PUBLIC LAW 110-94-OCT. 9, 2007

PESTICIDE REGISTRATION IMPROVEMENT RENEWAL ACT

Public Law 110–94 110th Congress

An Act

Oct. 9, 2007 [S. 1983]

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to renew and amend the provisions for the enhanced review of covered pesticide products, to authorize fees for certain pesticide products, to extend and improve the collection of maintenance fees, and for other purposes.

Pesticide Registration Improvement Renewal Act. 7 USC 136 note.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pesticide Registration Improvement Renewal Act".

SEC. 2. REVIEW OF APPLICATIONS.

Section 3(c)(3)(B)(ii) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(c)(3)(B)(ii)) is amended-

(1) in subparagraph (I), by striking "within 45 days" and all that follows through "and," and inserting "review the application in accordance with section 33(f)(4)(B) and,"; and (2) in subparagraph (II), by striking "within" and inserting "not later than the applicable decision review time established

pursuant to section 33(f)(4)(B), or, if no review time is established, not later than".

SEC. 3. REGISTRATION REVIEW.

Section 3(g)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(g)(1)) is amended—

(1) in subparagraph (A)-

(A) in the first sentence, by striking "The registrations" and inserting the following:

"(i) IN GENERAL.—The registrations"; (B) in the second sentence, by striking "The Administrator" and inserting the following:

"(ii) REGULATIONS.—In accordance with this subparagraph, the Administrator"; and

(C) by striking "The goal" and all that follows through

"No registration" and inserting the following:

"(iii) INITIAL REGISTRATION REVIEW.—The Administrator shall complete the registration review of each pesticide or pesticide case, which may be composed of 1 or more active ingredients and the products associated with the active ingredients, not later than the later of-

"(I) October 1, 2022; or "(II) the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered.

Deadline.

- "(iv) Subsequent registration review.—Not later Deadline. than 15 years after the date on which the initial registration review is completed under clause (iii) and each 15 years thereafter, the Administrator shall complete a subsequent registration review for each pesticide or pesticide
- case.
 "(v) CANCELLATION.—No registration"; (2) by redesignating subparagraph (B) as subparagraph
 - (3) by inserting after subparagraph (A) the following:
 - "(B) DOCKETING.-
 - "(i) IN GENERAL.—Subject to clause (ii), after meeting with 1 or more individuals that are not government employees to discuss matters relating to a registration review, the Administrator shall place in the docket minutes of the meeting, a list of attendees, and any documents exchanged at the meeting, not later than the earlier of—

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

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

"(ii) PROTECTED INFORMATION.—The Administrator shall identify, but not include in the docket, any confidential business information the disclosure of which is prohibited by section 10.".

SEC. 4. MAINTENANCE FEES.

(a) Total Amount of Fees.—Section 4(i)(5)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a-1(i)(5)(C)) is amended by striking "amount of" and all that follows through the end of clause (v) and inserting "amount of \$22,000,000 for each of fiscal years 2008 through 2012".

(b) Amounts for Registrants.—Section 4(i)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a–1(i)(5)

is amended-

(1) in subparagraph (D)—

(A) in clause (i), by striking by striking "shall be" and all that follows through the end of subclause (IV) and inserting "shall be \$71,000 for each of fiscal years 2008 through 2012; and"; and

(B) in clause (ii), by striking "shall be" and all that follows through the end of subclause (IV) and inserting "shall be \$123,000 for each of fiscal years 2008 through 2012."; and

(2) in subparagraph (E)(i)-

(A) in subclause (I), by striking "shall be" and all that follows through the end of item (dd) and inserting "shall be \$50,000 for each of fiscal years 2008 through 2012; and"; and

(B) in subclause (II), by striking "shall be" and all that follows through the end of item (dd) and inserting "shall be \$86,000 for each of fiscal years 2008 through 2012.".

(c) Extension of Authority for Collecting Maintenance FEES.—Section 4(i)(5)(H) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a-1(i)(5)(H) is amended by striking "2008" and inserting "2012."

Deadline.

(d) Other Fees.—

(1) IN GENERAL.—Section 4(i)(6) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a–1(i)(6)) is amended by striking "2010" and inserting "2014".

(2) PROHIBITION ON TOLERANCE FEES.—Section 408(m) of

the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(m))

is amended by adding at the end the following:

"(3) PROHIBITION.—During the period beginning on the effective date of the Pesticide Registration Improvement Renewal Act and ending on September 30, 2012, the Administrator shall not collect any tolerance fees under paragraph (1).". (e) Reregistration and Expedited Processing Fund.–

- (1) Source and use.—Section 4(k)(2)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a-1(k)(2)(A)) is amended—
 - (A) in the first sentence, by inserting "and to offset the costs of registration review under section 3(g)" after "paragraph (3)"
 - (B) in clause (i), by inserting "and to offset the costs of registration review under section 3(g)" after "paragraph (3)"; and
 - (C) in clause (ii), by inserting "and to offset the costs of registration review under section 3(g)" after "paragraph
- (2) EXPEDITED PROCESSING OF SIMILAR APPLICATIONS.—Section 4(k)(3)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a–1(k)(3)(A)) is amended by striking "2007 and 2008" and inserting "2008 through 2012".

SEC. 5. PESTICIDE REGISTRATION SERVICE FEES.

- (a) DOCUMENTATION.—Section 33(b)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w-8(b)(2)) is amended
 - (1) in subparagraph (C), by striking clause (ii) and inserting
 - the following:

 "(ii) payment of at least 25 percent of the registra
 "or a waiver from or tion service fee and a request for a waiver from or reduction of the remaining amount of the registration service fee."; and
 (2) by adding at the end the following:

- "(D) PAYMENT.—The registration service fee required under this subsection shall be due upon submission of the application.
- "(E) APPLICATIONS SUBJECT TO ADDITIONAL FEES.—An application may be subject to additional fees if-
 - "(i) the applicant identified the incorrect registration service fee and decision review period;
 - "(ii) after review of a waiver request, the Adminis-

trator denies the waiver request; or

- "(iii) after review of the application, the Administrator determines that a different registration service fee and decision review period apply to the application.
- "(F) Effect of failure to pay fees.—The Administrator shall reject any application submitted without the required registration service fee.
 - "(G) NON-REFUNDABLE PORTION OF FEES.—

Effective date. Termination date.

Deadline.

"(i) IN GENERAL.—The Administrator shall retain 25 percent of the applicable registration service fee.

"(ii) LIMITATION.—Any waiver, refund, credit or other reduction in the registration service fee shall not exceed 75 percent of the registration service fee.

"(H) COLLECTION OF UNPAID FEES.—In any case in which the Administrator does not receive payment of a registration service fee (or applicable portion of the registration service fee) by the date that is 30 days after the fee is due, the fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.".

(b) Amount of Fees.—Section 33(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w-8(b)) is amended-

(1) in paragraph (3)-

(A) in subparagraph (A), by striking "Pesticide Registration Improvement Act of 2003" and inserting "Pesticide

Registration Improvement Renewal Act"; and

(B) in subparagraph (B), by striking "S11631" and all that follows through the end of the subparagraph and inserting "S10409 through S10411, dated July 31, 2007.";

(2) by striking paragraph (6) and inserting the following:

"(6) FEE ADJUSTMENT.-

"(A) IN GENERAL.—Effective for a covered pesticide registration application received during the period beginning on October 1, 2008, and ending on September 30, 2010, the Administrator shall increase by 5 percent the registration service fee payable for the application under paragraph

"(B) Additional adjustment.—Effective for a covered pesticide registration application received on or after October 1, 2010, the Administrator shall increase by an additional 5 percent the registration service fee in effect as of September 30, 2010.

"(C) PUBLICATION.—The Administrator shall publish in the Federal Register the revised registration service

fee schedules.".

(c) Waivers and Reductions.—Section 33(b)(7)(F) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w-8(b)(7)(F)) is amended—

(1) in clause (ii), by striking "all" and inserting "75 percent"; and

(2) in clause (iv)(II), by striking "all" and inserting "75 percent of the applicable."

(d) Refunds.—Section 33(b)(8)(A) of the Federal Insecticide,

Fungicide, and Rodenticide Act (7 U.S.C. 136w–8(b)(8)(A)) is amended by striking "10 percent" and inserting "25 percent.".

(e) Pesticide Registration Fund.—Section 33(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w–8(c)) is amended-

(1) in paragraph (1)(B), by striking "paragraph (4)" and inserting "paragraph (5)";

(2) in paragraph (3)–

(A) by striking subparagraph (B) and inserting the following:

"(B) WORKER PROTECTION.—

Effective date.

Effective date.

Termination

Federal Register, publication.

- "(i) IN GENERAL.—For each of fiscal years 2008 through 2012, the Administrator shall use approximately $\frac{1}{17}$ of the amount in the Fund (but not less than \$1,000,000) to enhance scientific and regulatory activities relating to worker protection.
- "(ii) PARTNERSHIP GRANTS.—Of the amounts in the Fund, the Administrator shall use for partnership grants—
 - "(I) for each of fiscal years 2008 and 2009, \$750,000; and
 - "(II) for each of fiscal years 2010 through 2012, \$500,000.
- "(iii) PESTICIDE SAFETY EDUCATION PROGRAM.—Of the amounts in the Fund, the Administrator shall use \$500,000 for each of fiscal years 2008 through 2012 to carry out the pesticide safety education program."; and
- (B) by striking subparagraph (C); and

(3) in paragraph $(\bar{5})$ —

- (A) by redesignating subparagraphs (A) through (C) as clauses (i) through (iii), respectively;
 - (B) by striking "Amounts" and inserting the following:

"(A) IN GENERAL.—Amounts"; and

(C) by adding at the end the following:

- "(B) USE OF INVESTMENT INCOME.—After consultation with the Secretary of the Treasury, the Administrator may use income from investments described in clauses (ii) and (iii) of subparagraph (A) to carry out this section.".
- (f) ASSESSMENT OF FEES.—Section 33(d)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w-8(d)(2)) is amended by striking "For fiscal years 2004, 2005 and 2006 only, registration" and inserting "Registration".
- (g) Decision Review Times.—Section 33(f) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w–8(f)) is amended—
 - (1) in paragraph (1), by striking "Pesticide Registration Improvement Act of 2003" and inserting "Pesticide Registration Improvement Renewal Act":
 - Improvement Renewal Act";
 (2) in paragraph (2), by striking "S11631" and all that follows through the end of the paragraph and inserting "S10409 through S10411, dated July 31, 2007."; and
 - (3) in paragraph (4), by striking subparagraph (B) and inserting the following:

"(B) COMPLETENESS OF APPLICATION.—

- "(i) IN GENERAL.—Not later than 21 days after receiving an application and the required registration service fee, the Administrator shall conduct an initial screening of the contents of the application in accordance with clause (iii).
- "(ii) REJECTION.—If the Administrator determines under clause (i) that the application does not pass the initial screening and cannot be corrected within the 21-day period, the Administrator shall reject the application not later than 10 days after making the determination.

Deadlines.

"(iii) REQUIREMENTS OF SCREENING.—In conducting an initial screening of an application, the Administrator shall determine whether-

"(I)(aa) the applicable registration service fee

has been paid; or

"(bb) at least 25 percent of the applicable registration service fee has been paid and the application contains a waiver or refund request for the outstanding amount and documentation establishing the basis for the waiver request; and

"(II) the application contains all the necessary forms, data, and draft labeling, formatted in accordance with guidance published by the

Administrator.".

- (h) REPORTS.—Section 33(k) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w-8(k)) is amended-
 - (1) in paragraph (1), by striking "March 1, 2009" and inserting "March 1, 2014"; and (2) in paragraph (2)—

(A) in subparagraph (A)—

(i) by redesignating clauses (ii) through and (iv) as clauses (v) through (vii), respectively;

(ii) by inserting after clause (i) the following:

"(ii) the number of label amendments that have

been reviewed using electronic means;

- "(iii) the amount of money from the Reregistration and Expedited Processing Fund used to carry out inert ingredient review and review of similar applications under section 4(k)(3);
- '(iv) the number of applications completed for identical or substantially similar applications under section 3(c)(3)(B), including the number of such applications completed within 90 days pursuant to that section;"; and
 - (iii) in clause (vi) (as redesignated by clause (i))— (I) in subclause (II), by striking "and" at the end;
 - (II) in subclause (III), by striking "and" at the end; and

(III) by adding at the end the following:

- "(IV) providing for electronic submission and review of labels, including process improvements to further enhance the procedures used in electronic label review; and
- "(V) the allowance and use of summaries of acute toxicity studies; and";
- (B) in subparagraph (B), by striking "and" at the end; (C) in subparagraph (C), by striking the period at

the end and inserting a semicolon; and

(D) by adding at the end the following:

- "(D) a review of the progress in carrying out section 3(g), including-
 - "(i) the number of pesticides or pesticide cases reviewed:
 - "(ii) a description of the staffing and resources relating to the costs associated with the review and

decision making relating to reregistration and registration review for compliance with the deadlines specified

"(iii) to the extent determined appropriate by the Administrator and consistent with the authorities of the Administrator and limitations on delegation of functions by the Administrator, recommendations for-

"(I) process improvements in the handling of

registration review under section 3(g);

"(II) providing for accreditation of outside reviewers and the use of outside reviewers in the registration review process; and

"(III) streamlining the registration review

process, consistent with section 3(g);

"(E) a review of the progress in meeting the timeline requirements for the review of antimicrobial pesticide products under section 3(h); and

"(F) a review of the progress in carrying out the review of inert ingredients, including the number of applications pending, the number of new applications, the number of applications reviewed, staffing, and resources devoted to the review of inert ingredients and recommendations to improve the timeliness of review of inert ingredients.".

(i) TERMINATION OF EFFECTIVENESS.—Section 33(m) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w-

8(m)) is amended-

(1) in paragraph (1), by striking "2008" and inserting "2012"; and

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) in the subparagraph heading, by striking "2009" and inserting "2013"; and
(ii) by striking "2009" and inserting "2013"; and

(B) in subparagraphs (B) and (C)-

(i) in the subparagraph headings, by striking "2010"

each place it appears and inserting "2014"; and
(ii) by striking "2010" each place it appears and inserting "2014"; and

(C) in subparagraph (D), by striking "2008" each place it appears and inserting "2012".

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SEC. 6. EFFECTIVE DATE.

7 USC 136a note.

This Act and the amendments made by this Act take effect on October 1, 2007.

Approved October 9, 2007.