112TH CONGRESS
2D SESSION

S. 3552

AN ACT

To reauthorize the Federal Insecticide, Fungicide, and Rodenticide Act.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pesticide Registration Improvement Extension Act of 2012''.

SEC. 2. PESTICIDE REGISTRATION IMPROVEMENT.

(a) MAINTENANCE FEES.—

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

(A) in paragraph (5)—

(i) in subparagraph (C), by striking ''aggregate amount of'' and all that follows through the end of the subparagraph and inserting ''aggregate amount of $27,800,000 for each of fiscal years 2013 through 2017.'';

(ii) in subparagraph (D)—

(I) in clause (i), by striking ''shall be'' and all that follows through the semicolon and inserting ''shall be $115,500 for each of fiscal years 2013 through 2017;''; and

(II) in clause (ii), by striking ''shall be'' and all that follows through the period and inserting ''shall be $184,800 for each of fiscal years 2013 through 2017.'';

(iii) in subparagraph (E)(i)—

(I) in subclause (I), by striking ''shall be'' and all that follows through the semicolon and inserting ''shall be $70,600 for each of fiscal years 2013 through 2017;''; and

(II) in subclause (II), by striking ''shall be'' and all that follows through the period and inserting ''shall be $122,100 for each of fiscal years 2013 through 2017.'';

(iv) in subparagraph (F)—

(I) by striking ''paragraph (3)'' and inserting ''this paragraph''; and

(II) by striking ''Humans'' and inserting ''Human'';

(v) by redesignating subparagraphs (F) through (H) as subparagraphs (G) through (I), respectively;

(vi) by inserting after subparagraph (E) the following:

''(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.''; and

(vii) in subparagraph (I) (as redesignated by clause (v)), by striking ''2012'' and inserting ''2017'';

(B) in paragraph (6)—

(i) by striking ''2014'' and inserting ''2019''; and

(ii) by striking ''paragraphs (1) through (5)'' and inserting ''paragraph (1)'';

(C) by striking paragraphs (1), (2), (3), (4), and (7); and

(D) by redesignating paragraphs (5) and (6) as paragraphs (1) and (2), respectively.

(2) CONFORMING AMENDMENTS.—

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

(i) in subsection (d)(5)(B)(ii)(III), by striking ''subsection (i)(1)'' and inserting ''this section'';

(ii) in subsection (j), by striking ''subsection (i)(5)'' and inserting ''subsection (i)(1)''; and

(iii) in subsection (k)(5)—

(I) in the first sentence, by striking ''subsection (i)(5)(C)(ii)'' and inserting ''subsection (i)(1)(C)(ii)''; and

(II) in the third and sixth sentences, by striking ''subsection (i)(5)(C)'' each place it appears and inserting ''subsection (i)(1)(C)''.

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

(i) by striking ''section 4(i)(5)(E)(ii)'' each place it appears in clauses (i), (ii)(I), and (iv)(I) and inserting ''section 4(i)(1)(E)(ii)'';

(ii) by striking ''section 4(i)(5)(E)(ii)(I)(bb)'' each place it appears in clauses (ii)(II) and (iv)(II) and inserting ''section 4(i)(1)(E)(ii)(I)(bb)''; and

(iii) in clause (iv)(II)—

(I) by striking ''applicable.'' and inserting ''applicable''; and

(II) by striking ''revenues'' and inserting ''revenue''.

(3) 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 ''September 30, 2012'' and inserting ''September 30, 2017''.

(4) REREGISTRATION AND EXPEDITED PROCESSING FUND.—

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

(i) by inserting '', to enhance the information systems capabilities to improve the tracking of pesticide registration decisions,'' after ''paragraph (3)'' each place it appears; and

(ii) in clause (i)—

(I) by inserting ''offset'' before ''the costs of reregistration''; and

(II) by striking ''in the same portion as appropriated funds''.

(B) 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—

(i) in the matter preceding clause (i), by striking ''2008 through 2012, between

1/8 and 1/7'' and inserting ''2013 through 2017, between 1/9 and 1/8'';

(ii) in clause (i), by striking ''new''; and

(iii) in clause (ii), by striking ''any application'' and all that follows through ''that—'' and inserting ''any application that—''.

(C) ENHANCEMENTS OF INFORMATION TECHNOLOGY SYSTEMS FOR IMPROVEMENT IN REVIEW OF PESTICIDE APPLICATIONS.—Section 4(k) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a–1(k)) is amended—

(i) by redesignating paragraphs (4) and (5) as paragraphs (5) and (6), respectively;

(ii) by inserting after paragraph (3) the following:

''(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.''; and

(iii) in the first sentence of paragraph (6) (as redesignated by clause (i)), by striking ''to carry out the goals established under subsection (l)'' and inserting ''for the purposes described in paragraphs (2), (3), and (4) and to carry out the goals established under subsection (l)''.

(b) PESTICIDE REGISTRATION SERVICE FEES.—

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

(A) by striking paragraph (3) and inserting the following:

''(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

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

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
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
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

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

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
R122	10	Enriched isomer(s) of registered mixed-isomer active ingredient (2) (3)	18	287,643
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

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

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
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
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

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

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
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
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
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
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
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

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

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
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
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: ● product chemistry and/or ● acute toxicity and/or ● public health pest efficacy and/or ● child resistant packaging. (2) (3)	7	4,807
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: ● product chemistry and/or ● acute toxicity and/or ● public health pest efficacy and/or ● 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: ● product chemistry and/or ● acute toxicity and/or ● public health pest efficacy and/or ● animal safety studies and/or ● 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
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

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

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
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
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

"TABLE 6. — REGISTRATION DIVISION — OTHER ACTIONS— Continued

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
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
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

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

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
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
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

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

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
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
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
A540	87	New end use product; FIFRA §2(mm) uses only (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 ($)
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
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
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

"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 ($)
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
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

"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 ($)
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
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
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

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

EPA No.	New CR No.	Action	Decision Review Time (Months) (1)	Registration Service Fee ($)
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 reisolated. (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
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

"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 ($)
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: ● product chemistry and/or ● acute toxicity and/or ● public health pest efficacy and/or ● animal safety studies and/or ● 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
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

"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 ($)
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
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
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
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
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

"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 ($)
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
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
B790	153	Registration application; new (2) PIP; non-food/feed; SAP review. (5)	18	202,585

"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 ($)
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
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

"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 ($)
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
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
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

"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 ($)
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
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
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

"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 ($)
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
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
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
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.";

(B) in paragraph (6)—

(i) in subparagraph (A)—

(I) by striking ''October 1, 2008'' and inserting ''October 1, 2013''; and

(II) by striking ''September 30, 2010'' and inserting ''September 30, 2015''; and

(ii) in subparagraph (B)—

(I) by striking ''October 1, 2010'' and inserting ''October 1, 2015''; and

(II) by striking ''September 30, 2010'' and inserting ''September 30, 2015''; and

(C) in paragraph (8)(C)(ii)—

(i) in subclause (I), by striking ''or'' at the end;

(ii) in subclause (II), by striking the period at the end and inserting ''; or''; and

(iii) by adding at the end the following:

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

(2) PESTICIDE REGISTRATION FUND.—Section 33(c)(3)(B) of the Federal Insecticide, Fungicide,

and Rodenticide Act (7 U.S.C. 136w–8(c)(3)(B)) is amended—

(A) in clause (i), by striking ''2008 through 2012'' and inserting ''2013 through 2017'';

(B) in clause (ii), by striking ''grants'' and all that follows through the end of the clause and inserting ''grants, for each of fiscal years 2013 through 2017, $500,000.''; and

(C) in clause (iii), by striking ''2008 through 2012'' and inserting ''2013 through 2017''.

(3) ASSESSMENT OF FEES.—Section 33(d) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w–8(d)) is amended—

(A) in paragraph (2), by striking ''2002'' each place it appears and inserting ''2012'';

(B) by striking paragraph (4); and

(C) by redesignating paragraph (5) as paragraph (4).

(4) 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 by striking ''Pesticide Registration Improvement Act of 2003'' and inserting

''Pesticide Registration Improvement Extension Act of 2012''.

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

(A) in paragraph (1), by striking ''Pesticide Registration Improvement Renewal Act, the Administrator shall publish in the Federal Register'' and inserting ''Pesticide Registration Improvement Extension Act of 2012, the Administrator shall make publicly available'';

(B) in paragraph (2), by striking ''appearing in the Congressional Record on pages S10409'' and all that follows through the period and inserting ''provided under subsection (b)(3).''; and

(C) in paragraph (4)—

(i) in subparagraph (A), by inserting ''and fee'' before the period; and

(ii) in subparagraph (B)—

(I) by striking ''(B) COMPLETENESS OF APPLICATION'' and all that follows through ''Not later'' in clause (i) and inserting the following:

''(B) INITIAL CONTENT AND PRELIMINARY TECHNICAL SCREENINGS.—

''(i) SCREENINGS.—

''(I) INITIAL CONTENT.—Not later'';

(II) in clause (i) (as so designated) by adding at the end the following:

''(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).'';

(III) by striking clause (ii) and inserting the following:

''(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.'';

(IV) in clause (iii)—

(aa) in the heading, by inserting ''INITIAL CONTENT'' before ''SCREENING'' ;

(bb) in the matter preceding subclause (I), by inserting ''content'' after ''initial''; and

(cc) in subclause (II), by striking ''contains'' and inserting ''appears to contain''; and

(V) by adding at the end the following:

''(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 sec-

tion 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.''.

(6) REPORTS.—Section 33(k) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w–8(k)) is amended—

(A) in paragraph (1), by striking ''March 1, 2014'' and inserting ''March 1, 2017'';

(B) in paragraph (2)—

(i) in subparagraph (A)—

(I) in clause (vi)(V), by striking ''and'' at the end;

(II) in clause (vii)(II), by inserting ''and'' at the end; and

(III) by adding at the end the following:

''(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;'';

(ii) in subparagraph (E), by striking ''and'' at the end;

(iii) in subparagraph (F), by striking the period and inserting a semicolon; and

(iv) by adding at the end the following:

''(G) a review of the progress made toward—

''(i) carrying out section 4(k)(4) and the amounts from the Reregistration and Expedited Processing Fund used for the purposes described in that section;

''(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 in-

formation 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

''(vii) 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.''; and

(C) by adding at the end the following:

''(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.''.

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

(A) in paragraph (1), by striking ''2012'' and inserting ''2017''; and

(B) in paragraph (2)—

(i) in subparagraph (A)—

(I) in the heading, by striking ''2013'' and inserting ''2018'';

(II) by striking ''2013,'' and inserting ''2018,''; and

(III) by striking ''September 30, 2012'' and inserting ''September 30, 2017'';

(ii) in subparagraph (B)—

(I) in the heading, by striking ''2014'' and inserting ''2019'';

(II) by striking ''2014,'' and inserting ''2019,''; and

(III) by striking ''September 30, 2012'' and inserting ''September 30, 2017'';

(iii) in subparagraph (C)—

(I) in the heading, by striking ''2014'' and inserting ''2019''; and

(II) by striking ''September 30, 2014'' and inserting ''September 30, 2019''; and

(iv) in subparagraph (D), by striking ''2012'' each place it appears and inserting ''2017''.

(c) EFFECTIVE DATE.—This section and the amendments made by this section take effect on October 1, 2012.

(d) RELATIONSHIP TO OTHER LAW.—In the case of any conflict between this section (including the amendments made by this section) and a joint resolution making continuing appropriations for fiscal year 2013 (including any amendments made by such a joint resolution), this section and the amendments made by this section shall control.

Passed the Senate September 13, 2012.

Attest:

Secretary.

112TH CONGRESS
2D SESSION

S. 3552

AN ACT

To reauthorize the Federal Insecticide, Fungicide, and Rodenticide Act.