

“(a) STUDY.—Not later than September 30, 1992, the National Academy of Sciences shall conduct a study of the biological control programs and registration procedures utilized by the Food and Drug Administration, the Animal and Plant Health Inspection Service, and the Environmental Protection Agency.

“(b) DEVELOPMENT OF PROCEDURES.—Not later than 1 year after the completion of the study under subsection (a), the agencies and offices described in such subsection shall develop and implement a common process for reviewing and approving biological control applications that are submitted to such agencies and offices that shall be based on the study conducted under such subsection and the recommendation of the National Academy of Sciences, and other public comment.”

EDUCATION, STUDY, AND REPORT

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

“(a) EDUCATION.—The Administrator of the Environmental Protection Agency in cooperation with the Secretary of Agriculture and the Secretary of the Interior, promptly upon enactment of this Act [Oct. 7, 1988], shall conduct a program to inform and educate fully persons engaged in agricultural food and fiber commodity production of any proposed pesticide labeling program or requirements that may be imposed by the Administrator in compliance with the Endangered Species Act [of 1973] (16 U.S.C. 1531 et seq.). The Administrator also shall provide the public with notice of, and opportunity for comment on, the elements of any such program and requirements based on compliance with the Endangered Species Act [of 1973], including (but not limited to) an identification of any pesticides affected by the program; an explanation of the restriction or prohibition on the user or applicator of any such pesticide; an identification of those geographic areas affected by any pesticide restriction or prohibition; an identification of the effects of any restricted or prohibited pesticide on endangered or threatened species; and an identification of the endangered or threatened species along with a general description of the geographic areas in which such species are located wherein the application of a pesticide will be restricted, prohibited, or its use otherwise limited, unless the Secretary of the Interior determines that the disclosure of such information may create a substantial risk of harm to such species or its habitat.

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

“(c) REPORT.—The Administrator of the Environmental Protection Agency in cooperation with the Secretary of Agriculture and the Secretary of the Interior

shall submit a report within one year of the date of enactment of this Act [Oct. 7, 1988], presenting the results of the study conducted pursuant to subsection (b) of this section to the Committee on Merchant Marine and Fisheries and the Committee on Agriculture of the United States House of Representatives, and the Committee on Environment and Public Works and the Committee on Agriculture, Nutrition, and Forestry of the United States Senate.”

§ 136a-1. Reregistration of registered pesticides

(a) General rule

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

- (1) there are no outstanding data requirements; and
- (2) the requirements of section 136a(c)(5) of this title have been satisfied.

(b) Reregistration phases

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

- (1) The first phase shall include the listing under subsection (c) of the active ingredients of the pesticides that will be reregistered.
- (2) The second phase shall include the submission to the Administrator under subsection (d) of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants to replace such missing or inadequate data within the applicable time period.
- (3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (e).
- (4) The fourth phase shall include an independent, initial review by the Administrator under subsection (f) of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requests for additional data.
- (5) The fifth phase shall include the review by the Administrator under subsection (g) of data submitted for reregistration and appropriate regulatory action by the Administrator.

(c) Phase one

(1) Priority for reregistration

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

- (A) are in use on or in food or feed and may result in postharvest residues;
- (B) may result in residues of potential toxicological concern in potable ground water, edible fish, or shellfish;
- (C) have been determined by the Administrator before the effective date of this section to have significant outstanding data requirements; or

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

(2) Reregistration lists

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

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

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

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

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

Each list shall be published in the Federal Register.

(3) Judicial review

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

(4) Notice to registrants

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

(d) Phase two

(1) In general

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

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

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

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

(3) Missing or inadequate data

Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) and for

which the registrant submitted a notice under paragraph (2) of an intention to seek reregistration of such pesticide shall submit to the Administrator—

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

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

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

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

(B) either—

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

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

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

(4) Time periods

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

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

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

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

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

the registrant from complying with such period.

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

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

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

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

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

(5) Cancellation and removal

(A) If the registrant of a pesticide does not submit a notice under paragraph (2) or (3)

within the time prescribed by paragraph (4)(A), the Administrator shall issue a notice of intent to cancel the registration of such registrant for such pesticide and shall publish the notice in the Federal Register and allow 60 days for the submission of comments on the notice. On expiration of such 60 days, the Administrator, by order and without a hearing, may cancel the registration or take such other action, including extension of applicable time periods, as may be necessary to enable reregistration of such pesticide by another person.

(B)(i) If—

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

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

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

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

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

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

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

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

(6) Suspensions and penalties

The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 136a(c)(2)(B)(iv) of this title if the Administrator determines that (A) progress is insufficient to ensure the submission of the data required for such pesticide under a commitment made under paragraph (3)(B) within the time period prescribed by paragraph (4)(B) or (B) the registrant has not submitted such data to the Administrator within such time period. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to sup-

port 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

¹ See References in Text note below.

date of publication of the listing of such active ingredient; and

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

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

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

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

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

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

tablished by the Administrator for submission of the data.

(3) Cancellation

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

(B)(i) If the registrant of a pesticide submits the information required by paragraph (1) within the time prescribed by paragraph (2) and such information does not conform to the guidelines for submissions established by the Administrator, the Administrator shall deter-

mine whether the registrant made a good faith attempt to conform its submission to such guidelines.

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

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

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

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

(4) Guidelines

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

- (i) summarizing studies;
- (ii) reformatting studies;
- (iii) identifying adverse information; and
- (iv) identifying studies that have been submitted previously that may not meet the requirements of section 136a of this title or regulations issued under such section,

under paragraph (1).

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

(5) Monitoring

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

(f) Phase four

(1) Independent review and identification of outstanding data requirements

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

(B) The Administrator shall independently identify and publish in the Federal Register the outstanding data requirements for each active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (c)(2) and that is contained in a pesticide to be rereg-

istered under this section. The Administrator, at the same time, shall issue a notice under section 136a(c)(2)(B) of this title for the submission of the additional data that are required to meet such requirements.

(2) Time periods

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

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

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

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

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

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

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

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

(iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 136a(c)(2)(B) of this title or other provisions

of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(3) Suspensions and penalties

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

cordance with section 136a(c)(2)(B)(iv) of this title regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(g) Phase five

(1) Data review

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

(2) Reregistration and other actions

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

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

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

(B) PRODUCT-SPECIFIC DATA.—

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

(ii) TIMING.—

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

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

(C) After conducting the review required by paragraph (1) for each active ingredient of a pesticide and the review required by subparagraph (B) of this paragraph, the Administrator

shall determine whether to reregister a pesticide by determining whether such pesticide meets the requirements of section 136a(c)(5) of this title. If the Administrator determines that a pesticide is eligible to be reregistered, the Administrator shall reregister such pesticide within 6 months after the submission of the data concerning such pesticide under subparagraph (B).

(D) DETERMINATION TO NOT REREGISTER.—

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

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

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

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

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

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

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

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

(h) Compensation of data submitter

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

(i) Fees

(1) Maintenance fee

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

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

significantly reduce the availability of the pesticide for the use.

(C) TOTAL AMOUNT OF FEES.—The amount of each fee prescribed under subparagraph (A) shall be adjusted by the Administrator to a level that will result in the collection under this paragraph of, to the extent practicable, an aggregate amount of \$27,800,000 for each of fiscal years 2013 through 2017.

(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 \$115,500 for each of fiscal years 2013 through 2017; and

(ii) a registrant holding over 50 registrations shall be \$184,800 for each of fiscal years 2013 through 2017.

(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 \$70,600 for each of fiscal years 2013 through 2017; and

(II) a registrant holding over 50 pesticide registrations shall be \$122,100 for each of fiscal years 2013 through 2017.

(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) 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.

(H) 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.

(I) The authority provided under this paragraph shall terminate on September 30, 2017.²

(2) Other fees

Except as provided in section 136w-8 of this title, during the period beginning on October 25, 1988, and ending on September 30, 2019, the Administrator may not levy any other fees for the registration of a pesticide under this subchapter 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 fund and shall be available to the Administrator, without fiscal year limitation, specifically 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. 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. 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 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;

(ii) prohibit the use of such moneys derived from fees to pay for any costs other than those 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; and

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

(B) The Administrator shall also—

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

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

(3) Review of inert ingredients; expedited processing of similar applications

(A) 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 $\frac{1}{6}$ and $\frac{1}{8}$, of the maintenance fees collected in such fiscal year to obtain sufficient personnel and resources—

(i) to review and evaluate inert ingredients; and

(ii) to ensure the expedited processing and review of any application that—

(I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that

² So in original.

would differ in composition and labeling from any such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment;

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

(III) proposes the initial or amended registration of an end use pesticide that, if registered as proposed, would be used for a public health pesticide.

(B) Any amounts made available under subparagraph (A) shall be used to obtain sufficient personnel and resources to carry out the activities described in such subparagraph that are in addition to the personnel and resources available to carry out such activities on October 25, 1988.

(C) So long as the Administrator has not met the time frames specified in clause (ii) of section 136a(c)(3)(B) of this title with respect to any application subject to section 136a(c)(3)(B) of this title that was received prior to August 3, 1996, the Administrator shall use the full amount of the fees specified in subparagraph (A) for the purposes specified therein. Once all applications subject to section 136a(c)(3)(B) of this title that were received prior to August 3, 1996, have been acted upon, no limitation shall be imposed by the preceding sentence of this subparagraph so long as the Administrator meets the time frames specified in clause (ii) of section 136a(c)(3)(B) of this title on 90 percent of affected applications in a fiscal year. Should the Administrator not meet such time frames in a fiscal year, the limitations imposed by the first sentence of this subparagraph shall apply until all overdue applications subject to section 136a(c)(3)(B) of this title have been acted upon.

(4) Enhancements of information technology systems for improvement in review of pesticide applications

(A) In general

For each of fiscal years 2013 through 2017, the Administrator shall use not more than \$800,000 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 from the Reregistration and Expedited Processing Fund to improve the information systems capabilities for the Office of Pesticide Programs to enhance tracking of pesticide registration decisions, which shall include—

- (i) the electronic tracking of—
 - (I) registration submissions; and
 - (II) the status of conditional registrations;
- (ii) enhancing the database for information regarding endangered species assessments for registration review;

- (iii) implementing the capability to electronically review labels submitted with registration actions; and

- (iv) acquiring and implementing the capability to electronically assess and evaluate confidential statements of formula submitted with registration actions.

(5) 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.

(6) 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), (3), and (4) and to carry out the goals established under subsection (l). The Reregistration and Expedited Processing Fund shall be designated as an Environmental Protection Agency component for purposes of section 3515(c) of title 31. The annual audit required under section 3521 of such title of the financial statements of activities under this subchapter under section 3515(b) of such title shall include an audit of the fees collected under subsection (i)(1)(C) and disbursed, of the amount appropriated to match such fees, and of the Administrator's attainment of performance measures and goals established under subsection (l). Such an audit shall also include a review of the reasonableness of the overhead allocation and adequacy of disclosures of direct and indirect costs associated with carrying out the reregistration and expedited processing of the applications specified in paragraph (3), and the basis for and accuracy of all costs paid with moneys derived from such fees. The Inspector General shall conduct the annual audit and report the findings and recommendations of such audit to the Administrator and to the Committees on Agriculture of the House of Representatives and the Senate. The cost of such audit shall be paid for out of the fees collected under subsection (i)(1)(C).

(l) Performance measures and goals

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

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

and (B) in the current fiscal year and the succeeding fiscal year; and

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

(m) Judicial review

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

(n) Authorization of funds to develop public health data

(1) "Secretary" defined

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

(2) Consultation

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

(3) Benefits to support family

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

(4) Additional time

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

(5) Arrangements

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

(6) Support

The Secretary may provide for support of the required studies using funds authorized to

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

(7) Authorization of appropriations

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

(June 25, 1947, ch. 125, § 4, formerly § 3A, as added and renumbered § 4, Pub. L. 100-532, title I, § 102(a), title VIII, § 801(q)(2)(A), Oct. 25, 1988, 102 Stat. 2655, 2683; amended Pub. L. 101-624, title XIV, § 1493, Nov. 28, 1990, 104 Stat. 3628; Pub. L. 102-237, title X, § 1006(a)(4), (e), (f), Dec. 13, 1991, 105 Stat. 1895-1897; Pub. L. 104-170, title I, § 103, title II, §§ 210(c)(2), (f)(1), 232, 237, title V, § 501, Aug. 3, 1996, 110 Stat. 1490, 1496, 1498, 1508, 1509, 1536; Pub. L. 107-73, title III, [(1)-(4)], Nov. 26, 2001, 115 Stat. 686; Pub. L. 108-7, div. K, title III, [(1)-(4)], Feb. 20, 2003, 117 Stat. 513; Pub. L. 108-199, div. G, title V, § 501(c), (d)(1), (e), Jan. 23, 2004, 118 Stat. 419, 422; Pub. L. 108-271, § 8(b), July 7, 2004, 118 Stat. 814; Pub. L. 110-94, § 4(a)-(d)(1), (e), Oct. 9, 2007, 121 Stat. 1001, 1002; Pub. L. 112-177, § 2(a)(1), (2)(A), (4), Sept. 28, 2012, 126 Stat. 1327, 1329.)

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, as amended, 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.

Subsection (i)(1)(C)(ii) of this section, referred to in subsec. (k)(6), 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, as amended, 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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Subsec. (k)(2)(A)(i). Pub. L. 112-177, §2(a)(4)(A)(ii), inserted "offset" before "the costs of reregistration" and struck out "in the same portion as appropriated funds" before semicolon at end.

Subsec. (k)(3)(A). Pub. L. 112-177, §2(a)(4)(B), in introductory provisions, substituted "2013 through 2017, between 1/8 and 1/4" for "2008 through 2012, between 1/8 and 1/4"; in cl. (i), struck out "new" before "inert"; and, in cl. (ii), substituted "any application that—" for "any application that—".

Subsec. (k)(4). Pub. L. 112-177, §2(a)(4)(C)(ii), added par. (4). Former par. (4) redesignated (5).

Subsec. (k)(5). Pub. L. 112-177, §2(a)(4)(C)(i), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Pub. L. 112-177, §2(a)(2)(A)(iii), substituted "subsection (i)(1)(C)(ii)" for "subsection (i)(5)(C)(ii)" and "subsection (i)(1)(C)" for "subsection (i)(5)(C)" in two places.

Subsec. (k)(6). Pub. L. 112-177, §2(a)(4)(C)(i), (iii), redesignated par. (5) as (6) and substituted "for the purposes described in paragraphs (2), (3), and (4) and to carry out the goals established under subsection (l)" for "to carry out the goals established under subsection (l)".

2007—Subsec. (i)(5)(C). Pub. L. 110-94, §4(a), which directed substitution of "amount of \$22,000,000 for each of

fiscal years 2008 through 2012" for "amount of" and all that follows through the end of clause (v), was executed by making the substitution for "amount of—

- "(i) for fiscal year 2004, \$26,000,000;
- "(ii) for fiscal year 2005, \$27,000,000;
- "(iii) for fiscal year 2006, \$27,000,000;
- "(iv) for fiscal year 2007, \$21,000,000; and
- "(v) for fiscal year 2008, \$15,000,000."

to reflect the probable intent of Congress. The words "amount of" appeared in the heading and twice in the text.

Subsec. (i)(5)(D)(i). Pub. L. 110-94, §4(b)(1)(A), substituted "shall be \$71,000 for each of fiscal years 2008 through 2012; and" for "shall be—

- "(I) for fiscal year 2004, \$84,000;
- "(II) for each of fiscal years 2005 and 2006, \$87,000;
- "(III) for fiscal year 2007, \$68,000; and
- "(IV) for fiscal year 2008, \$55,000; and".

Subsec. (i)(5)(D)(ii). Pub. L. 110-94, §4(b)(1)(B), substituted "shall be \$123,000 for each of fiscal years 2008 through 2012." for "shall be—

- "(I) for fiscal year 2004, \$145,000;
- "(II) for each of fiscal years 2005 and 2006, \$151,000;
- "(III) for fiscal year 2007, \$117,000; and
- "(IV) for fiscal year 2008, \$95,000."

Subsec. (i)(5)(E)(i)(I). Pub. L. 110-94, §4(b)(2)(A), substituted "shall be \$50,000 for each of fiscal years 2008 through 2012; and" for "shall be—

- "(aa) for fiscal year 2004, \$59,000;
- "(bb) for each of fiscal years 2005 and 2006, \$61,000;
- "(cc) for fiscal year 2007, \$48,000; and
- "(dd) for fiscal year 2008, \$38,500; and".

Subsec. (i)(5)(E)(i)(II). Pub. L. 110-94, §4(b)(2)(B), substituted "shall be \$86,000 for each of fiscal years 2008 through 2012." for "shall be—

- "(aa) for fiscal year 2004, \$102,000;
- "(bb) for each of fiscal years 2005 and 2006, \$106,000;
- "(cc) for fiscal year 2007, \$82,000; and
- "(dd) for fiscal year 2008, \$66,500."

Subsec. (i)(5)(H). Pub. L. 110-94, §4(c), substituted "2012." for "2008".

Subsec. (i)(6). Pub. L. 110-94, §4(d)(1), substituted "2014" for "2010".

Subsec. (k)(2)(A). Pub. L. 110-94, §4(e)(1), inserted "and to offset the costs of registration review under section 136a(g) of this title" after "paragraph (3)" wherever appearing.

Subsec. (k)(3)(A). Pub. L. 110-94, §4(e)(2), substituted "2008 through 2012" for "2007 and 2008".

2004—Subsec. (g)(2)(A). Pub. L. 108-199, §501(c)(5)(A), added subpar. (A) and struck out former subpar. (A) which read as follows: "Within 1 year after the submission of all data concerning an active ingredient of a pesticide under subsection (f) of this section, the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration. For extraordinary circumstances, the Administrator may extend such period for not more than 1 additional year."

Subsec. (g)(2)(B). Pub. L. 108-199, §501(c)(5)(B), inserted subpar. (B) and cl. (i) headings, designated first sentence of existing provisions as cl. (i), inserted cl. (ii) and subcl. (I) headings, designated second sentence of existing provisions as cl. (ii)(I), substituted "Subject to subclause (II), the Administrator" for "The Administrator" in subcl. (I), and added subcl. (II).

Subsec. (g)(2)(D). Pub. L. 108-199, §501(c)(5)(C), inserted subpar. (D) and cl. (i) headings, designated existing provisions as cl. (i), and added cl. (ii).

Subsec. (i)(5)(A). Pub. L. 108-199, §501(c)(1)(A), inserted subpar. (A) heading and substituted "for each registration" for "of—

- "(i) \$650 for the first registration; and
- "(ii) \$1,300 for each additional registration".

Subsec. (i)(5)(C). Pub. L. 108-199, §501(c)(2), struck out cl. (i) designation before "The amount of each", inserted subpar. (C) heading, substituted "aggregate amount of—" for "aggregate amount of \$21,500,000 for fiscal year 2003.", added cls. (i) to (v), and struck out former cl. (ii), which related to collection of additional fees in fiscal years 1998, 1999, and 2000.

Subsec. (i)(5)(D). Pub. L. 108-199, § 501(c)(1)(B), inserted subpar. (D) heading, substituted “shall be—” for “shall be \$55,000; and” and added subcls. (I) to (IV) in cl. (i), and substituted “shall be—” for “shall be \$95,000.” and added subcls. (I) to (IV) in cl. (ii).

Subsec. (i)(5)(E)(i). Pub. L. 108-199, § 501(c)(1)(C), inserted subpar. (E) and cl. (i) headings, realigned margins of subcls. (I) and (II), substituted “shall be—” for “shall be \$38,500; and” and inserted items (aa) to (dd) in subcl. (I), and substituted “shall be—” for “shall be \$66,500.” and inserted items (aa) to (dd) in subcl. (II).

Subsec. (i)(5)(E)(ii). Pub. L. 108-199, § 501(c)(3), inserted cl. (ii) heading, redesignated existing provisions as subcl. (I), inserted subcl. (I) heading, substituted “In” for “For purposes of” in subcl. (I), redesignated former subcls. (I) and (II) as items (aa) and (bb) respectively, and realigned margins, substituted “500” for “150” in item (aa), substituted “global gross revenue from pesticides that did not exceed \$60,000,000.” for “gross revenue from chemicals that did not exceed \$40,000,000.” in item (bb), and added subcl. (II).

Subsec. (i)(5)(H). Pub. L. 108-199, § 501(c)(4), substituted “2008” for “2003”.

Subsec. (i)(6). Pub. L. 108-199, § 501(d)(1), substituted “Except as provided in section 136w-8 of this title, during” for “During”, and substituted “2010” for “2003”.

Subsec. (k)(2)(A)(i). Pub. L. 108-271 substituted “Government Accountability Office” for “General Accounting Office”.

Subsec. (k)(3). Pub. L. 108-199, § 501(e)(1), substituted “Review of inert ingredients; expedited” for “Expedited” in par. heading.

Subsec. (k)(3)(A). Pub. L. 108-199, § 501(e)(2), substituted “2004 through 2006, approximately \$3,300,000, and for each of fiscal years 2007 and 2008, between ¼ and ½, of the maintenance fees” for “1997 through 2003, not more than ¼ of the maintenance fees”, substituted “resources” for “resources to assure the expedited processing and review of any application that”, added cl. (i), inserted cl. (ii) designation and introductory provisions, and redesignated former cls. (i) to (iii) as subcls. (I) to (III), respectively, of cl. (ii).

2003—Pub. L. 108-7, which directed the amendment of “Section 136a-1 of title 7, U.S.C.”, was executed by making the amendments to this section, which is section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress. See below.

Subsec. (i)(5)(C)(i). Pub. L. 108-7, [(1)], substituted “\$21,500,000 for fiscal year 2003” for “\$17,000,000 fiscal year 2002”.

Subsec. (i)(5)(H). Pub. L. 108-7, [(2)], substituted “2003” for “2002”.

Subsec. (i)(6). Pub. L. 108-7, [(3)], substituted “2003” for “2002”.

Subsec. (k)(3)(A). Pub. L. 108-7, [(4)], substituted “2003” for “2002”.

2001—Pub. L. 107-73, which directed the amendment of “Section 136a-1 of title 7, U.S.C.”, was executed by making the amendments to this section, which is section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress. See below.

Subsec. (i)(5)(C)(i). Pub. L. 107-73, [(1)], substituted “\$17,000,000” for “\$14,000,000” and “fiscal year 2002” for “each fiscal year”.

Subsec. (i)(5)(H). Pub. L. 107-73, [(2)], substituted “2002” for “2001”.

Subsec. (i)(6). Pub. L. 107-73, [(3)], substituted “2002” for “2001”.

Subsec. (k)(3)(A). Pub. L. 107-73, [(4)], substituted “2002” for “2001” and “¼” for “½” in introductory provisions.

1996—Pub. L. 104-170, § 501, which directed amendment of section 4 without specifying the name of the Act being amended, was executed to this section, which is section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress.

Subsec. (d)(4)(B). Pub. L. 104-170, § 210(c)(2), inserted at end provisions authorizing extension of deadline for

production of residue chemistry data in case of minor use and setting forth conditions to be met for such extension in cls. (i) to (iv).

Subsec. (d)(6). Pub. L. 104-170, § 210(f)(1)(A), inserted at end provisions delaying upon written request action with regard to unsupported minor uses, authorizing refusal of request where there are health or environmental concerns, authorizing publication of notice in Federal Register and monitoring of development of data, setting forth procedures where registrant is not meeting or has not met schedule for production of data, and authorizing denial, modification, or revocation of temporary extension where use may cause adverse effect on environment and requiring notice of such revocation to registrant.

Subsec. (e)(2)(B). Pub. L. 104-170, § 210(c)(2), inserted at end provisions authorizing extension of deadline for production of residue chemistry data in case of minor use and setting forth conditions to be met for such extension in cls. (i) to (iv).

Subsec. (e)(3)(A). Pub. L. 104-170, § 210(f)(1)(B), inserted at end provisions delaying upon written request action with regard to unsupported minor uses, authorizing refusal of request where there are health or environmental concerns, authorizing publication of notice in Federal Register and monitoring of development of data, setting forth procedures where registrant is not meeting or has not met schedule for production of data, and authorizing denial, modification, or revocation of temporary extension where use may cause adverse effect on environment and requiring notice of such revocation to registrant.

Subsec. (f)(2)(B). Pub. L. 104-170, § 210(c)(2), inserted at end provisions authorizing extension of deadline for production of residue chemistry data in case of minor use and setting forth conditions to be met for such extension in cls. (i) to (iv).

Subsec. (f)(3). Pub. L. 104-170, § 210(f)(1)(A), inserted at end provisions delaying upon written request action with regard to unsupported minor uses, authorizing refusal of request where there are health or environmental concerns, authorizing publication of notice in Federal Register and monitoring of development of data, setting forth procedures where registrant is not meeting or has not met schedule for production of data, and authorizing denial, modification, or revocation of temporary extension where use may cause adverse effect on environment and requiring notice of such revocation to registrant.

Subsec. (g)(2)(E). Pub. L. 104-170, § 103, added subpar. (E).

Subsec. (i)(4)(B) to (D). Pub. L. 104-170, § 232(1), added subpar. (B) and redesignated former subpars. (B) and (C) as (C) and (D), respectively.

Subsec. (i)(5)(C). Pub. L. 104-170, § 501(a)(2), designated existing provisions as cl. (i) and added cl. (ii).

Subsec. (i)(5)(F), (G). Pub. L. 104-170, § 232(2), added subpar. (F) and redesignated former subpar. (F) as (G).

Subsec. (i)(5)(H). Pub. L. 104-170, § 501(a)(1), substituted “2001” for “1997”.

Pub. L. 104-170, § 232(2), redesignated subpar. (G) as (H).

Subsec. (i)(6). Pub. L. 104-170, § 501(a)(1), substituted “2001” for “1997”.

Subsec. (i)(7)(B). Pub. L. 104-170, § 232(3), substituted “, to determine the registrant’s eligibility” for “or to determine the registrant’s eligibility” and inserted before period at end “, or to determine the volume usage for public health pesticides”.

Subsec. (k)(1). Pub. L. 104-170, § 501(b), inserted “which shall be known as the Reregistration and Expedited Processing Fund” before period at end.

Subsec. (k)(2). Pub. L. 104-170, § 501(c), amended heading and text of par. (2) generally. Prior to amendment, text read as follows: “All fees collected by the Administrator under subsection (i) of this section shall be deposited into the fund and shall be available to the Administrator, without fiscal year limitation, to carry out reregistration and expedited processing of similar applications.”

Subsec. (k)(3)(A). Pub. L. 104-170, § 501(d)(1), which directed the amendment of introductory provisions by substituting “for each of the fiscal years 1997 through 2001, not more than ¼ of the maintenance fees collected in such fiscal year” for “for each of the fiscal years 1992, 1993, and 1994, ¼th of the maintenance fees collected, up to 2 million each year”, was executed by making the substitution for text which contained the phrase “\$2 million”, to reflect the probable intent of Congress.

Subsec. (k)(3)(A)(iii). Pub. L. 104-170, § 232(4), added cl. (iii).

Subsec. (k)(3)(C). Pub. L. 104-170, § 501(d)(2), added subpar. (C).

Subsec. (k)(5). Pub. L. 104-170, § 501(e), amended heading and text of par. (5) generally. Prior to amendment, text read as follows: “The Administrator shall—

“(A) provide an annual accounting of the fees collected and disbursed from the fund; and

“(B) take all steps necessary to ensure that expenditures from such fund are used only to carry out this section.”

Subsec. (l). Pub. L. 104-170, § 501(f), added subsec. (l). Former subsec. (l) redesignated (m).

Subsec. (m). Pub. L. 104-170, § 501(f), redesignated subsec. (l) as (m). Former subsec. (m) redesignated (n).

Pub. L. 104-170, § 237, added subsec. (m).

Subsec. (n). Pub. L. 104-170, § 501(f), redesignated subsec. (m) as (n).

1991—Subsec. (f)(3). Pub. L. 102-237, § 1006(a)(4), realigned margin.

Subsec. (i)(5). Pub. L. 102-237, § 1006(e), amended par. (5) generally, substituting, in subpar. (A), provisions relating to January 15 for provisions relating to March 1, in subpar. (A)(i), provisions relating to fee of \$650 for first registration for provisions relating to fee of \$425 for each registration for registrants holding not more than 50 registrations, and in subpar. (A)(ii), provisions relating to fee of \$1,300 for each additional registration up to 200 registrations, with no fee thereafter, for provisions relating to fee of \$425 for each registration up to 50, \$100 for each registration over 50, with no fee after 200 registrations, redesignating provisions formerly set out in subpar. (A), following cl. (ii), as subpar. (B), and substituting provisions relating to fee under this par. for provisions relating to fee under this subpar., redesignating former subpar. (B) as (C), striking former subpar. (C), which set maximum annual fee for registrants under subpar. (A)(i) at \$20,000, and for registrants under subpar. (A)(ii) at \$35,000, adding subpars. (D) and (E), and redesignating former subpars. (D) and (E) as (F) and (G), respectively.

Subsec. (k)(3)(A). Pub. L. 102-237, § 1006(f), substituted “for each of the fiscal years 1992, 1993, and 1994, ¼th 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.

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.

RELATIONSHIP OF PUB. L. 112-177 TO OTHER LAW

Pub. L. 112-177, § 2(d), Sept. 28, 2012, 126 Stat. 1407, provided that: “In the case of any conflict between this section [amending this section, section 136w-8 of this title, and section 346a of Title 21, Food and Drugs, and enacting provisions set out as a note under this section] (including the amendments made by this section) and a joint resolution making continuing appropriations for fiscal year 2013 (including any amendments made by such a joint resolution), this section and the amendments made by this section shall control.”

ADJUSTMENT OF MAXIMUM ANNUAL FEE PAYABLE BY PESTICIDE REGISTRANTS

Pub. L. 108-11, title II, Apr. 16, 2003, 117 Stat. 603, provided that: “Within 30 days of enactment of this Act [Apr. 16, 2003], the Administrator of the Environmental Protection Agency shall adjust each ‘maximum annual fee payable’ pursuant to 7 U.S.C. 136a-1(i)(5)(D) and (E) in a manner such that maintenance fee collections made to reach the level authorized in division K of Public Law 108-7 [see Tables for classification] shall be established in the same proportion as those maintenance fee collections authorized in Public Law 107-73 [see Tables for classification].”

§ 136b. Transferred

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. 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, 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.