In the Senate of the United States,

June 28, 2018.

Resolved, That the bill from the House of Representatives (H.R. 1029) entitled ''An Act to amend the Federal Insecticide, Fungicide, and Rodenticide Act to improve pesticide registration and other activities under the Act, to extend and modify fee authorities, and for other purposes.'', do pass with the following

AMENDMENTS:

(1) On page 2, line 3, strike **[**Pesticide Registration Enhancement Act of 2017**]** and insert *Pesticide Registration Improvement Extension Act of 2018*.

(2) On page 2, line14 and 15, strike **[**2017 through 2023**]** and insert *2019 through 2023*

(3) On page 2, line 20, strike **[**2017 through 2023**]** and insert *2019 through 2023*

(4) On page 3, line 2, strike **[**2017 through 2023**]** and insert *2019 through 2023*

(5)On page 3, line 7, strike [2017 through 2023] and insert *2019 through 2023*

(6)On page 3, line 11, strike [2017 through 2023] and insert *2019 through 2023*

(7)On page 3, line 13, strike [2023] and insert *2020*

(8)On page 3, line17 through line 20, strike and insert:

(1)(A) by striking "the date of enactment of this section and ending on September 30, 2019" and inserting "the effective date of the Pesticide Registration Improvement Extension Act of 2018 and ending on September 30, 2025"; and

(9)On page 4, line 4, strike [2023] and insert *2020*

(10)On page 4, line 14, after through insert: *the period at the end of*

(11)On page 5, line 20 and 21, strike [2017 through 2023] and insert *2018 through 2020*

(12)On page 6, line 8, strike [2017 through 2021] and insert *2018 through 2020*

(13)On page 7, line 5, after "powders," insert *or*

(14)On page 7, line 13 and 14, strike [June 30, 2017] and insert:

30 days after the effective date of the Pesticide Registration Improvement Extension Act of 2018.

(15) On page 7, line 25, strike [2020] and insert *2019*.

(16) On page 8, line 15, strike [time-to-time] and insert *time to time*

(17) On page 9, line 15, strike [2017 through 2023] and insert *2018 through 2020*

(18) On page 11, line 20 strike [COVERED APPLICATION] and insert *"COVERED APPLICATIONS"*

(19) On page 11, strike lines 25 through page 12 through line 11 and insert

(A) in subparagraph (A)—

(i) by striking "pesticide registration"; and

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

(B) in subparagraph (B)—

(i) by striking "pesticide registration"; and

(ii) by striking "2015" each place it appears and inserting "2021"; and

(20) On page 14 line 2 strike [2023] and insert *2020*

(21) On page 14 line 7 strike [2023] and insert *2020*

(22) On page 14 line 9 strike [2023] and insert *2020*

(23) On page 14 line 16 strike [Enhancement] and insert *Improvement Extension*

(24) On page 14 line 25 strike [(7 U.S.C. 136w–8(f)(1))] and insert *(7 U.S.C. 136w–8(f))*

(25) On page 15 line 4 strike [Enhancement] and insert *Improvement Extension*

(26) On page 16 line 2 strike [2023] and insert *2020*

(27) On page 18 line 18 strike [vector-born public health pests] and insert *invertebrate public health pests that may transmit vector-borne disease*

(28) On page 20 line 17 strike [2023] and insert *2020*

(29) On page 20, strike lines 22 and 23 and insert *"FISCAL YEAR 2024.—During fiscal year 2024"; and*

(30) On page 20 line 25 strike [2023] and insert *2020*

(31) On page 21, strike lines 4 and 5 and insert *"FISCAL YEAR 2025.—During fiscal year 2025"; and*

(32) On page 21 line 7 strike [2023] and insert *2020*

(33) On page 21 lines 10 and 11 strike [2019'' and inserting ''SEPTEMBER 30, 2025.—Effective September 30, 2025''; and] and insert *2019'' and inserting ''SEPTEMBER 30, 2025.—Effective September 30, 2025''; and*

(34) On page 21 line 14 strike [2023] and insert *2020*

(35) On page 21 line 22 through page 105 to the end strike and insert:

''(3) SCHEDULE OF COVERED APPLICATIONS AND OTHER ACTIONS AND THEIR REGISTRATION SERVICE FEES.—Subject to paragraph (6), the schedule of registration applications and other covered actions and their corresponding registration service fees shall be as follows:

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
R010	*1*	*New Active Ingredient, Food use. (2)(3)*	*24*	*753,082*
R020	*2*	*New Active Ingredient, Food use; reduced risk. (2)(3)*	*18*	*627,568*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
R040	*3*	*New Active Ingredient, Food use; Experimental Use Permit application; establish temporary tolerance; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)*	*18*	*462,502*
R060	*4*	*New Active Ingredient, Non-food use; outdoor. (2)(3)*	*21*	*523,205*
R070	*5*	*New Active Ingredient, Non-food use; outdoor; reduced risk. (2)(3)*	*16*	*436,004*
R090	*6*	*New Active Ingredient, Non-food use; outdoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)*	*16*	*323,690*
R110	*7*	*New Active Ingredient, Non-food use; indoor. (2)(3)*	*20*	*290,994*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
R120	*8*	*New Active Ingredient, Non-food use; indoor; reduced risk. (2)(3)*	*14*	*242,495*
R121	*9*	*New Active Ingredient, Non-food use; indoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)*	*18*	*182,327*
R122	*10*	*Enriched isomer(s) of registered mixed-isomer active ingredient. (2)(3)*	*18*	*317,128*
R123	*11*	*New Active Ingredient, Seed treatment only; includes agricultural and non-agricultural seeds; residues not expected in raw agricultural commodities. (2)(3)*	*18*	*471,861*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
R125	*12*	*New Active Ingredient, Seed treatment; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)*	*16*	*323,690*

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

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

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

"TABLE 2. — REGISTRATION DIVISION — NEW USES

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
R130	*13*	*First food use; indoor; food/food handling. (2) (3)*	*21*	*191,444*
R140	*14*	*Additional food use; Indoor; food/food handling. (3) (4)*	*15*	*44,672*
R150	*15*	*First food use. (2)(3)*	*21*	*317,104*
R155	*16 (new)*	*First food use, Experimental Use Permit application; a.i. registered for non-food outdoor use. (3)(4)*	*21*	*264,253*
R160	*17*	*First food use; reduced risk. (2)(3)*	*16*	*264,253*
R170	*18*	*Additional food use. (3) (4)*	*15*	*79,349*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
R175	*19*	*Additional food uses covered within a crop group resulting from the conversion of existing approved crop group(s) to one or more revised crop groups. (3)(4)*	*10*	*66,124*
R180	*20*	*Additional food use; reduced risk. (3)(4)*	*10*	*66,124*
R190	*21*	*Additional food uses; 6 or more submitted in one application. (3)(4)*	*15*	*476,090*
R200	*22*	*Additional Food Use; 6 or more submitted in one application; Reduced Risk. (3)(4)*	*10*	*396,742*
R210	*23*	*Additional food use; Experimental Use Permit application; establish temporary tolerance; no credit toward new use registration. (3)(4)*	*12*	*48,986*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
R220	*24*	*Additional food use; Experimental Use Permit application; crop destruct basis; no credit toward new use registration. (3)(4)*	*6*	*19,838*
R230	*25*	*Additional use; non-food; outdoor. (3) (4)*	*15*	*31,713*
R240	*26*	*Additional use; non-food; outdoor; reduced risk. (3)(4)*	*10*	*26,427*
R250	*27*	*Additional use; non-food; outdoor; Experimental Use Permit application; no credit toward new use registration. (3)(4)*	*6*	*19,838*
R251	*28*	*Experimental Use Permit application which requires no changes to the tolerance(s); non-crop destruct basis. (3)*	*8*	*19,838*
R260	*29*	*New use; non-food; indoor. (3) (4)*	*12*	*15,317*
R270	*30*	*New use; non-food; indoor; reduced risk. (3)(4)*	*9*	*12,764*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
R271	*31*	*New use; non-food; indoor; Experimental Use Permit application; no credit toward new use registration. (3)(4)*	*6*	*9,725*
R273	*32*	*Additional use; seed treatment; limited uptake into Raw Agricultural Commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food and/or non-food uses. (3)(4)*	*12*	*50,445*
R274	*33*	*Additional uses; seed treatment only; 6 or more submitted in one application; limited uptake into raw agricultural commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food and/or non-food uses. (3)(4)*	*12*	*302,663*

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

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

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

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

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
R280	*34*	*Establish import tolerance; new active ingredient or first food use. (2)*	*21*	*319,072*
R290	*35*	*Establish Import tolerance; Additional new food use.*	*15*	*63,816*
R291	*36*	*Establish import tolerances; additional food uses; 6 or more crops submitted in one petition.*	*15*	*382,886*
R292	*37*	*Amend an established tolerance (e.g., decrease or increase) and/or harmonize established tolerances with Codex MRLs; domestic or import; applicant-initiated.*	*11*	*45,341*
R293	*38*	*Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated.*	*12*	*53,483*
R294	*39*	*Establish tolerances for inadvertent residues; 6 or more crops submitted in one application; applicant-initiated.*	*12*	*320,894*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
R295	*40*	*Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; submission of corresponding label amendments which specify the necessary plantback restrictions; applicant-initiated. (3) (4)*	*15*	*66,124*
R296	*41*	*Establish tolerances for residues in rotational crops in response to a specific rotational crop petition; 6 or more crops submitted in one application; submission of corresponding label amendments which specify the necessary plantback restrictions; applicant-initiated. (3) (4)*	*15*	*396,742*
R297	*42*	*Amend 6 or more established tolerances (e.g., decrease or increase) in one petition; domestic or import; applicant-initiated.*	*11*	*272,037*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
R298	*43*	*Amend an established tolerance (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3) (4)*	*13*	*58,565*
R299	*44*	*Amend 6 or more established tolerances (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3) (4)*	*13*	*285,261*

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

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

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

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

"TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)*** (1)	***Registration Service Fee ($)***
R331	*56*	*New product; repack of identical registered end-use product as a manufacturing-use product, or identical registered manufacturing-use product as an end use product; same registered uses only. (2)(3)*	*3*	*2,530*
R332	*57*	*New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of completely new generic data package; registered uses only; requires review in RD and science divisions. (2)(3)*	*24*	*283,215*
R333	*58*	*New product; MUP or End use product with unregistered source of active ingredient; requires science data review; new physical form; etc. Cite-all or selective data citation where applicant owns all required data. (2)(3)*	*10*	*19,838*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)*** (1)	***Registration Service Fee ($)***
R334	*59*	*New product; MUP or End use product with unregistered source of the active ingredient; requires science data review; new physical form; etc. Selective data citation. (2)(3)*	*11*	*23,100*

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

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

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

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

"TABLE 5. — REGISTRATION DIVISION — AMENDMENTS

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
R340	*60*	*Amendment requiring data review within RD (e.g., changes to precautionary label statements); includes adding/modifying pest(s) claims for up to 2 target pests, excludes products requiring or citing an animal safety study. (2)(3)(4)*	*4*	*4,988*
R341	*61 (New)*	*Amendment requiring data review within RD (e.g., changes to precautionary label statements), includes adding/modifying pest(s) claims for greater than 2 target pests, excludes products requiring or citing an animal safety study. (2)(3)(4)*	*6*	*5,988*
R345	*62*	*Amending on-animal products previously registered, with the submission of data and/or waivers for only:* ● *animal safety and* ● *pest(s) requiring efficacy (4) and/or* ● *product chemistry and/or* ● *acute toxicity and/or* ● *child resistant packaging. (2)(3)*	*7*	*8,820*

"TABLE 5. — REGISTRATION DIVISION — AMENDMENTS— Continued

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
R350	*63*	*Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement). (2)(3)*	*9*	*13,226*
R351	*64*	*Amendment adding a new unregistered source of active ingredient. (2)(3)*	*8*	*13,226*
R352	*65*	*Amendment adding already approved uses; selective method of support; does not apply if the applicant owns all cited data. (2) (3)*	*8*	*13,226*
R371	*66*	*Amendment to Experimental Use Permit; (does not include extending a permit's time period). (3)*	*6*	*10,090*

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

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

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

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

"TABLE 6. — REGISTRATION DIVISION — OTHER ACTIONS

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
R124	*67*	*Conditional Ruling on Pre-application Study Waivers; applicant-initiated.*	*6*	*2,530*

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

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

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

"TABLE 7. — ANTIMICROBIALS DIVISION — NEW ACTIVE INGREDIENTS

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
A380	*71*	*New Active Ingredient; Indirect Food use; establish tolerance or tolerance exemption if required. (2)(3)*	*24*	*137,841*
A390	*72*	*New Active Ingredient; Direct Food use; establish tolerance or tolerance exemption if required. (2)(3)*	*24*	*229,733*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
A410	*73*	*New Active Ingredient Non-food use.(2)(3)*	*21*	*229,733*
A431	*74*	*New Active Ingredient, Non-food use; low-risk. (2)(3)*	*12*	*80,225*

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

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

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

"TABLE 8. — ANTIMICROBIALS DIVISION — NEW USES

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)*** (1)	***Registration Service Fee ($)***
A440	*75*	*New Use, Indirect Food Use, establish tolerance or tolerance exemption. (2)(3)(4)*	*21*	*31,910*
A441	*76*	*Additional Indirect food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application. (3)(4)(5)*	*21*	*114,870*
A450	*77*	*New use, Direct food use, establish tolerance or tolerance exemption. (2)(3)(4)*	*21*	*95,724*
A451	*78*	*Additional Direct food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application. (3)(4)(5)*	*21*	*182,335*
A500	*79*	*New use, non-food. (4)(5)*	*12*	*31,910*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)*** (1)	***Registration Service Fee ($)***
A501	*80*	*New use, non-food; 6 or more submitted in one application. (4)(5)*	*15*	*76,583*

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

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

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

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

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

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

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

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
A531	*82*	*New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient: selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner. (2)(3)*	*4*	*1,824*
A532	*83*	*New product; identical or substantially similar in composition and use to a registered product; registered active ingredient; unregistered source of active ingredient; cite-all data citation except for product chemistry; product chemistry data submitted. (2)(3)*	*5*	*5,107*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
A540	*84*	*New end use product; FIFRA §2(mm) uses only; up to 25 public health organisms. (2)(3)(5)(6)*	*5*	*5,107*
A541	*85 (new)*	*New end use product; FIFRA §2(mm) uses only; 26-50 public health organisms. (2)(3)(5)(6)*	*7*	*8,500*
A542	*86 (new)*	*New end use product; FIFRA §2(mm) uses only; ≥ 51 public health organisms. (2)(3)(5)*	*10*	*15,000*
A550	*87*	*New end-use product; uses other than FIFRA §2(mm); non-FQPA product. (2)(3)(5)*	*9*	*13,226*
A560	*88*	*New manufacturing use product; registered active ingredient; selective data citation. (2)(3)*	*6*	*12,596*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
A565	*89 (new)*	*New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of new generic data package; registered uses only; requires science review. (2)(3)*	*12*	*18,234*
A570	*90*	*Label amendment requiring data review; up to 25 public health organisms. (3)(4)(5)(6)*	*4*	*3,831*
A573	*91 (new)*	*Label amendment requiring data review; 26-50 public health organisms. (2)(3)(5)(7)*	*6*	*6,350*
A574	*92 (new)*	*Label amendment requiring data review; ≥ 51 public health organisms. (2)(3)(5)(7)*	*9*	*11,000*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
A572	*93*	*New Product or amendment requiring data review for risk assessment by Science Branch (e.g., changes to REI, or PPE, or use rate). (2)(3)(4)*	*9*	*13,226*

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

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

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

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

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

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

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

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
A520	*94*	*Experimental Use Permit application, non-food use. (2)*	*9*	*6,383*
A521	*95*	*Review of public health efficacy study protocol within AD, per AD Internal Guidance for the Efficacy Protocol Review Process; Code will also include review of public health efficacy study protocol and data review for devices making pesticidal claims; applicant-initiated; Tier 1.*	*4*	*4,726*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
A522	*96*	*Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; Code will also include review of public health efficacy study protocol and data review for devices making pesticidal claims; applicant-initiated; Tier 2.*	*12*	*12,156*
A537	*97 (new)*	*New Active Ingredient/New Use, Experimental Use Permit application; Direct food use; Establish tolerance or tolerance exemption if required. Credit 45% of fee toward new active ingredient/new use application that follows.*	*18*	*153,156*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
A538	*98 (new)*	*New Active Ingredient/New Use, Experimental Use Permit application; Indirect food use; Establish tolerance or tolerance exemption if required Credit 45% of fee toward new active ingredient/new use application that follows.*	*18*	*95,724*
A539	*99 (new)*	*New Active Ingredient/New Use, Experimental Use Permit application; Nonfood use. Credit 45% of fee toward new active ingredient/new use application that follows.*	*15*	*92,163*
A529	*100*	*Amendment to Experimental Use Permit; requires data review or risk assessment. (2)*	*9*	*11,429*
A523	*101*	*Review of protocol other than a public health efficacy study (i.e., Toxicology or Exposure Protocols).*	*9*	*12,156*

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
A571	*102*	*Science reassessment: Cancer risk, refined ecological risk, and/or endangered species; applicant-initiated.*	*18*	*95,724*
A533	*103 (new)*	*Exemption from the requirement of an Experimental Use Permit. (2)*	*4*	*2,482*
A534	*104 (new)*	*Rebuttal of agency reviewed protocol, applicant initiated.*	*4*	*4,726*
A535	*105 (new)*	*Conditional Ruling on Pre-application Study Waiver or Data Bridging Argument; applicant-initiated.*	*6*	*2,409*
A536	*106 (new)*	*Conditional Ruling on Pre-application Direct Food, Indirect Food, Nonfood use determination; applicant-initiated.*	*4*	*2,482*

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

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

"TABLE 11. — BIOPESTICIDES DIVISION — NEW ACTIVE INGREDIENTS

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

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

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

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

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

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

"TABLE 12. — BIOPESTICIDES DIVISION — NEW USES

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

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

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

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

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

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

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

"TABLE 13. — BIOPESTICIDES DIVISION — NEW PRODUCTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"TABLE 14. — BIOPESTICIDES DIVISION — AMENDMENTS

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

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

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

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

"TABLE 15. — BIOPESTICIDES DIVISION — SCLP

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

"TABLE 15. — BIOPESTICIDES DIVISION — SCLP— Continued

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

"TABLE 15. — BIOPESTICIDES DIVISION — SCLP— Continued

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
B720	*146*	*New product; registered source of active ingredient(s); requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (3)(6)*	*5*	*1,278*
B721	*147*	*New product; unregistered source of active ingredient. (3)(6)*	*7*	*2,676*

"TABLE 15. — BIOPESTICIDES DIVISION — SCLP— Continued

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
B722	*148*	*New use and/or amendment; petition to establish a tolerance or tolerance exemption. (4)(5)(6)*	*7*	*2,477*
B730	*149*	*Label amendment requiring data submission. (4)(6)*	*5*	*1,278*

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

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

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

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

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

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

"TABLE 16. — BIOPESTICIDES DIVISION — OTHER ACTIONS

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
B614	*150*	*Pre-application; Conditional Ruling on rationales for addressing a data requirement in lieu of data; applicant-initiated; applies to one rationale at a time.*	*3*	*2,530*

"TABLE 16. — BIOPESTICIDES DIVISION — OTHER ACTIONS—Continued

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
B615	*151*	*Rebuttal of agency reviewed protocol, applicant initiated.*	*3*	*2,530*
B682	*152*	*Protocol review; applicant initiated; excludes time for HSRB review.*	*3*	*2,432*

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

"TABLE 17. — BIOPESTICIDES DIVISION — PIP

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

"TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

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

"TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

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

"TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
B773	*159*	*Application to amend or extend an Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient. (12)*	*5*	*31,910*
B780	*160*	*Registration application; new (2) PIP; non-food/feed. (12)*	*12*	*159,537*
B790	*161*	*Registration application; new (2) PIP; non-food/feed; SAP review. (5)(12)*	*18*	*223,351*
B800	*162*	*Registration application; new (2) PIP; with petition to establish permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. (12)*	*13*	*172,300*
B810	*163*	*Registration application; new (2) PIP; with petition to establish permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. SAP review. (5)(12)*	*19*	*236,114*

"TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
B820	*164*	*Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient. (12)*	*15*	*204,208*
B840	*165*	*Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient. SAP review. (5)(12)*	*21*	*268,022*
B851	*166*	*Registration application; new event of a previously registered PIP active ingredient(s); no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s). (12)*	*9*	*127,630*
B870	*167*	*Registration application; registered (3) PIP; new product; new use; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (4) (12)*	*9*	*38,290*

"TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
B880	*168*	*Registration application; registered (3) PIP; new product or new terms of registration; additional data submitted; no petition since a permanent tolerance/ tolerance exemption is already established for the active ingredient(s). (6) (7) (12)*	*9*	*31,910*
B881	*169*	*Registration application; registered (3) PIP; new product or new terms of registration; additional data submitted; no petition since a permanent tolerance/ tolerance exemption is already established for the active ingredient(s). SAP review. (5)(6)(7)(12)*	*15*	*95,724*
B882	*170 (new)*	*Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption; SAP Review. (8)(12)*	*15*	*191,444*

"TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

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

"TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

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

"TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
B900	*177*	*Application to amend a registration, including actions such as extending an expiration date, modifying an IRM plan, or adding an insect to be controlled. (10)(11)(12)*	*6*	*12,764*
B901	*178*	*Application to amend a registration, including actions such as extending an expiration date, modifying an IRM plan, or adding an insect to be controlled. SAP review. (10) (11) (12)*	*12*	*76,578*
B902	*179*	*PIP Protocol review.*	*3*	*6,383*
B903	*180*	*Inert ingredient tolerance exemption; e.g., a marker such as NPT II; reviewed in BPPD.*	*6*	*63,816*
B904	*181*	*Import tolerance or tolerance exemption; processed commodities/food only (inert or active ingredient).*	*9*	*127,630*
B905	*182 (new)*	*SAP Review.*	*6*	*63,816*
B906	*183 (new)*	*Petition to establish a temporary tolerance/tolerance exemption for one or more active ingredients.*	*3*	*31,907*

"TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

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

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

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

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

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

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

(6) Registered PIPs stacked through conventional breeding.

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

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

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

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

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

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

"TABLE 18. — INERT INGREDIENTS

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)*** (1)	***Registration Service Fee ($)***
I001	*186*	*Approval of new food use inert ingredient. (2)(3)*	*13*	*27,000*
I002	*187*	*Amend currently approved inert ingredient tolerance or exemption from tolerance; new data. (2)*	*11*	*7,500*
I003	*188*	*Amend currently approved inert ingredient tolerance or exemption from tolerance; no new data. (2)*	*9*	*3,308*
I004	*189*	*Approval of new non-food use inert ingredient. (2)*	*6*	*11,025*
I005	*190*	*Amend currently approved non-food use inert ingredient with new use pattern; new data. (2)*	*6*	*5,513*

"TABLE 18. — INERT INGREDIENTS—Continued

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)*** (1)	***Registration Service Fee ($)***
I006	*191*	*Amend currently approved non-food use inert ingredient with new use pattern; no new data. (2)*	*3*	*3,308*
I007	*192*	*Approval of substantially similar non-food use inert ingredients when original inert is compositionally similar with similar use pattern. (2)*	*4*	*1,654*
I008	*193*	*Approval of new or amended polymer inert ingredient, food use. (2)*	*5*	*3,749*
I009	*194*	*Approval of new or amended polymer inert ingredient, non-food use. (2)*	*4*	*3,087*
I010	*195*	*Petition to amend a single tolerance exemption descriptor, or single non-food use descriptor, to add ≤ 10 CASRNs; no new data. (2)*	*6*	*1,654*
I011	*196 (new)*	*Approval of new food use safener with tolerance or exemption from tolerance. (2)(8)*	*24*	*597,683*
I012	*197 (new)*	*Approval of new non-food use safener. (2)(8)*	*21*	*415,241*

"TABLE 18. — INERT INGREDIENTS—Continued

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)*** (1)	***Registration Service Fee ($)***
I013	*198 (new)*	*Approval of additional food use for previously approved safener with tolerance or exemption from tolerance. (2)*	*15*	*62,975*
I014	*199 (new)*	*Approval of additional non-food use for previously approved safener. (2)*	*15*	*25,168*
I015	*200 (new)*	*Approval of new generic data for previously approved food use safener. (2)*	*24*	*269,728*
I016	*201 (new)*	*Approval of amendment(s) to tolerance and label for previously approved safener. (2)*	*13*	*55,776*

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

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

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

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

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

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

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

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

"TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS

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

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

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

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

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

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

EPA No.	***New CR No.***	***Action***	***Decision Review Time (Months)***(1)	***Registration Service Fee ($)***
M005	*206*	*New Product: Combination, Contains a combination of active ingredients from a registered and/or unregistered source; conventional, antimicrobial and/or biopesticide. Requires coordination with other regulatory divisions to conduct review of data, label and/or verify the validity of existing data as cited. Only existing uses for each active ingredient in the combination product. (6)(7)*	*9*	*22,050*
M006	*207*	*Request for up to 5 letters of certification (Gold Seal) for one actively registered product (excludes distributor products). (8)*	*1*	*277*
M007	*208*	*Request to extend Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(ii).*	*12*	*5,513*

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

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

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

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

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

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

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

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

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

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

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

SEC. 7. EXTENSION.

Notwithstanding any other provision of this Act or amendment made by this Act, any reference in this Act or an amendment made by this Act to "2020" shall be deemed to be a reference to "2023".

SEC. 8. AGRICULTURAL WORKER PROTECTION STANDARD; CERTIFICATION OF PESTICIDE APPLICATORS.

(a) IN GENERAL.—Except as provided in subsection (b), during the period beginning on the date of enactment of this Act and ending not earlier than October 1, 2021, the Administrator of the Environmental Protection Agency (referred to in this section as the "Administrator")—

(1) shall carry out—

(A) the final rule of the Administrator entitled "Pesticides; Agricultural Worker Protection Standard Revisions" (80 Fed. Reg. 67496 (November 2, 2015)); and

(B) the final rule of the Administrator entitled "Pesticides; Certification of Pesticide Applicators" (82 Fed. Reg. 952 (January 4, 2017)); and

(2) shall not revise or develop revisions to the rules described in subparagraphs (A) and (B) of paragraph (1).

(b) EXCEPTIONS.—Prior to October 1, 2021, the Administrator may propose, and after a notice and public comment period of not less than 90 days, promulgate revisions to the final rule described in subsection (a)(1)(A) addressing application exclusion zones under part 170 of title 40, Code of Federal Regulations, consistent with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.).

(c) GAO REPORT.—The Comptroller General of the United States shall—

(1) conduct a study on the use of the designated representative, including the effect of that use on the availability of pesticide application and hazard information and worker health and safety; and

(2) not later than October 1, 2021, make publically available a report describing the study under paragraph (1), including any recommendations to prevent the misuse of pesticide application and hazard information, if that misuse is identified.

Attest:

Secretary.

115TH CONGRESS
2D SESSION

H.R. 1029

AMENDMENTS