115TH CONGRESS
1ST SESSION

H. R. 1029

IN THE SENATE OF THE UNITED STATES

MARCH 21, 2017

Received; read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

AN ACT

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to improve pesticide registration and other activities under the Act, to extend and modify fee authorities, and for other purposes.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Pesticide Registration Enhancement Act of 2017''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. EXTENSION AND MODIFICATION OF MAINTENANCE FEE AUTHORITY.

(a) MAINTENANCE FEE.—Section 4(i)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a–1(i)(1)) is amended—

(1) in subparagraph (C), by striking ''an aggregate amount of $27,800,000 for each of fiscal years 2013 through 2017'' and inserting ''an average amount of $31,000,000 for each of fiscal years 2017 through 2023'';

(2) in subparagraph (D)—

(A) in clause (i), by striking ''$115,500 for each of fiscal years 2013 through 2017'' and inserting ''$129,400 for each of fiscal years 2017 through 2023''; and

(B) in clause (ii), by striking ''$184,800 for each of fiscal years 2013 through 2017''

and inserting ''$207,000 for each of fiscal years 2017 through 2023'';

(3) in subparagraph (E)(i)—

(A) in subclause (I), by striking ''$70,600 for each of fiscal years 2013 through 2017'' and inserting ''$79,100 for each of fiscal years 2017 through 2023''; and

(B) in subclause (II), by striking ''$122,100 for each of fiscal years 2013 through 2017'' and inserting ''$136,800 for each of fiscal years 2017 through 2023''; and

(4) in subparagraph (I), by striking ''2017'' and inserting ''2023''.

(b) PROHIBITION ON OTHER FEES.—Section 4(i)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a–1(i)(2)) is amended—

(1) by striking ''during the period beginning on the date of enactment of this section and ending on September 30, 2019'' and inserting ''until September 30, 2025''; and

(2) by inserting after ''registration of a pesticide under this Act'' the following: ''or any other action covered under a table specified in section 33(b)(3),''.

(c) EXTENSION OF PROHIBITION ON TOLERANCE FEES.—Section 408(m)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(m)(3)) is amended by striking ''2017'' and inserting ''2023''.

SEC. 3. REREGISTRATION AND EXPEDITED PROCESSING FUND.

(a) AUTHORIZED USE OF FUND.—Section 4(k)(2)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a–1(k)(2)(A)) is amended—

(1) in the first sentence, by striking ''the fund'' and inserting ''the Reregistration and Expedited Processing Fund'';

(2) by striking ''paragraph (3),'' in the first sentence and all that follows through the second sentence and inserting the following: ''paragraph (3), to offset the costs of registration review under section 3(g), including the costs associated with any review under the Endangered Species Act of 1973 (16 U.S.C. 1531 et. seq.) required as part of the registration review, to offset the costs associated with tracking and implementing registration review decisions, including registration review decisions designed to reduce risk, for the purposes specified in paragraphs (4) and (5), and to enhance the informa-

tion systems capabilities to improve the tracking of pesticide registration decisions.'';

(3) in clause (i), by striking ''are allocated solely'' and all that follows through ''3(g);'' and inserting the following: ''are allocated solely for the purposes specified in the first sentence of this subparagraph;''; and

(4) in clause (ii), by striking ''necessary to achieve'' and all that follows through ''3(g);'' and inserting the following: ''necessary to achieve the purposes specified in the first sentence of this subparagraph;''.

(b) SET-ASIDE FOR REVIEW OF INERT INGREDIENTS AND 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, in the matter preceding clause (i), by striking ''The Administrator shall use'' and all that follows through ''personnel and resources—'' and inserting the following: ''For each of fiscal years 2017 through 2023, the Administrator shall use between 1/9 and 1/8 of the maintenance fees collected in such fiscal year to obtain sufficient personnel and resources—''.

(c) SET-ASIDE FOR EXPEDITED RULEMAKING AND GUIDANCE DEVELOPMENT FOR CERTAIN PURPOSES.—

Paragraph (4) of section 4(k) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a–1(k)) is amended to read as follows:

''(4) EXPEDITED RULEMAKING AND GUIDANCE DEVELOPMENT FOR CERTAIN PRODUCT PERFORMANCE DATA REQUIREMENTS.—

''(A) SET-ASIDE.—For each of fiscal years 2017 through 2021, the Administrator shall use not more than $500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

''(B) PRODUCTS CLAIMING EFFICACY AGAINST INVERTEBRATE PESTS OF SIGNIFICANT PUBLIC HEALTH OR ECONOMIC IMPORTANCE.—The Administrator shall use amounts made available under subparagraph (A) to develop, receive comments with respect to, finalize, and implement the necessary rulemaking and guidance for product performance data requirements to evaluate products claiming efficacy against the following invertebrate pests of significant public health or economic importance (in order of importance):

''(i) Bed bugs.

''(ii) Premise (including crawling insects, flying insects, and baits).

''(iii) Pests of pets (including pet pests controlled by spot-ons, collars, shampoos, powders, dips).

''(iv) Fire ants.

''(C) DEADLINES FOR GUIDANCE.—The Administrator shall develop, and publish guidance required by subparagraph (B) with respect to claims of efficacy against pests described in such subparagraph as follows:

''(i) With respect to bed bugs, issue final guidance not later than June 30, 2017.

''(ii) With respect to pests specified in clause (ii) of such subparagraph—

''(I) submit draft guidance to the Scientific Advisory Panel and for public comment not later than June 30, 2018; and

''(II) complete any response to comments received with respect to such draft guidance and finalize the guidance not later than September 30, 2020.

"(iii) With respect to pests specified in clauses (iii) and (iv) of such subparagraph—

"(I) submit to the Scientific Advisory Panel and for public comment draft guidance not later than June 30, 2019; and

"(II) complete any response to comments received with respect to such draft guidance and finalize the guidance not later than March 31, 2021.

"(D) REVISION.—The Administrator shall revise the guidance required by subparagraph (B) from time-to-time, but shall permit applicants and registrants sufficient time to obtain data that meet the requirements specified in such revised guidance.

"(E) DEADLINE FOR PRODUCT PERFORMANCE DATA REQUIREMENTS.—The Administrator shall, not later than September 30, 2021, issue regulations prescribing product performance data requirements for any pesticide intended for preventing, destroying, repelling, or mitigating any invertebrate pest of significant

public health or economic importance specified in clauses (i) through (iv) of subparagraph (B).''.

(d) SET-ASIDE FOR GOOD LABORATORY PRACTICES INSPECTIONS.—Section 4(k) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a–1(k)) is amended—

(1) by redesignating paragraphs (5) and (6) as paragraphs (6) and (7), respectively;

(2) by inserting after paragraph (4) the following new paragraph:

''(5) GOOD LABORATORY PRACTICES INSPECTIONS.—

''(A) SET-ASIDE.—For each of fiscal years 2017 through 2023, the Administrator shall use not more than $500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

''(B) ACTIVITIES.—The Administrator shall use amounts made available under subparagraph (A) for enhancements to the good laboratory practices standards compliance monitoring program established under part 160 of title 40 of the Code of Federal Regulations (or

successor regulations), with respect to laboratory inspections and data audits conducted in support of pesticide product registrations under this Act. As part of such monitoring program, the Administrator shall make available to each laboratory inspected under such program in support of such registrations a preliminary summary of inspection observations not later than 60 days after the date on which such an inspection is completed.''; and

(3) in paragraph (7), as so redesignated, by striking '' paragraphs (2), (3), and (4)'' and inserting '' paragraphs (2), (3), (4), and (5)''.

SEC. 4. EXPERIMENTAL USE PERMITS FOR PESTICIDES.

Section 5(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136c(a)) is amended—

(1) by striking ''permit for a pesticide.'' and inserting ''permit for a pesticide. An application for an experimental use permit for a covered application under section 33(b) shall conform with the requirements of that section.''; and

(2) by inserting ''(or in the case of an application for an experimental use permit for a covered application under section 33(b), not later than the last day of the applicable timeframe for such appli-

cation specified in such section)'' after ''all required supporting data''.

SEC. 5. PESTICIDE REGISTRATION SERVICE FEES.

(a) EXTENSION AND MODIFICATION OF FEE AUTHORITY.—Section 33(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w–8(b)) is amended—

(1) in paragraph (2)—

(A) in the heading, by striking ''PESTICIDE REGISTRATION''; and

(B) in subparagraph (A), by inserting ''or for any other action covered by a table specified in paragraph (3)'' after ''covered by this Act that is received by the Administrator on or after the effective date of the Pesticide Registration Improvement Act of 2003'';

(2) in paragraph (5)—

(A) in the heading, by striking ''PESTICIDE REGISTRATION APPLICATIONS'' and inserting ''COVERED APPLICATION''; and

(B) by striking ''pesticide registration application'' both places it appears and inserting ''covered application'';

(3) in paragraph (6)—

(A) in subparagraph (A)—

(i) by striking ''pesticide registration''; and

(ii) by striking ''October 1, 2013, and ending on September 30, 2015'' and inserting ''October 1, 2019, and ending on September 30, 2021'';

(B) in subparagraph (B)—

(i) by striking ''pesticide registration''; and

(ii) by striking ''2015'' both places in appears, and inserting ''2021''; and

(C) in subparagraph (C), by striking ''revised registration service fee schedules'' and inserting ''service fee schedules revised pursuant to this paragraph'';

(4) in paragraph (7)—

(A) in subparagraph (A)—

(i) by striking ''covered pesticide registration'' and inserting ''covered application''; and

(ii) by inserting before the period at the end the following: '', except that no waiver or fee reduction shall be provided in connection with a request for a letter of

certification (commonly referred to as a Gold Seal letter)''; and

(B) in subparagraph (F)(i), by striking ''pesticide registration''; and

(5) in paragraph (8)—

(A) in subparagraph (A), by striking ''pesticide registration'';

(B) in subparagraph (B)(i), by striking ''pesticide registration''; and

(C) in subparagraph (C)—

(i) in clause (i), by striking ''pesticide registration'' and inserting ''covered''; and

(ii) in clause (ii)(I), by striking ''pesticide registration'' and inserting ''covered''.

(b) PESTICIDE REGISTRATION FUND SET-ASIDES FOR WORKER PROTECTION, PARTNERSHIP GRANTS, AND PESTICIDE SAFETY EDUCATION.—Section 33(c)(3)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w–8(c)(3)(B)) is amended—

(1) in the heading, by inserting '', PARTNERSHIP GRANTS, AND PESTICIDE SAFETY EDUCATION'' after ''WORKER PROTECTION'';

(2) in clause (i)—

(A) by striking ''2017'' and inserting ''2023''; and

(B) by inserting before the period at the end the following:'', with an emphasis on field-worker populations in the United States'';

(3) in clause (ii), by striking ''2017'' and inserting ''2023''; and

(4) in clause (iii), by striking ''2017'' and inserting ''2023''.

(c) REFORMS TO REDUCE DECISION TIME REVIEW PERIODS.—Section 33(e) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w–8(e)) is amended—

(1) by striking ''Pesticide Registration Improvement Extension Act of 2012'' and inserting ''Pesticide Registration Enhancement Act of 2017''; and

(2) by inserting at the end the following new sentence: ''Such reforms shall include identifying opportunities for streamlining review processes for applications for a new active ingredient or a new use and providing prompt feedback to applicants during such review process.''.

(d) DECISION TIME REVIEW PERIODS.—Section 33(f) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w–8(f)(1)) is amended—

(1) in paragraph (1)—

(A) by striking ''Pesticide Registration Improvement Extension Act of 2012'' and inserting ''Pesticide Registration Enhancement Act of 2017''; and

(B) by inserting after ''covered pesticide registration actions'' the following: ''or for any other action covered by a table specified in subsection (b)(3)'';

(2) in paragraph (3), by striking subparagraph (C) and inserting the following new subparagraph:

''(C) applications for any other action covered by a table specified in subsection (b)(3).''; and

(3) in paragraph (4)(A)—

(A) by striking ''a pesticide registration application'' and inserting ''a covered application''; and

(B) by striking ''covered pesticide registration application'' and inserting ''covered application''.

(e) REPORTING REQUIREMENTS.—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 ''2017'' and inserting ''2023''; and

(2) in paragraph (2)—

(A) in subparagraph (D), by striking clause (i) and inserting the following new clause:

''(i) the number of pesticides or pesticide cases reviewed and the number of registration review decisions completed, including—

''(I) the number of cases cancelled;

''(II) the number of cases requiring risk mitigation measures;

''(III) the number of cases removing risk mitigation measures;

''(IV) the number of cases with no risk mitigation needed; and

''(V) the number of cases in which risk mitigation has been fully implemented;'';

(B) in subparagraph (G)—

(i) in clause (i)—

(I) by striking ''section 4(k)(4)'' and inserting ''paragraphs (4) and (5) of section 4(k)''; and

(II) by striking ''that section'' and inserting ''such paragraphs'';

(ii) by striking clauses (ii), (iii), (iv), (v), and (vi);

(iii) by inserting after clause (i) the following new clause:

''(ii) implementing enhancements to—

''(I) the electronic tracking of covered applications;

''(II) the electronic tracking of conditional registrations;

''(III) the endangered species database;

''(IV) the electronic review of labels submitted with covered applications; and

''(V) the electronic review and assessment of confidential statements of formula submitted with covered applications; and''; and

(iv) by redesignating clause (vii) as clause (iii);

(C) in subparagraph (I), by striking ''and'' at the end;

(D) in subparagraph (J), by striking the period at the end and inserting a semicolon; and

(E) by adding at the end the following new subparagraphs:

''(K) a review of the progress made in developing, updating, and implementing product performance test guidelines for pesticide products that are intended to control invertebrate pests of significant public health importance and, by regulation, prescribing product performance data requirements for such pesticide products registered under section 3;

''(L) a review of the progress made in the priority review and approval of new pesticides to control vector-born public health pests for use in the United States, including each territory or possession of the United States, and United States military installations globally;

''(M) a review of the progress made in implementing enhancements to the good laboratory practices standards compliance monitoring program established under part 160 of title 40

of the Code of Federal Regulations (or successor regulations);

''(N) the number of approvals for active ingredients, new uses, and pesticide end use products granted in connection with the Design for the Environment program (or any successor program) of the Environmental Protection Agency; and

''(O) with respect to funds in the Pesticide Registration Fund reserved under subsection (c)(3), a review that includes—

''(i) a description of the amount and use of such funds—

''(I) to carry out activities relating to worker protection under clause (i) of subsection (c)(3)(B);

''(II) to award partnership grants under clause (ii) of such subsection; and

''(III) to carry out the pesticide safety education program under clause (iii) of such subsection;

''(ii) an evaluation of the appropriateness and effectiveness of the activities,

grants, and program described in clause (i);

''(iii) a description of how stakeholders are engaged in the decision to fund such activities, grants, and program; and

''(iv) with respect to activities relating to worker protection carried out under subparagraph (B)(i) of such subsection, a summary of the analyses from stakeholders, including from worker community-based organizations, on the appropriateness and effectiveness of such activities.''.

(f) 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 ''2017'' and inserting ''2023''; and

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) by striking ''FISCAL YEAR 2018.—During fiscal year 2018'' and inserting ''FISCAL YEAR 2024.—During fiscal year 2024''; and

(ii) by striking ''2017'' and inserting ''2023'';

(B) in subparagraph (B)—

(i) by striking ''FISCAL YEAR 2019.—During fiscal year 2019'' and inserting ''FISCAL YEAR 2025.—During fiscal year 2025''; and

(ii) by striking ''2017'' and inserting ''2023'';

(C) in subparagraph (C), by striking ''SEPTEMBER 30, 2019.—Effective September 30, 2019'' and inserting ''SEPTEMBER 30, 2025.—Effective September 30, 2025''; and

(D) in subparagraph (D), by striking ''2017'' both places it appears and inserting ''2023''.

SEC. 6. REVISION OF TABLES REGARDING COVERED PESTICIDE REGISTRATION APPLICATIONS AND OTHER COVERED ACTIONS AND THEIR CORRESPONDING REGISTRATION SERVICE FEES.

Paragraph (3) of section 33(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w–8(b)) is amended to read as follows:

''(3) SCHEDULE OF COVERED APPLICATIONS AND OTHER ACTIONS AND THEIR REGISTRATION SERVICE FEES.—Subject to paragraph (6), the schedule of registration applications and other cov-

ered actions and their corresponding registration service fees shall be as follows:

"TABLE 1. — REGISTRATION DIVISION — NEW ACTIVE INGREDIENTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R010	1	New Active Ingredient, Food use. (2)(3)	24	753,082
R020	2	New Active Ingredient, Food use; reduced risk. (2)(3)	18	627,568
R040	3	New Active Ingredient, Food use; Experimental Use Permit application; establish temporary tolerance; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)	18	462,502
R060	4	New Active Ingredient, Non-food use; outdoor. (2)(3)	21	523,205
R070	5	New Active Ingredient, Non-food use; outdoor; reduced risk. (2)(3)	16	436,004

"TABLE 1. — REGISTRATION DIVISION — NEW ACTIVE INGREDIENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R090	6	New Active Ingredient, Nonfood use; outdoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)	16	323,690
R110	7	New Active Ingredient, Nonfood use; indoor. (2)(3)	20	290,994
R120	8	New Active Ingredient, Nonfood use; indoor; reduced risk. (2)(3)	14	242,495
R121	9	New Active Ingredient, Nonfood use; indoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)	18	182,327

''TABLE 1. — REGISTRATION DIVISION — NEW ACTIVE INGREDIENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R122	10	Enriched isomer(s) of registered mixed-isomer active ingredient. (2)(3)	18	317,128
R123	11	New Active Ingredient, Seed treatment only; includes agricultural and non-agricultural seeds; residues not expected in raw agricultural commodities. (2)(3)	18	471,861
R125	12	New Active Ingredient, Seed treatment; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)	16	323,690

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

''TABLE 2. — REGISTRATION DIVISION — NEW USES

EPA No.	**New CR No.**	**Action**	**Decision Review Time (Months)**(1)	**FY'17 & FY'18 Registration Service Fee ($)**
R130	13	First food use; indoor; food/food handling. (2) (3)	21	191,444
R140	14	Additional food use; Indoor; food/food handling. (3) (4)	15	44,672
R150	15	First food use. (2)(3)	21	317,104

"TABLE 2. — REGISTRATION DIVISION — NEW USES— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R155	16 (new)	First food use, Experimental Use Permit application; a.i. registered for non-food outdoor use. (3)(4)	21	264,253
R160	17	First food use; reduced risk. (2)(3)	16	264,253
R170	18	Additional food use. (3) (4)	15	79,349
R175	19	Additional food uses covered within a crop group resulting from the conversion of existing approved crop group(s) to one or more revised crop groups. (3)(4)	10	66,124
R180	20	Additional food use; reduced risk. (3)(4)	10	66,124
R190	21	Additional food uses; 6 or more submitted in one application. (3)(4)	15	476,090
R200	22	Additional Food Use; 6 or more submitted in one application; Reduced Risk. (3)(4)	10	396,742

"TABLE 2. — REGISTRATION DIVISION — NEW USES— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R210	23	Additional food use; Experimental Use Permit application; establish temporary tolerance; no credit toward new use registration. (3)(4)	12	48,986
R220	24	Additional food use; Experimental Use Permit application; crop destruct basis; no credit toward new use registration. (3)(4)	6	19,838
R230	25	Additional use; non-food; outdoor. (3) (4)	15	31,713
R240	26	Additional use; non-food; outdoor; reduced risk. (3)(4)	10	26,427
R250	27	Additional use; non-food; outdoor; Experimental Use Permit application; no credit toward new use registration. (3)(4)	6	19,838

"TABLE 2. — REGISTRATION DIVISION — NEW USES— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R251	28	Experimental Use Permit application which requires no changes to the tolerance(s); non-crop destruct basis. (3)	8	19,838
R260	29	New use; non-food; indoor. (3) (4)	12	15,317
R270	30	New use; non-food; indoor; reduced risk. (3)(4)	9	12,764
R271	31	New use; non-food; indoor; Experimental Use Permit application; no credit toward new use registration. (3)(4)	6	9,725
R273	32	Additional use; seed treatment; limited uptake into Raw Agricultural Commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food and/or non-food uses. (3)(4)	12	50,445

"TABLE 2. — REGISTRATION DIVISION — NEW USES— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R274	33	Additional uses; seed treatment only; 6 or more submitted in one application; limited uptake into raw agricultural commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food and/or nonfood uses. (3)(4)	12	302,663

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screen, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

''TABLE 3. — REGISTRATION DIVISION — IMPORT AND OTHER TOLERANCES

EPA No.	**New CR No.**	**Action**	**Decision Review Time (Months)**(1)	**FY'17 & FY'18 Registration Service Fee ($)**
R280	34	Establish import tolerance; new active ingredient or first food use. (2)	21	319,072
R290	35	Establish Import tolerance; Additional new food use.	15	63,816

"TABLE 3. — REGISTRATION DIVISION — IMPORT AND OTHER TOLERANCES—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R291	36	Establish import tolerances; additional food uses; 6 or more crops submitted in one petition.	15	382,886
R292	37	Amend an established tolerance (e.g., decrease or increase) and/or harmonize established tolerances with Codex MRLs; domestic or import; applicant-initiated.	11	45,341
R293	38	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated.	12	53,483
R294	39	Establish tolerances for inadvertent residues; 6 or more crops submitted in one application; applicant-initiated.	12	320,894

"TABLE 3. — REGISTRATION DIVISION — IMPORT AND OTHER TOLERANCES—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R295	40	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; submission of corresponding label amendments which specify the necessary plantback restrictions; applicant-initiated. (3) (4)	15	66,124
R296	41	Establish tolerances for residues in rotational crops in response to a specific rotational crop petition; 6 or more crops submitted in one application; submission of corresponding label amendments which specify the necessary plantback restrictions; applicant-initiated. (3) (4)	15	396,742

''TABLE 3. — REGISTRATION DIVISION — IMPORT AND OTHER TOLERANCES—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R297	42	Amend 6 or more established tolerances (e.g., decrease or increase) in one petition; domestic or import; applicant-initiated.	11	272,037
R298	43	Amend an established tolerance (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3) (4)	13	58,565
R299	44	Amend 6 or more established tolerances (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3) (4)	13	285,261

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) Amendment applications to add the revised use pattern(s) to registered product labels are covered by the base fee for the category. All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the amendment application package is subject to the registration service fee for a new product or a new inert approval. However, if an amendment application only proposes to register the amendment for a new product and there are no amendments in the application, then review of one new product application is covered by the base fee. All such associated applications that are submitted together will be subject to the category decision review time.

"TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R300	45	New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; no data review on acute toxicity, efficacy or CRP – only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix. (2)(3)	4	1,582

"TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R301	46	New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy (identical data citation and claims to cited product(s)), where applicant does not own all required data and does not have a specific authorization letter from data owner. (2)(3)	4	1,897

"TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R310	47	New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: ● product chemistry and/or ● acute toxicity and/or ● child resistant packaging and/or ● pest(s) requiring efficacy (4) - for up to 3 target pests. (2)(3)	7	7,301

"TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R314	48	New end use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: ● product chemistry and/or ● acute toxicity and/or ● child resistant packaging and/or ● pest(s) requiring efficacy (4) - for up to 3 target pests. (2)(3)	8	8,626

"TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R319	49	New end use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: ● product chemistry and/or ● acute toxicity and/or ● child resistant packaging and/or ● pest(s) requiring efficacy (4) - for 4 to 7 target pests. (2)(3)	10	12,626

"TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R318	50 (new)	New end use product containing four or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: ● product chemistry and/or ● acute toxicity and/or ● child resistant packaging and/or ● pest(s) requiring efficacy (4) - for up to 3 target pests. (2)(3)	9	13,252

"TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R321	51 (new)	New end use product containing four or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: ● product chemistry and/or ● acute toxicity and/or ● child resistant packaging and/or ● pest(s) requiring efficacy (4) - for 4 to 7 target pests. (2)(3)	11	17,252

"TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R315	52	New end-use, on-animal product, registered source of active ingredient(s), with the submission of data and/or waivers for only: ● animal safety and ● pest(s) requiring efficacy (4) and/or ● product chemistry and/or ● acute toxicity and/or ● child resistant packaging. (2) (3)	9	9,820

"TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R316	53 (new)	New end-use or manufacturing product with registered source(s) of active ingredient(s) including products containing two or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; and requires review of data and/or waivers for only: ● product chemistry and/or ● acute toxicity and/or ● child resistant packaging and/or ● pest(s) requiring efficacy (4) - for greater than 3 and up to 7 target pests. (2)(3)	9	11,301

"TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R317	54 (new)	New end-use or manufacturing product with registered source(s) of active ingredient(s) including products containing 2 or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; and requires review of data and/or waivers for only: ● product chemistry and/or ● acute toxicity and/or ● child resistant packaging and/or ● pest(s) requiring efficacy (4) - for greater than 7 target pests. (2)(3)	10	15,301
R320	55	New product; new physical form; requires data review in science divisions. (2)(3)	12	13,226

"TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R331	56	New product; repack of identical registered end-use product as a manufacturing-use product, or identical registered manufacturing-use product as an end use product; same registered uses only. (2)(3)	3	2,530
R332	57	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of completely new generic data package; registered uses only; requires review in RD and science divisions. (2)(3)	24	283,215

"TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R333	58	New product; MUP or End use product with unregistered source of active ingredient; requires science data review; new physical form; etc. Cite-all or selective data citation where applicant owns all required data. (2)(3)	10	19,838
R334	59	New product; MUP or End use product with unregistered source of the active ingredient; requires science data review; new physical form; etc. Selective data citation. (2)(3)	11	23,100

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) For the purposes of classifying proposed registration actions into PRIA categories, ''pest(s) requiring efficacy'' are: public health pests listed in PR Notice 2002-1, livestock pests (e.g. Horn flies, Stable flies), wood-destroying pests (e.g. termites, carpenter ants, wood-boring beetles) and certain invasive species (e.g. Asian Longhorned beetle, Emerald Ashborer). This list may be updated/refined as invasive pest needs arise. To determine the number of pests for the PRIA categories, pests have been placed into groups (general; e.g., cockroaches) and pest specific (specifically a test species). If seeking a label claim against a pest group (general), use the group listing below and each group will count as 1. The general pests groups are: mites, dust mites, chiggers, ticks, hard ticks, soft ticks, cattle ticks, scorpions, spiders, centipedes, lice, fleas, cockroaches, keds, bot flies, screwworms, filth flies, blow flies, house flies, flesh flies, mosquitoes, biting flies, horse flies, stable flies, deer flies, sand flies, biting midges, black flies, true bugs, bed bugs, stinging bees, wasps, yellow jackets, hornets, ants (excluding carpenter ants), fire and harvester ants, wood destroying beetles, carpenter ants, termites, subterranean termites, dry wood termites, arboreal termites, damp wood termites and invasive species. If seeking a claim against a specific pest without a general claim then each specific pest will count as 1.

''TABLE 5. — REGISTRATION DIVISION — AMENDMENTS

EPA No.	**New CR No.**	**Action**	**Decision Review Time (Months)**(1)	**FY'17 & FY'18 Registration Service Fee ($)**
R340	60	Amendment requiring data review within RD (e.g., changes to precautionary label statements); includes adding/modifying pest(s) claims for up to 2 target pests, excludes products requiring or citing an animal safety study. (2)(3)(4)	4	4,988

"TABLE 5. — REGISTRATION DIVISION — AMENDMENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R341	61 (New)	Amendment requiring data review within RD (e.g., changes to precautionary label statements), includes adding/modifying pest(s) claims for greater than 2 target pests, excludes products requiring or citing an animal safety study. (2)(3)(4)	6	5,988
R345	62	Amending on-animal products previously registered, with the submission of data and/or waivers for only: ● animal safety and ● pest(s) requiring efficacy (4) and/or ● product chemistry and/or ● acute toxicity and/or ● child resistant packaging. (2)(3)	7	8,820
R350	63	Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement). (2)(3)	9	13,226

"TABLE 5. — REGISTRATION DIVISION — AMENDMENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
R351	64	Amendment adding a new unregistered source of active ingredient. (2)(3)	8	13,226
R352	65	Amendment adding already approved uses; selective method of support; does not apply if the applicant owns all cited data. (2)(3)	8	13,226
R371	66	Amendment to Experimental Use Permit; (does not include extending a permit's time period). (3)	6	10,090

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) For the purposes of classifying proposed registration actions into PRIA categories, ''pest(s) requiring efficacy'' are: public health pests listed in PR Notice 2002-1, livestock pests (e.g. Horn flies, Stable flies), wood-destroying pests (e.g. termites, carpenter ants, wood-boring beetles) and certain invasive species (e.g. Asian Longhorned beetle, Emerald Ashborer). This list may be updated/refined as invasive pest needs arise. To determine the number of pests for the PRIA categories, pests have been placed into groups (general; e.g., cockroaches) and pest specific (specifically a test species). If seeking a label claim against a pest group (general), use the group listing below and each group will count as 1. The general pests groups are: mites, dust mites, chiggers, ticks, hard ticks, soft ticks, cattle ticks, scorpions, spiders, centipedes, lice, fleas, cockroaches, keds, bot flies, screwworms, filth flies, blow flies, house flies, flesh flies, mosquitoes, biting flies, horse flies, stable flies, deer flies, sand flies, biting midges, black flies, true bugs, bed bugs, stinging bees, wasps, yellow jackets, hornets, ants (excluding carpenter ants), fire and harvester ants, wood destroying beetles, carpenter ants, termites, subterranean termites, dry wood termites, arboreal termites, damp wood termites and invasive species. If seeking a claim against a specific pest without a general claim then each specific pest will count as 1.

''TABLE 6. — REGISTRATION DIVISION — OTHER ACTIONS

EPA No.	**New CR No.**	**Action**	**Decision Review Time (Months)**(1)	**FY'17 & FY'18 Registration Service Fee ($)**
R124	67	Conditional Ruling on Pre-application Study Waivers; applicant-initiated.	6	2,530
R272	68	Review of Study Protocol applicant-initiated; excludes DART, pre-registration conference, Rapid Response review, DNT protocol review, protocol needing HSRB review.	3	2,530
R275	69	Rebuttal of agency reviewed protocol, applicant initiated.	3	2,530
R370	70	Cancer reassessment; applicant-initiated.	18	198,250

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

"TABLE 7. — ANTIMICROBIALS DIVISION — NEW ACTIVE INGREDIENTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
A380	71	New Active Ingredient; Indirect Food use; establish tolerance or tolerance exemption if required. (2)(3)	24	137,841
A390	72	New Active Ingredient; Direct Food use; establish tolerance or tolerance exemption if required. (2)(3)	24	229,733
A410	73	New Active Ingredient Non-food use.(2)(3)	21	229,733
A431	74	New Active Ingredient, Non-food use; low-risk. (2)(3)	12	80,225

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

"TABLE 8. — ANTIMICROBIALS DIVISION — NEW USES

EPA No.	**New CR No.**	**Action**	**Decision Review Time (Months)**(1)	**FY'17 & FY'18 Registration Service Fee ($)**
A440	75	New Use, Indirect Food Use, establish tolerance or tolerance exemption. (2)(3)(4)	21	31,910
A441	76	Additional Indirect food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application. (3)(4)(5)	21	114,870
A450	77	New use, Direct food use, establish tolerance or tolerance exemption. (2)(3)(4)	21	95,724

"TABLE 8. — ANTIMICROBIALS DIVISION — NEW USES—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
A451	78	Additional Direct food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application. (3)(4)(5)	21	182,335
A500	79	New use, nonfood. (4)(5)	12	31,910
A501	80	New use, nonfood; 6 or more submitted in one application. (4)(5)	15	76,583

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) If EPA data rules are amended to newly require clearance under section 408 of the FFDCA for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.

(4) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(5) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screen, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

"TABLE 9. — ANTIMICROBIALS DIVISION — NEW PRODUCTS AND AMENDMENTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
A530	81	New product, identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite all data citation or selective data citation where applicant owns all required data; or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing use product that requires no data submission nor data matrix. (2)(3)	4	1,278

"TABLE 9. — ANTIMICROBIALS DIVISION — NEW PRODUCTS AND AMENDMENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
A531	82	New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient: selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner. (2)(3)	4	1,824

"TABLE 9. — ANTIMICROBIALS DIVISION — NEW PRODUCTS AND AMENDMENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
A532	83	New product; identical or substantially similar in composition and use to a registered product; registered active ingredient; unregistered source of active ingredient; cite-all data citation except for product chemistry; product chemistry data submitted. (2)(3)	5	5,107
A540	84	New end use product; FIFRA §2(mm) uses only; up to 25 public health organisms. (2)(3)(5)(6)	5	5,107
A541	85 (new)	New end use product; FIFRA §2(mm) uses only; 26-50 public health organisms. (2)(3)(5)(6)	7	8,500

"TABLE 9. — ANTIMICROBIALS DIVISION — NEW PRODUCTS AND AMENDMENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
A542	86 (new)	New end use product; FIFRA §2(mm) uses only; ≥ 51 public health organisms. (2)(3)(5)	10	15,000
A550	87	New end-use product; uses other than FIFRA §2(mm); non-FQPA product. (2)(3)(5)	9	13,226
A560	88	New manufacturing use product; registered active ingredient; selective data citation. (2)(3)	6	12,596
A565	89 (new)	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of new generic data package; registered uses only; requires science review. (2)(3)	12	18,234

"TABLE 9. — ANTIMICROBIALS DIVISION — NEW PRODUCTS AND AMENDMENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
A570	90	Label amendment requiring data review; up to 25 public health organisms. (3)(4)(5)(6)	4	3,831
A573	91 (new)	Label amendment requiring data review; 26-50 public health organisms. (2)(3)(5)(7)	6	6,350
A574	92 (new)	Label amendment requiring data review; ≥ 51 public health organisms. (2)(3)(5)(7)	9	11,000
A572	93	New Product or amendment requiring data review for risk assessment by Science Branch (e.g., changes to REI, or PPE, or use rate). (2)(3)(4)	9	13,226

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4)(a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

(5) The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements.

(6) Once a submission for a new product with public health organisms has been submitted and classified in either A540 or A541, additional organisms submitted for the same product before expiration of the first submission's original decision review time period will result in reclassification of both the original and subsequent submission into the appropriate new category based on the sum of the number or organisms in both submissions. A reclassification would result in a new PRIA start date and require additional fees to meet the fee of the new category.

(7) Once a submission for a label amendment with public health organisms has been submitted and classified in either A570 or A573, additional organisms submitted for the same product before expiration of the first submission's original decision review time period will result in reclassification of both the original and subsequent submission into the appropriate new category based on the sum of the number or organisms in both submissions. A reclassification would result in a new PRIA start date and require additional fees to meet the fee of the new category.

"TABLE 10. — ANTIMICROBIALS DIVISION — EXPERIMENTAL USE PERMITS AND OTHER ACTIONS

EPA No.	**New CR No.**	**Action**	**Decision Review Time (Months)**(1)	**FY'17 & FY'18 Registration Service Fee ($)**
A520	94	Experimental Use Permit application, non-food use. (2)	9	6,383

''TABLE 10. — ANTIMICROBIALS DIVISION — EXPERIMENTAL USE PERMITS AND OTHER ACTIONS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
A521	95	Review of public health efficacy study protocol within AD, per AD Internal Guidance for the Efficacy Protocol Review Process; Code will also include review of public health efficacy study protocol and data review for devices making pesticidal claims; applicant-initiated; Tier 1.	4	4,726
A522	96	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; Code will also include review of public health efficacy study protocol and data review for devices making pesticidal claims; applicant-initiated; Tier 2.	12	12,156

''TABLE 10. — ANTIMICROBIALS DIVISION — EXPERIMENTAL USE PERMITS AND OTHER ACTIONS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
A537	97 (new)	New Active Ingredient/New Use, Experimental Use Permit application; Direct food use; Establish tolerance or tolerance exemption if required. Credit 45% of fee toward new active ingredient/new use application that follows.	18	153,156
A538	98 (new)	New Active Ingredient/New Use, Experimental Use Permit application; Indirect food use; Establish tolerance or tolerance exemption if required Credit 45% of fee toward new active ingredient/new use application that follows.	18	95,724

''TABLE 10. — ANTIMICROBIALS DIVISION — EXPERIMENTAL USE PERMITS AND OTHER ACTIONS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
A539	99 (new)	New Active Ingredient/New Use, Experimental Use Permit application; Nonfood use. Credit 45% of fee toward new active ingredient/new use application that follows.	15	92,163
A529	100	Amendment to Experimental Use Permit; requires data review or risk assessment. (2)	9	11,429
A523	101	Review of protocol other than a public health efficacy study (i.e., Toxicology or Exposure Protocols).	9	12,156
A571	102	Science reassessment: Cancer risk, refined ecological risk, and/or endangered species; applicant-initiated.	18	95,724

''TABLE 10. — ANTIMICROBIALS DIVISION — EXPERIMENTAL USE PERMITS AND OTHER ACTIONS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
A533	103 (new)	Exemption from the requirement of an Experimental Use Permit. (2)	4	2,482
A534	104 (new)	Rebuttal of agency reviewed protocol, applicant initiated.	4	4,726
A535	105 (new)	Conditional Ruling on Pre-application Study Waiver or Data Bridging Argument; applicant-initiated.	6	2,409
A536	106 (new)	Conditional Ruling on Pre-application Direct Food, Indirect Food, Nonfood use determination; applicant-initiated.	4	2,482

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

''TABLE 11. — BIOPESTICIDES DIVISION — NEW ACTIVE INGREDIENTS

EPA No.	**New CR No.**	**Action**	**Decision Review Time (Months)**(1)	**FY'17 & FY'18 Registration Service Fee ($)**
B580	107	New active ingredient; food use; petition to establish a tolerance. (2)(3)	20	51,053
B590	108	New active ingredient; food use; petition to establish a tolerance exemption. (2)(3)	18	31,910
B600	109	New active ingredient; non-food use. (2)(3)	13	19,146
B610	110	New active ingredient; Experimental Use Permit application; petition to establish a temporary tolerance or temporary tolerance exemption. (3)	10	12,764

"TABLE 11. — BIOPESTICIDES DIVISION — NEW ACTIVE INGREDIENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B611	111	New active ingredient; Experimental Use Permit application; petition to establish permanent tolerance exemption. (3)	12	12,764
B612	112	New active ingredient; no change to a permanent tolerance exemption. (2)(3)	10	17,550
B613	113	New active ingredient; petition to convert a temporary tolerance or a temporary tolerance exemption to a permanent tolerance or tolerance exemption. (2)(3)	11	17,550
B620	114	New active ingredient; Experimental Use Permit application; non-food use including crop destruct. (3)	7	6,383

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

''TABLE 12. — BIOPESTICIDES DIVISION — NEW USES

EPA No.	**New CR No.**	**Action**	**Decision Review Time (Months)**(1)	**FY'17 & FY'18 Registration Service Fee ($)**
B630	115	First food use; petition to establish a tolerance exemption. (2)(4)	13	12,764
B631	116	New food use; petition to amend an established tolerance. (3)(4)	12	12,764

"TABLE 12. — BIOPESTICIDES DIVISION — NEW USES—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B640	117	First food use; petition to establish a tolerance. (2)(4)	19	19,146
B643	118	New Food use; petition to amend an established tolerance exemption. (3)(4)	10	12,764
B642	119	First food use; indoor; food/food handling. (2)(4)	12	31,910
B644	120	New use, no change to an established tolerance or tolerance exemption. (3)(4)	8	12,764
B650	121	New use; non-food. (3)(4)	7	6,383
B645	122 (new)	New food use; Experimental Use Permit application; petition to amend or add a tolerance exemption. (4)	12	12,764
B646	123 (new)	New use; non-food use including crop destruct; Experimental Use Permit application. (4)	7	6,383

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screen, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

(4) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

"TABLE 13. — BIOPESTICIDES DIVISION — NEW PRODUCTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B652	124	New product; registered source of active ingredient; requires petition to amend established tolerance or tolerance exemption; requires 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (2)(3)	13	12,764

"TABLE 13. — BIOPESTICIDES DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B660	125	New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product. No data review, or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data or authorization from data owner is demonstrated. Category includes 100% repackage of registered end-use or manufacturing-use product that requires no data submission or data matrix. For microbial pesticides, the active ingredient(s) must not be re-isolated. (2)(3)	4	1,278

"TABLE 13. — BIOPESTICIDES DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B670	126	New product; registered source of active ingredient(s); requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (2)(3)	7	5,107

"TABLE 13. — BIOPESTICIDES DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B671	127	New product; unregistered source of active ingredient(s); requires a petition to amend an established tolerance or tolerance exemption; requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (2)(3)	17	12,764

"TABLE 13. — BIOPESTICIDES DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B672	128	New product; unregistered source of active ingredient(s); non-food use or food use requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (2)(3)	13	9,118

"TABLE 13. — BIOPESTICIDES DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B673	129	New product MUP/EP; unregistered source of active ingredient(s); citation of Technical Grade Active Ingredient (TGAI) data previously reviewed and accepted by the Agency. Requires an Agency determination that the cited data supports the new product. (2)(3)	10	5,107
B674	130	New product MUP; Repack of identical registered end-use product as a manufacturing-use product; same registered uses only. (2)(3)	4	1,278
B675	131	New Product MUP; registered source of active ingredient; submission of completely new generic data package; registered uses only. (2)(3)	10	9,118

"TABLE 13. — BIOPESTICIDES DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B676	132	New product; more than one active ingredient where one active ingredient is an unregistered source; product chemistry data must be submitted; requires: 1) submission of product specific data, and 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (2)(3)	13	9,118

"TABLE 13. — BIOPESTICIDES DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B677	133	New end-use non-food animal product with submission of two or more target animal safety studies; includes data and/or waivers of data for only: ● product chemistry and/or ● acute toxicity and/or ● public health pest efficacy and/or ● animal safety studies and/or ● child resistant packaging. (2)(3)	10	8,820

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

"TABLE 14. — BIOPESTICIDES DIVISION — AMENDMENTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B621	134	Amendment; Experimental Use Permit; no change to an established temporary tolerance or tolerance exemption. (3)	7	5,107
B622	135	Amendment; Experimental Use Permit; petition to amend an established or temporary tolerance or tolerance exemption. (3)	11	12,764
B641	136	Amendment of an established tolerance or tolerance exemption.	13	12,764
B680	137	Amendment; registered sources of active ingredient(s); no new use(s); no changes to an established tolerance or tolerance exemption. Requires data submission. (2)(3)	5	5,107
B681	138	Amendment; unregistered source of active ingredient(s). Requires data submission. (2)(3)	7	6,079
B683	139	Label amendment; requires review/update of previous risk assessment(s) without data submission (e.g., labeling changes to REI, PPE, PHI). (2)(3)	6	5,107
B684	140	Amending non-food animal product that includes submission of target animal safety data; previously registered. (2)(3)	8	8,820
B685	141 (new)	Amendment; add a new biochemical unregistered source of active ingredient or a new microbial production site. Requires submission of analysis of samples data and source/production site-specific manufacturing process description. (3)	5	5,107

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

''TABLE 15. — BIOPESTICIDES DIVISION — SCLP

EPA No.	**New CR No.**	**Action**	**Decision Review Time (Months)**(1)	**FY'17 & FY'18 Registration Service Fee ($)**
B690	142	New active ingredient; food or non-food use. (2)(6)	7	2,554
B700	143	Experimental Use Permit application; new active ingredient or new use. (6)	7	1,278
B701	144	Extend or amend Experimental Use Permit. (6)	4	1,278

''TABLE 15. — BIOPESTICIDES DIVISION — SCLP— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B710	145	New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption. No data review, or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data or authorization from data owner is demonstrated. Category includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission or data matrix. (3)(6)	4	1,278

''TABLE 15. — BIOPESTICIDES DIVISION — SCLP— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B720	146	New product; registered source of active ingredient(s); requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (3)(6)	5	1,278

"TABLE 15. — BIOPESTICIDES DIVISION — SCLP— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B721	147	New product; unregistered source of active ingredient. (3)(6)	7	2,676
B722	148	New use and/or amendment; petition to establish a tolerance or tolerance exemption. (4)(5)(6)	7	2,477
B730	149	Label amendment requiring data submission. (4)(6)	5	1,278

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(4) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

(5) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screen, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

(6) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

"TABLE 16. — BIOPESTICIDES DIVISION — OTHER ACTIONS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B614	150	Pre-application; Conditional Ruling on rationales for addressing a data requirement in lieu of data; applicant-initiated; applies to one rationale at a time.	3	2,530
B615	151	Rebuttal of agency reviewed protocol, applicant initiated.	3	2,530
B682	152	Protocol review; applicant initiated; excludes time for HSRB review.	3	2,432

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

"TABLE 17. — BIOPESTICIDES DIVISION — PIP

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B740	153	Experimental Use Permit application; no petition for tolerance/tolerance exemption. Includes: 1. non-food/feed use(s) for a new (2) or registered (3) PIP (12); 2. food/feed use(s) for a new or registered PIP with crop destruct (12); 3. food/feed use(s) for a new or registered PIP in which an established tolerance/tolerance exemption exists for the intended use(s). (4)(12)	6	95,724

"TABLE 17. — BIOPESTICIDES DIVISION — PIP— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B741	154 (new)	Experimental Use Permit application; no petition for tolerance/tolerance exemption. Includes: 1. non-food/feed use(s) for a new (2) or registered (3) PIP; 2. food/feed use(s) for a new or registered PIP with crop destruct; 3. food/feed use(s) for a new or registered PIP in which an established tolerance/tolerance exemption exists for the intended use(s); SAP Review. (12)	12	159,538
B750	155	Experimental Use Permit application; with a petition to establish a temporary or permanent tolerance/tolerance exemption for the active ingredient. Includes new food/feed use for a registered (3) PIP. (4)(12)	9	127,630

"TABLE 17. — BIOPESTICIDES DIVISION — PIP— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B770	156	Experimental Use Permit application; new (2) PIP; with petition to establish a temporary tolerance/ tolerance exemption for the active ingredient; credit 75% of B771 fee toward registration application for a new active ingredient that follows; SAP review. (5)(12)	15	191,444
B771	157	Experimental Use Permit application; new (2) PIP; with petition to establish a temporary tolerance/ tolerance exemption for the active ingredient; credit 75% of B771 fee toward registration application for a new active ingredient that follows. (12)	10	127,630
B772	158	Application to amend or extend an Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active ingredient is unaffected. (12)	3	12,764

"TABLE 17. — BIOPESTICIDES DIVISION — PIP— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B773	159	Application to amend or extend an Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient. (12)	5	31,910
B780	160	Registration application; new (2) PIP; non-food/feed. (12)	12	159,537
B790	161	Registration application; new (2) PIP; non-food/feed; SAP review. (5)(12)	18	223,351
B800	162	Registration application; new (2) PIP; with petition to establish permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/ tolerance exemption. (12)	13	172,300

"TABLE 17. — BIOPESTICIDES DIVISION — PIP— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B810	163	Registration application; new (2) PIP; with petition to establish permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/ tolerance exemption. SAP review. (5)(12)	19	236,114
B820	164	Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient. (12)	15	204,208
B840	165	Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient. SAP review. (5)(12)	21	268,022

"TABLE 17. — BIOPESTICIDES DIVISION — PIP— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B851	166	Registration application; new event of a previously registered PIP active ingredient(s); no petition since permanent tolerance/ tolerance exemption is already established for the active ingredient(s). (12)	9	127,630
B870	167	Registration application; registered (3) PIP; new product; new use; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (4) (12)	9	38,290
B880	168	Registration application; registered (3) PIP; new product or new terms of registration; additional data submitted; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (6) (7) (12)	9	31,910

"TABLE 17. — BIOPESTICIDES DIVISION — PIP— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B881	169	Registration application; registered (3) PIP; new product or new terms of registration; additional data submitted; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). SAP review. (5)(6)(7)(12)	15	95,724
B882	170 (new)	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/ tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption; SAP Review. (8)(12)	15	191,444

"TABLE 17. — BIOPESTICIDES DIVISION — PIP— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B883	171	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/ tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. (8) (12)	9	127,630
B884	172	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/ tolerance exemption for the active ingredient. (8)(12)	12	159,537
B885	173	Registration application; registered (3) PIP, seed increase; breeding stack of previously approved PIPs, same crop; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (9)(12)	6	31,910

"TABLE 17. — BIOPESTICIDES DIVISION — PIP— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B886	174 (new)	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient. SAP Review. (8) (12)	18	223,351
B890	175	Application to amend a seed increase registration; converts registration to commercial registration; no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s). (12)	9	63,816
B891	176	Application to amend a seed increase registration; converts registration to a commercial registration; no petition since a permanent tolerance/tolerance exemption already established for the active ingredient(s); SAP review. (5)(12)	15	127,630

"TABLE 17. — BIOPESTICIDES DIVISION — PIP— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B900	177	Application to amend a registration, including actions such as extending an expiration date, modifying an IRM plan, or adding an insect to be controlled. (10)(11)(12)	6	12,764
B901	178	Application to amend a registration, including actions such as extending an expiration date, modifying an IRM plan, or adding an insect to be controlled. SAP review. (10) (11) (12)	12	76,578
B902	179	PIP Protocol review.	3	6,383
B903	180	Inert ingredient tolerance exemption; e.g., a marker such as NPT II; reviewed in BPPD.	6	63,816
B904	181	Import tolerance or tolerance exemption; processed commodities/food only (inert or active ingredient).	9	127,630
B905	182 (new)	SAP Review.	6	63,816

"TABLE 17. — BIOPESTICIDES DIVISION — PIP— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
B906	183 (new)	Petition to establish a temporary tolerance/tolerance exemption for one or more active ingredients.	3	31,907
B907	184 (new)	Petition to establish a temporary tolerance/tolerance exemption for one or more active ingredients based on an existing temporary tolerance/tolerance exemption.	3	12,764
B908	185 (new)	Petition to establish a temporary tolerance/tolerance exemption for one or more active ingredients or inert ingredients.	3	44,671

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) New PIP = a PIP with an active ingredient that has not been registered.

(3) Registered PIP = a PIP with an active ingredient that is currently registered.

(4) Transfer registered PIP through conventional breeding for new food/feed use, such as from field corn to sweet corn.

(5) The scientific data involved in this category are complex. EPA often seeks technical advice from the Scientific Advisory Panel on risks that pesticides pose to wildlife, farm workers, pesticide applicators, non-target species, as well as insect resistance, and novel scientific issues surrounding new technologies. The scientists of the SAP neither make nor recommend policy decisions. They provide advice on the science used to make these decisions. Their advice is invaluable to the EPA as it strives to protect humans and the environment from risks posed by pesticides. Due to the time it takes to schedule and prepare for meetings with the SAP, additional time and costs are needed.

(6) Registered PIPs stacked through conventional breeding.

(7) Deployment of a registered PIP with a different IRM plan (e.g., seed blend).

(8) The negotiated acreage cap will depend upon EPA's determination of the potential environmental exposure, risk(s) to non-target organisms, and the risk of targeted pest developing resistance to the pesticidal substance. The uncertainty of these risks may reduce the allowable acreage, based upon the quantity and type of non-target organism data submitted and the lack of insect resistance management data, which is usually not required for seed-increase registrations. Registrants are encouraged to consult with EPA prior to submission of a registration application in this category.

(9) Application can be submitted prior to or concurrently with an application for commercial registration.

(10) For example, IRM plan modifications that are applicant-initiated.

(11) EPA-initiated amendments shall not be charged fees.

(12) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

"TABLE 18. — INERT INGREDIENTS

EPA No.	**New CR No.**	**Action**	**Decision Review Time (Months)**(1)	**FY'17 & FY'18 Registration Service Fee ($)**
I001	186	Approval of new food use inert ingredient. (2)(3)	13	27,000
I002	187	Amend currently approved inert ingredient tolerance or exemption from tolerance; new data. (2)	11	7,500
I003	188	Amend currently approved inert ingredient tolerance or exemption from tolerance; no new data. (2)	9	3,308

''TABLE 18. — INERT INGREDIENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
I004	189	Approval of new non-food use inert ingredient. (2)	6	11,025
I005	190	Amend currently approved non-food use inert ingredient with new use pattern; new data. (2)	6	5,513
I006	191	Amend currently approved non-food use inert ingredient with new use pattern; no new data. (2)	3	3,308
I007	192	Approval of substantially similar non-food use inert ingredients when original inert is compositionally similar with similar use pattern. (2)	4	1,654
I008	193	Approval of new or amended polymer inert ingredient, food use. (2)	5	3,749
I009	194	Approval of new or amended polymer inert ingredient, non-food use. (2)	4	3,087

''TABLE 18. — INERT INGREDIENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
I010	195	Petition to amend a single tolerance exemption descriptor, or single non-food use descriptor, to add ≤ 10 CASRNs; no new data. (2)	6	1,654
I011	196 (new)	Approval of new food use safener with tolerance or exemption from tolerance. (2)(8)	24	597,683
I012	197 (new)	Approval of new non-food use safener. (2)(8)	21	415,241
I013	198 (new)	Approval of additional food use for previously approved safener with tolerance or exemption from tolerance. (2)	15	62,975
I014	199 (new)	Approval of additional non-food use for previously approved safener. (2)	15	25,168
I015	200 (new)	Approval of new generic data for previously approved food use safener. (2)	24	269,728

''TABLE 18. — INERT INGREDIENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
I016	201 (new)	Approval of amendment(s) to tolerance and label for previously approved safener. (2)	13	55,776

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) If another covered application is submitted that depends upon an application to approve an inert ingredient, each application will be subject to its respective registration service fee. The decision review time line for both submissions will be the longest of the associated applications. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.

(3) If EPA data rules are amended to newly require clearance under section 408 of the FFDCA for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.

(4) Any other covered application that is associated with and dependent on the HSRB review will be subject to its separate registration service fee. The decision review times for the associated actions run concurrently, but will end at the date of the latest review time.

(5) Any other covered application that is associated with and dependent on the SAP review will be subject to its separate registration service fee. The decision review time for the associated action will be extended by the decision review time for the SAP review.

(6) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(7) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(8) If a new safener is submitted in the same package as a new active ingredient, and that new active ingredient is determined to be reduced risk, then the safener would get the same reduced timeframe as the new active ingredient.

"TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
M001	202	Study protocol requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of an active ingredient. (4)	9	7,938
M002	203	Completed study requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of an active ingredient. (4)	9	7,938

"TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
M003	204	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of less than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA § 25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (5)	12	63,945

"TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
M004	205	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of greater than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA § 25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (5)	18	63,945

"TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
M005	206	New Product: Combination, Contains a combination of active ingredients from a registered and/or unregistered source; conventional, antimicrobial and/or biopesticide. Requires coordination with other regulatory divisions to conduct review of data, label and/or verify the validity of existing data as cited. Only existing uses for each active ingredient in the combination product. (6)(7)	9	22,050
M006	207	Request for up to 5 letters of certification (Gold Seal) for one actively registered product (excludes distributor products). (8)	1	277

"TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
M007	208	Request to extend Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(ii).	12	5,513
M008	209	Request to grant Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(vi) for a minor use, when a FIFRA Section 2(ll)(2) determination is required.	15	1,654
M009	210 (new)	Non-FIFRA Regulated Determination: Applicant initiated, per product.	4	2,363
M010	211 (new)	Conditional ruling on pre-application, product substantial similarity.	4	2,363
M011	212 (new)	Label amendment to add the DfE logo; requires data review; no other label changes. (9)	4	3,648

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

(2) If another covered application is submitted that depends upon an application to approve an inert ingredient, each application will be subject to its respective registration service fee. The decision review time line for both submissions will be the longest of the associated applications. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.

(3) If EPA data rules are amended to newly require clearance under section 408 of the FFDCA for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.

(4) Any other covered application that is associated with and dependent on the HSRB review will be subject to its separate registration service fee. The decision review times for the associated actions run concurrently, but will end at the date of the latest review time.

(5) Any other covered application that is associated with and dependent on the SAP review will be subject to its separate registration service fee. The decision review time for the associated action will be extended by the decision review time for the SAP review.

(6) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(7) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(8) Due to low fee and short time frame this category is not eligible for small business waivers. Gold seal applies to one registered product.

(9) This category includes amendments the sole purpose of which is to add DfE (or equivalent terms that do not use ''safe'' or derivatives of ''safe'') logos to a label. DfE is a voluntary program. A label bearing a DfE logo is not considered an Agency endorsement because the ingredients in the qualifying product must meet objective, scientific criteria established and widely publicized by EPA.''.

Passed the House of Representatives March 20, 2017.

Attest: KAREN L. HAAS,

Clerk.