

110TH CONGRESS  
1ST SESSION

# 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.

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IN THE SENATE OF THE UNITED STATES

AUGUST 2, 2007

Mr. HARKIN (for himself and Mr. CHAMBLISS) introduced the following bill;  
which was read twice, considered, read the third time, and passed

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## A BILL

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.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pesticide Registration  
5 Improvement Renewal Act”.

1 **SEC. 2. REVIEW OF APPLICATIONS.**

2 Section 3(c)(3)(B)(ii) of the Federal Insecticide,  
3 Fungicide, and Rodenticide Act (7 U.S.C.  
4 136a(c)(3)(B)(ii)) is amended—

5 (1) in subparagraph (I), by striking “within 45  
6 days” and all that follows through “and,” and in-  
7 serting “review the application in accordance with  
8 section 33(f)(4)(B) and,”; and

9 (2) in subparagraph (II), by striking “within”  
10 and inserting “not later than the applicable decision  
11 review time established pursuant to section  
12 33(f)(4)(B), or, if no review time is established, not  
13 later than”.

14 **SEC. 3. REGISTRATION REVIEW.**

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

17 (1) in subparagraph (A)—

18 (A) in the first sentence, by striking “The  
19 registrations” and inserting the following:

20 “(i) IN GENERAL.—The registrations”;

21 (B) in the second sentence, by striking  
22 “The Administrator” and inserting the fol-  
23 lowing:

24 “(ii) REGULATIONS.—In accordance with  
25 this subparagraph, the Administrator”; and

1 (C) by striking “The goal” and all that fol-  
2 lows through “No registration” and inserting  
3 the following:

4 “(iii) INITIAL REGISTRATION REVIEW.—  
5 The Administrator shall complete the registra-  
6 tion review of each pesticide or pesticide case,  
7 which may be composed of 1 or more active in-  
8 gredients and the products associated with the  
9 active ingredients, not later than the later of—

10 “(I) October 1, 2022; or

11 “(II) the date that is 15 years after  
12 the date on which the first pesticide con-  
13 taining a new active ingredient is reg-  
14 istered.

15 “(iv) SUBSEQUENT REGISTRATION RE-  
16 VIEW.—Not later than 15 years after the date  
17 on which the initial registration review is com-  
18 pleted under clause (iii) and each 15 years  
19 thereafter, the Administrator shall complete a  
20 subsequent registration review for each pes-  
21 ticide or pesticide case.

22 “(v) CANCELLATION.—No registration”;

23 (2) by redesignating subparagraph (B) as sub-  
24 paragraph (C); and

1           (3) by inserting after subparagraph (A) the fol-  
2       lowing:

3           “(B) DOCKETING.—

4                   “(i) IN GENERAL.—Subject to clause (ii),  
5       after meeting with 1 or more individuals that  
6       are not government employees to discuss mat-  
7       ters relating to a registration review, the Ad-  
8       ministrators shall place in the docket minutes of  
9       the meeting, a list of attendees, and any docu-  
10      ments exchanged at the meeting, not later than  
11      the earlier of—

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

14                   “(II) the date of issuance of the reg-  
15      istration review decision.

16                   “(ii) PROTECTED INFORMATION.—The Ad-  
17      ministrators shall identify, but not include in the  
18      docket, any confidential business information  
19      the disclosure of which is prohibited by section  
20      10.”.

21 **SEC. 4. MAINTENANCE FEES.**

22           (a) TOTAL AMOUNT OF FEES.—Section 4(i)(5)(C) of  
23      the Federal Insecticide, Fungicide, and Rodenticide Act  
24      (7 U.S.C. 136a–1(i)(5)(C)) is amended by striking  
25      “amount of” and all that follows through the end of clause

1 (v) and inserting “amount of \$22,000,000 for each of fis-  
2 cal years 2008 through 2012”.

3 (b) AMOUNTS FOR REGISTRANTS.—Section 4(i)(5) of  
4 the Federal Insecticide Fungicide, and Rodenticide Act (7  
5 U.S.C. 136a–1(i)(5)) is amended—

6 (1) in subparagraph (D)—

7 (A) in clause (i), by striking by striking  
8 “shall be” and all that follows through the end  
9 of subclause (IV) and inserting “shall be  
10 \$71,000 for each of fiscal years 2008 through  
11 2012; and”; and

12 (B) in clause (ii), by striking “shall be”  
13 and all that follows through the end of sub-  
14 clause (IV) and inserting “shall be \$123,000  
15 for each of fiscal years 2008 through 2012.”;  
16 and

17 (2) in subparagraph (E)(i)—

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

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

1 (c) EXTENSION OF AUTHORITY FOR COLLECTING  
2 MAINTENANCE FEES.—Section 4(i)(5)(H) of the Federal  
3 Insecticide, Fungicide, and Rodenticide Act (7 U.S.C.  
4 136a–1(i)(5)(H)) is amended by striking “2008” and in-  
5 serting “2012.”

6 (d) OTHER FEES.—

7 (1) IN GENERAL.—Section 4(i)(6) of the Fed-  
8 eral Insecticide, Fungicide, and Rodenticide Act (7  
9 U.S.C. 136a–1(i)(6)) is amended by striking “2010”  
10 and inserting “2014”.

11 (2) PROHIBITION ON TOLERANCE FEES.—Sec-  
12 tion 408(m) of the Federal Food, Drug, and Cos-  
13 metic Act (21 U.S.C. 346a(m)) is amended by add-  
14 ing at the end the following:

15 “(3) PROHIBITION.—During the period begin-  
16 ning on the effective date of the Pesticide Registra-  
17 tion Improvement Renewal Act and ending on Sep-  
18 tember 30, 2012, the Administrator shall not collect  
19 any tolerance fees under paragraph (1).”.

20 (e) REREGISTRATION AND EXPEDITED PROCESSING  
21 FUND.—

22 (1) SOURCE AND USE.—Section 4(k)(2)(A) of  
23 the Federal Insecticide, Fungicide, and Rodenticide  
24 Act (7 U.S.C. 136a–1(k)(2)(A)) is amended—

1 (A) in the first sentence, by inserting “and  
2 to offset the costs of registration review under  
3 section 3(g)” after “paragraph (3)”;

4 (B) in clause (i), by inserting “and to off-  
5 set the costs of registration review under sec-  
6 tion 3(g)” after “paragraph (3)”; and

7 (C) in clause (ii), by inserting “and to off-  
8 set the costs of registration review under sec-  
9 tion 3(g)” after “paragraph (3)”.

10 (2) EXPEDITED PROCESSING OF SIMILAR AP-  
11 PPLICATIONS.—Section 4(k)(3)(A) of the Federal In-  
12 secticide, Fungicide, and Rodenticide Act (7 U.S.C.  
13 136a–1(k)(3)(A)) is amended by striking “2007 and  
14 2008” and inserting “2008 through 2012”.

15 **SEC. 5. PESTICIDE REGISTRATION SERVICE FEES.**

16 (a) DOCUMENTATION.—Section 33(b)(2) of the Fed-  
17 eral Insecticide, Fungicide, and Rodenticide Act (7 U.S.C.  
18 136w–8(b)(2)) is amended—

19 (1) in subparagraph (C), by striking clause (ii)  
20 and inserting the following:

21 “(ii) payment of at least 25 percent of  
22 the registration service fee and a request  
23 for a waiver from or reduction of the re-  
24 maining amount of the registration service  
25 fee.”; and

1 (2) by adding at the end the following:

2 “(D) PAYMENT.—The registration service  
3 fee required under this subsection shall be due  
4 upon submission of the application.

5 “(E) APPLICATIONS SUBJECT TO ADDI-  
6 TIONAL FEES.—An application may be subject  
7 to additional fees if—

8 “(i) the applicant identified the incor-  
9 rect registration service fee and decision  
10 review period;

11 “(ii) after review of a waiver request,  
12 the Administrator denies the waiver re-  
13 quest; or

14 “(iii) after review of the application,  
15 the Administrator determines that a dif-  
16 ferent registration service fee and decision  
17 review period apply to the application.

18 “(F) EFFECT OF FAILURE TO PAY FEES.—  
19 The Administrator shall reject any application  
20 submitted without the required registration  
21 service fee.

22 “(G) NON-REFUNDABLE PORTION OF  
23 FEES.—

1           “(i) IN GENERAL.—The Administrator  
2           shall retain 25 percent of the applicable  
3           registration service fee.

4           “(ii) LIMITATION.—Any waiver, re-  
5           fund, credit or other reduction in the reg-  
6           istration service fee shall not exceed 75  
7           percent of the registration service fee.

8           “(H) COLLECTION OF UNPAID FEES.—In  
9           any case in which the Administrator does not  
10          receive payment of a registration service fee (or  
11          applicable portion of the registration service  
12          fee) by the date that is 30 days after the fee  
13          is due, the fee shall be treated as a claim of the  
14          United States Government subject to sub-  
15          chapter II of chapter 37 of title 31, United  
16          States Code.”.

17          (b) AMOUNT OF FEES.—Section 33(b) of the Federal  
18          Insecticide, Fungicide, and Rodenticide Act (7 U.S.C.  
19          136w-8(b)) is amended—

20                 (1) in paragraph (3)—

21                         (A) in subparagraph (A), by striking “Pes-  
22                         ticide Registration Improvement Act of 2003”  
23                         and inserting “Pesticide Registration Improve-  
24                         ment Renewal Act”; and

1 (B) in subparagraph (B), by striking  
2 “S11631” and all that follows through the end  
3 of the subparagraph and inserting “S10409  
4 through S10411, dated July 31, 2007.”; and  
5 (2) by striking paragraph (6) and inserting the  
6 following:

7 “(6) FEE ADJUSTMENT.—

8 “(A) IN GENERAL.—Effective for a covered  
9 pesticide registration application received dur-  
10 ing the period beginning on October 1, 2008,  
11 and ending on September 30, 2010, the Admin-  
12 istrator shall increase by 5 percent the registra-  
13 tion service fee payable for the application  
14 under paragraph (3).

15 “(B) ADDITIONAL ADJUSTMENT.—Effec-  
16 tive for a covered pesticide registration applica-  
17 tion received on or after October 1, 2010, the  
18 Administrator shall increase by an additional 5  
19 percent the registration service fee in effect as  
20 of September 30, 2010.

21 “(C) PUBLICATION.—The Administrator  
22 shall publish in the Federal Register the revised  
23 registration service fee schedules.”.

24 (c) WAIVERS AND REDUCTIONS.—Section  
25 33(b)(7)(F) of the Federal Insecticide, Fungicide, and

1 Rodenticide Act (7 U.S.C. 136w-8(b)(7)(F)) is amend-  
2 ed—

3 (1) in clause (ii), by striking “all” and inserting  
4 “75 percent”; and

5 (2) in clause (iv)(II), by striking “all” and in-  
6 serting “75 percent of the applicable.”.

7 (d) REFUNDS.—Section 33(b)(8)(A) of the Federal  
8 Insecticide, Fungicide, and Rodenticide Act (7 U.S.C.  
9 136w-8(b)(8)(A)) is amended by striking “10 percent”  
10 and inserting “25 percent.”.

11 (e) PESTICIDE REGISTRATION FUND.—Section 33(c)  
12 of the Federal Insecticide, Fungicide, and Rodenticide Act  
13 (7 U.S.C. 136w-8(c)) is amended—

14 (1) in paragraph (1)(B), by striking “para-  
15 graph (4)” and inserting “paragraph (5)”;

16 (2) in paragraph (3)—

17 (A) by striking subparagraph (B) and in-  
18 serting the following:

19 “(B) WORKER PROTECTION.—

20 “(i) IN GENERAL.—For each of fiscal  
21 years 2008 through 2012, the Adminis-  
22 trator shall use approximately  $\frac{1}{17}$  of the  
23 amount in the Fund (but not less than  
24 \$1,000,000) to enhance scientific and reg-

1                   ulatory activities relating to worker protec-  
2                   tion.

3                   “(ii) PARTNERSHIP GRANTS.—Of the  
4                   amounts in the Fund, the Administrator  
5                   shall use for partnership grants—

6                               “(I) for each of fiscal years 2008  
7                               and 2009, \$750,000; and

8                               “(II) for each of fiscal years  
9                               2010 through 2012, \$500,000.

10                   “(iii) PESTICIDE SAFETY EDUCATION  
11                   PROGRAM.—Of the amounts in the Fund,  
12                   the Administrator shall use \$500,000 for  
13                   each of fiscal years 2008 through 2012 to  
14                   carry out the pesticide safety education  
15                   program.”; and

16                   (B) by striking subparagraph (C); and

17                   (3) in paragraph (5)—

18                               (A) by redesignating subparagraphs (A)  
19                   through (C) as clauses (i) through (iii), respec-  
20                   tively;

21                               (B) by striking “Amounts” and inserting  
22                   the following:

23                               “(A) IN GENERAL.—Amounts”; and

24                               (C) by adding at the end the following:

1           “(B) USE OF INVESTMENT INCOME.—  
2           After consultation with the Secretary of the  
3           Treasury, the Administrator may use income  
4           from investments described in clauses (ii) and  
5           (iii) of subparagraph (A) to carry out this sec-  
6           tion.”.

7           (f) ASSESSMENT OF FEES.—Section 33(d)(2) of the  
8           Federal Insecticide, Fungicide, and Rodenticide Act (7  
9           U.S.C. 136w-8(d)(2)) is amended by striking “For fiscal  
10          years 2004, 2005 and 2006 only, registration” and insert-  
11          ing “Registration”.

12          (g) DECISION REVIEW TIMES.—Section 33(f) of the  
13          Federal Insecticide, Fungicide, and Rodenticide Act (7  
14          U.S.C. 136w-8(f)) is amended—

15               (1) in paragraph (1), by striking “Pesticide  
16          Registration Improvement Act of 2003” and insert-  
17          ing “Pesticide Registration Improvement Renewal  
18          Act”;

19               (2) in paragraph (2), by striking “S11631” and  
20          all that follows through the end of the paragraph  
21          and inserting “S10409 through S10411, dated July  
22          31, 2007.”; and

23               (3) in paragraph (4), by striking subparagraph  
24          (B) and inserting the following:

25                       “(B) COMPLETENESS OF APPLICATION.—

1           “(i) IN GENERAL.—Not later than 21  
2           days after receiving an application and the  
3           required registration service fee, the Ad-  
4           ministrator shall conduct an initial screen-  
5           ing of the contents of the application in ac-  
6           cordance with clause (iii).

7           “(ii) REJECTION.—If the Adminis-  
8           trator determines under clause (i) that the  
9           application does not pass the initial screen-  
10          ing and cannot be corrected within the 21-  
11          day period, the Administrator shall reject  
12          the application not later than 10 days after  
13          making the determination.

14          “(iii) REQUIREMENTS OF SCREEN-  
15          ING.—In conducting an initial screening of  
16          an application, the Administrator shall de-  
17          termine whether—

18                 “(I)(aa) the applicable registra-  
19                 tion service fee has been paid; or

20                 “(bb) at least 25 percent of the  
21                 applicable registration service fee has  
22                 been paid and the application contains  
23                 a waiver or refund request for the  
24                 outstanding amount and documenta-

1                   tion establishing the basis for the  
2                   waiver request; and

3                   “(II) the application contains all  
4                   the necessary forms, data, and draft  
5                   labeling, formatted in accordance with  
6                   guidance published by the Adminis-  
7                   trator.”.

8           (h) REPORTS.—Section 33(k) of the Federal Insecti-  
9   cide, Fungicide, and Rodenticide Act (7 U.S.C. 136w-  
10 8(k)) is amended—

11           (1) in paragraph (1), by striking “March 1,  
12           2009” and inserting “March 1, 2014”; and

13           (2) in paragraph (2)—

14           (A) in subparagraph (A)—

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

18           (ii) by inserting after clause (i) the  
19           following

20           “(ii) the number of label amendments  
21           that have been reviewed using electronic  
22           means;

23           “(iii) the amount of money from the  
24           Reregistration and Expedited Processing  
25           Fund used to carry out inert ingredient re-

1 view and review of similar applications  
2 under section 4(k)(3);

3 “(iv) the number of applications com-  
4 pleted for identical or substantially similar  
5 applications under section 3(e)(3)(B), in-  
6 cluding the number of such applications  
7 completed within 90 days pursuant to that  
8 section;”; and

9 (iii) in clause (vi) (as redesignated by  
10 clause (i))—

11 (I) in subclause (II), by striking  
12 “and” at the end;

13 (II) in subclause (III), by strik-  
14 ing “and” at the end; and

15 (III) by adding at the end the  
16 following:

17 “(IV) providing for electronic  
18 submission and review of labels, in-  
19 cluding process improvements to fur-  
20 ther enhance the procedures used in  
21 electronic label review; and

22 “(V) the allowance and use of  
23 summaries of acute toxicity studies;  
24 and”;

1 (B) in subparagraph (B), by striking  
2 “and” at the end;

3 (C) in subparagraph (C), by striking the  
4 period at the end and inserting a semicolon;  
5 and

6 (D) by adding at the end the following:

7 “(D) a review of the progress in carrying  
8 out section 3(g), including—

9 “(i) the number of pesticides or pes-  
10 ticide cases reviewed;

11 “(ii) a description of the staffing and  
12 resources relating to the costs associated  
13 with the review and decision making relat-  
14 ing to reregistration and registration re-  
15 view for compliance with the deadlines  
16 specified in this Act;

17 “(iii) to the extent determined appro-  
18 priate by the Administrator and consistent  
19 with the authorities of the Administrator  
20 and limitations on delegation of functions  
21 by the Administrator, recommendations  
22 for—

23 “(I) process improvements in the  
24 handling of registration review under  
25 section 3(g);

1                   “(II) providing for accreditation  
2                   of outside reviewers and the use of  
3                   outside reviewers in the registration  
4                   review process; and

5                   “(III) streamlining the registra-  
6                   tion review process, consistent with  
7                   section 3(g);

8                   “(E) a review of the progress in meeting  
9                   the timeline requirements for the review of anti-  
10                  microbial pesticide products under section 3(h);  
11                  and

12                  “(F) a review of the progress in carrying  
13                  out the review of inert ingredients, including  
14                  the number of applications pending, the number  
15                  of new applications, the number of applications  
16                  reviewed, staffing, and resources devoted to the  
17                  review of inert ingredients and recommenda-  
18                  tions to improve the timeliness of review of  
19                  inert ingredients.”.

20                  (i) TERMINATION OF EFFECTIVENESS.—Section  
21                  33(m) of the Federal Insecticide, Fungicide, and  
22                  Rodenticide Act (7 U.S.C. 136w–8(m)) is amended—

23                         (1) in paragraph (1), by striking “2008” and  
24                         inserting “2012”; and

25                         (2) in paragraph (2)—

1 (A) in subparagraph (A)—

2 (i) in the subparagraph heading, by  
3 striking “2009” and inserting “2013”; and

4 (ii) by striking “2009” and inserting  
5 “2013”; and

6 (B) in subparagraphs (B) and (C)—

7 (i) in the subparagraph headings, by  
8 striking “2010” each place it appears and  
9 inserting “2014”; and

10 (ii) by striking “2010” each place it  
11 appears and inserting “2014”; and

12 (C) in subparagraph (D), by striking  
13 “2008” each place it appears and inserting  
14 “2012”.

15 **SEC. 6. EFFECTIVE DATE.**

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

○