid.

(e) Reforms to reduce decision time review periods and prevent double payment of registration fees

(1) Reduction of decision time review periods

To the maximum extent practicable consistent with the degrees of risk presented by pesticides and the type of review appropriate to evaluate risks, the Administrator shall identify and evaluate reforms to the pesticide registration process under this subchapter with the goal of reducing decision review periods in effect on the effective date of the Pesticide Registration Improvement Extension Act of 2018 for pesticide registration actions for covered pesticide registration applications (including reduced risk applications). Such reforms shall include identifying opportunities for streamlining review processes for applications for a new active ingredient or a new use and providing prompt feedback to applicants during such review process.

(2) Prevention of double payment of registration service fees

The Administrator shall develop and implement a process to determine the appropriate fee category or categories for an application that qualifies for more than one fee category in order to assist applicants and prevent unnecessary payment of fees for multiple categories for a single application.

(f) Decision time review periods

(1) In general

Not later than 30 days after the effective date of the Pesticide Registration Improvement Act of 2022, the Administrator shall make publicly available a schedule of decision review periods for covered pesticide registration actions or for any other action covered by a table specified in subsection (b)(3)(B) and corresponding registration service fees under this subchapter.

(2) Report

The schedule shall be the same as the applicable schedule provided under subsection (b)(3)(B).

(3) Applications subject to decision time review periods

The decision time review periods specified in paragraph (1) shall apply to—

(A) covered pesticide registration applications subject to registration service fees under subsection (b)(2);

(B) covered pesticide registration applications for which an applicant has voluntarily paid registration service fees under subsection (b)(4); and

(C) applications for any other action covered by a table specified in subsection (b)(3)(B).

(4) Start of decision time review period

(A) In general

Except as provided in subparagraphs (C), (D), and (E), in the case of a covered application accompanied by the registration service fee required under this section, the decision time review period begins 21 days after the date on which the Administrator receives the covered application and fee.

(B) Initial content and preliminary technical screenings

(i) Screenings

(I) Initial content

Not later than 21 days after receiving an application and the required registration service fee, the Administrator shall conduct an initial screening of the contents of the application in accordance with clause (iii).

(II) Preliminary technical screening

After conducting the initial content screening described in subclause (I) and in accordance with clause (iv), the Administrator shall conduct a preliminary technical screening—

(aa) not later than 45 days after the date on which the decision time review period begins (for applications with decision time review periods of not more than 180 days); and

(bb) not later than 90 days after the date on which the decision time review period begins (for applications with decision time review periods greater than 180 days).

(III) Final fee category

The fee category of a covered application or other actions may not be changed, without providing the information to the applicant, after completion of the preliminary technical screening described in clause (iv).

(ii) Rejection

(I) In general

If the Administrator determines at any time before the Administrator completes the preliminary technical screening under clause (i)(II) that the application failed the initial content or preliminary technical screening and the applicant does not correct the failure before the date that is 10 business days after the applicant receives a notification of the failure, the Administrator shall reject the application.

(II) Written notification

The Administrator shall make every effort to provide a written notification of a rejection under subclause (I) during the 10-day period that begins on the date the Administrator completes the preliminary technical screening.

(iii) Requirements of initial content screening

In conducting an initial content screening of an application, the Administrator shall automate the process, to the maximum extent practicable, and determine whether—

(I)(aa) the applicable registration service fee has been paid; or

(bb) at least 25 percent of the applicable registration service fee has been paid and the application contains a waiver or refund request for the outstanding amount and documentation establishing the basis for the waiver request; and

(II) the application appears to contain all the necessary forms, data, and draft labeling, formatted in accordance with guidance published by the Administrator.

(iv) Requirements of preliminary technical screening

In conducting a preliminary technical screening of an application, the Administrator shall —

(I) determine if the application and the data and information submitted with the application are accurate and complete;

(II) determine if the application, data, and information are consistent with the proposed labeling and any proposal for a tolerance or exemption from the requirement for a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a), and are such that, subject to full review under the standards of this subchapter, could result in the granting of the application;

(III) determine, if applicable, whether an application qualifies for a reduced risk determination under subsection (c)(10) or (h) of section 136a of this title;

(IV) grant or deny any data waiver requests submitted by the applicant with the application;

(V) verify and validate the accuracy of the fee category selected by the applicant; and

(VI) notify the applicant, in writing, if a new or different fee category is required and calculate the new decision review time based on the original submission date.

(C) Applications with waiver or reduction requests

(i) In general

In the case of an application submitted with a request for a waiver or reduction of registration service fees under subsection (b)(7), the decision time review period shall be

determined in accordance with this subparagraph.

(ii) Request granted with no additional fees required

If the Administrator grants the waiver or reduction request and no additional fee is required, the decision time review period begins on the earlier of—

(I) the date on which the Administrator grants the request; or

(II) the date that is 60 days after the date of receipt of the application.

(iii) Request granted with additional fees required

If the Administrator grants the waiver or reduction request, in whole or in part, but an additional registration service fee is required, the decision time review period begins on the date on which the Administrator receives certification of payment of the applicable registration service fee.

(iv) Request denied

If the Administrator denies the waiver or reduction request, the decision time review period begins on the date on which the Administrator receives certification of payment of the applicable registration service fee.

(D) Pending applications

(i) In general

The start of the decision time review period for applications described in clause (ii) shall be the date on which the Administrator receives certification of payment of the applicable registration service fee.

(ii) Applications

Clause (i) applies to—

(I) covered pesticide registration applications for which voluntary fees have been paid under subsection (b)(4); and

(II) covered pesticide registration applications received on or after the effective date of the Pesticide Registration Improvement Act of 2003 but submitted without the applicable registration service fee required under this section due to the inability of the Administrator to assess fees under subsection (d)(1).

(E) Applications for reduced risk

(i) Fee

If an application for a reduced risk new active ingredient or a reduced risk new use is determined not to qualify as reduced risk, the applicant shall pay the difference in fee for the corresponding non-reduced risk application.

(ii) Decision review time period

After receipt by the Administrator of the original covered reduced risk application and fee, the decision time review period for the corresponding non-reduced risk application shall begin within the time periods described in subparagraph (A), based on the submission date of the original covered reduced risk application.

(5) Extension of decision time review period

(A) Notification

If the Administrator cannot meet a decision time review period under this subsection, the Administrator shall notify the applicant, in writing, of—

(i) the reasons why additional time is needed; and

(ii) the number of days needed that would allow the Administrator to make a regulatory decision.

(B) Extension by negotiation or mutual agreement

The Administrator, acting solely through the Director of the Office of Pesticide Programs, and the applicant may mutually agree, in writing, to extend a decision time review period under

this subsection if—

(i) there is new or additional data or information from the applicant that is necessary for the Administrator to make a decision on the application that cannot be made available within the original decision time review period; or

(ii) a public comment period associated with the application generates significant comments that cannot be addressed within the original decision time review period.

(C) Priority

Once a decision time review period for a covered action described in subsection (b)(3)(B) is missed or extended, the Administrator shall make any action on the application a priority.

(g) Judicial review

(1) In general

Any applicant adversely affected by the failure of the Administrator to make a determination on the application of the applicant for registration of a new active ingredient or new use for which a registration service fee is paid under this section may obtain judicial review of the failure solely under this section.

(2) Scope

(A) In general

In an action brought under this subsection, the only issue on review is whether the Administrator failed to make a determination on the application specified in paragraph (1) by the end of the applicable decision time review period required under subsection (f) for the application.

(B) Other actions

No other action authorized or required under this section shall be judicially reviewable by a Federal or State court.

(3) Timing

(A) In general

A person may not obtain judicial review of the failure of the Administrator to make a determination on the application specified in paragraph (1) before the expiration of the 2-year period that begins on the date on which the decision time review period for the application ends.

(B) Meeting with Administrator

To be eligible to seek judicial review under this subsection, a person seeking the review shall first request in writing, at least 120 days before filing the complaint for judicial review, a decision review meeting with the Administrator.

(4) Remedies

The Administrator may not be required or permitted to refund any portion of a registration service fee paid in response to a complaint that the Administrator has failed to make a determination on the covered pesticide registration application specified in paragraph (1) by the end of the applicable decision review period.

(h) Accounting

The Administrator shall—

(1) provide an annual accounting of the registration service fees paid to the Administrator and disbursed from the Fund, by providing financial statements in accordance with—

(A) the Chief Financial Officers Act of 1990 (Public Law 101–576; 104 Stat. 2838) and amendments made by that Act; and

(B) the Government Management Reform Act of 1994 (Public Law 103–356; 108 Stat. 3410) and amendments made by that Act;

(2) provide an accounting describing expenditures from the Fund authorized under subsection (c); and

(3) provide an annual accounting describing collections and expenditures authorized under subsection (d).

(i) Auditing

(1) Financial statements of agencies

For the purpose of section 3515(c) of title 31, the Fund shall be considered a component of an executive agency.

(2) Components

The annual audit required under sections 3515(b) and 3521 of that title of the financial statements of activities under this section shall include an analysis of—

(A) the fees collected under subsection (b) and disbursed;

(B) compliance with subsection (f);

(C) the amount appropriated to meet the requirements of subsection (d)(1); and

(D) the reasonableness of the allocation of the overhead allocation of costs associated with the review and decisionmaking pertaining to applications under this section.

(3) Inspector General

The Inspector General of the Environmental Protection Agency shall—

(A) conduct the annual audit required under this subsection; and

(B) report the findings and recommendations of the audit to the Administrator and to the appropriate committees of Congress.

(j) Personnel levels

All full-time equivalent positions supported by fees authorized and collected under this section shall not be counted against the agency-wide personnel level goals of the Environmental Protection Agency.

(k) Reports and information technology

(1) Reports

(A) In general

Not later than 120 days after the last day of each of fiscal years 2023 through 2027, the Administrator shall publish an annual report describing—

(i) actions taken under this section;

(ii) registrant submissions not covered by subsection (b)(3)(B);

(iii) the initial content and preliminary technical screenings required in subsection (f)(4)(B); and

(iv) staffing relating to implementing the Pesticide Registration Improvement Act of 2022 and the amendments made by that Act.

(B) Contents

Each report published under subparagraph (A) shall include a summary of the following information:

(i) Actions under this section

To the extent practicable, data for each action taken under this section that is completed during the fiscal year covered by the report or pending at the conclusion of that fiscal year, organized by registering division, including—

(I) the Action Code;

(II) the application receipt date;

(III) the electronic portal tracking number assigned to the application at the time of submission to the electronic submission portal or the Environmental Protection Agency tracking number;

(IV) the original decision due date based on the Action Code;

(V) the dates of any renegotiations and the renegotiated due dates, if applicable;
(VI) the reasons for each renegotiation, if applicable;
(VII) if the submission had to be recoded, reassigned codes, if applicable;
(VIII) the date that the submission was recoded, if applicable;
(IX) the decision completion date, if the action has been completed;
(X) the status of the action, which may be—
(aa) failed initial content screen;
(bb) failed preliminary technical screen;
(cc) approved;
(dd) withdrawn;
(ee) denied;
(ff) do not grant; or
(gg) pending;

(XI) the reason for any denial or do not grant decision, if applicable;
(XII) a review of the progress made in carrying out each requirement of subsections (e) and (f), including, to the extent determined appropriate by the Administrator and consistent with the authorities of the Administrator and limitations on delegation of functions by the Administrator, recommendations for the allowance and use of summaries of acute toxicity studies;
(XIII) a review of the progress in carrying out section 136a(g) of this title, including—
(aa) [3] the number of pesticides or pesticide cases reviewed and the number of registration review decisions completed, including—
(AA) the number of cases cancelled;
(BB) the number of cases requiring risk mitigation measures;
(CC) the number of cases removing risk mitigation measures;
(DD) the number of cases with no risk mitigation needed; and
(EE) the number of cases in which risk mitigation has been fully implemented;

(XIV) a review of the progress made toward implementing enhancements to—
(aa) the electronic tracking of conditional registrations; and
(bb) the endangered species database;

(XV) a review of the progress made in updating the Pesticide Incident Data System, including progress toward making the information contained in the System available to the public (as the Administrator determines is appropriate);
(XVI) an assessment of the public availability of summary pesticide usage data;
(XVII) the number of the active ingredients approved, new uses, and pesticide end use products granted in connection with the Design for the Environment program (or any successor program) of the Environmental Protection Agency;
(XVIII) with respect to funds in the Reregistration and Expedited Processing Fund described under section 136a–1(k) of this title, a review that includes—
(aa) a description of the amount and use of such funds—
(AA) to carry out activities relating to worker protection under subparagraphs (G) and (H) of section 136a–1(i)(1) of this title;
(BB) to award partnership grants under subparagraph (I) of such section; and
(CC) to carry out the pesticide safety education program under subparagraph (J) of such section;

(bb) an evaluation of the appropriateness and effectiveness of the activities, grants, and program under subparagraphs (G), (H), (I), and (J) of such section;
(cc) a description of how stakeholders are engaged in the decision to fund such activities, grants, and program in accordance with the stakeholder input provided under such subparagraphs; and

(dd) with respect to activities relating to worker protection carried out under subparagraphs (G) and (H) of section 136a–1(i)(1) of this title, a summary of the analyses from stakeholders, including from worker community-based organizations, on the appropriateness and effectiveness of such activities.

(XIX) beginning two years after enactment, report on the progress of meeting the deadlines listed in paragraph (5) of section 136a(f) of this title; and

(XX) a review of progress made in implementing the pesticide surveillance program referred to in paragraph (8) of section 136a–1(k) of this title.

(ii) Registrant submissions not covered by subsection (b)(3)(B)

Each registrant submission not covered by subsection (b)(3)(B), that is completed during the fiscal year covered by the report or pending at the conclusion of that fiscal year, organized by registering division, including—

(I) the submission date;

(II) the electronic portal tracking number assigned to the application at the time of the submission of the application to the electronic submission portal;

(III) the type of regulatory action, as defined by statute or guidance document, and the specific label action;

(IV) the status of the action;

(V) the due date;

(VI) the reason for the outcome; and

(VII) the completion date, if applicable.

(iii) Screening process

Data for the initial content screens and preliminary technical screens that are completed during the fiscal year covered by the report or pending at the conclusion of that fiscal year, organized by registering division, including—

(I) the number of applications successfully passing each type of screen;

(II) the number of applications that failed the screening process for each type of screen;

(III) the number of notifications issued by the Administrator under subsection (f)(4)(B)(ii)(II);

(IV) the number of notifications issued by the Administrator under subsection (f)(4)(B)(ii)(I) and the number of applications resulting in a rejection; and

(V) the number of notifications issued under section 152.105 of title 40, Code of Federal Regulations (or successor regulations), and to the extent practicable, the reasons for that issuance.

(iv) Staffing

Data on the staffing relating to work covered under the Pesticide Registration Improvement Act of 2022 and the amendments made by that Act, organized by registering division, including—

(I) the number of new hires and personnel departures;

(II) the number of full-time equivalents at the end of each fiscal year;

(III) the number of full-time equivalents working on registration review activities; and

(IV) the number of full-time equivalents working on registrant submissions not covered by subsection (b)(3)(B).

(C) Publication

The Administrator shall publish each report under subparagraph (A)—

(i) on the website of the Environmental Protection Agency; and

(ii) by such other methods as the Administrator determines to be the most effective for efficiently disseminating the report.

(2) Information technology

(A) System

Not later than 1 year after December 29, 2022, the Administrator shall establish an information technology system that—

(i) includes all registering divisions in the Office of Pesticide Programs;

(ii) provides a real-time, accurate, tracking system for all regulatory submissions to the Office of Pesticide Programs;

(iii) provides a [4] real-time, accessible information [4] that provides each applicant confidential, online access to the status and progress of the regulatory submissions of the applicant; and

(iv) updates the electronic submission portal—

(I) to ensure that label reviews are limited to current label changes, to the maximum extent practicable;

(II) to automate, to the extent practicable, minor, low risk regulatory actions; and

(III) to allow self-certification of certain regulatory actions, as determined by the Administrator.

(B) Access to registration data and decisions

The Administrator shall implement efforts to expand existing, and develop new, information technology tools and databases to improve access by Environmental Protection Agency employees to data used to fulfill registrations, and public access to information about regulatory decisionmaking tools, including opportunities for—

(i) analysis of the impact of submitted studies on Environmental Protection Agency assessments and decisions;

(ii) facilitation of read-across or computational model development to help fill information gaps;

(iii) tracking and reporting submission and decision metrics relating to the use and acceptance of test methods; and

(iv) drafting and publication of policies communicating Environmental Protection Agency acceptance of novel technologies or approaches.

(l) Savings clause

Nothing in this section affects any other duties, obligations, or authorities established by any other section of this subchapter, including the right to judicial review of duties, obligations, or authorities established by any other section of this subchapter.

(m) Termination of effectiveness

(1) In general

Except as provided in paragraph (2), the authority provided by this section terminates on September 30, 2027.

(2) Phase out

(A) Fiscal year 2028

During fiscal year 2028, the requirement to pay and collect registration service fees applies, except that the level of registration service fees payable under this section shall be reduced 40 percent below the level in effect on September 30, 2027.

(B) Fiscal year 2029

During fiscal year 2029, the requirement to pay and collect registration service fees applies, except that the level of registration service fees payable under this section shall be reduced 70 percent below the level in effect on September 30, 2027.

(C) September 30, 2029

Effective September 30, 2029, the requirement to pay and collect registration service fees terminates.

(D) Decision review periods

(i) Pending applications

In the case of an application received under this section before September 30, 2027, the application shall be reviewed in accordance with subsection (f).

(ii) New applications

In the case of an application received under this section on or after September 30, 2027, subsection (f) shall not apply to the application.

(June 25, 1947, ch. 125, §33, as added Pub. L. 108–199, div. G, title V, §501(f)(2), Jan. 23, 2004, 118 Stat. 422; amended Pub. L. 110–94, §5, Oct. 9, 2007, 121 Stat. 1002; Pub. L. 110–193, §1(a), Mar. 6, 2008, 122 Stat. 649; Pub. L. 112–177, §2(a)(2)(B), (b), Sept. 28, 2012, 126 Stat. 1328, 1330; Pub. L. 116–8, §§5, 6, Mar. 8, 2019, 133 Stat. 487, 491; Pub. L. 117–328, div. HH, title VI, §§705, 706, Dec. 29, 2022, 136 Stat. 6008, 6018.)

Editorial Notes

References in Text

The effective date of the Pesticide Registration Improvement Act of 2003, and the effective date of this section, referred to in text, is the effective date of section 501 of Pub. L. 108–199, which is the date that is 60 days after Jan. 23, 2004, unless otherwise provided, see section 501(h) of Pub. L. 108–199, set out as an Effective Date of 2004 Amendment note under section 136a of this title.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(2)(B)(ii), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Paragraph (3), referred to in subsec. (b)(6)(A), probably should be a reference to paragraph (3)(B). Amendment by section 705(a)(1)(B) of Pub. L. 117–328 substituting "paragraph (3)(B)" for "paragraph (3)" wherever appearing in subsec. (b) was followed by the general amendment of subsec. (b)(6)(A) by section 705(a)(1)(D)(i) of Pub. L. 117–328, which contained the reference to paragraph (3).

Section 2 of Public Law 89–106, referred to in subsec. (b)(7)(E)(i), was formerly classified to secton 450i of this title prior to editorial reclassification and renumbering as section 3157 of this title.

The Endangered Species Act of 1973, referred to in subsec. (c)(3)(B)(i), is Pub. L. 93–205, Dec. 28, 1973, 87 Stat. 884, which is classified principally to chapter 35 (§1531 et seq.) of Title 16, Conservation. For complete classification of this Act to the Code, see Short Title note set out under section 1531 of Title 16 and Tables.

The Pesticide Registration Improvement Act of 2022, referred to in subsecs. (c)(3)(C)(ii)(I), (iii)(I)(aa)(BB) and (k)(1)(A)(iv), (B)(iv), is title VI (§701 et seq.) of div. HH of Pub. L. 117–328, Dec. 29, 2022, 136 Stat. 5996. For complete classification of this Act to the Code, see Short Title of 2022 Amendment note set out under section 136 of this title and Tables.

The effective date of the Pesticide Registration Improvement Extension Act of 2018, referred to in subsec. (e), means the effective date of Pub. L. 116–8, which was approved Mar. 8, 2019.

The effective date of the Pesticide Registration Improvement Act of 2022, referred to in subsec. (f)(1), means the effective date of title VI of div. HH of Pub. L. 117–263, which was approved Dec. 29, 2022.

The Chief Financial Officers Act of 1990, referred to in subsec. (h)(1)(A), is Pub. L. 101–576, Nov. 15, 1990, 104 Stat. 2838. For complete classification of this Act to the Code, see Short Title of 1990 Amendment note set out under section 501 of Title 31, Money and Finance, and Tables.

The Government Management Reform Act of 1994, referred to in subsec. (h)(1)(B), is Pub. L. 103–356, Oct. 13, 1994, 108 Stat. 3410. For complete classification of this Act to the Code, see Short Title of 1994 Amendment note set out under section 3301 of Title 31, Money and Finance, and Tables.

Two years after enactment, referred to in subsec. (k)(1)(B)(i)(XIX), means two years after the enactment of section 136a(f)(5) of this title, as enacted by Pub. L. 117–328, which was approved Dec. 29, 2022.

Prior Provisions

A prior section 33 of act June 25, 1947, ch. 125, was renumbered section 34 and is classified to section 136x of this title.

Amendments

2022—Subsec. (b). Pub. L. 117–328, §705(a)(1)(B), substituted "paragraph (3)(B)" for "paragraph (3)" wherever appearing. Subsec. (b)(6)(A) was subsequently amended generally by Pub. L. 117–328, §705(a)(1)(D)(i), after which "paragraph (3)" appeared in text.

Subsec. (b)(2)(E)(iii). Pub. L. 117–328, §705(a)(1)(A), substituted "on completion of, where appropriate, the initial screening of the contents of the application or the preliminary technical screening" for "after review".

Subsec. (b)(3). Pub. L. 117–328, §705(a)(1)(C), designated existing provisions as subpar. (B), inserted heading, and added subpar. (A).

Subsec. (b)(3)(B). Pub. L. 117–328, §706, added subpar. (B) and struck out former subpar. (B), as designated by section 705(a)(1)(C) of Pub. L. 117–263, which set out the schedule of covered applications and other actions and their registration service fees.

Subsec. (b)(6)(A), (B). Pub. L. 117–328, §705(a)(1)(D), which directed amendment of subpars. (A) and (B) "to read as follows" but did not include subpar. designations or headings, was executed by amending the text only and retaining the existing designations and headings, to reflect the probable intent of Congress. Prior to amendment, subpars. (A) and (B) related to fee adjustment between Oct. 1, 2019, and Sept. 30, 2021, and an additional fee adjustment starting on Oct. 1, 2021.

Subsec. (b)(7)(A). Pub. L. 117–328, §705(a)(1)(E), substituted "(including a Gold Seal letter and a Certificate of Establishment)" for "(commonly referred to as a Gold Seal letter)".

Subsec. (c)(3)(B), (C). Pub. L. 117–328, §705(b)(1), added subpars. (B) and (C) and struck out former subpar. (B). Prior to amendment, text of subpar. (B) read as follows:

"(i) In general.—For each of fiscal years 2013 through 2023, the Administrator shall use approximately 1/17 of the amount in the Fund (but not less than $1,000,000) to enhance scientific and regulatory activities relating to worker protection, with an emphasis on field-worker populations in the United States.

"(ii) Partnership grants.—Of the amounts in the Fund, the Administrator shall use for partnership grants, for each of fiscal years 2013 through 2023, $500,000.

"(iii) Pesticide safety education program.—Of the amounts in the Fund, the Administrator shall use $500,000 for each of fiscal years 2013 through 2023 to carry out the pesticide safety education program."

Subsec. (c)(4)(B), (C). Pub. L. 117–328, §705(b)(2), added subpar. (B) and redesignated former subpar. (B) as (C).

Subsec. (d)(2). Pub. L. 117–328, §705(c), struck out "(as in existence in fiscal year 2012)" after "for the functions" and substituted "$166,000,000." for "the amount of appropriations for covered functions for fiscal year 2012 (excluding the amount of any fees appropriated for the fiscal year)."

Subsec. (e). Pub. L. 117–328, §705(d), substituted "Reforms to reduce decision time review periods and prevent double payment of registration fees" for "Reforms to reduce decision time review periods" in subsec. heading, designated existing provisions as par. (1) and inserted par. heading, and added par. (2).

Subsec. (f). Pub. L. 117–328, §705(a)(2), substituted "subsection (b)(3)(B)" for "subsection (b)(3)" wherever appearing.

Subsec. (f)(1). Pub. L. 117–328, §705(e)(1), substituted "Pesticide Registration Improvement Act of 2022" for "Pesticide Registration Improvement Extension Act of 2018".

Subsec. (f)(4)(B)(i)(III). Pub. L. 117–328, §705(e)(2)(A)(i), added subcl. (III).

Subsec. (f)(4)(B)(iii). Pub. L. 117–328, §705(e)(2)(A)(ii), inserted "automate the process, to the maximum extent practicable, and" before "determine" in introductory provisions.

Subsec. (f)(4)(B)(iv). Pub. L. 117–328, §705(e)(2)(A)(iii), struck out "determine if" after "shall" in introductory provisions, inserted "determine if" at beginning of subcls. (I) and (II), and added subcls. (III) to (VI).

Subsec. (f)(4)(E). Pub. L. 117–328, §705(e)(2)(B), added subpar. (E) and struck out former subpar. (E). Prior to amendment, text read as follows: "In the case of a covered pesticide registration application listed in the Registration Division 2003 Work Plan of the Office of Pesticide Programs of the Environmental Protection Agency, the decision time review period begins on the date that is 30 days after the effective date of the Pesticide Registration Improvement Act of 2003."

Subsec. (f)(5). Pub. L. 117–328, §705(e)(3), added par. (5) and struck out former par. (5). Prior to amendment, text read as follows: "The Administrator and the applicant may mutually agree in writing to extend a decision time review period under this subsection."

Subsec. (k). Pub. L. 117–328, §705(f), added subsec. (k) and struck out former subsec. (k) which related to publication of annual reports and submission of another report to Congress.

Subsec. (m). Pub. L. 117–328, §705(g)(1), substituted "2027" for "2023" wherever appearing.

Subsec. (m)(2)(A). Pub. L. 117–328, §705(g)(2)(A), substituted "2028" for "2024" in heading and text.

Subsec. (m)(2)(B), (C). Pub. L. 117–328, §705(g)(2)(B), substituted "2029" for "2025" in heading and text.

2019—Subsec. (b)(2). Pub. L. 116–8, §5(a)(1)(A), struck out "pesticide registration" after "Covered" in heading.

Subsec. (b)(2)(A). Pub. L. 116–8, §5(a)(1)(B), inserted "or for any other action covered by a table specified in paragraph (3)" after "Pesticide Registration Improvement Act of 2003".

Subsec. (b)(3). Pub. L. 116–8, §6, amended par. (3) generally. Prior to amendment, par. (3) related to schedule of covered applications and registration service fees.

Subsec. (b)(5). Pub. L. 116–8, §5(a)(2), substituted "covered applications" for "pesticide registration applications" in heading and "covered application" for "pesticide registration application" in two places in text.

Subsec. (b)(6)(A). Pub. L. 116–8, §5(a)(3)(A), struck out "pesticide registration" after "Effective for a covered" and substituted "October 1, 2019, and ending on September 30, 2021" for "October 1, 2013, and ending on September 30, 2015".

Subsec. (b)(6)(B). Pub. L. 116–8, §5(a)(3)(B), struck out "pesticide registration" after "Effective for a covered" and substituted "2021" for "2015" in two places.

Subsec. (b)(6)(C). Pub. L. 116–8, §5(a)(3)(C), substituted "service fee schedules revised pursuant to this paragraph" for "revised registration service fee schedules".

Subsec. (b)(7)(A). Pub. L. 116–8, §5(a)(4)(A), substituted "covered application" for "covered pesticide registration" and inserted before period at end ", except that no waiver or fee reduction shall be provided in connection with a request for a letter of certification (commonly referred to as a Gold Seal letter)".

Subsec. (b)(7)(F)(i). Pub. L. 116–8, §5(a)(4)(B), struck out "pesticide registration" after "for a covered".

Subsec. (b)(8)(A). Pub. L. 116–8, §5(a)(5)(A), struck out "pesticide registration" after "a covered".

Subsec. (b)(8)(B)(i). Pub. L. 116–8, §5(a)(5)(B), struck out "pesticide registration" after "If a covered".

Subsec. (b)(8)(C)(i). Pub. L. 116–8, §5(a)(5)(C)(i), substituted "case of a covered" for "case of a pesticide registration".

Subsec. (b)(8)(C)(ii)(I). Pub. L. 116–8, §5(a)(5)(C)(ii), substituted "covered" for "pesticide registration".

Subsec. (c)(3)(B). Pub. L. 116–8, §5(b)(1), inserted ", partnership grants, and pesticide safety education" after "Worker protection" in heading.

Subsec. (c)(3)(B)(i). Pub. L. 116–8, §5(b)(2), substituted "2023" for "2017" and inserted before period at end ", with an emphasis on field-worker populations in the United States".

Subsec. (c)(3)(B)(ii). Pub. L. 116–8, §5(b)(3), substituted "2023" for "2017".

Subsec. (c)(3)(B)(iii). Pub. L. 116–8, §5(b)(4), substituted "2023" for "2017".

Subsec. (e). Pub. L. 116–8, §5(c), substituted "Pesticide Registration Improvement Extension Act of 2018" for "Pesticide Registration Improvement Extension Act of 2012" and inserted at end "Such reforms shall include identifying opportunities for streamlining review processes for applications for a new active ingredient or a new use and providing prompt feedback to applicants during such review process."

Subsec. (f)(1). Pub. L. 116–8, §5(d)(1), substituted "Pesticide Registration Improvement Extension Act of 2018" for "Pesticide Registration Improvement Extension Act of 2012" and inserted "or for any other action covered by a table specified in subsection (b)(3)" after "covered pesticide registration actions".

Subsec. (f)(3)(C). Pub. L. 116–8, §5(d)(2), added subpar. (C) and struck out former subpar. (C) which read as follows: "covered pesticide registration applications listed in the Registration Division 2003 Work Plan of the Office of Pesticide Programs of the Environmental Protection Agency."

Subsec. (f)(4)(A). Pub. L. 116–8, §5(d)(3), substituted "a covered application" for "a pesticide registration application" and "the covered application" for "the covered pesticide registration application".

Subsec. (k)(1). Pub. L. 116–8, §5(e)(1), substituted "2023" for "2017".

Subsec. (k)(2)(D)(i). Pub. L. 116–8, §5(e)(2)(A), added cl. (i) and struck out former cl. (i) which read as follows: "the number of pesticides or pesticide cases reviewed;".

Subsec. (k)(2)(G)(i). Pub. L. 116–8, §5(e)(2)(B)(i), substituted "paragraphs (4) and (5) of section 136a–1(k) of this title" for "section 136a–1(k)(4) of this title" and "such paragraphs" for "that section".

Subsec. (k)(2)(G)(ii) to (vii). Pub. L. 116–8, §5(e)(2)(B)(ii)–(iv), added cl. (ii), redesignated cl. (vii) as (iii), and struck out former cls. (ii) to (vi) which read as follows:

"(ii) implementing systems for the electronic tracking of registration submissions by December 31, 2013;

"(iii) implementing a system for tracking the status of conditional registrations, including making nonconfidential information related to the conditional registrations publicly available by December 31, 2013;

"(iv) implementing enhancements to the endangered species knowledge database, including making nonconfidential information related to the database publicly available;

"(v) implementing the capability to electronically submit and review labels submitted with registration actions;

"(vi) acquiring and implementing the capability to electronically assess and evaluate confidential statements of formula submitted with registration actions by December 31, 2014; and".

Subsec. (k)(2)(K) to (O). Pub. L. 116–8, §5(e)(2)(C)–(E), added subpars. (K) to (O).

Subsec. (m)(1). Pub. L. 116–8, §5(f)(1), substituted "2023" for "2017".

Subsec. (m)(2)(A). Pub. L. 116–8, §5(f)(2)(A), in heading, substituted "Fiscal year 2024" for "Fiscal year 2018" and in text, substituted "2024" for "2018" and "2023" for "2017".

Subsec. (m)(2)(B). Pub. L. 116–8, §5(f)(2)(B), in heading, substituted "Fiscal year 2025" for "Fiscal year 2019" and in text, substituted "2025" for "2019" and "2023" for "2017".

Subsec. (m)(2)(C). Pub. L. 116–8, §5(f)(2)(C), substituted "2025" for "2019" in heading and text.

Subsec. (m)(2)(D). Pub. L. 116–8, §5(f)(2)(D), substituted "2023" for "2017" in cls. (i) and (ii).

2012—Subsec. (b)(3). Pub. L. 112–177, §2(b)(1)(A), added par. (3) and struck out former par. (3) which related to schedule of covered applications and registration service fees.

Subsec. (b)(6)(A). Pub. L. 112–177, §2(b)(1)(B)(i), substituted "October 1, 2013" for "October 1, 2008" and "September 30, 2015" for "September 30, 2010".

Subsec. (b)(6)(B). Pub. L. 112–177, §2(b)(1)(B)(ii), substituted "October 1, 2015" for "October 1, 2010" and "September 30, 2015" for "September 30, 2010".

Subsec. (b)(7)(F)(i). Pub. L. 112–177, §2(a)(2)(B)(i), substituted "section 136a–1 (i)(1)(E)(ii)" for "section 136a–1(i)(5)(E)(ii)".

Subsec. (b)(7)(F)(ii). Pub. L. 112–177, §2(a)(2)(B)(i), (ii), substituted "section 136a–1 (i)(1)(E)(ii)" for "section 136a–1(i)(5)(E)(ii)" in subcl. (I) and "section 136a–1(i)(1)(E)(ii)(I)(bb)" for "136a–1(i)(5)(E)(ii)(I)(bb)" in subcl. (II).

Subsec. (b)(7)(F)(iv)(I). Pub. L. 112–177, §2(a)(2)(B)(i), substituted "section 136a–1 (i)(1)(E)(ii)" for "section 136a–1(i)(5)(E)(ii)".

Subsec. (b)(7)(F)(iv)(II). Pub. L. 112–177, §2(a)(2)(B)(ii), (iii), substituted "applicable" for "applicable.", "revenue" for "revenues", and "section 136a–1(i)(1)(E)(ii)(I)(bb)" for "section 136a–1(i)(5)(E)(ii)(I)(bb)".

Subsec. (b)(8)(C)(ii)(III). Pub. L. 112–177, §2(b)(1)(C), added subcl. (III).

Subsec. (c)(3)(B)(i). Pub. L. 112–177, §2(b)(2)(A), substituted "2013 through 2017" for "2008 through 2012".

Subsec. (c)(3)(B)(ii). Pub. L. 112–177, §2(b)(2)(B), substituted "grants, for each of fiscal years 2013 through 2017, $500,000." for "grants—

"(I) for each of fiscal years 2008 and 2009, $750,000; and

"(II) for each of fiscal years 2010 through 2012, $500,000."

Subsec. (c)(3)(B)(iii). Pub. L. 112–177, §2(b)(2)(C), substituted "2013 through 2017" for "2008 through 2012".

Subsec. (d)(2). Pub. L. 112–177, §2(b)(3)(A), substituted "2012" for "2002" in two places.

Subsec. (d)(4), (5). Pub. L. 112–177, §2(b)(3)(B), (C), redesignated par. (5) as (4) and struck out former par. (4). Prior to amendment, text of par. (4) read as follows: "The requirements of paragraph (2) shall have been considered to have been met for any fiscal year if the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2002) of the Office of Pesticide Programs of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) is not more than 3 percent below the amount of appropriations for covered functions for fiscal year 2002 (excluding the amount of any fees appropriated for the fiscal year)."

Subsec. (e). Pub. L. 112–177, §2(b)(4), substituted "Pesticide Registration Improvement Extension Act of 2012" for "Pesticide Registration Improvement Act of 2003".

Subsec. (f)(1). Pub. L. 112–177, §2(b)(5)(A), substituted "Pesticide Registration Improvement Extension Act of 2012, the Administrator shall make publicly available" for "Pesticide Registration Improvement Renewal Act, the Administrator shall publish in the Federal Register".

Subsec. (f)(2). Pub. L. 112–177, §2(b)(5)(B), substituted "provided under subsection (b)(3)." for "appearing in the Congressional Record on pages S10409 through S10411, dated July 31, 2007."

Subsec. (f)(4)(A). Pub. L. 112–177, §2(b)(5)(C)(i), inserted "and fee" before period at end.

Subsec. (f)(4)(B). Pub. L. 112–177, §2(b)(5)(C)(ii)(I), substituted "Initial content and preliminary technical screenings" for "Completeness of application" in heading.

Subsec. (f)(4)(B)(i). Pub. L. 112–177, §2(b)(5)(C)(ii)(I), (II), substituted "Screenings" for "In general" in cl. heading, designated existing provisions as subcl. (I) and inserted subcl. heading, and added subcl. (II).

Subsec. (f)(4)(B)(ii). Pub. L. 112–177, §2(b)(5)(C)(ii)(III), added cl. (ii) and struck out former cl. (ii). Prior to amendment, text read as follows: "If the Administrator determines under clause (i) that the application does not pass the initial screening and cannot be corrected within the 21-day period, the Administrator shall reject the application not later than 10 days after making the determination."

Subsec. (f)(4)(B)(iii). Pub. L. 112–177, §2(b)(5)(C)(ii)(IV), inserted "initial content" before "screening" in heading, "content" before "screening" in introductory provisions, and substituted "appears to contain" for "contains" in subcl. (II).

Subsec. (f)(4)(B)(iv). Pub. L. 112–177, §2(b)(5)(C)(ii)(V), added cl. (iv).

Subsec. (k)(1). Pub. L. 112–177, §2(b)(6)(A), substituted "March 1, 2017" for "March 1, 2014".

Subsec. (k)(2)(A)(viii). Pub. L. 112–177, §2(b)(6)(B)(i), added cl. (viii).

Subsec. (k)(2)(G) to (J). Pub. L. 112–177, §2(b)(6)(B)(ii)–(iv), added subpars. (G) to (J).

Subsec. (k)(4). Pub. L. 112–177, §2(b)(6)(C), added par. (4).

Subsec. (m)(1). Pub. L. 112–177, §2(b)(7)(A), substituted "2017" for "2012".

Subsec. (m)(2)(A). Pub. L. 112–177, §2(b)(7)(B)(i), substituted "2018" for "2013" in heading and "2018," for "2013," and "September 30, 2017" for "September 30, 2012" in text.

Subsec. (m)(2)(B). Pub. L. 112–177, §2(b)(7)(B)(ii), substituted "2019" for "2014" in heading and "2019," for "2014," and "September 30, 2017" for "September 30, 2012" in text.

Subsec. (m)(2)(C). Pub. L. 112–177, §2(b)(7)(B)(iii), substituted "2019" for "2014" in heading and "September 30, 2019" for "September 30, 2014" in text.

Subsec. (m)(2)(D). Pub. L. 112–177, §2(b)(7)(B)(iv), substituted "2017" for "2012" in cls. (i) and (ii).

2008—Subsec. (b)(7)(D)(i). Pub. L. 110–193, §1(a)(1)(A)(i), added cl. (i) and struck out former cl. (i). Prior to amendment, text read as follows: "The Administrator may waive or reduce a registration service fee for an application for minor uses for a pesticide."

Subsec. (b)(7)(D)(ii). Pub. L. 110–193, §1(a)(1)(A)(ii), inserted "or exemption" after "waiver".

Subsec. (b)(7)(E). Pub. L. 110–193, §1(a)(1)(B)(ii), substituted "exempt an application from the registration service fee" for "waive the registration service fee for an application" in introductory provisions.

Pub. L. 110–193, §1(a)(1)(B)(i), substituted "exemption" for "waiver" in heading.

Subsec. (b)(7)(E)(ii). Pub. L. 110–193, §1(a)(1)(B)(iii), substituted "exemption" for "waiver".

Subsec. (m)(2)(A), (B). Pub. L. 110–193, §1(a)(2), substituted "2012" for "2008".

2007—Subsec. (b)(2)(C)(ii). Pub. L. 110–94, §5(a)(1), added cl. (ii) and struck out former cl. (ii) which read as follows: "a request for a waiver from or reduction of the registration service fee."

Subsec. (b)(2)(D) to (H). Pub. L. 110–94, §5(a)(2), added subpars. (D) to (H).

Subsec. (b)(3)(A). Pub. L. 110–94, §5(b)(1)(A), substituted "Pesticide Registration Improvement Renewal Act" for "Pesticide Registration Improvement Act of 2003".

Subsec. (b)(3)(B). Pub. L. 110–94, §5(b)(1)(B), substituted "S10409 through S10411, dated July 31, 2007." for "S11631 through S11633, dated September 17, 2003."

Subsec. (b)(6). Pub. L. 110–94, §5(b)(2), added par. (6) and struck out former par. (6). Prior to amendment, text of par. (6) read as follows: "Effective for a covered pesticide registration application received on or after October 1, 2005, the Administrator shall—

"(A) increase by 5 percent the service fee payable for the application under paragraph (3); and

"(B) publish in the Federal Register the revised registration service fee schedule."

Subsec. (b)(7)(F)(ii). Pub. L. 110–94, §5(c)(1), substituted "75 percent" for "all" in introductory provisions.

Subsec. (b)(7)(F)(iv)(II). Pub. L. 110–94, §5(c)(2), substituted "75 percent of the applicable." for "all".

Subsec. (b)(8)(A). Pub. L. 110–94, §5(d), substituted "25 percent." for "10 percent".

Subsec. (c)(1)(B). Pub. L. 110–94, §5(e)(1), substituted "paragraph (5)" for "paragraph (4)".

Subsec. (c)(3)(B). Pub. L. 110–94, §5(e)(2)(A), added subpar. (B) and struck out former subpar. (B). Prior to amendment, text of subpar. (B) read as follows: "For each of fiscal years 2004 through 2008, the Administrator shall use approximately 1/17 of the amount in the Fund (but not more than $1,000,000, and not less than $750,000, for any fiscal year) to enhance current scientific and regulatory activities related to worker protection."

Subsec. (c)(3)(C). Pub. L. 110–94, §5(e)(2)(B), struck out subpar. (C). Text read as follows: "For each of fiscal years 2004 and 2005, the Administrator shall use approximately 1/34 of the amount in the Fund (but not to exceed $500,000 for any fiscal year) for the review and evaluation of new inert ingredients."

Subsec. (c)(5). Pub. L. 110–94, §5(e)(3), designated existing provisions as subpar. (A), inserted heading, redesignated former subpars. (A) to (C) as cls. (i) to (iii), respectively, of subpar. (A) and added subpar. (B).

Subsec. (d)(2). Pub. L. 110–94, §5(f), which directed substitution of "Registration" for "For fiscal years 2004, 2005 and 2006 only, registration", was executed by making the substitution for text which contained a comma after "2005" to reflect the probable intent of Congress.

Subsec. (f)(1). Pub. L. 110–94, §5(g)(1), substituted "Pesticide Registration Improvement Renewal Act" for "Pesticide Registration Improvement Act of 2003".

Subsec. (f)(2). Pub. L. 110–94, §5(g)(2), substituted "S10409 through S10411, dated July 31, 2007." for "S11631 through S11633, dated September 17, 2003."

Subsec. (f)(4)(B). Pub. L. 110–94, §5(g)(3), added subpar. (B) and struck out former subpar. (B) which provided criteria for determining completeness of pesticide registration applications.

Subsec. (k)(1). Pub. L. 110–94, §5(h)(1), substituted "March 1, 2014" for "March 1, 2009".

Subsec. (k)(2)(A)(ii) to (v). Pub. L. 110–94, §5(h)(2)(A)(i), (ii), added cls. (ii) to (iv) and redesignated former cl. (ii) as (v). Former cls. (iii) and (iv) redesignated (vi) and (vii), respectively.

Subsec. (k)(2)(A)(vi). Pub. L. 110–94, §5(h)(2)(A)(i), (iii), redesignated cl. (iii) as (vi) and added subcls. (IV) and (V).

Subsec. (k)(2)(A)(vii). Pub. L. 110–94, §5(h)(2)(A)(i), redesignated cl. (iv) as (vii).

Subsec. (k)(2)(D) to (F). Pub. L. 110–94, §5(h)(2)(B)–(D), added subpars. (D) to (F).

Subsec. (m)(1). Pub. L. 110–94, §5(i)(1), substituted "2012" for "2008".

Subsec. (m)(2)(A). Pub. L. 110–94, §5(i)(2)(A), substituted "2013" for "2009" in heading and text.

Subsec. (m)(2)(B), (C). Pub. L. 110–94, §5(i)(2)(B), substituted "2014" for "2010" in headings and text.

Subsec. (m)(2)(D). Pub. L. 110–94, §5(i)(2)(C), substituted "2012" for "2008" in two places.

Statutory Notes and Related Subsidiaries

Effective Date of 2012 Amendment

Amendment by Pub. L. 112–177 effective Oct. 1, 2012, see section 2(c) of Pub. L. 112–177, set out as a note under section 136a–1 of this title.

Effective Date of 2008 Amendment

Pub. L. 110–193, §1(b), Mar. 6, 2008, 122 Stat. 650, provided that: "The amendments made by subsection (a) [amending this section] take effect on October 1, 2007."

Effective Date of 2007 Amendment

Amendment by Pub. L. 110–94 effective Oct. 1, 2007, see section 6 of Pub. L. 110–94, set out as a note under section 136a of this title.

Effective Date

Section effective on the date that is 60 days after Jan. 23, 2004, except as otherwise provided, see section 501(h) of Pub. L. 108–199, set out as an Effective Date of 2004 Amendment note under section 136a of this title.

Implementation Dates With Respect to Fees

Increases in registration service fees specified in this section, as amended by title VI of div. HH of Pub. L. 117–328, not effective until 60 days after Dec. 29, 2022, regardless of whether this section specifies such increases to be effective for fiscal year 2023, see section 708(a)(1) of Pub. L. 117–328, set out in a note under section 136a–1 of this title.

Extension of Limitations on Fee Amounts and Usage of Fees

Subsection (c)(3)(B) of this section to continue in effect through Sept. 30, 2018, see section 401(a) of Pub. L. 115–141, formerly set out as a note under section 136a–1 of this title.

Pub. L. 115–141, div. M, title IV, §401(b)(2), Mar. 23, 2018, 132 Stat. 1050, extended the authority provided by this section until Sept. 30, 2018.

[1] *See References in Text note below.*

[2] *So in original. The period probably should not appear.*

[3] *So in original. There is no item (bb).*

[4] *So in original.*

§136x. Severability

If any provision of this subchapter or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this subchapter which can be given effect without regard to the invalid provision or application, and to this end the provisions of this subchapter are severable.

(June 25, 1947, ch. 125, §34, formerly §26, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 998; renumbered §30, Pub. L. 95–396, §24(1), Sept. 30, 1978, 92 Stat. 836; renumbered §33, Pub. L. 104–170, title I, §121(1), Aug. 3, 1996, 110 Stat. 1492; renumbered §34, Pub. L. 108–199, div. G, title V, §501(f)(1), Jan. 23, 2004, 118 Stat. 422.)

Editorial Notes

Prior Provisions

A prior section 34 of act June 25, 1947, ch. 125, was renumbered section 35 and is classified to section 136y of this title.

Statutory Notes and Related Subsidiaries

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§136y. Authorization of appropriations

There is authorized to be appropriated to carry out this subchapter (other than section 136u(a) of this title)—

(1) $83,000,000 for fiscal year 1989, of which not more than $13,735,500 shall be available for research under this subchapter;

(2) $95,000,000 for fiscal year 1990, of which not more than $14,343,600 shall be available for research under this subchapter; and

(3) $95,000,000 for fiscal year 1991, of which not more than $14,978,200 shall be available for research under this subchapter.

(June 25, 1947, ch. 125, §35, formerly §27, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 998; amended Pub. L. 94–51, July 2, 1975, 89 Stat. 257; Pub. L. 94–109, Oct. 10, 1975, 89 Stat. 571; Pub. L. 94–140, §3, Nov. 28, 1975, 89 Stat. 752; renumbered §31 and amended Pub. L. 95–396, §§24(1), 25, Sept. 30, 1978, 92 Stat. 836, 838; Pub. L. 96–539, §3, Dec. 17, 1980, 94 Stat. 3195; Pub. L. 98–201, §2, Dec. 2, 1983, 97 Stat. 1380; Pub. L. 99–198, title XVII, §1768, Dec. 23, 1985, 99 Stat. 1656; Pub. L. 100–532, title VII, §701, Oct. 25, 1988, 102 Stat. 2679; renumbered §34, Pub. L. 104–170, title I, §121(1), Aug. 3, 1996, 110 Stat. 1492; renumbered §35, Pub. L. 108–199, div. G, title V, §501(f)(1), Jan. 23, 2004, 118 Stat. 422.)

Editorial Notes

Codification

Another section 1768 of Pub. L. 99–198 enacted sections 154a and 159 and amended sections 151, 154, and 157 of Title 21, Food and Drugs.

Amendments

1988—Pub. L. 100–532 amended section generally. Prior to amendment, section read as follows: "There is authorized to be appropriated to carry out this subchapter for the period beginning October 1, 1985, and

ending September 30, 1986, $68,604,200 of which not more than $11,993,100 shall be available for research under this subchapter."

1985—Pub. L. 99–198 substituted provisions authorizing appropriations of $68,604,200 for fiscal year 1986 of which not more than $11,993,100 shall be available for research for former provisions which had authorized appropriations for fiscal years 1973 through 1984.

1983—Pub. L. 98–201 authorized necessary appropriations for period beginning Oct. 1, 1983, and ending Sept. 30, 1984, not in excess of $64,200,000.

1980—Pub. L. 96–539 inserted provisions authorizing appropriations for period beginning Oct. 1, 1979, and ending Sept. 30, 1980, and for period beginning Oct. 1, 1980, and ending Sept. 30, 1981.

1978—Pub. L. 95–396, §25, substituted appropriations authorization of $46,636,000 for period beginning Oct. 1, 1976, and ending Sept. 30, 1977, for prior authorization of $23,600,000 for period beginning Oct. 1, 1976, and ending Mar. 31, 1977, and authorized appropriations of $54,500,000 for period beginning Oct. 1, 1977, and ending Sept. 30, 1978, and such sums as may be necessary, limited to $70,000,000, for period beginning Oct. 1, 1978, and ending Sept. 30, 1979.

1975—Pub. L. 94–140 authorized appropriation of $47,868,000 to carry out provisions of this subchapter for period beginning Oct. 1, 1975, and ending Sept. 30, 1976, and $23,600,000 for period beginning Oct. 1, 1976, and ending Mar. 31, 1977.

Pub. L. 94–109 inserted provisions authorizing appropriation of $5,983,500 for period beginning Oct. 1, 1975 and ending Nov. 15, 1975.

Pub. L. 94–51 authorized appropriation of $11,967,000 to carry out provisions of this subchapter for period beginning July 1, 1975, and ending Sept. 30, 1975.

Statutory Notes and Related Subsidiaries

Effective Date of 1988 Amendment

Pub. L. 100–532, title VII, §701, Oct. 25, 1988, 102 Stat. 2679, provided that amendment made by Pub. L. 100–532 is effective Oct. 1, 1988.

Effective Date

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.