

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 this section 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 this section 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) of this section.
- (4) The fourth phase shall include an independent, initial review by the Administrator under subsection (f) of this section 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 this section 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) of this section, 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) of this section 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) of this section 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) of this section 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) of this section 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) of this section 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) of this section, 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) of this section, 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) of this section, 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) of this section 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) of this section 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 subsection (i)(1) of 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 pes-

ticide 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) of this section who has submitted a notice under subsection (d)(2) of this section 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 sub-chronic 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)<sup>1</sup> 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) of this section, 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) of this section, 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) of this section, 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

<sup>1</sup> See References in Text note below.

registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

**(3) Cancellation**

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

(B)(i) If the registrant of a pesticide submits the information required by paragraph (1) within the time prescribed by paragraph (2)

and such information does not conform to the guidelines for submissions established by the Administrator, the Administrator shall determine whether the registrant made a good faith attempt to conform its submission to such guidelines.

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

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

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

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

**(4) Guidelines**

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

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

under paragraph (1).

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

**(5) Monitoring**

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

**(f) Phase four**

**(1) Independent review and identification of outstanding data requirements**

(A) The Administrator shall review the submissions of all registrants of pesticides containing a particular active ingredient under subsections (d)(3) and (e)(1) of this section 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) of this section.

(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) of this section 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) of this section, 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) of this section, 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) of this section, not later than 33 months after the date of the listing of such active ingredient.

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

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

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

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

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

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

**(3) Suspensions and penalties**

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

supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 136a(c)(2)(B)(iv) of this title regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

**(g) Phase five**

**(1) Data review**

The Administrator shall conduct a thorough examination of all data submitted under this section concerning an active ingredient listed under subsection (c)(2) of this section 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) of this section 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)<sup>2</sup> 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) Initial fee for food or feed use pesticide active ingredients**

The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (c)(2) of this section and that is an active ingredient of any

<sup>2</sup> See References in Text note below.

pesticide registered for a major food or feed use shall collectively pay a fee of \$50,000 on submission of information under paragraphs (2) and (3) of subsection (d) of this section for such ingredient.

**(2) Final fee for food or feed use pesticide active ingredients**

(A) The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (c)(2) of this section and that is an active ingredient of any pesticide registered for a major food or feed use shall collectively pay a fee of \$100,000—

(i) on submission of information for such ingredient under subsection (e)(1) of this section if data are reformatted under subsection (e)(1)(C) of this section; or

(ii) on submission of data for such ingredient under subsection (e)(2)(B) of this section if data are not reformatted under subsection (e)(1)(C) of this section.

(B) The registrants of pesticides that contain an active ingredient that is listed under subsection (c)(2)(A) of this section and that is an active ingredient of any pesticide registered for a major food or feed use shall collectively pay a fee of \$150,000 at such time as the Administrator shall prescribe.

**(3) Fees for other pesticide active ingredients**

(A) The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (c)(2) of this section and that is not an active ingredient of any pesticide registered for a major food or feed use shall collectively pay fees in amounts determined by the Administrator. Such fees may not be less than one-half of, nor greater than, the fees required by paragraphs (1) and (2). A registrant shall pay such fees at the times corresponding to the times fees prescribed by paragraphs (1) and (2) are to be paid.

(B) The registrants of pesticides that contain an active ingredient that is listed under subsection (c)(2)(A) of this section and that is not an active ingredient of any pesticide that is registered for a major food or feed use shall collectively pay a fee of not more than \$100,000 and not less than \$50,000 at such time as the Administrator shall prescribe.

**(4) Reduction or waiver of fees for minor use and other pesticides**

(A) An active ingredient that is contained only in pesticides that are registered solely for agricultural or nonagricultural minor uses, or a pesticide the value or volume of use of which is small, shall be exempt from the fees prescribed by paragraph (3).

(B) The Administrator shall exempt any public health pesticide from the payment of the fee prescribed under paragraph (3) 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.

(C) An antimicrobial active ingredient, the production level of which does not exceed 1,000,000 pounds per year, shall be exempt from the fees prescribed by paragraph (3). For purposes of this subparagraph, the term “antimicrobial active ingredient” means any active ingredient that is contained only in pesticides that are not registered for any food or feed use and that are—

(i) sanitizers intended to reduce the number of living bacteria or viable virus particles on inanimate surface or in water or air;

(ii) bacteriostats intended to inhibit the growth of bacteria in the presence of moisture;

(iii) disinfectants intended to destroy or irreversibly inactivate bacteria, fungi, or viruses on surfaces or inanimate objects;

(iv) sterilizers intended to destroy viruses and all living bacteria, fungi, and their spores on inanimate surfaces; or

(v) fungicides or fungistats.

(D)(i) Notwithstanding any other provision of this subsection, in the case of a small business registrant of a pesticide, the registrant shall pay a fee for the reregistration of each active ingredient of the pesticide that does not exceed an amount determined in accordance with this subparagraph.

(ii) If during the 3-year period prior to reregistration the average annual gross revenue of the registrant from pesticides containing such active ingredient is—

(I) less than \$5,000,000, the registrant shall pay 0.5 percent of such revenue;

(II) \$5,000,000 or more but less than \$10,000,000, the registrant shall pay 1 percent of such revenue; or

(III) \$10,000,000 or more, the registrant shall pay 1.5 percent of such revenue, but not more than \$150,000.

(iii) For the purpose of this subparagraph, a small business registrant is a corporation, partnership, or unincorporated business that—

(I) has 150 or fewer employees; and

(II) during the 3-year period prior to reregistration, had an average annual gross revenue from chemicals that did not exceed \$40,000,000.

**(5) 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 \$22,000,000 for each of fiscal years 2008 through 2012<sup>3</sup>

(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 \$71,000 for each of fiscal years 2008 through 2012; and

(ii) a registrant holding over 50 registrations shall be \$123,000 for each of fiscal years 2008 through 2012.

(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 \$50,000 for each of fiscal years 2008 through 2012; and

(II) a registrant holding over 50 pesticide registrations shall be \$86,000 for each of fiscal years 2008 through 2012.

(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) The Administrator shall exempt any public health pesticide from the payment of the fee prescribed under paragraph (3) if, in consultation with the Secretary of Health and Humans<sup>4</sup> 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.

(G) If any fee prescribed by this paragraph with respect to the registration of a pesticide is not paid by a registrant by the time pre-

scribed, the Administrator, by order and without hearing, may cancel the registration.

(H) The authority provided under this paragraph shall terminate on September 30, 2012..<sup>5</sup>

#### (6) 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, 2014, the Administrator may not levy any other fees for the registration of a pesticide under this subchapter except as provided in paragraphs (1) through (5).

#### (7) Apportionment

(A) If two or more registrants are required to pay any fee prescribed by paragraph (1), (2), or (3) with respect to a particular active ingredient, the fees for such active ingredient shall be apportioned among such registrants on the basis of the market share in United States sales of the active ingredient for the 3 calendar years preceding the date of payment of such fee, except that—

(i) small business registrants that produce the active ingredient shall pay fees in accordance with paragraph (4)(C); and

(ii) registrants who have no market share but who choose to reregister a pesticide containing such active ingredient shall pay the lesser of—

(I) 15 percent of the reregistration fee; or

(II) a proportionate amount of such fee based on the lowest percentage market share held by any registrant active in the marketplace.

In no event shall registrants who have no market share but who choose to reregister a pesticide containing such active ingredient collectively pay more than 25 percent of the total active ingredient reregistration fee.

(B) The Administrator, by order, may require any registrant to submit such reports as the Administrator determines to be necessary to allow the Administrator to determine and apportion fees under this subsection, to determine the registrant's eligibility for a reduction or waiver of a fee, or to determine the volume usage for public health pesticides.

(C) If any such report is not submitted by a registrant after receiving notice of such report requirement, or if any fee prescribed by this subsection (other than paragraph (5)) for an active ingredient is not paid by a registrant to the Administrator by the time prescribed under this subsection, the Administrator, by order and without hearing, may cancel each registration held by such registrant of a pesticide containing the active ingredient with respect to which the fee is imposed. The Administrator shall reapportion the fee among the remaining registrants and notify the registrants that the registrants are required to pay to the Administrator any unpaid balance of the fee within 30 days after receipt of such notice.

#### (j) Exemption of certain registrants

The requirements of subsections (d), (e), (f), and (i) of this section (other than subsection

<sup>3</sup> So in original. Probably should be followed by a period.

<sup>4</sup> So in original. Probably should be “Human”.

<sup>5</sup> So in original.

(i)(5) of this section) 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) of this section 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) 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 the costs of reregistration and expedited processing of the applications specified in paragraph (3) and to offset the costs of registration review under section 136a(g) of this title in the same portion as appropriated funds;

(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) 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) of this section; 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 2008 through 2012, between  $\frac{1}{8}$  and  $\frac{1}{7}$ , of the maintenance fees collected in such fiscal year to obtain sufficient personnel and resources—

(i) to review and evaluate new 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 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) 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.

**(5) Accounting and performance**

The Administrator shall take all steps necessary to ensure that expenditures from fees authorized by subsection (i)(5)(C)(ii)<sup>6</sup> of this section are used only to carry out the goals established under subsection (l) of this section. 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)(5)(C) of this section 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) of this section. 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)(5)(C) of this section.

**(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) of this section 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) of this section 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) of this section, 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.

<sup>6</sup> See References in Text note below.

(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.)

## 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)(5)(C)(ii) of this section, referred to in subsec. (k)(5), was repealed and a new subsec. (i)(5)(C)(ii) was added by Pub. L. 108-199, div. G, title V, § 501(c)(2), Jan. 23, 2004, 118 Stat. 420.

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

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  $\frac{1}{8}$  and  $\frac{1}{7}$ , 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 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 " $\frac{1}{10}$ " for " $\frac{1}{4}$ " 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  $\frac{1}{2}$  of the maintenance fees collected in such fiscal year" for "for each of the fiscal years 1992, 1993, and 1994,  $\frac{1}{7}$ 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), 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, ½th 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 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.

#### 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 pes-

ticides 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.

#### (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