

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 pes-

ticide 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 re-

¹ See References in Text note below.

quired 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 submis-

sion 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 resolu-

tion 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 sub-

mission 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 nec-

essary 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 avail-

able 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 (1) of this section, the Administrator shall take appropriate regulatory action.

graph (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 registration 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 subchapter, 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 registration 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 re-

port 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 $\frac{1}{9}$ and $\frac{1}{6}$ 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 $\frac{1}{9}$ and $\frac{1}{6}$, 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 subparagraph. (F). Former subparagraph. (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 subparagraph. (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 $\frac{1}{6}$ and $\frac{1}{5}$ ” for “2008 through 2012, between $\frac{1}{6}$ and $\frac{1}{5}$;” 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 subparagraph. (A) and struck out former subparagraph. (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.”

istration. 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 subparagraph. (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 subparagraph. (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 subparagraph. (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 subparagraph. (C) heading, substituted “aggregate amount of—” for “aggregate amount of \$21,500,000 for fiscal year 2003.”, added cl. (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 subparagraph. (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 subparagraph. (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 $\frac{1}{2}$ and $\frac{1}{4}$ of the maintenance fees” for “1997 through 2003, not more than $\frac{1}{10}$ 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 cl. (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 “ $\frac{1}{10}$ ” for “ $\frac{1}{7}$ ” 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 cl. (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 cl. (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 cl. (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 subparagraph. (E).

Subsec. (i)(4)(B) to (D). Pub. L. 104-170, §232(1), added subparagraph. (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 $\frac{1}{4}$ of the maintenance fees collected in such fiscal year” for “for each of the fiscal years 1992, 1993, and 1994, $\frac{1}{4}$ th 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), re-aligned 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, $\frac{1}{4}$ th 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 sec-

tion] (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].”

§ 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 136c 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