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Part 1

PESTICIDE REGISTRATION ENHANCEMENT ACT OF 2017

MARCH 20, 2017.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. CONAWAY, from the Committee on Agriculture, submitted the following

R E P O R T

[To accompany H.R. 1029]

[Including cost estimate of the Congressional Budget Office]

The Committee on Agriculture, to whom was referred the bill (H.R. 1029) 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, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment is as follows:

Strike all after the enacting clause and insert the following:

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 information 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.

Subsection (a) of section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136c) is amended to read as follows:

"(a) APPLICATION AND ISSUANCE.—

"(1) APPLICATION.—Any person may apply to the Administrator for an experimental use permit for a pesticide. An application for an experimental use permit may be filed at any time.

"(2) REQUIREMENTS.—An application for an experimental use permit shall conform with the requirements of section 33(b).

"(3) ISSUANCE.—The decision whether to grant an experimental use permit shall be made within the time-frame specified in the applicable covered application category specified in section 33(b)(3).".

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 it 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 covered 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, Non-food 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, Non-food use; indoor. (2)(3)	20	290,994
R120	8	New Active Ingredient, Non-food use; indoor; reduced risk. (2)(3)	14	242,495
R121	9	New Active Ingredient, Non-food 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
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
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
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

''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 ($)
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
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
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 non-food 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
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
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 plant-back restrictions; applicant-initiated. (3) (4)	15	66,124

''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 ($)
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 plant-back restrictions; applicant-initiated. (3) (4)	15	396,742
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
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
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
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
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
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
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
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
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

''TABLE 7. — ANTIMICROBIALS DIVISION — NEW ACTIVE INGREDIENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
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, non-food. (4)(5)	12	31,910
A501	80	New use, non-food; 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% repackage of registered end-use or manufacturing use product that requires no data submission nor data matrix. (2)(3)	4	1,278
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
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
A542	86 (new)	New end use product; FIFRA §2(mm) uses only; = 51 public health organisms. (2)(3)(5)	10	15,000

''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 ($)
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
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
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
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
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 Preapplication Study Waiver or Data Bridging Argument; applicant-initiated.	6	2,409
A536	106 (new)	Conditional Ruling on Preapplication 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
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
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% re-package 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
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
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
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
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

''TABLE 14. — BIOPESTICIDES DIVISION — AMENDMENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
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
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
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
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
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

''TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
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
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
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
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

''TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
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
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
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
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
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
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

"TABLE 18. — INERT INGREDIENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
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
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
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
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
M007	208	Request to extend Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(ii).	12	5,513

''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 ($)
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.".

BRIEF EXPLANATION

The Pesticide Registration Enhancement Act of 2017, H.R. 1029, reauthorizes provisions in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that couple the collection of fees with specific decision review periods for pesticide registrations and maintenance activities.

PURPOSE AND NEED FOR LEGISLATION

The first derivation of this program, known as PRIA, was passed in 2003 to provide predictable timelines in the pesticide registration process and increase transparency between EPA and the registrant community.

The original PRIA legislation updated the process for collecting maintenance fees and required EPA to conduct pesticide reviews in a specific timeframe. It also authorized a new type of fee—registration service fees—to defray costs associated with EPA review of applications for registering new pesticide active ingredients and products, adding new uses to existing pesticide registrations, establishing and amending tolerances, and amending pesticide labels. PRIA established a schedule outlining the fee amounts associated with each specific activity. It also promoted shorter decision review periods for reduced-risk applications.

The current PRIA legislation expires on September 30, 2017. H.R. 1029 extends the Act with minor adjustments. It reauthorizes existing provisions for seven years, as opposed to the five year extensions in previous iterations of PRIA. The legislation provides two increases of 5% each on registration fees over the seven years. H.R. 1029 also provides a $500,000 set aside for EPA to meet deadlines for efficacy guidelines for pesticides to combat bed bugs (which have shut down schools, hotels, dorms, and movie theaters), and crawling and flying insects, which will inform industry what efficacy tests are required. The bill increases maintenance fees to $31 million annually from 2017–2023 and provides increased funding for grant programs, promoting Good Laboratory Practices, and farm worker protection education. This iteration also sets the appropriations trigger level at 2012 budget levels of $128 million ensuring that the industry fee supplements appropriations.

The committee believes that after many years as a successful program, PRIA continues to provide predictable timelines for over 200 product categories allowing industry to grow and innovate, adding jobs to the U.S. economy and providing additional options for consumers.

SECTION-BY-SECTION ANALYSIS OF LEGISLATION

Section I. Short title; Table of Contents

Section 1 of the bill designates the title of the bill as the "Pesticide Registration Enhancement Act of 2017" and enumerates the table of contents.

Section 2. Extension and modification of maintenance fee authority

Section 2 of the bill amends section 4(i) of FIFRA (7 U.S.C. 136a-1(i)(1)).

Subsection (a) extends the maintenance fee provision until 2023 as well as increasing the total amount of maintenance fees to $31 million. The section does the same for the fees for small businesses.

Subsection (b) extends the prohibition on levying registration fees not otherwise authorized under PRIA, including a prohibition on tolerance fees.

Subsection (c) is a conforming amendment to the Federal Food, Drug, and Cosmetic Act to extend the prohibition on collection of tolerance fees.

Section 3. Registration and Expedited Processing Fund

Section 3 amends section 4(k) of FIFRA (7 U.S.C. 136a-1(k)(2)(A)).

Subsection (a) includes additional uses for the fees collected such as defraying the costs of registration review, including the cost associated with Endangered Species Act review, as well as offsetting the costs associated with tracking and implementing registration review decisions.

Subsection (b) updates the date for review of inert ingredients through fiscal year 2023.

Subsection (c) provides funds for EPA to develop and finalize guidance for product performance data requirements for certain invertebrate pests of significance public importance. The subsection further establishes a timeline for the development of such guidance.

Subsection (d) creates a new set-aside for good laboratory practices inspections.

Section 4. Experimental use permits for pesticides

Section 4 amends section 5 of FIFRA to codify timeframes for experimental use permits consistent with the categories in section 33(b).

Section 5. Pesticide registration service fees

Section 5 amends section 33 of FIFRA (7 U.S.C. 136w-8).

Subsection (a) clarifies that applications for inert ingredients, Gold Seal letters, and any other actions that are not specifically pesticide activities are subject to a registration service fee.

The subsection further extends two existing 5 percent increases to the registration service fees. This subsection also includes the small business waiver, except for requests for the Gold Seal letter of certification, which are low cost fees.

Subsection (b) extends the set-aside for worker protection, partnership grants, and pesticide safety education until 2023. It further emphasizes that activities relating to worker protection shall focus on field worker populations in the United States.

Subsection (c) directs EPA to look for streamlining opportunities for review process applications.

Subsection (d) provides several clarifying and conforming amendments.

Subsection (e) extends the annual reporting requirements until 2023 and amends the required content of the reports to encourage greater transparency in pesticide registrations. It also requires reporting on the implementation of the product performing test guidelines, a review of the good laboratory practices standards compliance monitoring program, a reporting on the current "Safer Choice" program.

Subsection (f) extends the termination of effectiveness section until September 30, 2023, including the current two year phase out period.

Section 6. Revision of tables regarding covered pesticide registration applications and other covered actions and their corresponding registration service fees

Section 6 codifies the necessary changes to the schedule of registration applications and the corresponding tables included in the statute.

COMMITTEE CONSIDERATION

I. HEARINGS

The Committee held a round table discussion on February 14, 2017 to review reauthorization of the Pesticide Registration Improvement Act (PRIA).

Members of the Committee heard presentations and discussed reauthorization of the Pesticide Registration Improvement Act (PRIA). PRIA first passed Congress in 2003 with the full support of the registrant community (comprised of large and small companies ranging from pesticide and biopesticide manufacturers to antimicrobial companies, to biotech firms), as well as labor and environmental advocates. The nature of PRIA is very technical, but the widespread benefits across industries has gained it consistent bipartisan support. PRIA has been authorized three times, with most recent reauthorization due to expire on September 30, 2017. During the round table discussion, the following participants gave presentations on the reauthorization of PRIA:

- Beau Greenwood, CropLife America, Washington, DC
- Steve Goldberg, CropLife America, Washington, DC
- Steve Christenson, Ecolab, St. Paul, MN
- Virginia Ruiz, Farmworker Justice, Washington, DC

II. FULL COMMITTEE

The Committee on Agriculture met, pursuant to notice, with a quorum present, on February 16, 2017, to consider H.R. 1029, Pesticide Registration Enhancement Act of 2017.

H.R. 1029 was placed before the Committee for consideration. Without objection, a first reading of the bill was waived and it was open for amendment at any point.

Chairman Conaway and Mr. Peterson were recognized for statements. Chairman Conaway recognized Mr. Davis for a technical amendment, which passed by a voice vote. Mr. Peterson was recognized to offer a motion that the bill H.R. 1029 be reported, as amended, favorably to the House with the recommendation that it do pass. The motion was subsequently approved by voice vote.

At the conclusion of the meeting, Chairman Conaway advised Members that pursuant to the rules of the House of Representatives Members had until February 21, 2017, to file any supplemental, minority, additional, or dissenting views with the Committee.

Without objection, staff was given permission to make any necessary clerical, technical or conforming changes to reflect the intent of the Committee. Chairman Conaway thanked all the Members and adjourned the meeting.

COMMITTEE VOTES

In compliance with clause 3(b) of rule XIII of the House of Representatives, H.R. 1029 was reported by voice vote with a majority quorum present. There was no request for a recorded vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee on Agriculture's oversight findings and recommendations are reflected in the body of this report.

BUDGET ACT COMPLIANCE (SECTIONS 308, 402, AND 423)

The provisions of clause 3(c)(2) of rule XIII of the Rules of the House of Representatives and section 308(a)(1) of the Congressional Budget Act of 1974 (relating to estimates of new budget authority, new spending authority, new credit authority, or increased or decreased revenues or tax expenditures) are not considered applicable. The estimate and comparison required to be prepared by the Director of the Congressional Budget Office under clause 3(c)(3) of rule XIII of the Rules of the House of Representatives and sections 402 and 423 of the Congressional Budget Act of 1974 submitted to the Committee prior to the filing of this report are as follows:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, March 20, 2017.

Hon. K. MICHAEL CONAWAY,
Chairman, Committee on Agriculture,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 1029, the Pesticide Registration Enhancement Act of 2017.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Jon Sperl.

Sincerely,

MARK P. HADLEY
(For Keith Hall).

Enclosure.

H.R. 1029—Pesticide Registration Enhancement Act of 2017

Summary: H.R. 1029 would modify the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the law that regulates the distribution, sale, and use of pesticides, with the aim of strengthening the Environmental Protection Agency's (EPA's) ability to evaluate and regulate pesticides. Under FIFRA, the EPA is required to evaluate the safety of new pesticides entering the market by conducting risk assessments and must periodically reevaluate the health and environmental effects of pesticides. The EPA charges fees to pesticide manufacturers and distributors to cover the agency's costs of performing those registration and reregistration activities.

The legislation would extend the agency's authority to charge those fees—currently set to expire in 2018—and also would increase the total amount of fees that the agency is allowed to

charge. Additional fees would lead to a net reduction in spending over the next five years of $1 million for related activities; such spending is subject to appropriation. CBO estimates that enacting the bill would reduce direct spending by $24 million over the 2018–2022 period, but would have no significant net effect on direct spending over the 2018–2027 period.

Because enacting the bill would affect direct spending, pay-as-you-go procedures apply. Enacting the bill would not affect revenues. CBO estimates that enacting H.R. 1029 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2028.

The bill would impose intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that the cost of those mandates would fall below the annual thresholds for intergovernmental and private-sector mandates established in UMRA ($78 million and $156 million in 2017, respectively, adjusted annually for inflation).

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 1029 is shown in the following table. The costs of this legislation fall within budget function 300 (natural resources and environment).

	By fiscal year, in millions of dollars—												
	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2017–2022	2017–2027
INCREASES OR DECREASES (-) IN DIRECT SPENDING [a]													
Estimated Budget Authority	0	0	0	0	0	0	0	0	0	0	0	0	0
Estimated Outlays	0	0	−6	−6	−5	−4	−2	26	0	0	0	−24	0

[a] In addition CBO estimates that spending subject to appropriation would be reduced by about $1 million over the 2017–2022 period.

Basis of estimate: For this estimate, CBO assumes that the legislation will be enacted late in fiscal year 2017 and that the necessary amounts will be appropriated each year beginning in 2018.

Some of EPA's activities under FIFRA—those related to registering pesticides—are funded with fees that may only be collected if allowed for in appropriation acts. Other EPA activities—those related to the reregistration of pesticides—are funded with fees that are authorized to be collected and spent without further appropriation.

Changes in spending subject to appropriation

H.R. 1029 would extend the authority for the EPA to collect fees for registering new pesticides entering the market through 2025 and also would increase the level of those fees.

In 2016, the EPA collected $17 million in pesticide registration fees and spent approximately $19 million including some fees collected in previous years.

Based on information from the EPA about the number and type of pesticides that the agency expects to review in future years and assuming appropriation action consistent with the bill, CBO estimates that under H.R. 1029 the EPA would collect $17 million in registration fees in 2018, with those collections increasing to $19 million per year by 2023. In total, CBO estimates that the agency would collect about $92 million in pesticide registration fees over the 2018–2022 period and spend slightly less over that period, resulting in a net collection of around $1 million.

Changes in direct spending

The EPA also periodically reviews and reregisters pesticides that are already on the market. Under FIFRA, the EPA is authorized to collect up to $28 million per year in fees to offset the costs of those activities through 2018. The agency is authorized to spend those fees, which are recorded in the budget as reductions in direct spending, without further appropriation.

H.R. 1029 would extend the agency's authority to collect those fees through 2023 and would raise the statutory cap to $31 million per year. In 2016, the EPA collected $28 million in reregistration fees and spent $16 million on related activities.

Under H.R. 1029, CBO estimates that the EPA would collect and spend $186 million in reregistration fees over the 2018–2027 period. CBO expects that the EPA's collection of fees would continue to exceed spending in most years, resulting in a reduction in direct spending of $24 million over the 2018–2022 period. However, under the bill the agency's authority to collect receipts would expire after 2023. CBO estimates that the EPA would spend the accumulated balances of fees for reregistration activities in 2024.

Pay-As-You-Go considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending; therefore, pay-as-you-go procedures apply. The net changes in outlays that are subject to those pay-as-you-go procedures are shown in the following table.

CBO ESTIMATE OF PAY-AS-YOU-GO EFFECTS FOR H.R. 1029, AS ORDERED REPORTED BY THE HOUSE COMMITTEE ON AGRICULTURE ON FEBRUARY 16, 2017

	By fiscal year, in millions of dollars—												
	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2017–2022	2017–2027
NET INCREASE OR DECREASE (−) IN THE DEFICIT													
Statutory Pay-As-You-Go Impact	0	0	−6	−6	−5	−4	−2	26	0	0	0	−24	0

Increase in long-term direct spending and deficits: CBO estimates that enacting H.R. 1029 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2028.

Intergovernmental and private-sector impact: The bill would impose intergovernmental and private-sector mandates as defined in UMRA by extending reregistration fees for the use of pesticides through 2023. CBO estimates that those fees would total $31 million annually and that most of the amount collected would be borne by private entities. (Public entities usually receive waivers from reregistration fees for minor uses or public health purposes.) The bill would impose an additional private-sector mandate by extending pesticide registration fees through 2025. CBO estimates that those fees would total $18 million annually, on average, during the first five years that the mandate is in effect. In aggregate, CBO estimates that the cost of mandates in the bill would fall below the annual thresholds for intergovernmental and private-sector mandates established in UMRA ($78 million and $156 million in 2017, respectively, adjusted annually for inflation).

Estimate prepared by: Federal costs: Jon Sperl; Impact on state, local, and tribal governments: Zach Byrum; Impact on the private sector: Amy Petz.

Estimate approved by: H. Samuel Papenfuss, Deputy Assistant Director for Budget Analysis.

PERFORMANCE GOALS AND OBJECTIVES

H.R. 1029 does not authorize funding, therefore, clause 3(c)(4) of rule XIII of the Rules of the House of Representatives is inapplicable.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(2) of rule XIII of the Rules of the House of Representatives, the Committee report incorporates the cost estimate prepared by the Director of the Congressional Budget Office pursuant to sections 402 and 423 of the Congressional Budget Act of 1974.

ADVISORY COMMITTEE STATEMENT

No advisory committee within the meaning of section 5(b) of the Federal Advisory Committee Act was created by this legislation.

APPLICABILITY TO THE LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act (Public Law 104–1).

FEDERAL MANDATES STATEMENT

The Committee adopted as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act (Public Law 104–4).

EARMARK STATEMENT REQUIRED BY CLAUSE 9 OF RULE XXI OF THE RULES OF HOUSE OF REPRESENTATIVES

H.R. 1029 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(e), 9(f), or 9(g) of rule XXI of the Rules of the House Representatives.

DUPLICATION OF FEDERAL PROGRAMS

This bill does not establish or reauthorize a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee does not believe that the legislation directs an executive branch official to conduct any specific rule making proceedings within the meaning of 5 U.S.C. 551.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

* * * * * * *

SEC. 4. REREGISTRATION OF REGISTERED PESTICIDES.

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

(1) there are no outstanding data requirements; and

(2) the requirements of section 3(c)(5) have been satisfied.

(b) REREGISTRATION PHASES.—Reregistrations of pesticides under this section shall be carried out in the following phases:

(1) The first phase shall include the listing under subsection (c) of the active ingredients of the pesticides that will be reregistered.

(2) The second phase shall include the submission to the Administrator under subsection (d) of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants to replace such missing or inadequate data within the applicable time period.

(3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (e).

(4) The fourth phase shall include an independent, initial review by the Administrator under subsection (f) of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requests for additional data.

(5) The fifth phase shall include the review by the Administrator under subsection (g) of data submitted for reregistration and appropriate regulatory action by the Administrator.

(c) PHASE ONE.—

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

(A) are in use on or in food or feed and may result in postharvest residues;

(B) may result in residues of potential toxicological concern in potable ground water, edible fish, or shellfish;

(C) have been determined by the Administrator before the effective date of this section to have significant outstanding data requirements; or

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

(2) REREGISTRATION LISTS.—For purposes of reregistration under this section, the Administrator shall by order—

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

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

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

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

Each list shall be published in the Federal Register.

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

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

(d) PHASE TWO.—

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

(2) NOTICE OF INTENT TO SEEK OR NOT TO SEEK REREGISTRATION.—

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

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

(3) MISSING OR INADEQUATE DATA.—Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) and for which the registrant submitted a notice under paragraph (2) of an intention to seek reregistration of such pesticide shall submit to the Administrator—

(A) in accordance with regulations issued by the Administrator under section 3, an identification of—

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

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

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

(B) either—

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

(ii) an offer to share in the cost to be incurred by a person who has made a commitment under clause (i) to replace or submit the data and an offer to submit to arbitration as described by section 3(c)(2)(B) with regard to such cost sharing.

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

(4) TIME PERIODS.—

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

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

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

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

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

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (3)(B) within a reasonable period of time, as determined by the Adminis-

trator, but not more than 48 months after the date the registrant submitted the commitment. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of the date of enactment of the Food Quality Protection Act of 1996 if—

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

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

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

(iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 3(c)(2)(B) or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(5) CANCELLATION AND REMOVAL.—

(A) If the registrant of a pesticide does not submit a notice under paragraph (2) or (3) within the time prescribed by paragraph (4)(A), the Administrator shall issue a notice

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

(B)(i) If—

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

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

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

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

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

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

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

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

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

any action pursuant to this paragraph in regard to such unsupported minor use until the final deadline established as of the date of enactment of the Food Quality Protection Act of 1996, for the submission of data under this section for the supported uses identified pursuant to this paragraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a determination the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 6(f)(1). If the Administrator grants an extension under this paragraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 3(c)(2)(B)(iv) regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 6(f)(2). Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(e) PHASE THREE.—

(1) INFORMATION ABOUT STUDIES.—Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) who has submitted a notice under subsection (d)(2) of an intent to seek the reregistration of such pesticide shall submit, in accordance with the guidelines issued under paragraph (4), to the Administrator—

(A) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient and considered by the registrant to be adequate to meet the requirements of section 3 and the regulations issued under such section;

(B) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient that may not comply with the requirements of section 3 and the regulations issued under such section but which the registrant asserts should be deemed to comply with such requirements and regulations;

(C) a reformat of the data from each study summarized under subparagraph (A) or (B) by the registrant concerning chronic dosing, oncogenicity, reproductive effects,

mutagenicity, neurotoxicity, teratogenicity, or residue chemistry of the active ingredient that were submitted to the Administrator before January 1, 1982;

(D) where data described in subparagraph (C) are not required for the active ingredient by regulations issued under section 3, a reformat of acute and subchronic dosing data submitted by the registrant to the Administrator before January 1, 1982, that the registrant considers to be adequate to meet the requirements of section 3 and the regulations issued under such section;

(E) an identification of data that are required to be submitted to the Administrator under section 6(a)(2) indicating an adverse effect of the pesticide;

(F) an identification of any other information available that in the view of the registrant supports the registration;

(G) a certification that the registrant or the Administrator possesses or has access to the raw data used in or generated by the studies that the registrant summarized under subparagraph (A) or (B);

(H) either—

(i) a commitment to submit data to fill each outstanding data requirement identified by the registrant; or

(ii) an offer to share in the cost of developing such data to be incurred by a person who has made a commitment under clause (i) to submit such data, and an offer to submit to arbitration as described by section 3(c)(2)(B) with regard to such cost sharing; and

(I) evidence of compliance with section 3(c)(1)(D)(ii) and regulations issued thereunder with regard to previously submitted data as if the registrant were now seeking the original registration of the pesticide.

A registrant who submits a certification under subparagraph (G) that is false shall be considered to have violated this Act and shall be subject to the penalties prescribed by section 14.

(2) TIME PERIODS.—

(A) The information required by paragraph (1) shall be submitted to the Administrator—

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

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

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

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (1)(H) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment under such para-

graph. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of the date of enactment of the Food Quality Protection Act of 1996 if—

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

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

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

(iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 3(c)(2)(B) or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(3) CANCELLATION.—

(A) If the registrant of a pesticide fails to submit the information required by paragraph (1) within the time prescribed by paragraph (2), the Administrator, by order and without hearing, shall cancel the registration of such pes-

ticide. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this subparagraph in regard to such unsupported minor use until the final deadline established as of the date of enactment of the Food Quality Protection Act of 1996, for the submission of data under this section for the supported uses identified pursuant to this subparagraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 6(f)(1). If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 3(c)(2)(B)(iv) regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 6(f)(2). Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(B)(i) If the registrant of a pesticide submits the information required by paragraph (1) within the time prescribed by paragraph (2) and such information does not conform to the guidelines for submissions established by the Administrator, the Administrator shall determine whether the registrant made a good faith attempt to conform its submission to such guidelines.

(ii) If the Administrator determines that the registrant made a good faith attempt to conform its submission to such guidelines, the Administrator shall provide the reg-

istrant a reasonable period of time to make any necessary changes or corrections.

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

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

(III) If a hearing is requested, a hearing shall be conducted under section 6(d), except that the only matter for resolution at the hearing shall be whether the registrant made a good faith attempt to conform its submission to such guidelines. The hearing shall be held and a determination made within 75 days after receipt of a request for hearing.

(4) GUIDELINES.—

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

(i) summarizing studies;

(ii) reformatting studies;

(iii) identifying adverse information; and

(iv) identifying studies that have been submitted previously that may not meet the requirements of section 3 or regulations issued under such section,

under paragraph (1).

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

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

(f) PHASE FOUR.—

(1) INDEPENDENT REVIEW AND IDENTIFICATION OF OUTSTANDING DATA REQUIREMENTS.—

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

(B) The Administrator shall independently identify and publish in the Federal Register the outstanding data requirements for each active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (c)(2) and that is contained in a pesticide to be reregistered under this section. The Administrator, at the same time, shall issue a notice under section 3(c)(2)(B) for the submission of the additional data that are required to meet such requirements.

(2) TIME PERIODS.—

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

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

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

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

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

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

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

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

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

(iv) of section 3(c)(2)(B) or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(3) SUSPENSIONS AND PENALTIES.—The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 3(c)(2)(B)(iv) if the Administrator determines that (A) tests necessary to fill an outstanding data requirement for such pesticide have not been initiated within 1 year after the issuance of a notice under paragraph (1)(B), or (B) progress is insufficient to ensure submission of the data referred to in clause (A) within the time period prescribed by paragraph (2)(B) or the required data have not been submitted to the Administrator within such time period. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this paragraph in regard to such unsupported minor use until the final deadline established as of the date of enactment of the Food Quality Protection Act of 1996, for the submission of data under this section for the supported uses identified pursuant to this paragraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a determination the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 6(f)(1). If the Administrator grants an extension under this paragraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 3(c)(2)(B)(iv) regarding the continued registration of the af-

fected products with the minor and other uses and shall inform the public of such action in accordance with section 6(f)(2). Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(g) PHASE FIVE.—

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

(2) REREGISTRATION AND OTHER ACTIONS.—

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

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

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

(B) PRODUCT-SPECIFIC DATA.—

(i) IN GENERAL.—Before reregistering a pesticide, the Administrator shall obtain any needed product-specific data regarding the pesticide by use of section 3(c)(2)(B) and shall review such data within 90 days after its submission.

(ii) TIMING.—

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

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

(C) After conducting the review required by paragraph (1) for each active ingredient of a pesticide and the review required by subparagraph (B) of this paragraph, the Administrator shall determine whether to reregister a pes-

ticide by determining whether such pesticide meets the requirements of section 3(c)(5). If the Administrator determines that a pesticide is eligible to be reregistered, the Administrator shall reregister such pesticide within 6 months after the submission of the data concerning such pesticide under subparagraph (B).

(D) DETERMINATION TO NOT REREGISTER.—

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

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

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

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

(ii) determine whether such tolerance or exemption meets the requirements of that Act;

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

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

(v) commence promptly such proceedings under this Act and section 408 of the Federal Food, Drug, and Cosmetic Act as are warranted by such determinations.

(h) COMPENSATION OF DATA SUBMITTER.—If data that are submitted by a registrant under subsection (d), (e), (f), or (g) are used to support the application of another person under section 3, the registrant who submitted such data shall be entitled to compensation for the use of such data as prescribed by section 3(c)(1)(D). In determining the amount of such compensation, the fees paid by the registrant under this section shall be taken into account.

(i) FEES.—

(1) MAINTENANCE FEE.—

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

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

significantly reduce the availability of the pesticide for the use.

(C) TOTAL AMOUNT OF FEES.—The amount of each fee prescribed under subparagraph (A) shall be adjusted by the Administrator to a level that will result in the collection under this paragraph of, to the extent practicable, [an aggregate amount of $27,800,000 for each of fiscal years 2013 through 2017] *an average amount of $31,000,000 for each of fiscal years 2017 through 2023*.

(D) MAXIMUM AMOUNT OF FEES FOR REGISTRANTS.—The maximum annual fee payable under this paragraph by—

(i) a registrant holding not more than 50 pesticide registrations shall be [$115,500 for each of fiscal years 2013 through 2017] *$129,400 for each of fiscal years 2017 through 2023*; and

(ii) a registrant holding over 50 registrations shall be [$184,800 for each of fiscal years 2013 through 2017] *$207,000 for each of fiscal years 2017 through 2023*.

(E) MAXIMUM AMOUNT OF FEES FOR SMALL BUSINESSES.—

(i) IN GENERAL.—For a small business, the maximum annual fee payable under this paragraph by—

(I) a registrant holding not more than 50 pesticide registrations shall be [$70,600 for each of fiscal years 2013 through 2017] *$79,100 for each of fiscal years 2017 through 2023*; and

(II) a registrant holding over 50 pesticide registrations shall be [$122,100 for each of fiscal years 2013 through 2017] *$136,800 for each of fiscal years 2017 through 2023*.

(ii) DEFINITION OF SMALL BUSINESS.—

(I) IN GENERAL.—In clause (i), the term "small business" means a corporation, partnership, or unincorporated business that—

(aa) has 500 or fewer employees; and

(bb) during the 3-year period prior to the most recent maintenance fee billing cycle, had an average annual global gross revenue from pesticides that did not exceed $60,000,000.

(II) AFFILIATES.—

(aa) IN GENERAL.—In the case of a business entity with 1 or more affiliates, the gross revenue limit under subclause (I)(bb) shall apply to the gross revenue for the entity and all of the affiliates of the entity, including parents and subsidiaries, if applicable.

(bb) AFFILIATED PERSONS.—For the purpose of item (aa), persons are affiliates of each other if, directly or indirectly, either person controls or has the power to control the other person, or a third person controls or has the power to control both persons.

(cc) INDICIA OF CONTROL.—For the purpose of item (aa), indicia of control include interlocking management or ownership, identity of

interests among family members, shared facilities and equipment, and common use of employees.

(F) FEE REDUCTION FOR CERTAIN SMALL BUSINESSES.—

(i) DEFINITION.—In this subparagraph, the term "qualified small business entity" means a corporation, partnership, or unincorporated business that—

(I) has 500 or fewer employees;

(II) during the 3-year period prior to the most recent maintenance fee billing cycle, had an average annual global gross revenue from all sources that did not exceed $10,000,000; and

(III) holds not more than 5 pesticide registrations under this paragraph.

(ii) WAIVER.—Except as provided in clause (iii), the Administrator shall waive 25 percent of the fee under this paragraph applicable to the first registration of any qualified small business entity under this paragraph.

(iii) LIMITATION.—The Administrator shall not grant a waiver under clause (ii) to a qualified small business entity if the Administrator determines that the entity has been formed or manipulated primarily for the purpose of qualifying for the waiver.

(G) The Administrator shall exempt any public health pesticide from the payment of the fee prescribed under this paragraph if, in consultation with the Secretary of Health and Human Services, the Administrator determines, based on information supplied by the registrant, that the economic return to the registrant from sales of the pesticide does not support the registration or reregistration of the pesticide.

(H) If any fee prescribed by this paragraph with respect to the registration of a pesticide is not paid by a registrant by the time prescribed, the Administrator, by order and without hearing, may cancel the registration.

(I) The authority provided under this paragraph shall terminate on September 30, [2017] *2023*.

(2) OTHER FEES.—Except as provided in section 33, [during the period beginning on the date of enactment of this section and ending on September 30, 2019] *until September 30, 2025*, the Administrator may not levy any other fees for the registration of a pesticide under this Act *or any other action covered under a table specified in section 33(b)(3),* except as provided in paragraph (1).

(j) EXEMPTION OF CERTAIN REGISTRANTS.—The requirements of subsections (d), (e), (f), and (i) (other than subsection (i)(1)) regarding data concerning an active ingredient and fees for review of such data shall not apply to any person who is the registrant of a pesticide to the extent that, under section 3(c)(2)(D), the person would not be required to submit or cite such data to obtain an initial registration of such pesticide.

(k) REREGISTRATION AND EXPEDITED PROCESSING FUND.—

(1) ESTABLISHMENT.—There shall be established in the Treasury of the United States a reregistration and expedited

processing fund which shall be known as the Reregistration and Expedited Processing Fund.

(2) SOURCE AND USE.—

(A) All moneys derived from fees collected by the Administrator under subsection (i) shall be deposited in [the fund] *the Reregistration and Expedited Processing Fund* and shall be available to the Administrator, without fiscal year limitation, specifically to offset the costs of reregistration and expedited processing of the applications specified in [paragraph (3), to enhance the information systems capabilities to improve the tracking of pesticide registration decisions, and to offset the costs of registration review under section 3(g). Such moneys derived from fees may not be expended in any fiscal year to the extent such moneys derived from fees would exceed money appropriated for use by the Administrator and expended in such year for such costs of reregistration and expedited processing of such applications.] *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 information systems capabilities to improve the tracking of pesticide registration decisions.* The Administrator shall, prior to expending any such moneys derived from fees—

(i) effective October 1, 1997, adopt specific and cost accounting rules and procedures as approved by the General Accounting Office and the Inspector General of the Environmental Protection Agency to ensure that moneys derived from fees [are allocated solely to the costs of reregistration and expedited processing of the applications specified in paragraph (3), to enhance the information systems capabilities to improve the tracking of pesticide registration decisions, and to offset the costs of registration review under section 3(g);] *are allocated solely for the purposes specified in the first sentence of this subparagraph;*

(ii) prohibit the use of such moneys derived from fees to pay for any costs other than those [necessary to achieve reregistration and expedited processing of the applications specified in paragraph (3), to enhance the information systems capabilities to improve the tracking of pesticide registration decisions, and to offset the costs of registration review under section 3(g);] *necessary to achieve the purposes specified in the first sentence of this subparagraph;* and

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

(B) The Administrator shall also—

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

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

(3) REVIEW OF INERT INGREDIENTS; EXPEDITED PROCESSING OF SIMILAR APPLICATIONS.—

(A) **[**The Administrator shall use for each of the fiscal years 2004 through 2006, approximately $3,300,000, and for each of fiscal years 2013 through 2017, between 1/9 and 1/8, of the maintenance fees collected in such fiscal year to obtain sufficient personnel and resources—**]** *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—*

(i) to review and evaluate inert ingredients; and

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

(I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from any such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment;

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

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

(B) Any amounts made available under subparagraph (A) shall be used to obtain sufficient personnel and resources to carry out the activities described in such subparagraph that are in addition to the personnel and resources available to carry out such activities on the date of enactment of this section

(C) So long as the Administrator has not met the time frames specified in clause (ii) of section 3(c)(3)(B) with respect to any application subject to section 3(c)(3)(B) that was received prior to the date of enactment of the Food Quality Protection Act of 1996, the Administrator shall use the full amount of the fees specified in subparagraph (A) for the purposes specified therein. Once all applications subject to section 3(c)(3)(B) that were received prior to such date of enactment have been acted upon, no limitation shall be imposed by the preceding sentence of this subparagraph so long as the Administrator meets the time

frames specified in clause (ii) of section 3(c)(3)(B) on 90 percent of affected applications in a fiscal year. Should the Administrator not meet such time frames in a fiscal year, the limitations imposed by the first sentence of this subparagraph shall apply until all overdue applications subject to section 3(c)(3)(B) have been acted upon.

[(4) ENHANCEMENTS OF INFORMATION TECHNOLOGY SYSTEMS FOR IMPROVEMENT IN REVIEW OF PESTICIDE APPLICATIONS.—

[(A) IN GENERAL.—For each of fiscal years 2013 through 2017, the Administrator shall use not more than $800,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

[(B) ACTIVITIES.—The Administrator shall use amounts made available from the Reregistration and Expedited Processing Fund to improve the information systems capabilities for the Office of Pesticide Programs to enhance tracking of pesticide registration decisions, which shall include—

[(i) the electronic tracking of—

[(I) registration submissions; and

[(II) the status of conditional registrations;

[(ii) enhancing the database for information regarding endangered species assessments for registration review;

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

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

(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).

(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.

[(5)**]** *(6)* UNUSED FUNDS.—Money in the fund not currently needed to carry out this section shall be—

(A) maintained on hand or on deposit;

(B) invested in obligations of the United States or guaranteed thereby; or

(C) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

[(6)] *(7)* ACCOUNTING AND PERFORMANCE.—The Administrator shall take all steps necessary to ensure that expenditures from fees authorized by subsection (i)(1)(C)(ii) are used only for the purposes described in [paragraphs (2), (3), and (4)] *paragraphs (2), (3), (4), and (5)* and to carry out the goals established under subsection (l). The Reregistration and Expedited Processing Fund shall be designated as an Environmental Protection Agency component for purposes of section 3515(c) of title 31, United States Code. The annual audit required under section 3521 of such title of the financial statements of activities under this Act under section 3515(b) of such title shall include an audit of the fees collected under subsection (i)(1)(C) and disbursed, of the amount appropriated to match such fees, and of the Administrator's attainment of performance measures and goals established under subsection (l). Such an audit shall also include a review of the reasonableness of the overhead allocation and adequacy of disclosures of direct and indirect costs associated with carrying out the reregistration and expedited processing of the applications specified in paragraph (3), and the basis for and accuracy of all costs paid with moneys derived from such fees. The Inspector General shall conduct the annual audit and report the findings and recommendations of such audit to the Administrator and to the Committees on Agriculture of the House of Representatives and the Senate. The cost of such audit shall be paid for out of the fees collected under subsection (i)(1)(C).

(l) PERFORMANCE MEASURES AND GOAL.—The Administrator shall establish and publish annually in the Federal Register performance measures and goals. Such measures and goals shall include—

(1) the number of products reregistered, canceled, or amended, the status of reregistration, the number and type of data requests under section 3(c)(2)(B) issued to support product reregistration by active ingredient, the progress in reducing the number of unreviewed, required reregistration studies, the aggregate status of tolerances reassessed, and the number of applications for registration submitted under subsection (k)(3) that were approved or disapproved;

(2) the future schedule for reregistrations, including the projection for such schedules that will be issued under subsection (g)(2)(A) and (B) in the current fiscal year and the succeeding fiscal year; and

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

(m) JUDICIAL REVIEW.—Any failure of the Administrator to take any action required by this section shall be subject to judicial review under the procedures prescribed by section 16(b).

(n) AUTHORIZATION OF FUNDS TO DEVELOP PUBLIC HEALTH DATA.—

(1) DEFINITION.—For the purposes of this section, "Secretary" means the Secretary of Health and Human Services, acting through the Public Health Service.

(2) CONSULTATION.—In the case of a pesticide registered for use in public health programs for vector control or for other uses the Administrator determines to be human health protection uses, the Administrator shall, upon timely request by the registrant or any other interested person, or on the Administrator's own initiative may, consult with the Secretary prior to taking final action to suspend registration under section 3(c)(2)(B)(iv), or cancel a registration under section 4, 6(e), or 6(f). In consultation with the Secretary, the Administrator shall prescribe the form and content of requests under this section.

(3) BENEFITS TO SUPPORT FAMILY.—The Administrator, after consulting with the Secretary, shall make a determination whether the potential benefits of continued use of the pesticide for public health or health protection purposes are of such significance as to warrant a commitment by the Secretary to conduct or to arrange for the conduct of the studies required by the Administrator to support continued registration under section 3 or reregistration under section 4.

(4) ADDITIONAL TIME.—If the Administrator determines that such a commitment is warranted and in the public interest, the Administrator shall notify the Secretary and shall, to the extent necessary, amend a notice issued under section 3(c)(2)(B) to specify additional reasonable time periods for submission of the data.

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

(6) SUPPORT.—The Secretary may provide for support of the required studies using funds authorized to be appropriated under this section, the Public Health Service Act, or other appropriate authorities. After a determination is made under subsection (d), the Secretary shall notify the Committees on Appropriations of the House of Representatives and the Senate of the sums required to conduct the necessary studies.

(7) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out the purposes of this section $12,000,000 for fiscal year 1997, and such sums as may be necessary for succeeding fiscal years.

SEC. 5. EXPERIMENTAL USE PERMITS.

[(a) ISSUANCE.—Any person may apply to the Administrator for an experimental use permit for a pesticide. The Administrator shall review the application. After completion of the review, but not later than one hundred and twenty days after receipt of the application and all required supporting data, the Administrator shall either issue the permit or notify the applicant of the Administrator's de-

termination not to issue the permit and the reasons therefor. The applicant may correct the application or request a waiver of the conditions for such permit within thirty days of receipt by the applicant of such notification. The Administrator may issue an experimental use permit only if the Administrator determines that the applicant needs such permit in order to accumulate information necessary to register a pesticide under section 3 of this Act. An application for an experimental use permit may be filed at any time.]

(a) APPLICATION AND ISSUANCE.—

(1) APPLICATION.—Any person may apply to the Administrator for an experimental use permit for a pesticide. An application for an experimental use permit may be filed at any time.

(2) REQUIREMENTS.—An application for an experimental use permit shall conform with the requirements of section 33(b).

(3) ISSUANCE.—The decision whether to grant an experimental use permit shall be made within the time-frame specified in the applicable covered application category specified in section 33(b)(3).

(b) TEMPORARY TOLERANCE LEVEL.—If the Administrator determines that the use of a pesticide may reasonably be expected to result in any residue on or in food or feed, the Administrator may establish a temporary tolerance level for the residue of the pesticide before issuing the experimental use permit.

(c) USE UNDER PERMIT.—Use of a pesticide under an experimental use permit shall be under the supervision of the Administrator, and shall be subject to such terms and conditions and be for such period of time as the Administrator may prescribe in the permit.

(d) STUDIES.—When any experimental use permit is issued for a pesticide containing any chemical or combination of chemicals which has not been included in any previously registered pesticide, the Administrator may specify that studies be conducted to detect whether the use of the pesticide under the permit may cause unreasonable adverse effects on the environment. All results of such studies shall be reported to the Administrator before such pesticide may be registered under section 3.

(e) REVOCATION.—The Administrator may revoke any experimental use permit, at any time, if the Administrator finds that its terms or conditions are being violated, or that its terms and conditions are inadequate to avoid unreasonable adverse effects on the environment.

(f) STATE ISSUANCE OF PERMITS.—Notwithstanding the foregoing provisions of this section, the Administrator shall, under such terms and conditions as the Administrator may by regulations prescribe, authorize any State to issue an experimental use permit for a pesticide. All provisions of section 11 relating to State plans shall apply with equal force to a State plan for the issuance of experimental use permits under this section.

(g) EXEMPTION FOR AGRICULTURAL RESEARCH AGENCIES.—Notwithstanding the foregoing provisions of this section, the Administrator may issue an experimental use permit for a pesticide to any public or private agricultural research agency or educational institution which applies for such permit. Each permit shall not exceed more than a one-year period or such other specific time as the Administrator may prescribe. Such permit shall be issued under such

terms and conditions restricting the use of the pesticide as the Administrator may require. Such pesticide may be used only by such research agency or educational institution for purposes of experimentation.

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SEC. 33. PESTICIDE REGISTRATION SERVICE FEES.

(a) DEFINITION OF COSTS.—In this section, the term "costs", when used with respect to review and decisionmaking pertaining to an application for which registration service fees are paid under this section, means—

(1) costs to the extent that—

(A) officers and employees provide direct support for the review and decisionmaking for covered pesticide applications, associated tolerances, and corresponding risk and benefits information and analyses;

(B) persons and organizations under contract with the Administrator engage in the review of the applications, and corresponding risk and benefits information and assessments; and

(C) advisory committees and other accredited persons or organizations, on the request of the Administrator, engage in the peer review of risk or benefits information associated with covered pesticide applications;

(2) costs of management of information, and the acquisition, maintenance, and repair of computer and telecommunication resources (including software), used to support review of pesticide applications, associated tolerances, and corresponding risk and benefits information and analyses; and

(3) costs of collecting registration service fees under subsections (b) and (c) and reporting, auditing, and accounting under this section.

(b) FEES.—

(1) IN GENERAL.—Effective beginning on the effective date of the Pesticide Registration Improvement Act of 2003, the Administrator shall assess and collect covered pesticide registration service fees in accordance with this section.

(2) COVERED [PESTICIDE REGISTRATION] APPLICATIONS.—

(A) IN GENERAL.—An application for the registration of a pesticide covered by this Act that is received by the Administrator on or after the effective date of the Pesticide Registration Improvement Act of 2003 *or for any other action covered by a table specified in paragraph (3)* shall be subject to a registration service fee under this section.

(B) EXISTING APPLICATIONS.—

(i) IN GENERAL.—Subject to clause (ii), an application for the registration of a pesticide that was submitted to the Administrator before the effective date of the Pesticide Registration Improvement Act of 2003 and is pending on that effective date shall be subject to a service fee under this section if the application is for the registration of a new active ingredient that is not listed in the Registration Division 2003 Work Plan of the Office of Pesticide Programs of the Environmental Protection Agency.

(ii) TOLERANCE OR EXEMPTION FEES.—The amount of any fee otherwise payable for an application described in clause (i) under this section shall be reduced by the amount of any fees paid to support the related petition for a pesticide tolerance or exemption under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(C) DOCUMENTATION.—An application subject to a registration service fee under this section shall be submitted with documentation certifying—

(i) payment of the registration service fee; or

(ii) payment of at least 25 percent of the registration service fee and a request for a waiver from or reduction of the remaining amount of the registration service fee.

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

(E) APPLICATIONS SUBJECT TO ADDITIONAL FEES.—An application may be subject to additional fees if—

(i) the applicant identified the incorrect registration service fee and decision review period;

(ii) after review of a waiver request, the Administrator denies the waiver request; or

(iii) after review of the application, the Administrator determines that a different registration service fee and decision review period apply to the application.

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

(G) NON-REFUNDABLE PORTION OF FEES.—

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

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

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

[(3) SCHEDULE OF COVERED APPLICATIONS AND REGISTRATION SERVICE FEES.—Subject to paragraph (6), the schedule of covered pesticide registration applications and 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)	Registration Service Fee ($)
R010	1	New Active Ingredient, Food use (2) (3)	24	569,221
R020	2	New Active Ingredient, Food use; reduced risk (2) (3)	18	569,221
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	419,502
R060	4	New Active Ingredient, Non-food use; outdoor (2) (3)	21	395,467
R070	5	New Active Ingredient, Non-food use; outdoor; reduced risk (2) (3)	16	395,467

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R090	6	New Active Ingredient, Non-food use; outdoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient (3)	16	293,596
R110	7	New Active Ingredient, Non-food use; indoor (2) (3)	20	219,949
R120	8	New Active Ingredient, Non-food use; indoor; reduced risk (2) (3)	14	219,949
R121	9	New Active Ingredient, Non-food use; indoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows (3)	18	165,375
R122	10	Enriched isomer(s) of registered mixed-isomer active ingredient (2) (3)	18	287,643

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R123	11	New Active Ingredient, Seed treatment only; includes agricultural and non-agricultural seeds; residues not expected in raw agricultural commodities (2) (3)	18	427,991
R125 New	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	293,596

[(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)	Registration Service Fee ($)
R130	13	First food use; indoor; food/food handling (2) (3)	21	173,644
R140	14	Additional food use; Indoor; food/food handling (3) (4)	15	40,518
R150	15	First food use (2) (3)	21	239,684
R160	16	First food use; reduced risk (2) (3)	16	239,684
R170	17	Additional food use (3) (4)	15	59,976
R175 New	18	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	59,976
R180	19	Additional food use; reduced risk (3) (4)	10	59,976
R190	20	Additional food uses; 6 or more submitted in one application (3) (4)	15	359,856
R200	21	Additional food uses; 6 or more submitted in one application; reduced risk (3) (4)	10	359,856

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R210	22	Additional food use; Experimental Use Permit application; establish temporary tolerance; no credit toward new use registration (3) (4)	12	44,431
R220	23	Additional food use; Experimental Use Permit application; crop destruct basis; no credit toward new use registration (3) (4)	6	17,993
R230	24	Additional use; non-food; outdoor (3) (4)	15	23,969
R240	25	Additional use; non-food; outdoor; reduced risk (3) (4)	10	23,969
R250	26	Additional use; non-food; outdoor; Experimental Use Permit application; no credit toward new use registration (3) (4)	6	17,993
R251 New	27	Experimental Use Permit application which requires no changes to the tolerance(s); non-crop destruct basis (3)	8	17,993

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R260	28	New use; non-food; indoor (3) (4)	12	11,577
R270	29	New use; non-food; indoor; reduced risk (3) (4)	9	11,577
R271	30	New use; non-food; indoor; Experimental Use Permit application; no credit toward new use registration (3) (4)	6	8,820
R273	31	Additional use; seed treatment; limited uptake into raw agricultural commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food or non-food uses (3) (4)	12	45,754

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R274	32	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 non-food uses (3) (4)	12	274,523

[(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)	Registration Service Fee ($)
R280	33	Establish import tolerance; new active ingredient or first food use (2)	21	289,407
R290	34	Establish import tolerance; additional food use	15	57,882

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R291	35	Establish import tolerances; additional food uses; 6 or more crops submitted in one petition	15	347,288
R292	36	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated	11	41,124
R293	37	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated	12	48,510
R294	38	Establish tolerances for inadvertent residues; 6 or more crops submitted in one application; applicant-initiated	12	291,060
R295	39	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; applicant-initiated	15	59,976

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R296	40	Establish tolerances for residues in rotational crops in response to a specific rotational crop petition; 6 or more crops submitted in one application; applicant-initiated	15	359,856
R297 New	41	Amend 6 or more established tolerances (e.g., decrease or increase) in one petition; domestic or import; applicant-initiated	11	246,744
R298 New	42	Amend an established tolerance (e.g., decrease or increase); domestic or import; submission of amended labels (requiring science review) in addition to those associated with the amended tolerance; applicant-initiated (3)	13	53,120

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R299 New	43	Amend 6 or more established tolerances (e.g., decrease or increase); domestic or import; submission of amended labels (requiring science review) in addition to those associated with the amended tolerance; applicant-initiated (3)	13	258,740

[(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 4. — REGISTRATION DIVISION — NEW PRODUCTS

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R300	44	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	1,434

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R301	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; 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	1,720

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R310	46	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; requires review of data package within RD only; includes data and/or waivers of data for only: **g** product chemistry and/or **g** acute toxicity and/or **g** public health pest efficacy and/or **g** child resistant packaging. (2) (3)	7	4,807

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R314 New	47	New end use product containing two 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; requires review of data package within RD only; includes data and/or waivers of data for only: **g** product chemistry and/or **g** acute toxicity and/or **g** public health pest efficacy and/or **g** child resistant packaging. (2) (3)	8	6,009

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R315 New	48	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: **g** product chemistry and/or **g** acute toxicity and/or **g** public health pest efficacy and/or **g** animal safety studies and/or **g** child resistant packaging (2) (3)	9	8,000
R320	49	New product; new physical form; requires data review in science divisions (2) (3)	12	11,996
R331	50	New product; repack of identical registered end-use product as a manufacturing-use product; same registered uses only (2) (3)	3	2,294

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R332	51	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	256,883
R333 New	52	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	17,993

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R334 New	53	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	17,993

[(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 5. — REGISTRATION DIVISION — AMENDMENTS TO REGISTRATION

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R340	54	Amendment requiring data review within RD (e.g., changes to precautionary label statements) (2) (3)	4	3,617
R345 New	55	Amending non-food animal product that includes submission of target animal safety data; previously registered (2) (3)	7	8,000
R350	56	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	11,996
R351 New	57	Amendment adding a new unregistered source of active ingredient. (2) (3)	8	11,996

[TABLE 5. — REGISTRATION DIVISION — AMENDMENTS TO REGISTRATION—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R352 New	58	Amendment adding already approved uses; selective method of support; does not apply if the applicant owns all cited data (2) (3)	8	11,996

[TABLE 5. — REGISTRATION DIVISION — AMENDMENTS TO REGISTRATION—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R371	59	Amendment to Experimental Use Permit; (does not include extending a permit's time period) (3)	6	9,151

[(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 6. — REGISTRATION DIVISION — OTHER ACTIONS

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R124	60	Conditional Ruling on Preapplication Study Waivers; applicant-initiated	6	2,294
R272	61	Review of Study Protocol applicant-initiated; excludes DART, pre-registration conference, Rapid Response review, DNT protocol review, protocol needing HSRB review	3	2,294
R275 New	62	Rebuttal of agency reviewed protocol, applicant initiated	3	2,294
R370	63	Cancer reassessment; applicant-initiated	18	179,818

[(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)	Registration Service Fee ($)
A380	64	Food use; establish tolerance exemption (2) (3)	24	104,187

[TABLE 7. — ANTIMICROBIALS DIVISION — NEW ACTIVE INGREDIENTS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
A390	65	Food use; establish tolerance (2) (3)	24	173,644
A400	66	Non-food use; outdoor; FIFRA § 2(mm) uses (2) (3)	18	86,823
A410	67	Non-food use; outdoor; uses other than FIFRA § 2(mm) (2) (3)	21	173,644
A420	68	Non-food use; indoor; FIFRA § 2(mm) uses (2) (3)	18	57,882
A430	69	Non-food use; indoor; uses other than FIFRA § 2(mm) (2) (3)	20	86,823
A431	70	Non-food use; indoor; low-risk, low-toxicity food-grade active ingredient(s); efficacy testing for public health claims required under GLP and following DIS/TSS or AD-approved study protocol (2) (3)	12	60,638

[(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)	Registration Service Fee ($)
A440	71	First food use; establish tolerance exemption (2) (3) (4)	21	28,942
A450	72	First food use; establish tolerance (2) (3) (4)	21	86,823
A460	73	Additional food use; establish tolerance exemption (3) (4) (5)	15	11,577
A470	74	Additional food use; establish tolerance (3) (4) (5)	15	28,942
A471 New	75	Additional food uses; establish tolerances; 6 or more submitted in one application (3) (4) (5)	15	173,652
A480	76	Additional use; non-food; outdoor; FIFRA § 2(mm) uses (4) (5)	9	17,365
A481 New	77	Additional non-food outdoor uses; FIFRA § 2(mm) uses; 6 or more submitted in one application (4) (5)	9	104,190
A490	78	Additional use; non-food; outdoor; uses other than FIFRA § 2(mm) (4) (5)	15	28,942

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
A491 New	79	Additional non-food; outdoor; uses other than FIFRA § 2(mm); 6 or more submitted in one application (4) (5)	15	173,652
A500	80	Additional use; non-food, indoor, FIFRA § 2(mm) uses (4) (5)	9	11,577
A501 New	81	Additional non-food; indoor; FIFRA § 2(mm) uses; 6 or more submitted in one application (4) (5)	9	69,462
A510	82	Additional use; non-food; indoor; uses other than FIFRA § 2(mm) (4) (5)	12	11,577
A511 New	83	Additional non-food; indoor; uses other than FIFRA § 2(mm); 6 or more submitted in one application (4) (5)	12	69,462

[(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)	Registration Service Fee ($)
A530	84	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 when applicant owns all required data, or applicant submits specific authorization letter for 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	1,159

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
A531	85	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	1,654
A532	86	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	4,631

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

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
A540	87	New end use product; FIFRA § 2(mm) uses only (2) (3)	5	4,631
A550	88	New end-use product; uses other than FIFRA § 2(mm); non-FQPA product (2) (3)	7	4,631
A560	89	New manufacturing-use product; registered active ingredient; selective data citation (2) (3)	12	17,365
A570	90	Label amendment requiring data review (3) (4)	4	3,474
A572 New	91	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	11,996

[(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.

[TABLE 10. — ANTIMICROBIALS DIVISION — EXPERIMENTAL USE PERMITS AND OTHER TYPE OF ACTIONS

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
A520	92	Experimental Use Permit application, Non-Food Use (2)	9	5,789

[TABLE 10. — ANTIMICROBIALS DIVISION — EXPERIMENTAL USE PERMITS AND OTHER TYPE OF ACTIONS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
A521	93	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	3	2,250
A522	94	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	11,025

[TABLE 10. — ANTIMICROBIALS DIVISION — EXPERIMENTAL USE PERMITS AND OTHER TYPE OF ACTIONS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
A524 New	95	New Active Ingredient, Experimental Use Permit application; Food Use Requires Tolerance. Credit 45% of fee toward new active ingredient application that follows. (2)	18	138,916
A525 New	96	New Active Ingredient, Experimental Use Permit application; Food Use Requires Tolerance Exemption. Credit 45% of fee toward new active ingredient application that follows. (2)	18	83,594
A526 New	97	New Active Ingredient, Experimental Use Permit application; Non-Food, Outdoor Use. Credit 45% of fee toward new active ingredient application that follows. (2)	15	86,823

[TABLE 10. — ANTIMICROBIALS DIVISION — EXPERIMENTAL USE PERMITS AND OTHER TYPE OF ACTIONS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
A527 New	98	New Active Ingredient, Experimental Use Permit application; Non-Food, Indoor Use. Credit 45% of fee toward new active ingredient application that follows. (2)	15	58,000
A528 New	99	Experimental Use Permit application, Food Use; Requires Tolerance or Tolerance Exemption (2)	15	20,260
A529 New	100	Amendment to Experimental Use Permit; requires data review or risk assessment (2)	9	10,365
A523 New	101	Review of protocol other than a public health efficacy study (i.e., Toxicology or Exposure Protocols)	9	11,025

[TABLE 10. — ANTIMICROBIALS DIVISION — EXPERIMENTAL USE PERMITS AND OTHER TYPE OF ACTIONS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
A571 New	102	Science reassessment: Cancer risk, refined ecological risk, and/or endangered species; applicant-initiated	18	86,823

[(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 AND POLLUTION PREVENTION DIVISION — MICROBIAL AND BIOCHEMICAL PESTICIDES; NEW ACTIVE INGREDIENTS

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B580	103	New active ingredient; food use; petition to establish a tolerance (2)	19	46,305
B590	104	New active ingredient; food use; petition to establish a tolerance exemption (2)	17	28,942
B600	105	New active ingredient; non-food use (2)	13	17,365
B610	106	New active ingredient; Experimental Use Permit application; petition to establish a temporary tolerance or temporary tolerance exemption	10	11,577
B611 New	107	New active ingredient; Experimental Use Permit application; petition to establish permanent tolerance exemption	12	11,577
B612 New	108	New active ingredient; no change to a permanent tolerance exemption (2)	10	15,918

[TABLE 11. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — MICROBIAL AND BIOCHEMICAL PESTICIDES; NEW ACTIVE INGREDIENTS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B613 New	109	New active ingredient; petition to convert a temporary tolerance or a temporary tolerance exemption to a permanent tolerance or tolerance exemption (2)	11	15,918

[TABLE 11. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — MICROBIAL AND BIOCHEMICAL PESTICIDES; NEW ACTIVE INGREDIENTS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B620	110	New active ingredient; Experimental Use Permit application; non-food use including crop destruct	7	5,789

[(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, except where the new inert approval decision review time is greater than that for the new active ingredient, in which case the associated new active ingredient will be subject to the new inert approval 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.

[TABLE 12. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — MICROBIAL AND BIOCHEMICAL PESTICIDES; NEW USES

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B630	111	First food use; petition to establish a tolerance exemption (2)	13	11,577
B631	112	New food use; petition to amend an established tolerance (3)	12	11,577
B640	113	First food use; petition to establish a tolerance (2)	19	17,365
B643 New	114	New Food use; petition to amend tolerance exemption (3)	10	11,577
B642 New	115	First food use; indoor; food/food handling (2)	12	28,942
B644 New	116	New use, no change to an established tolerance or tolerance exemption (3)	8	11,577
B650	117	New use; non-food (3)	7	5,789

[(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.

[TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — MICROBIAL AND BIOCHEMICAL PESTICIDES; NEW PRODUCTS

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B652 New	118	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)	13	11,577

[TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — MICROBIAL AND BIOCHEMICAL PESTICIDES; NEW PRODUCTS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B660	119	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. For microbial pesticides, the active ingredient(s) must not be re-isolated. (2)	4	1,159

[TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — MICROBIAL AND BIOCHEMICAL PESTICIDES; NEW PRODUCTS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B670	120	New product; registered source of active ingredient(s); no change in 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)	7	4,631

[TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — MICROBIAL AND BIOCHEMICAL PESTICIDES; NEW PRODUCTS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B671	121	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)	17	11,577

[TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — MICROBIAL AND BIOCHEMICAL PESTICIDES; NEW PRODUCTS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B672	122	New product; unregistered source of active ingredient(s); non-food use or food use with a tolerance or tolerance exemption previously established for the 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)	13	8,269
B673 New	123	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)	10	4,631

[TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — MICROBIAL AND BIOCHEMICAL PESTICIDES; NEW PRODUCTS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B674 New	124	New product MUP; Repack of identical registered end-use product as a manufacturing-use product; same registered uses only (2)	4	1,159
B675 New	125	New Product MUP; registered source of active ingredient; submission of completely new generic data package; registered uses only. (2)	10	8,269
B676 New	126	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)	13	8,269

[TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — MICROBIAL AND BIOCHEMICAL PESTICIDES; NEW PRODUCTS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B677 New	127	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: **g** product chemistry and/or **g** acute toxicity and/or **g** public health pest efficacy and/or **g** animal safety studies and/or **g** child resistant packaging (2)	10	8,000

[(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.

[TABLE 14. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — MICROBIAL AND BIOCHEMICAL PESTICIDES; AMENDMENTS

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B621	128	Amendment; Experimental Use Permit; no change to an established temporary tolerance or tolerance exemption.	7	4,631

[TABLE 14. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — MICROBIAL AND BIOCHEMICAL PESTICIDES; AMENDMENTS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B622 New	129	Amendment; Experimental Use Permit; petition to amend an established or temporary tolerance or tolerance exemption.	11	11,577
B641	130	Amendment of an established tolerance or tolerance exemption.	13	11,577
B680	131	Amendment; registered source of active ingredient(s); no new use(s); no changes to an established tolerance or tolerance exemption. Requires data submission. (2)	5	4,631
B681	132	Amendment; unregistered source of active ingredient(s). Requires data submission. (2)	7	5,513
B683 New	133	Label amendment; requires review/update of previous risk assessment(s) without data submission (e.g., labeling changes to REI, PPE, PHI). (2)	6	4,631

[TABLE 14. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — MICROBIAL AND BIOCHEMICAL PESTICIDES; AMENDMENTS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B684 New	134	Amending non-food animal product that includes submission of target animal safety data; previously registered (2)	8	8,000

[(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.

[TABLE 15. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — STRAIGHT CHAIN LEPIDOPTERAN PHEROMONES(SCLPS)

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B690	135	New active ingredient; food or non-food use. (2)	7	2,316

[TABLE 15. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — STRAIGHT CHAIN LEPIDOPTERAN PHEROMONES(SCLPS)—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B700	136	Experimental Use Permit application; new active ingredient or new use.	7	1,159
B701	137	Extend or amend Experimental Use Permit.	4	1,159
B710	138	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)	4	1,159

[TABLE 15. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — STRAIGHT CHAIN LEPIDOPTERAN PHEROMONES(SCLPS)—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B720	139	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)	5	1,159
B721	140	New product; unregistered source of active ingredient. (3)	7	2,426

[TABLE 15. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — STRAIGHT CHAIN LEPIDOPTERAN PHEROMONES(SCLPS)—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B722	141	New use and/or amendment; petition to establish a tolerance or tolerance exemption. (4) (5)	7	2,246
B730	142	Label amendment requiring data submission. (4)	5	1,159

[(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, except where the new inert approval decision review time is greater than that for the new active ingredient, in which case the associated new active ingredient will be subject to the new inert approval 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.

[TABLE 16. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — OTHER ACT

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B614 New	143	Conditional Ruling on Preapplication Study Waivers; applicant-initiated	3	2,294
B615 New	144	Rebuttal of agency reviewed protocol, applicant initiated	3	2,294

[TABLE 16. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — OTHER ACT—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B682	145	Protocol review; applicant initiated; excludes time for HSRB review	3	2,205

[(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 AND POLLUTION PREVENTION DIVISION — PLANT INCORPORATED PROTECTANTS (PIPS)

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B740	146	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). (4)	6	86,823

[TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — PLANT INCORPORATED PROTECTANTS (PIPS)—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B750	147	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)	9	115,763
B770	148	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)	15	173,644

[TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — PLANT INCORPORATED PROTECTANTS (PIPS)—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B771	149	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.	10	115,763
B772	150	Application to amend or extend an Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active ingredient is unaffected.	3	11,577
B773	151	Application to amend or extend an Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient.	5	28,942
B780	152	Registration application; new (2) PIP; non-food/feed.	12	144,704

[TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — PLANT INCORPORATED PROTECTANTS (PIPS)—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B790	153	Registration application; new (2) PIP; non-food/feed; SAP review. (5)	18	202,585
B800	154	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	231,585
B810	155	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)	18	289,407
B820	156	Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient.	15	289,407

[TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — PLANT INCORPORATED PROTECTANTS (PIPS)—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B840	157	Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/ tolerance exemption of an active ingredient. SAP review. (5)	21	347,288
B851	158	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).	9	115,763
B870	159	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)	9	34,729

[TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — PLANT INCORPORATED PROTECTANTS (PIPS)—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B880	160	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)	9	28,942
B881	161	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)	15	86,823

[TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — PLANT INCORPORATED PROTECTANTS (PIPS)—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B883 New	162	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)	9	115,763
B884 New	163	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	144,704

[TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — PLANT INCORPORATED PROTECTANTS (PIPS)—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B885 New	164	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)	9	86,823
B890	165	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).	9	57,882

[TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — PLANT INCORPORATED PROTECTANTS (PIPS)—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B891	166	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)	15	115,763
B900	167	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)	6	11,577
B901	168	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	69,458
B902	169	PIP protocol review	3	5,789

[TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION — PLANT INCORPORATED PROTECTANTS (PIPS)—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
B903	170	Inert ingredient tolerance exemption; e.g., a marker such as NPT II; reviewed in BPPD.	6	57,882
B904	171	Import tolerance or tolerance exemption; processed commodities/food only (inert or active ingredient).	9	115,763

[(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.

[TABLE 18. — INERT INGREDIENTS, EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
I001	172	Approval of new food use inert ingredient (2) (3)	12	18,000
I002 New	173	Amend currently approved inert ingredient tolerance or exemption from tolerance; new data (2)	10	5,000
I003 New	174	Amend currently approved inert ingredient tolerance or exemption from tolerance; no new data (2)	8	3,000
I004 New	175	Approval of new non-food use inert ingredient (2)	8	10,000

[TABLE 18. — INERT INGREDIENTS, EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
I005 New	176	Amend currently approved non-food use inert ingredient with new use pattern; new data (2)	8	5,000
I006 New	177	Amend currently approved non-food use inert ingredient with new use pattern; no new data (2)	6	3,000
I007 New	178	Approval of substantially similar non-food use inert ingredients when original inert is compositionally similar with similar use pattern (2)	4	1,500
I008 New	179	Approval of new polymer inert ingredient, food use (2)	5	3,400
I009 New	180	Approval of new polymer inert ingredient, non food use (2)	4	2,800
I010 New	181	Petition to amend a tolerance exemption descriptor to add one or more CASRNs; no new data (2)	6	1,500

[TABLE 18. — INERT INGREDIENTS, EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
M001 New	182	Study protocol requiring Human Studies Review Board review as defined in 40 CFR 26 in support of an active ingredient (4)	9	7,200
M002 New	183	Completed study requiring Human Studies Review Board review as defined in 40 CFR 26 in support of an active ingredient (4)	9	7,200
M003 New	184	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	58,000

[TABLE 18. — INERT INGREDIENTS, EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
M004 New	185	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	58,000

[TABLE 18. — INERT INGREDIENTS, EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
M005 New	186	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	20,000
M006 New	187	Request for up to 5 letters of certification (Gold Seal) for one actively registered product.	1	250
M007 New	188	Request to extend Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(ii)	12	5,000

[TABLE 18. — INERT INGREDIENTS, EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

[EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
M008 New	189	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	10	1,500

[(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 associated with and dependent upon a pending application for an inert ingredient action, each application will be subject to its respective registration service fee. The decision review time for the other associated covered application will be extended to match the PRIA due date of the pending inert ingredient action, unless the PRIA due date for the other associated covered action is further out, in which case it will be subject to its own decision review time. 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.]

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

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 ($)***
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*
R090	*6*	*New Active Ingredient, Non-food 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, Non-food use; indoor. (2)(3)*	*20*	*290,994*
R120	*8*	*New Active Ingredient, Non-food use; indoor; reduced risk. (2)(3)*	*14*	*242,495*
R121	*9*	*New Active Ingredient, Non-food 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*
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*
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*

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 ($)***
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*
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*
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*

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 ($)*
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*
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 non-food 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*
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 plant-back 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 plant-back restrictions; applicant-initiated. (3) (4)*	*15*	*396,742*
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% repackage of registered end-use or manufacturing-use product that requires no data submission nor data matrix. (2)(3)*	*4*	*1,582*
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*
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*
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*
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*
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*
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*
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*

TABLE 5. — REGISTRATION DIVISION — AMENDMENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	FY'17 & FY'18 Registration Service Fee ($)
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
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*

TABLE 7. — ANTIMICROBIALS DIVISION — NEW ACTIVE INGREDIENTS—Continued

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)*** (1)	***FY'17 & FY'18 Registration Service Fee ($)***
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*
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, non-food. (4)(5)*	*12*	*31,910*
A501	*80*	*New use, non-food; 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*
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*
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*
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*
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*

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 ($)***
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*
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*
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*
A533	*103 (new)*	*Exemption from the requirement of an Experimental Use Permit. (2)*	*4*	*2,482*

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 ($)
A534	104 (new)	Rebuttal of agency reviewed protocol, applicant initiated.	4	4,726
A535	105 (new)	Conditional Ruling on Preapplication Study Waiver or Data Bridging Argument; applicant-initiated.	6	2,409
A536	106 (new)	Conditional Ruling on Preapplication 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; nonfood use. (2)(3)	13	19,146

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 ($)***
B610	*110*	*New active ingredient; Experimental Use Permit application; petition to establish a temporary tolerance or temporary tolerance exemption. (3)*	*10*	*12,764*
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*
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*
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*
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*
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*
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*

TABLE 14. — BIOPESTICIDES DIVISION — AMENDMENTS— Continued

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)*** (1)	***FY'17 & FY'18 Registration Service Fee ($)***
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*
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% repackage of registered end-use or manufacturing-use product that requires no data submission or data matrix. (3)(6)*	*4*	*1,278*
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*
B721	*147*	*New product; unregistered source of active ingredient. (3)(6)*	*7*	*2,676*

TABLE 15. — BIOPESTICIDES DIVISION — SCLP—Continued

EPA No.	*New CR No.*	*Action*	*Decision Review Time (Months)*(1)	*FY'17 & FY'18 Registration Service Fee ($)*
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*
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*
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*

TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)*** (1)	***FY'17 & FY'18 Registration Service Fee ($)***
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*
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*
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*
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*

TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)*** (1)	***FY'17 & FY'18 Registration Service Fee ($)***
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*
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*
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*

TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)*** (1)	***FY'17 & FY'18 Registration Service Fee ($)***
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*
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*
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*

TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***FY'17 & FY'18 Registration Service Fee ($)***
B905	*182 (new)*	*SAP Review.*	*6*	*63,816*
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*
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*
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*
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*
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*
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*

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 ($)*
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.

(4) PENDING PESTICIDE REGISTRATION APPLICATIONS.—

(A) IN GENERAL.—An applicant that submitted a registration application to the Administrator before the effective date of the Pesticide Registration Improvement Act of 2003, but that is not required to pay a registration service fee under paragraph (2)(B), may, on a voluntary basis, pay a registration service fee in accordance with paragraph (2)(B).

(B) VOLUNTARY FEE.—The Administrator may not compel payment of a registration service fee for an application described in subparagraph (A).

(C) DOCUMENTATION.—An application for which a voluntary registration service fee is paid under this paragraph shall be submitted with documentation certifying—

(i) payment of the registration service fee; or

(ii) a request for a waiver from or reduction of the registration service fee.

(5) RESUBMISSION OF [PESTICIDE REGISTRATION APPLICATIONS] *COVERED APPLICATION*.—If a [pesticide registration application] *covered application* is submitted by a person that paid the fee for the application under paragraph (2), is determined by the Administrator to be complete, and is not approved or is withdrawn (without a waiver or refund), the submission of the same [pesticide registration application] *covered application* by the same person (or a licensee, assignee, or successor of the person) shall not be subject to a fee under paragraph (2).

(6) FEE ADJUSTMENT.—

(A) IN GENERAL.—Effective for a covered [pesticide registration] application received during the period beginning on [October 1, 2013, and ending on September 30, 2015] *October 1, 2019, and ending on September 30, 2021*, the Administrator shall increase by 5 percent the registration service fee payable for the application under paragraph (3).

(B) ADDITIONAL ADJUSTMENT.—Effective for a covered [pesticide registration] application received on or after October 1, [2015] *2021*, the Administrator shall increase by an additional 5 percent the registration service fee in effect as of September 30, [2015] *2021*.

(C) PUBLICATION.—The Administrator shall publish in the Federal Register the [revised registration service fee schedules] *service fee schedules revised pursuant to this paragraph*.

(7) WAIVERS AND REDUCTIONS.—

(A) IN GENERAL.—An applicant for a [covered pesticide registration] *covered application* may request the Administrator to waive or reduce the amount of a registration service fee payable under this section under the circumstances described in subparagraphs (D) through (G)*, 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)*.

(B) DOCUMENTATION.—

(i) IN GENERAL.—A request for a waiver from or reduction of the registration service fee shall be accom-

panied by appropriate documentation demonstrating the basis for the waiver or reduction.

(ii) CERTIFICATION.—The applicant shall provide to the Administrator a written certification, signed by a responsible officer, that the documentation submitted to support the waiver or reduction request is accurate.

(iii) INACCURATE DOCUMENTATION.—An application shall be subject to the applicable registration service fee payable under paragraph (3) if, at any time, the Administrator determines that—

(I) the documentation supporting the waiver or reduction request is not accurate; or

(II) based on the documentation or any other information, the waiver or reduction should not have been granted or should not be granted.

(C) DETERMINATION TO GRANT OR DENY REQUEST.—As soon as practicable, but not later than 60 days, after the date on which the Administrator receives a request for a waiver or reduction of a registration service fee under this paragraph, the Administrator shall—

(i) determine whether to grant or deny the request; and

(ii) notify the applicant of the determination.

(D) MINOR USES.—

(i) IN GENERAL.—The Administrator may exempt from, or waive a portion of, the registration service fee for an application for minor uses for a pesticide.

(ii) SUPPORTING DOCUMENTATION.—An applicant requesting a waiver or exemption under this subparagraph shall provide supporting documentation that demonstrates, to the satisfaction of the Administrator, that anticipated revenues from the uses that are the subject of the application would be insufficient to justify imposition of the full application fee.

(E) IR–4 EXEMPTION.—The Administrator shall exempt an application from the registration service fee if the Administrator determines that—

(i) the application is solely associated with a tolerance petition submitted in connection with the Inter-Regional Project Number 4 (IR–4) as described in section 2 of Public Law 89–106 (7 U.S.C. 450i(e)); and

(ii) the exemption is in the public interest.

(F) SMALL BUSINESSES.—

(i) IN GENERAL.—The Administrator shall waive 50 percent of the registration service fees payable by an entity for a covered ⟦pesticide registration⟧ application under this section if the entity is a small business (as defined in section 4(i)(1)(E)(ii)) at the time of application.

(ii) WAIVER OF FEES.—The Administrator shall waive 75 percent of the registration service fees payable by an entity under this section if the entity—

(I) is a small business (as defined in section 4(i)(1)(E)(ii)) at the time of application; and

(II) has average annual global gross revenues described in section 4(i)(1)(E)(ii)(I)(bb) that does not exceed $10,000,000, at the time of application.

(iii) FORMATION FOR WAIVER.—The Administrator shall not grant a waiver under this subparagraph if the Administrator determines that the entity submitting the application has been formed or manipulated primarily for the purpose of qualifying for the waiver.

(iv) DOCUMENTATION.—An entity requesting a waiver under this subparagraph shall provide to the Administrator—

(I) documentation demonstrating that the entity is a small business (as defined in section 4(i)(1)(E)(ii)) at the time of application; and

(II) if the entity is requesting a waiver of 75 percent of the applicable registration service fees payable under this section, documentation demonstrating that the entity has an average annual global gross revenue described in section 4(i)(1)(E)(ii)(I)(bb) that does not exceed $10,000,000, at the time of application.

(G) FEDERAL AND STATE AGENCY EXEMPTIONS.—An agency of the Federal Government or a State government shall be exempt from covered registration service fees under this section.

(8) REFUNDS.—

(A) EARLY WITHDRAWALS.—If, during the first 60 days after the beginning of the applicable decision time review period under subsection (f)(3), a covered [pesticide registration] application is withdrawn by the applicant, the Administrator shall refund all but 25 percent of the total registration service fee payable under paragraph (3) for the application.

(B) WITHDRAWALS AFTER THE FIRST 60 DAYS OF DECISION REVIEW TIME PERIOD.—

(i) IN GENERAL.—If a covered [pesticide registration] application is withdrawn after the first 60 days of the applicable decision time review period, the Administrator shall determine what portion, if any, of the total registration service fee payable under paragraph (3) for the application may be refunded based on the proportion of the work completed at the time of withdrawal.

(ii) TIMING.—The Administrator shall—

(I) make the determination described in clause (i) not later than 90 days after the date the application is withdrawn; and

(II) provide any refund as soon as practicable after the determination.

(C) DISCRETIONARY REFUNDS.—

(i) IN GENERAL.—In the case of a [pesticide registration] *covered* application that has been filed with the Administrator and has not been withdrawn by the applicant, but for which the Administrator has not yet made a final determination, the Administrator may re-

fund a portion of a covered registration service fee if the Administrator determines that the refund is justified.

(ii) BASIS.—The Administrator may provide a refund for an application under this subparagraph—

(I) on the basis that, in reviewing the application, the Administrator has considered data submitted in support of another [pesticide registration] *covered* application;

(II) on the basis that the Administrator completed portions of the review of the application before the effective date of this section; or

(III) on the basis that the Administrator rejected the application under subsection (f)(4)(B).

(D) CREDITED FEES.—In determining whether to grant a refund under this paragraph, the Administrator shall take into account any portion of the registration service fees credited under paragraph (2) or (4).

(c) PESTICIDE REGISTRATION FUND.—

(1) ESTABLISHMENT.—There is established in the Treasury of the United States a Pesticide Registration Fund to be used in carrying out this section (referred to in this section as the "Fund"), consisting of—

(A) such amounts as are deposited in the Fund under paragraph (2);

(B) any interest earned on investment of amounts in the Fund under paragraph (5); and

(C) any proceeds from the sale or redemption of investments held in the Fund.

(2) DEPOSITS IN FUND.—Subject to paragraph (4), the Administrator shall deposit fees collected under this section in the Fund.

(3) EXPENDITURES FROM FUND.—

(A) IN GENERAL.—Subject to subparagraphs (B) and (C) and paragraph (4), the Administrator may make expenditures from the Fund—

(i) to cover the costs associated with the review and decisionmaking pertaining to all applications for which registration service fees have been paid under this section; and

(ii) to otherwise carry out this section.

(B) WORKER PROTECTION*, PARTNERSHIP GRANTS, AND PESTICIDE SAFETY EDUCATION*.—

(i) IN GENERAL.—For each of fiscal years 2013 through [2017] *2023*, the Administrator shall use approximately 1/17 of the amount in the Fund (but not less than $1,000,000) to enhance scientific and regulatory activities relating to worker protection*, with an emphasis on field-worker populations in the United States*.

(ii) PARTNERSHIP GRANTS.—Of the amounts in the Fund, the Administrator shall use for partnership grants, for each of fiscal years 2013 through [2017] *2023*, $500,000.

(iii) PESTICIDE SAFETY EDUCATION PROGRAM.—Of the amounts in the Fund, the Administrator shall use $500,000 for each of fiscal years 2013 through [2017] *2023* to carry out the pesticide safety education program.

(4) COLLECTIONS AND APPROPRIATIONS ACTS.—The fees authorized by this section and amounts deposited in the Fund—

(A) shall be collected and made available for obligation only to the extent provided in advance in appropriations Acts; and

(B) shall be available without fiscal year limitation.

(5) UNUSED FUNDS.—

(A) IN GENERAL.—Amounts in the Fund not currently needed to carry out this section shall be—

(i) maintained readily available or on deposit;

(ii) invested in obligations of the United States or guaranteed by the United States; or

(iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

(B) USE OF INVESTMENT INCOME.—After consultation with the Secretary of the Treasury, the Administrator may use income from investments described in clauses (ii) and (iii) of subparagraph (A) to carry out this section.

(d) ASSESSMENT OF FEES.—

(1) DEFINITION OF COVERED FUNCTIONS.—In this subsection, the term "covered functions" means functions of the Office of Pesticide Programs of the Environmental Protection Agency, as identified in key programs and projects of the final operating plan for the Environmental Protection Agency submitted as part of the budget process for fiscal year 2002, regardless of any subsequent transfer of 1 or more of the functions to another office or agency or the subsequent transfer of a new function to the Office of Pesticide Programs.

(2) MINIMUM AMOUNT OF APPROPRIATIONS.—Registration service fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2012) of the Office of Pesticide Programs of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for covered functions for fiscal year 2012 (excluding the amount of any fees appropriated for the fiscal year).

(3) USE OF FEES.—Registration service fees authorized by this section shall be available, in the aggregate, only to defray increases in the costs associated with the review and decision-making for the review of pesticide registration applications and associated tolerances (including increases in the number of full-time equivalent positions in the Environmental Protection Agency engaged in those activities) over the costs for fiscal year 2002, excluding costs paid from fees appropriated for the fiscal year.

(4) SUBSEQUENT AUTHORITY.—If the Administrator does not assess registration service fees under subsection (b) during any

portion of a fiscal year as the result of paragraph (2) and is subsequently permitted to assess the fees under subsection (b) during the fiscal year, the Administrator shall assess and collect the fees, without any modification in rate, at any time during the fiscal year, notwithstanding any provisions of subsection (b) relating to the date fees are to be paid.

(e) REFORMS TO REDUCE DECISION TIME REVIEW PERIODS.—To the maximum extent practicable consistent with the degrees of risk presented by pesticides and the type of review appropriate to evaluate risks, the Administrator shall identify and evaluate reforms to the pesticide registration process under this Act with the goal of reducing decision review periods in effect on the effective date of the ⟦Pesticide Registration Improvement Extension Act of 2012⟧ *Pesticide Registration Enhancement Act of 2017* for pesticide registration actions for covered pesticide registration applications (including reduced risk applications). *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.*

(f) DECISION TIME REVIEW PERIODS.—

(1) IN GENERAL.—Not later than 30 days after the effective date of the ⟦Pesticide Registration Improvement Extension Act of 2012⟧ *Pesticide Registration Enhancement Act of 2017*, the Administrator shall make publicly available a schedule of decision review periods for covered pesticide registration actions *or for any other action covered by a table specified in subsection (b)(3)* and corresponding registration service fees under this Act.

(2) REPORT.—The schedule shall be the same as the applicable schedule provided under subsection (b)(3).

(3) APPLICATIONS SUBJECT TO DECISION TIME REVIEW PERIODS.—The decision time review periods specified in paragraph (1) shall apply to—

(A) covered pesticide registration applications subject to registration service fees under subsection (b)(2);

(B) covered pesticide registration applications for which an applicant has voluntarily paid registration service fees under subsection (b)(4); and

⟦(C) covered pesticide registration applications listed in the Registration Division 2003 Work Plan of the Office of Pesticide Programs of the Environmental Protection Agency.⟧

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

(4) START OF DECISION TIME REVIEW PERIOD.—

(A) IN GENERAL.—Except as provided in subparagraphs (C), (D), and (E), in the case of ⟦a pesticide registration application⟧ *a covered application* accompanied by the registration service fee required under this section, the decision time review period begins 21 days after the date on which the Administrator receives the ⟦covered pesticide registration application⟧ *covered application* and fee.

(B) INITIAL CONTENT AND PRELIMINARY TECHNICAL SCREENINGS.—

(i) SCREENINGS.—

(I) INITIAL CONTENT.—Not later than 21 days after receiving an application and the required registration service fee, the Administrator shall conduct an initial screening of the contents of the application in accordance with clause (iii).

(II) PRELIMINARY TECHNICAL SCREENING.—After conducting the initial content screening described in subclause (I) and in accordance with clause (iv), the Administrator shall conduct a preliminary technical screening—

(aa) not later than 45 days after the date on which the decision time review period begins (for applications with decision time review periods of not more than 180 days); and

(bb) not later than 90 days after the date on which the decision time review period begins (for applications with decision time review periods greater than 180 days).

(ii) REJECTION.—

(I) IN GENERAL.—If the Administrator determines at any time before the Administrator completes the preliminary technical screening under clause (i)(II) that the application failed the initial content or preliminary technical screening and the applicant does not correct the failure before the date that is 10 business days after the applicant receives a notification of the failure, the Administrator shall reject the application.

(II) WRITTEN NOTIFICATION.—The Administrator shall make every effort to provide a written notification of a rejection under subclause (I) during the 10-day period that begins on the date the Administrator completes the preliminary technical screening.

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

(I)(aa) the applicable registration service fee has been paid; or

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

(II) the application appears to contain all the necessary forms, data, and draft labeling, formatted in accordance with guidance published by the Administrator.

(iv) REQUIREMENTS OF PRELIMINARY TECHNICAL SCREENING.—In conducting a preliminary technical screening of an application, the Administrator shall determine if—

(I) the application and the data and information submitted with the application are accurate and complete; and

(II) the application, data, and information are consistent with the proposed labeling and any proposal for a tolerance or exemption from the requirement for a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a), and are such that, subject to full review under the standards of this Act, could result in the granting of the application.

(C) APPLICATIONS WITH WAIVER OR REDUCTION REQUESTS.—

(i) IN GENERAL.—In the case of an application submitted with a request for a waiver or reduction of registration service fees under subsection (b)(7), the decision time review period shall be determined in accordance with this subparagraph.

(ii) REQUEST GRANTED WITH NO ADDITIONAL FEES REQUIRED.—If the Administrator grants the waiver or reduction request and no additional fee is required, the decision time review period begins on the earlier of—

(I) the date on which the Administrator grants the request; or

(II) the date that is 60 days after the date of receipt of the application.

(iii) REQUEST GRANTED WITH ADDITIONAL FEES REQUIRED.—If the Administrator grants the waiver or reduction request, in whole or in part, but an additional registration service fee is required, the decision time review period begins on the date on which the Administrator receives certification of payment of the applicable registration service fee.

(iv) REQUEST DENIED.—If the Administrator denies the waiver or reduction request, the decision time review period begins on the date on which the Administrator receives certification of payment of the applicable registration service fee.

(D) PENDING APPLICATIONS.—

(i) IN GENERAL.—The start of the decision time review period for applications described in clause (ii) shall be the date on which the Administrator receives certification of payment of the applicable registration service fee.

(ii) APPLICATIONS.—Clause (i) applies to—

(I) covered pesticide registration applications for which voluntary fees have been paid under subsection (b)(4); and

(II) covered pesticide registration applications received on or after the effective date of the Pesticide Registration Improvement Act of 2003 but submitted without the applicable registration service fee required under this section due to the inability of the Administrator to assess fees under subsection (d)(1).

(E) 2003 WORK PLAN.—In the case of a covered pesticide registration application listed in the Registration Division 2003 Work Plan of the Office of Pesticide Programs of the Environmental Protection Agency, the decision time review period begins on the date that is 30 days after the effective date of the Pesticide Registration Improvement Act of 2003.

(5) EXTENSION OF DECISION TIME REVIEW PERIOD.—The Administrator and the applicant may mutually agree in writing to extend a decision time review period under this subsection.

(g) JUDICIAL REVIEW.—

(1) IN GENERAL.—Any applicant adversely affected by the failure of the Administrator to make a determination on the application of the applicant for registration of a new active ingredient or new use for which a registration service fee is paid under this section may obtain judicial review of the failure solely under this section.

(2) SCOPE.—

(A) IN GENERAL.—In an action brought under this subsection, the only issue on review is whether the Administrator failed to make a determination on the application specified in paragraph (1) by the end of the applicable decision time review period required under subsection (f) for the application.

(B) OTHER ACTIONS.—No other action authorized or required under this section shall be judicially reviewable by a Federal or State court.

(3) TIMING.—

(A) IN GENERAL.—A person may not obtain judicial review of the failure of the Administrator to make a determination on the application specified in paragraph (1) before the expiration of the 2-year period that begins on the date on which the decision time review period for the application ends.

(B) MEETING WITH ADMINISTRATOR.—To be eligible to seek judicial review under this subsection, a person seeking the review shall first request in writing, at least 120 days before filing the complaint for judicial review, a decision review meeting with the Administrator.

(4) REMEDIES.—The Administrator may not be required or permitted to refund any portion of a registration service fee paid in response to a complaint that the Administrator has failed to make a determination on the covered pesticide registration application specified in paragraph (1) by the end of the applicable decision review period.

(h) ACCOUNTING.—The Administrator shall—

(1) provide an annual accounting of the registration service fees paid to the Administrator and disbursed from the Fund, by providing financial statements in accordance with—

(A) the Chief Financial Officers Act of 1990 (Public Law 101–576; 104 Stat. 2838) and amendments made by that Act; and

(B) the Government Management Reform Act of 1994 (Public Law 103–356; 108 Stat. 3410) and amendments made by that Act;

(2) provide an accounting describing expenditures from the Fund authorized under subsection (c); and

(3) provide an annual accounting describing collections and expenditures authorized under subsection (d).

(i) AUDITING.—

(1) FINANCIAL STATEMENTS OF AGENCIES.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of an executive agency.

(2) COMPONENTS.—The annual audit required under sections 3515(b) and 3521 of that title of the financial statements of activities under this section shall include an analysis of—

(A) the fees collected under subsection (b) and disbursed;

(B) compliance with subsection (f);

(C) the amount appropriated to meet the requirements of subsection (d)(1); and

(D) the reasonableness of the allocation of the overhead allocation of costs associated with the review and decision-making pertaining to applications under this section.

(3) INSPECTOR GENERAL.—The Inspector General of the Environmental Protection Agency shall—

(A) conduct the annual audit required under this subsection; and

(B) report the findings and recommendations of the audit to the Administrator and to the appropriate committees of Congress.

(j) PERSONNEL LEVELS.—All full-time equivalent positions supported by fees authorized and collected under this section shall not be counted against the agency-wide personnel level goals of the Environmental Protection Agency.

(k) REPORTS.—

(1) IN GENERAL.—Not later than March 1, 2005, and each March 1 thereafter through March 1, [2017] *2023*, the Administrator shall publish an annual report describing actions taken under this section.

(2) CONTENTS.—The report shall include—

(A) a review of the progress made in carrying out each requirement of subsections (e) and (f), including—

(i) the number of applications reviewed, including the decision times for each application specified in subsection (f);

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

(iii) the amount of money from the Reregistration and Expedited Processing Fund used to carry out inert ingredient review and review of similar applications under section 4(k)(3);

(iv) the number of applications completed for identical or substantially similar applications under section 3(c)(3)(B), including the number of such applications completed within 90 days pursuant to that section;

(v) the number of actions pending in each category of actions described in subsection (f)(3), as well as the number of inert ingredients;

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

(I) expanding the use of self-certification in all appropriate areas of the registration process;

(II) providing for accreditation of outside reviewers and the use of outside reviewers to conduct the review of major portions of applications;

(III) reviewing the scope of use of the notification process to cover broader categories of registration actions;

(IV) providing for electronic submission and review of labels, including process improvements to further enhance the procedures used in electronic label review; and

(V) the allowance and use of summaries of acute toxicity studies;

(vii) the use of performance-based contracts, other contracts, and procurement to ensure that—

(I) the goals of this Act for the timely review of applications for registration are met; and

(II) the registration program is administered in the most productive and cost effective manner practicable; and

(viii) the number of extensions of decision time review periods agreed to under subsection (f)(5) along with a description of the reason that the Administrator was unable to make a decision within the initial decision time review period;

(B) a description of the staffing and resources relating to the costs associated with the review and decisionmaking pertaining to applications;

(C) a review of the progress in meeting the timeline requirements of section 4(g);

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

[(i) the number of pesticides or pesticide cases reviewed;**]**

(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;

(ii) a description of the staffing and resources relating to the costs associated with the review and decision making relating to reregistration and registration

review for compliance with the deadlines specified in this Act;

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

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

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

(III) streamlining the registration review process, consistent with section 3(g);

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

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

(G) a review of the progress made toward—

(i) carrying out **[**section 4(k)(4)**]** *paragraphs (4) and (5) of section 4(k)* and the amounts from the Reregistration and Expedited Processing Fund used for the purposes described in **[**that section**]** *such paragraphs*;

[(ii) implementing systems for the electronic tracking of registration submissions by December 31, 2013;

[(iii) implementing a system for tracking the status of conditional registrations, including making nonconfidential information related to the conditional registrations publicly available by December 31, 2013;

[(iv) implementing enhancements to the endangered species knowledge database, including making nonconfidential information related to the database publicly available;

[(v) implementing the capability to electronically submit and review labels submitted with registration actions;

[(vi) acquiring and implementing the capability to electronically assess and evaluate confidential statements of formula submitted with registration actions by December 31, 2014; and**]**

(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

[(vii)] *(iii)* facilitating public participation in certain registration actions and the registration review process by providing electronic notification to interested parties of additions to the public docket;

(H) the number of applications rejected by the Administrator under the initial content and preliminary technical screening conducted under subsection (f)(4);

(I) a review of the progress made in updating the Pesticide Incident Data System, including progress toward making the information contained in the System available to the public (as the Administrator determines is appropriate); [and]

(J) an assessment of the public availability of summary pesticide usage data[.]*;*

(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.

(3) METHOD.—The Administrator shall publish a report required by this subsection by such method as the Administrator determines to be the most effective for efficiently disseminating the report, including publication of the report on the Internet site of the Environmental Protection Agency.

(4) OTHER REPORT.—

(A) SCOPE.—In addition to the annual report described in paragraph (1), not later than October 1, 2016, the Administrator shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report that includes an analysis of the impact of maintenance fees on small businesses that have—

(i) 10 or fewer employees; and

(ii) annual global gross revenue that does not exceed $2,000,000.

(B) INFORMATION REQUIRED.—In conducting the analysis described in subparagraph (A), the Administrator shall collect, and include in the report under that subparagraph, information on—

(i) the number of small businesses described in subparagraph (A) that are paying maintenance fees; and

(ii) the number of registrations each company holds.

(l) SAVINGS CLAUSE.—Nothing in this section affects any other duties, obligations, or authorities established by any other section of this Act, including the right to judicial review of duties, obligations, or authorities established by any other section of this Act.

(m) TERMINATION OF EFFECTIVENESS.—

(1) IN GENERAL.—Except as provided in paragraph (2), the authority provided by this section terminates on September 30, [2017] *2023*.

(2) PHASE OUT.—

(A) [FISCAL YEAR 2018.—] *FISCAL YEAR 2024.*— [During fiscal year 2018] *During fiscal year 2024*, the requirement to pay and collect registration service fees applies, except that the level of registration service fees payable under this section shall be reduced 40 percent below the level in effect on September 30, [2017] *2023*.

(B) [FISCAL YEAR 2019.—] *FISCAL YEAR 2025.*— [During fiscal year 2019] *During fiscal year 2025*, the requirement to pay and collect registration service fees applies, except that the level of registration service fees payable under this section shall be reduced 70 percent below the level in effect on September 30, [2017] *2023*.

(C) [SEPTEMBER 30, 2019.—] *SEPTEMBER 30, 2025.*— [Effective September 30, 2019] *Effective September 30, 2025*, the requirement to pay and collect registration service fees terminates.

(D) DECISION REVIEW PERIODS.—

(i) PENDING APPLICATIONS.—In the case of an application received under this section before September

30, [2017] *2023*, the application shall be reviewed in accordance with subsection (f).

(ii) NEW APPLICATIONS.—In the case of an application received under this section on or after September 30, [2017] *2023*, subsection (f) shall not apply to the application.

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FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER IV—FOOD

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TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

SEC. 408. (a) REQUIREMENT FOR TOLERANCE OR EXEMPTION.—

(1) GENERAL RULE.—Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 402(a)(2)(B) unless—

(A) a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

(B) an exemption from the requirement of a tolerance is in effect under this section for the pesticide chemical residue.

For the purposes of this section, the term "food", when used as a noun without modification, shall mean a raw agricultural commodity or processed food.

(2) PROCESSED FOOD.—Notwithstanding paragraph (1)—

(A) if a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B) despite the lack of a tolerance for the pesticide chemical residue in or on the processed food if the pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section, such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

(B) if an exemption for the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B).

(3) RESIDUES OF DEGRADATION PRODUCTS.—If a pesticide chemical residue is present in or on a food because it is a metabolite or other degradation product of a precursor substance that itself is a pesticide chemical or pesticide chemical residue, such a residue shall not be considered to be unsafe within the meaning of section 402(a)(2)(B) despite the lack of a tolerance or exemption from the need for a tolerance for such residue in or on such food if—

(A) the Administrator has not determined that the degradation product is likely to pose any potential health risk from dietary exposure that is of a different type than, or of a greater significance than, any risk posed by dietary exposure to the precursor substance;

(B) either—

(i) a tolerance is in effect under this section for residues of the precursor substance in or on the food, and the combined level of residues of the degradation product and the precursor substance in or on the food is at or below the stoichiometrically equivalent level that would be permitted by the tolerance if the residue consisted only of the precursor substance rather than the degradation product; or

(ii) an exemption from the need for a tolerance is in effect under this section for residues of the precursor substance in or on the food; and

(C) the tolerance or exemption for residues of the precursor substance does not state that it applies only to particular named substances and does not state that it does not apply to residues of the degradation product.

(4) EFFECT OF TOLERANCE OR EXEMPTION.—While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, the food shall not by reason of bearing or containing any amount of such a residue be considered to be adulterated within the meaning of section 402(a)(1).

(b) AUTHORITY AND STANDARD FOR TOLERANCE.—

(1) AUTHORITY.—The Administrator may issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food—

(A) in response to a petition filed under subsection (d); or

(B) on the Administrator's own initiative under subsection (e).

As used in this section, the term "modify" shall not mean expanding the tolerance to cover additional foods.

(2) STANDARD.—

(A) GENERAL RULE.—

(i) STANDARD.—The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

(ii) DETERMINATION OF SAFETY.—As used in this section, the term "safe", with respect to a tolerance for a

pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(iii) RULE OF CONSTRUCTION.—With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

(B) TOLERANCES FOR ELIGIBLE PESTICIDE CHEMICAL RESIDUES.—

(i) DEFINITION.—As used in this subparagraph, the term "eligible pesticide chemical residue" means a pesticide chemical residue as to which—

(I) the Administrator is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health (referred to in this section as a "nonthreshold effect");

(II) the lifetime risk of experiencing the nonthreshold effect is appropriately assessed by quantitative risk assessment; and

(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to in this section as a "threshold effect"), the Administrator determines that the level of aggregate exposure is safe.

(ii) DETERMINATION OF TOLERANCE.—Notwithstanding subparagraph (A)(i), a tolerance for an eligible pesticide chemical residue may be left in effect or modified under this subparagraph if—

(I) at least one of the conditions described in clause (iii) is met; and

(II) both of the conditions described in clause (iv) are met.

(iii) CONDITIONS REGARDING USE.—For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) Use of the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue.

(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.

(iv) CONDITIONS REGARDING RISK.—For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that would be allowed under subparagraph (A) for such effect.

(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect.

(v) REVIEW.—Five years after the date on which the Administrator makes a determination to leave in effect or modify a tolerance under this subparagraph, and thereafter as the Administrator deems appropriate, the Administrator shall determine, after notice and opportunity for comment, whether it has been demonstrated to the Administrator that a condition described in clause (iii)(I) or clause (iii)(II) continues to exist with respect to the tolerance and that the yearly and lifetime risks from aggregate exposure to such residue continue to comply with the limits specified in clause (iv). If the Administrator determines by such date that such demonstration has not been made, the Administrator shall, not later than 180 days after the date of such determination, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

(vi) INFANTS AND CHILDREN.—Any tolerance under this subparagraph shall meet the requirements of subparagraph (C).

(C) EXPOSURE OF INFANTS AND CHILDREN.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator—

(i) shall assess the risk of the pesticide chemical residue based on—

(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population;

(II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

(III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity; and

(ii) shall—

(I) ensure that there is a reasonable certainty that no harm will result to infants and children

from aggregate exposure to the pesticide chemical residue; and

(II) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.

The Secretary of Health and Human Services and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children. In the case of threshold effects, for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.

(D) FACTORS.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall consider, among other relevant factors—

(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue;

(ii) the nature of any toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies;

(iii) available information concerning the relationship of the results of such studies to human risk;

(iv) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);

(v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;

(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;

(viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects; and

(ix) safety factors which in the opinion of experts qualified by scientific training and experience to evalu-

ate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

(E) DATA AND INFORMATION REGARDING ANTICIPATED AND ACTUAL RESIDUE LEVELS.—

(i) AUTHORITY.—In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and information on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by the Food and Drug Administration.

(ii) REQUIREMENT.—If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) require that data be provided five years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1), or an order under subsection (f)(2), as appropriate, to modify or revoke the tolerance.

(F) PERCENT OF FOOD ACTUALLY TREATED.—In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator—

(i) finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;

(ii) finds that the exposure estimate does not understate exposure for any significant subpopulation group;

(iii) finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator; and

(iv) provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

(3) DETECTION METHODS.—

(A) GENERAL RULE.—A tolerance for a pesticide chemical residue in or on a food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a prac-

tical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

(B) DETECTION LIMIT.—A tolerance for a pesticide chemical residue in or on a food shall not be established at or modified to a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (A).

(4) INTERNATIONAL STANDARDS.—In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

(c) AUTHORITY AND STANDARD FOR EXEMPTIONS.—

(1) AUTHORITY.—The Administrator may issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food—

(A) in response to a petition filed under subsection (d); or

(B) on the Administrator's initiative under subsection (e).

(2) STANDARD.—

(A) GENERAL RULE.—

(i) STANDARD.—The Administrator may establish or leave in effect an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the exemption is safe. The Administrator shall modify or revoke an exemption if the Administrator determines it is not safe.

(ii) DETERMINATION OF SAFETY.—The term "safe", with respect to an exemption for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(B) FACTORS.—In making a determination under this paragraph, the Administrator shall take into account, among other relevant considerations, the considerations set forth in subparagraphs (C) and (D) of subsection (b)(2).

(3) LIMITATION.—An exemption from the requirement for a tolerance for a pesticide chemical residue in or on food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary—

(A) that there is a practical method for detecting and measuring the levels of such pesticide chemical residue in or on food; or

(B) that there is no need for such a method, and states the reasons for such determination in issuing the regulation establishing or modifying the exemption.

(d) PETITION FOR TOLERANCE OR EXEMPTION.—

(1) PETITIONS AND PETITIONERS.—Any person may file with the Administrator a petition proposing the issuance of a regulation—

(A) establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food; or

(B) establishing, modifying, or revoking an exemption from the requirement of a tolerance for such a residue.

(2) PETITION CONTENTS.—

(A) ESTABLISHMENT.—A petition under paragraph (1) to establish a tolerance or exemption for a pesticide chemical residue shall be supported by such data and information as are specified in regulations issued by the Administrator, including—

(i)(I) an informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition; and

(II) a statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice of filing of the petition to be published under this subsection and as part of a proposed or final regulation issued under this section;

(ii) the name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the residue;

(iii) data showing the recommended amount, frequency, method, and time of application of that pesticide chemical;

(iv) full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations;

(v) full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the analytical methods used;

(vi) a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed;

(vii) a proposed tolerance for the pesticide chemical residue, if a tolerance is proposed;

(viii) if the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing method(s) used to produce that food;

(ix) such information as the Administrator may require to make the determination under subsection (b)(2)(C);

(x) such information as the Administrator may require on whether the pesticide chemical may have an

effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects;

(xi) information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue;

(xii) practical methods for removing any amount of the residue that would exceed any proposed tolerance; and

(xiii) such other data and information as the Administrator requires by regulation to support the petition.

If information or data required by this subparagraph is available to the Administrator, the person submitting the petition may cite the availability of the information or data in lieu of submitting it. The Administrator may require a petition to be accompanied by samples of the pesticide chemical with respect to which the petition is filed.

(B) MODIFICATION OR REVOCATION.—The Administrator may by regulation establish the requirements for information and data to support a petition to modify or revoke a tolerance or to modify or revoke an exemption from the requirement for a tolerance.

(3) NOTICE.—A notice of the filing of a petition that the Administrator determines has met the requirements of paragraph (2) shall be published by the Administrator within 30 days after such determination. The notice shall announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed or shall set forth the petitioner's statement of why such a method is not needed. The notice shall include the summary required by paragraph (2)(A)(i)(I).

(4) ACTIONS BY THE ADMINISTRATOR.—

(A) IN GENERAL.—The Administrator shall, after giving due consideration to a petition filed under paragraph (1) and any other information available to the Administrator—

(i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance (which final regulation shall be issued without further notice and without further period for public comment);

(ii) issue a proposed regulation under subsection (e), and thereafter issue a final regulation under such subsection; or

(iii) issue an order denying the petition.

(B) PRIORITIES.—The Administrator shall give priority to petitions for the establishment or modification of a tolerance or exemption for a pesticide chemical residue that appears to pose a significantly lower risk to human health from dietary exposure than pesticide chemical residues that have tolerances in effect for the same or similar uses.

(C) EXPEDITED REVIEW OF CERTAIN PETITIONS.—

(i) DATE CERTAIN FOR REVIEW.—If a person files a complete petition with the Administrator proposing the issuance of a regulation establishing a tolerance or exemption for a pesticide chemical residue that presents a lower risk to human health than a pesticide chemical residue for which a tolerance has been left in effect or modified under subsection (b)(2)(B), the Administrator shall complete action on such petition under this paragraph within 1 year.

(ii) REQUIRED DETERMINATIONS.—If the Administrator issues a final regulation establishing a tolerance or exemption for a safer pesticide chemical residue under clause (i), the Administrator shall, not later than 180 days after the date on which the regulation is issued, determine whether a condition described in subclause (I) or (II) of subsection (b)(2)(B)(iii) continues to exist with respect to a tolerance that has been left in effect or modified under subsection (b)(2)(B). If such condition does not continue to exist, the Administrator shall, not later than 180 days after the date on which the determination under the preceding sentence is made, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

(e) ACTION ON ADMINISTRATOR'S OWN INITIATIVE.—

(1) GENERAL RULE.—The Administrator may issue a regulation—

(A) establishing, modifying, suspending under subsection (l)(3), or revoking a tolerance for a pesticide chemical or a pesticide chemical residue;

(B) establishing, modifying, suspending under subsection (l)(3), or revoking an exemption of a pesticide chemical residue from the requirement of a tolerance; or

(C) establishing general procedures and requirements to implement this section.

(2) NOTICE.—Before issuing a final regulation under paragraph (1), the Administrator shall issue a notice of proposed rulemaking and provide a period of not less than 60 days for public comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

(f) SPECIAL DATA REQUIREMENTS.—

(1) REQUIRING SUBMISSION OF ADDITIONAL DATA.—If the Administrator determines that additional data or information are reasonably required to support the continuation of a tolerance or exemption that is in effect under this section for a pesticide chemical residue on a food, the Administrator shall—

(A) issue a notice requiring the person holding the pesticide registrations associated with such tolerance or exemption to submit the data or information under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act;

(B) issue a rule requiring that testing be conducted on a substance or mixture under section 4 of the Toxic Substances Control Act; or

(C) publish in the Federal Register, after first providing notice and an opportunity for comment of not less than 60 days' duration, an order—

(i) requiring the submission to the Administrator by one or more interested persons of a notice identifying the person or persons who will submit the required data and information;

(ii) describing the type of data and information required to be submitted to the Administrator and stating why the data and information could not be obtained under the authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act or section 4 of the Toxic Substances Control Act;

(iii) describing the reports of the Administrator required to be prepared during and after the collection of the data and information;

(iv) requiring the submission to the Administrator of the data, information, and reports referred to in clauses (ii) and (iii); and

(v) establishing dates by which the submissions described in clauses (i) and (iv) must be made.

The Administrator may under subparagraph (C) revise any such order to correct an error. The Administrator may under this paragraph require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

(2) NONCOMPLIANCE.—If a submission required by a notice issued in accordance with paragraph (1)(A), a rule issued under paragraph (1)(B), or an order issued under paragraph (1)(C) is not made by the time specified in such notice, rule, or order, the Administrator may by order published in the Federal Register modify or revoke the tolerance or exemption in question. In any review of such an order under subsection (g)(2), the only material issue shall be whether a submission required under paragraph (1) was not made by the time specified.

(g) EFFECTIVE DATE, OBJECTIONS, HEARINGS, AND ADMINISTRATIVE REVIEW.—

(1) EFFECTIVE DATE.—A regulation or order issued under subsection (d)(4), (e)(1), or (f)(2) shall take effect upon publication unless the regulation or order specifies otherwise. The Administrator may stay the effectiveness of the regulation or order if, after issuance of such regulation or order, objections are filed with respect to such regulation or order pursuant to paragraph (2).

(2) FURTHER PROCEEDINGS.—

(A) OBJECTIONS.—Within 60 days after a regulation or order is issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C), any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed ob-

jectionable and stating reasonable grounds therefor. If the regulation or order was issued in response to a petition under subsection (d)(1), a copy of each objection filed by a person other than the petitioner shall be served by the Administrator on the petitioner.

(B) HEARING.—An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Administrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections. The presiding officer in such a hearing may authorize a party to obtain discovery from other persons and may upon a showing of good cause made by a party issue a subpoena to compel testimony or production of documents from any person. The presiding officer shall be governed by the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, such a subpoena may be enforced by a Federal district court.

(C) FINAL DECISION.—As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted. If a hearing was held under subparagraph (B), such order and any revision to the regulation or prior order shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at such hearing, and shall set forth in detail the findings of facts and the conclusions of law or policy upon which the order or regulation is based.

(h) JUDICIAL REVIEW.—

(1) PETITION.—In a case of actual controversy as to the validity of any regulation issued under subsection (e)(1)(C), or any order issued under subsection (f)(1)(C) or (g)(2)(C), or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

(2) RECORD AND JURISDICTION.—A copy of the petition under paragraph (1) shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title 28, United States Code. Upon the filing of

such a petition, the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part. As to orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.

(3) ADDITIONAL EVIDENCE.—If a party applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the proceeding before the Administrator, the court may order that the additional evidence (and evidence in rebuttal thereof) shall be taken before the Administrator in the manner and upon the terms and conditions the court deems proper. The Administrator may modify prior findings as to the facts by reason of the additional evidence so taken and may modify the order or regulation accordingly. The Administrator shall file with the court any such modified finding, order, or regulation.

(4) FINAL JUDGMENT; SUPREME COURT REVIEW.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or any order and any regulation which is the subject of such an order shall be final, subject to review by the Supreme Court of the United States as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

(5) APPLICATION.—Any issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law.

(i) CONFIDENTIALITY AND USE OF DATA.—

(1) GENERAL RULE.—Data and information that are or have been submitted to the Administrator under this section or section 409 in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act.

(2) EXCEPTIONS.—

(A) IN GENERAL.—Data and information that are entitled to confidential treatment under paragraph (1) may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

(i) employees of the United States authorized by the Administrator to examine such data and information in the carrying out of their official duties under this Act or other Federal statutes intended to protect the public health; or

(ii) contractors with the United States authorized by the Administrator to examine such data and information in the carrying out of contracts under this Act or such statutes.

(B) CONGRESS.—This subsection does not authorize the withholding of data or information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(3) SUMMARIES.—Notwithstanding any provision of this subsection or other law, the Administrator may publish the informative summary required by subsection (d)(2)(A)(i) and may, in issuing a proposed or final regulation or order under this section, publish an informative summary of the data relating to the regulation or order.

(j) STATUS OF PREVIOUSLY ISSUED REGULATIONS.—

(1) REGULATIONS UNDER SECTION 406.—Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in accordance with section 701(e), under the authority of section 406(a) upon the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsections (d) and (e), and shall be subject to review under subsection (q).

(2) REGULATIONS UNDER SECTION 409.—Regulations that established tolerances for substances that are pesticide chemical residues in or on processed food, or that otherwise stated the conditions under which such pesticide chemicals could be safely used, and that were issued under section 409 on or before the date of the enactment of this paragraph, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsection (d) or (e), and shall be subject to review under subsection (q).

(3) REGULATIONS UNDER SECTION 408.—Regulations that established tolerances or exemptions under this section that were issued on or before the date of the enactment of this paragraph shall remain in effect unless modified or revoked under subsection (d) or (e), and shall be subject to review under subsection (q).

(4) CERTAIN SUBSTANCES.—With respect to a substance that is not included in the definition of the term "pesticide chemical" under section 201(q)(1) but was so included on the day before the date of the enactment of the Antimicrobial Regulation Technical Corrections Act of 1998, the following applies as of such date of enactment:

(A) Notwithstanding paragraph (2), any regulation applying to the use of the substance that was in effect on the day before such date, and was on such day deemed in such paragraph to have been issued under this section, shall be considered to have been issued under section 409.

(B) Notwithstanding paragraph (3), any regulation applying to the use of the substance that was in effect on such day and was issued under this section (including any such regulation issued before the date of the enactment of the Food Quality Protection Act of 1996) is deemed to have been issued under section 409.

(k) TRANSITIONAL PROVISION.—If, on the day before the date of the enactment of this subsection, a substance that is a pesticide

chemical was, with respect to a particular pesticidal use of the substance and any resulting pesticide chemical residue in or on a particular food—

(1) regarded by the Administrator or the Secretary as generally recognized as safe for use within the meaning of the provisions of subsection (a) or section 201(s) as then in effect; or

(2) regarded by the Secretary as a substance described by section 201(s)(4);

such a pesticide chemical residue shall be regarded as exempt from the requirement for a tolerance, as of the date of enactment of this subsection. The Administrator shall by regulation indicate which substances are described by this subsection. Any exemption under this subsection may be modified or revoked as if it had been issued under subsection (c).

(l) HARMONIZATION WITH ACTION UNDER OTHER LAWS.—

(1) COORDINATION WITH FIFRA.—To the extent practicable and consistent with the review deadlines in subsection (q), in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act.

(2) REVOCATION OF TOLERANCE OR EXEMPTION FOLLOWING CANCELLATION OF ASSOCIATED REGISTRATIONS.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, cancels the registration of each pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit its use in connection with the production, storage, or transportation of such food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall revoke any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A revocation under this paragraph shall become effective not later than 180 days after—

(A) the date by which each such cancellation of a registration has become effective; or

(B) the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

(3) SUSPENSION OF TOLERANCE OR EXEMPTION FOLLOWING SUSPENSION OF ASSOCIATED REGISTRATIONS.—

(A) SUSPENSION.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, suspends the use of each registered pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply

to actions taken under this paragraph. A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

(B) EFFECT OF SUSPENSION.—The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. While a suspension of a tolerance or exemption is effective the tolerance or exemption shall not be considered to be in effect. If the suspension of use of the pesticide under that Act is terminated, leaving the registration of the pesticide for such use in effect under that Act, the Administrator shall rescind any associated suspension of tolerance or exemption.

(4) TOLERANCES FOR UNAVOIDABLE RESIDUES.—In connection with action taken under paragraph (2) or (3), or with respect to pesticides whose registrations were suspended or canceled prior to the date of the enactment of this paragraph under the Federal Insecticide, Fungicide, and Rodenticide Act, if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue. In establishing such a tolerance, the Administrator shall take into account both the factors set forth in subsection (b)(2) and the unavoidability of the residue. Subsection (e) shall apply to the establishment of such tolerance. The Administrator shall review any such tolerance periodically and modify it as necessary so that it allows no greater level of the pesticide chemical residue than is unavoidable.

(5) PESTICIDE RESIDUES RESULTING FROM LAWFUL APPLICATION OF PESTICIDE.—Notwithstanding any other provision of this Act, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that—

(A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act; and

(B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this Act;

unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e), the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

(6) TOLERANCE FOR USE OF PESTICIDES UNDER AN EMERGENCY EXEMPTION.—If the Administrator grants an exemption under

section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136p) for a pesticide chemical, the Administrator shall establish a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue. Such a tolerance or exemption from a tolerance shall have an expiration date. The Administrator may establish such a tolerance or exemption without providing notice or a period for comment on the tolerance or exemption. The Administrator shall promulgate regulations within 365 days after the date of the enactment of this paragraph governing the establishment of tolerances and exemptions under this paragraph. Such regulations shall be consistent with the safety standard under subsections (b)(2) and (c)(2) and with section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

(m) FEES.—

(1) AMOUNT.—The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section. Under the regulations, the performance of the Administrator's services or other functions under this section, including—

(A) the acceptance for filing of a petition submitted under subsection (d);

(B) establishing, modifying, leaving in effect, or revoking a tolerance or establishing, modifying, leaving in effect, or revoking an exemption from the requirement for a tolerance under this section;

(C) the acceptance for filing of objections under subsection (g); or

(D) the certification and filing in court of a transcript of the proceedings and the record under subsection (h);

may be conditioned upon the payment of such fees. The regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purposes of this subsection.

(2) DEPOSIT.—All fees collected under paragraph (1) shall be deposited in the Reregistration and Expedited Processing Fund created by section 4(k) of the Federal Insecticide, Fungicide, and Rodenticide Act. Such fees shall be available to the Administrator, without fiscal year limitation, for the performance of the Administrator's services or functions as specified in paragraph (1).

(3) PROHIBITION.—During the period beginning on the effective date of the Pesticide Registration Improvement Renewal Act and ending on September 30, [2017] *2023*, the Administrator shall not collect any tolerance fees under paragraph (1).

(n) NATIONAL UNIFORMITY OF TOLERANCES.—

(1) QUALIFYING PESTICIDE CHEMICAL RESIDUE.—For purposes of this subsection, the term "qualifying pesticide chemical residue" means a pesticide chemical residue resulting from the use, in production, processing, or storage of a food, of a pesticide chemical that is an active ingredient and that—

(A) was first approved for such use in a registration of a pesticide issued under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act on or after April 25, 1985, on the basis of data determined by the Administrator to meet all applicable requirements for data prescribed by regulations in effect under that Act on April 25, 1985; or

(B) was approved for such use in a reregistration eligibility determination issued under section 4(g) of that Act on or after the date of enactment of this subsection.

(2) QUALIFYING FEDERAL DETERMINATION.—For purposes of this subsection, the term "qualifying Federal determination" means a tolerance or exemption from the requirement for a tolerance for a qualifying pesticide chemical residue that—

(A) is issued under this section after the date of the enactment of this subsection and determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption); or

(B)(i) pursuant to subsection (j) is remaining in effect or is deemed to have been issued under this section, or is regarded under subsection (k) as exempt from the requirement for a tolerance; and

(ii) is determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption).

(3) LIMITATION.—The Administrator may make the determination described in paragraph (2)(B)(ii) only by issuing a rule in accordance with the procedure set forth in subsection (d) or (e) and only if the Administrator issues a proposed rule and allows a period of not less than 30 days for comment on the proposed rule. Any such rule shall be reviewable in accordance with subsections (g) and (h).

(4) STATE AUTHORITY.—Except as provided in paragraphs (5), (6), and (8) no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of such pesticide chemical residue in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination. A State or political subdivision shall be deemed to establish or enforce a regulatory limit on a pesticide chemical residue in or on a food if it purports to prohibit or penalize the production, processing, shipping, or other handling of a food because it contains a pesticide residue (in excess of a prescribed limit).

(5) PETITION PROCEDURE.—

(A) IN GENERAL.—Any State may petition the Administrator for authorization to establish in such State a regulatory limit on a qualifying pesticide chemical residue in or on any food that is not identical to the qualifying Federal determination applicable to such qualifying pesticide chemical residue.

(B) PETITION REQUIREMENTS.—Any petition under subparagraph (A) shall—

(i) satisfy any requirements prescribed, by rule, by the Administrator; and

(ii) be supported by scientific data about the pesticide chemical residue that is the subject of the petition or about chemically related pesticide chemical residues, data on the consumption within such State of food bearing the pesticide chemical residue, and data on exposure of humans within such State to the pesticide chemical residue.

(C) AUTHORIZATION.—The Administrator may, by order, grant the authorization described in subparagraph (A) if the Administrator determines that the proposed State regulatory limit—

(i) is justified by compelling local conditions; and

(ii) would not cause any food to be a violation of Federal law.

(D) TREATMENT.—In lieu of any action authorized under subparagraph (C), the Administrator may treat a petition under this paragraph as a petition under subsection (d) to modify or revoke a tolerance or an exemption. If the Administrator determines to treat a petition under this paragraph as a petition under subsection (d), the Administrator shall thereafter act on the petition pursuant to subsection (d).

(E) REVIEW.—Any order of the Administrator granting or denying the authorization described in subparagraph (A) shall be subject to review in the manner described in subsections (g) and (h).

(6) URGENT PETITION PROCEDURE.—Any State petition to the Administrator pursuant to paragraph (5) that demonstrates that consumption of a food containing such pesticide residue level during the period of the food's likely availability in the State will pose a significant public health threat from acute exposure shall be considered an urgent petition. If an order by the Administrator to grant or deny the requested authorization in an urgent petition is not made within 30 days of receipt of the petition, the petitioning State may establish and enforce a temporary regulatory limit on a qualifying pesticide chemical residue in or on the food. The temporary regulatory limit shall be validated or terminated by the Administrator's final order on the petition.

(7) RESIDUES FROM LAWFUL APPLICATION.—No State or political subdivision may enforce any regulatory limit on the level of a pesticide chemical residue that may appear in or on any food if, at the time of the application of the pesticide that resulted in such residue, the sale of such food with such residue level was lawful under this section and under the law of such State, unless the State demonstrates that consumption of the food containing such pesticide residue level during the period of the food's likely availability in the State will pose an unreasonable dietary risk to the health of persons within such State.

(8) SAVINGS.—Nothing in this Act preempts the authority of any State or political subdivision to require that a food containing a pesticide chemical residue bear or be the subject of

a warning or other statement relating to the presence of the pesticide chemical residue in or on such food.

(o) CONSUMER RIGHT TO KNOW.—Not later than 2 years after the date of the enactment of the Food Quality Protection Act of 1996, and annually thereafter, the Administrator shall, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, publish in a format understandable to a lay person, and distribute to large retail grocers for public display (in a manner determined by the grocer), the following information, at a minimum:

(1) A discussion of the risks and benefits of pesticide chemical residues in or on food purchased by consumers.

(2) A listing of actions taken under subparagraph (B) of subsection (b)(2) that may result in pesticide chemical residues in or on food that present a yearly or lifetime risk above the risk allowed under subparagraph (A) of such subsection, and the food on which the pesticide chemicals producing the residues are used.

(3) Recommendations to consumers for reducing dietary exposure to pesticide chemical residues in a manner consistent with maintaining a healthy diet, including a list of food that may reasonably substitute for food listed under paragraph (2).

Nothing in this subsection shall prevent retail grocers from providing additional information.

(p) ESTROGENIC SUBSTANCES SCREENING PROGRAM.—

(1) DEVELOPMENT.—Not later than 2 years after the date of enactment of this section, the Administrator shall in consultation with the Secretary of Health and Human Services develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.

(2) IMPLEMENTATION.—Not later than 3 years after the date of enactment of this section, after obtaining public comment and review of the screening program described in paragraph (1) by the scientific advisory panel established under section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act or the science advisory board established by section 8 of the Environmental Research, Development, and Demonstration Act of 1978 (42 U.S.C. 4365), the Administrator shall implement the program.

(3) SUBSTANCES.—In carrying out the screening program described in paragraph (1), the Administrator—

(A) shall provide for the testing of all pesticide chemicals; and

(B) may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such substance.

(4) EXEMPTION.—Notwithstanding paragraph (3), the Administrator may, by order, exempt from the requirements of this section a biologic substance or other substance if the Adminis-

trator determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen.

(5) COLLECTION OF INFORMATION.—

(A) IN GENERAL.—The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to a person who manufactures or imports a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program described in paragraph (1), and submit information obtained from the testing to the Administrator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information.

(B) PROCEDURES.—To the extent practicable the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information.

(C) FAILURE OF REGISTRANTS TO SUBMIT INFORMATION.—

(i) SUSPENSION.—If a registrant of a substance referred to in paragraph (3)(A) fails to comply with an order under subparagraph (A) of this paragraph, the Administrator shall issue a notice of intent to suspend the sale or distribution of the substance by the registrant. Any suspension proposed under this paragraph shall become final at the end of the 30-day period beginning on the date that the registrant receives the notice of intent to suspend, unless during that period a person adversely affected by the notice requests a hearing or the Administrator determines that the registrant has complied fully with this paragraph.

(ii) HEARING.—If a person requests a hearing under clause (i), the hearing shall be conducted in accordance with section 554 of title 5, United States Code. The only matter for resolution at the hearing shall be whether the registrant has failed to comply with an order under subparagraph (A) of this paragraph. A decision by the Administrator after completion of a hearing shall be considered to be a final agency action.

(iii) TERMINATION OF SUSPENSIONS.—The Administrator shall terminate a suspension under this subparagraph issued with respect to a registrant if the Administrator determines that the registrant has complied fully with this paragraph.

(D) NONCOMPLIANCE BY OTHER PERSONS.—Any person (other than a registrant) who fails to comply with an order under subparagraph (A) shall be liable for the same penalties and sanctions as are provided under section 16 of the Toxic Substances Control Act (15 U.S.C. 2601 and following) in the case of a violation referred to in that section. Such penalties and sanctions shall be assessed and imposed in the same manner as provided in such section 16.

(6) AGENCY ACTION.—In the case of any substance that is found, as a result of testing and evaluation under this section, to have an endocrine effect on humans, the Administrator shall, as appropriate, take action under such statutory authority as is available to the Administrator, including consideration under other sections of this Act, as is necessary to ensure the protection of public health.

(7) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of this section, the Administrator shall prepare and submit to Congress a report containing—

(A) the findings of the Administrator resulting from the screening program described in paragraph (1);

(B) recommendations for further testing needed to evaluate the impact on human health of the substances tested under the screening program; and

(C) recommendations for any further actions (including any action described in paragraph (6)) that the Administrator determines are appropriate based on the findings.

(q) SCHEDULE FOR REVIEW.—

(1) IN GENERAL.—The Administrator shall review tolerances and exemptions for pesticide chemical residues in effect on the day before the date of the enactment of the Food Quality Protection Act of 1996, as expeditiously as practicable, assuring that—

(A) 33 percent of such tolerances and exemptions are reviewed within 3 years of the date of enactment of such Act;

(B) 66 percent of such tolerances and exemptions are reviewed within 6 years of the date of enactment of such Act; and

(C) 100 percent of such tolerances and exemptions are reviewed within 10 years of the date of enactment of such Act.

In conducting a review of a tolerance or exemption, the Administrator shall determine whether the tolerance or exemption meets the requirements of subsections (b)(2) or (c)(2) and shall, by the deadline for the review of the tolerance or exemption, issue a regulation under subsection (d)(4) or (e)(1) to modify or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements.

(2) PRIORITIES.—In determining priorities for reviewing tolerances and exemptions under paragraph (1), the Administrator shall give priority to the review of the tolerances or exemptions that appear to pose the greatest risk to public health.

(3) PUBLICATION OF SCHEDULE.—Not later than 12 months after the date of the enactment of the Food Quality Protection Act of 1996, the Administrator shall publish a schedule for review of tolerances and exemptions established prior to the date of the enactment of the Food Quality Protection Act of 1996. The determination of priorities for the review of tolerances and exemptions pursuant to this subsection is not a rulemaking and shall not be subject to judicial review, except that failure to take final action pursuant to the schedule established by this paragraph shall be subject to judicial review.

(r) TEMPORARY TOLERANCE OR EXEMPTION.—The Administrator may, upon the request of any person who has obtained an experi-

mental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon the Administrator's own initiative, establish a temporary tolerance or exemption for the pesticide chemical residue for the uses covered by the permit. Subsections (b)(2), (c)(2), (d), and (e) shall apply to actions taken under this subsection.

(s) SAVINGS CLAUSE.—Nothing in this section shall be construed to amend or modify the provisions of the Toxic Substances Control Act or the Federal Insecticide, Fungicide, and Rodenticide Act.

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