



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2019-0543; FRL-10000-37]

Pesticides; Revised Fee Schedule for Covered Applications Under the Pesticide

Registration Improvement Extension Act of 2018 (PRIA 4)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is publishing a revised list of pesticide registration service fees applicable to pesticide applications covered under the Pesticide Registration Improvement Extension Act of 2018 (PRIA 4), which was signed into law and became effective March 8, 2019. As specified in the law and effective October 1, 2019, the registration service fees for covered pesticide registration applications received on or after that date will be increased by 5%. The revised fees will remain in effect through September 30, 2021.

FOR FURTHER INFORMATION CONTACT: Stephen A. Schaible, PRIA Coordinator, Office of Pesticide Programs, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, D.C., 20460-0001; telephone number: (703)308-9362; email address: schaible.stephen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are requesting registration of a new pesticide product or amendment to an existing pesticide product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), petitioning to establish a tolerance or tolerance

exemption for an active ingredient or inert ingredient under the Federal Food, Drug, and Cosmetic Act (FFDCA), or otherwise seeking a regulatory determination under FIFRA or FFDCA for certain activities specified under PRIA. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Agricultural pesticide manufacturers (NAICS code 325320)
- Antimicrobial pesticide manufacturers (NAICS code 325611, 325612)
- Antifoulant pesticide manufacturers (NAICS code 325510)
- Wood preservative manufacturers (NAICS code 325194)

B. How Can I Get Copies of this Document and Other Related Information?

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2019-0543, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

II. Background

A. What Action is the Agency Taking?

The Pesticide Registration Improvement Act of 2003 (PRIA) established a new section

33 of FIFRA creating a registration service fee system for certain types of pesticide applications, establishment of tolerances, and certain other regulatory decisions under FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 33 also created a schedule of decision review times for applications covered by the service fee system. The Agency began administering the registration service fee system for covered applications received on or after March 23, 2004.

On March 8, 2019, the Pesticide Registration Improvement Extension Act of 2018 was signed into law by the President, revising, among other things, FIFRA section 33. The new law reauthorized the service fee system through fiscal year 2023 and established fees and review times for applications received during fiscal years 2019 (as of March 8, 2019) through 2023. As required by section 33(b)(6)(A) of FIFRA, the registration service fees for covered pesticide registration applications received on or after October 1, 2019, increase by 5% (rounding up to the nearest dollar) from the fee amounts established by the law (Public Law 116-8).

B. What is the Agency's Authority for Taking this Action?

The increase in these registration service fees is required by section 33(b)(6)(A) of FIFRA. The publication of these revised registration service fee schedules is required by section 33(b)(6)(C) of FIFRA as amended (U.S.C. Title 7, Ch. 6, Subchapter II, Section 136w-8).

III. Elements of the Fee Schedule

This unit explains how to read the fee schedule tables and includes a key to terminology published with the table.

A. The Pesticide Registration Improvement Extension Act of 2018 Fee Schedule

The fee schedule provided in the Pesticide Registration Improvement Extension Act of 2018 identifies the registration service fees and decision times and is organized according to the organizational units of the Office of Pesticide Programs (OPP) within EPA. Thereafter, the

categories within the organizational unit sections of the table are further categorized according to the type of application being submitted, the use patterns involved, or, in some cases, upon the type of pesticide that is the subject of the application. The fee categories differ by Division. Not all application types are covered by, or subject to, the fee system.

B. Fee Schedule and Decision Review Times

In this notice, EPA has retained the format of the tables included in the Pesticide Registration Improvement Extension Act of 2018. The schedules are presented as 19 tables, organized by OPP Division and by type of application or pesticide subject to the fee. Unit IV presents fee tables for the Registration Division (RD) (6 tables), the Antimicrobials Division (AD) (4 tables), the Biopesticides and Pollution Prevention Division (BPPD) (7 tables), Inert Ingredients (1 table), Miscellaneous (1 table).

C. How to Read the Tables

1. Each table consists of the following columns:

- The column titled “EPA No.” assigns an EPA identifier to each fee category. There are 212 categories spread across the 3 Divisions. There are 70 RD categories, 36 AD categories, 79 BPPD categories, 16 inert categories, and 11 miscellaneous categories. For tracking purposes, OPP has assigned a 3-digit identifier to each category, beginning with RD categories, followed by AD, BPPD, inert and miscellaneous categories. The categories are prefaced with a letter designation indicating which Division of OPP is responsible for applications in that category (R=Registration Division, A=Antimicrobials Division, B=Biopesticides and Pollution Prevention Division, I=inert ingredients, M= miscellaneous).

The column titled “CR No.” cross-references the current Congressional Record category number for convenience. However, EPA will be using the categories as numbered in the “EPA

No.” column in its tracking systems.

- The column titled “Action” describes what registration actions are covered by each category.

- The column titled “Decision Review Time” lists the decision times in months for each type of action.

- The column titled “FY’20 – FY’21 Fees (\$)” lists the registration service fee for the action for fiscal year 2020 (October 1, 2019 through September 30, 2020) and fiscal year 2021 (October 1, 2020 through September 30, 2021).

2. *The following acronyms are used in some of the tables:*

- DART – Dose Adequacy Response Team.
- DNT – Developmental Neurotoxicity.
- DfE – Design for the Environment.
- HSRB – Human Studies Review Board.
- GW/SW – Ground Water/Surface Water.
- PHI – Pre-Harvest Interval.
- PPE – Personal Protective Equipment.
- REI – Restricted Entry Interval.
- SAP – FIFRA Scientific Advisory Panel.

IV. PRIA Fee Schedule Tables--Effective October 1, 2019

A. Registration Division (RD)

The Registration Division of OPP is responsible for the processing of pesticide applications and associated tolerance petitions for pesticides that are termed "conventional chemicals," excluding pesticides intended for antimicrobial uses. The term "conventional

chemical" is a term of art that is intended to distinguish synthetic chemicals from those that are of naturally occurring or non-synthetic origin, synthetic chemicals that are identical to naturally occurring chemicals and microbial pesticides. Tables 1 through 6 cover RD actions.

Table 1. Registration Division - New Active Ingredients

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
R010	1	New Active Ingredient, Food use ⁽²⁾⁽³⁾	24	790,737
R020	2	New Active Ingredient, Food use; reduced risk ⁽²⁾⁽³⁾	18	658,947
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	485,628
R060	4	New Active Ingredient, Non-food use; outdoor ⁽²⁾⁽³⁾	21	549,366
R070	5	New Active Ingredient, Non-food use; outdoor; reduced risk ⁽²⁾⁽³⁾	16	457,805
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	339,875
R110	7	New Active Ingredient, Non-food use; indoor ⁽²⁾⁽³⁾	20	305,544
R120	8	New Active Ingredient, Non-food use; indoor; reduced risk ⁽²⁾⁽³⁾	14	254,620
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	191,444
R122	10	Enriched isomer(s) of registered mixed-isomer active ingredient ⁽²⁾⁽³⁾	18	332,985
R123	11	New Active Ingredient, Seed treatment only; includes agricultural and non-agricultural seeds; residues not expected in raw agricultural commodities ⁽²⁾⁽³⁾	18	495,455
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	16	339,875

		follows ⁽³⁾		
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¹A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

²All 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.

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

Table 2. Registration Division - New Uses

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
R130	13	First food use; indoor; food/food handling ⁽²⁾⁽³⁾	21	201,017
R140	14	Additional food use; Indoor; food/food handling ⁽³⁾⁽⁴⁾	15	46,906
R150	15	First food use ⁽²⁾⁽³⁾	21	332,960
R155	16 (new)	First food use, Experimental Use Permit application; a.i. registered for non-food outdoor use ⁽³⁾⁽⁴⁾	21	277,466
R160	17	First food use; reduced risk ⁽²⁾⁽³⁾	16	277,466
R170	18	Additional food use ⁽³⁾⁽⁴⁾	15	83,317

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	69,431
R180	20	Additional food use; reduced risk ⁽³⁾⁽⁴⁾	10	69,431
R190	21	Additional food uses; 6 or more submitted in one application ⁽³⁾⁽⁴⁾	15	499,895
R200	22	Additional Food Use; 6 or more submitted in one application; Reduced Risk ⁽³⁾⁽⁴⁾	10	416,580
R210	23	Additional food use; Experimental Use Permit application; establish temporary tolerance; no credit toward new use registration ⁽³⁾⁽⁴⁾	12	51,436
R220	24	Additional food use; Experimental Use Permit application; crop destruct basis; no credit toward new use registration ⁽³⁾⁽⁴⁾	6	20,830
R230	25	Additional use; non-food; outdoor ⁽³⁾⁽⁴⁾	15	33,299
R240	26	Additional use; non-food; outdoor; reduced risk ⁽³⁾⁽⁴⁾	10	27,749
R250	27	Additional use; non-food; outdoor; Experimental Use Permit application; no credit toward new use registration ⁽³⁾⁽⁴⁾	6	20,830
R251	28	Experimental Use Permit application which requires no changes to the tolerance(s); non-crop destruct basis ⁽³⁾	8	20,830
R260	29	New use; non-food; indoor ⁽³⁾⁽⁴⁾	12	16,083
R270	30	New use; non-food; indoor; reduced risk ⁽³⁾⁽⁴⁾	9	13,403
R271	31	New use; non-food; indoor; Experimental Use Permit application; no credit toward new use registration ⁽³⁾⁽⁴⁾	6	10,212
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	52,968
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	317,797

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

²All 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.

³Where 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.

⁴Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application.

Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant’s initiative to support the application after completion of the technical deficiency screen, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

Table 3. Registration Division - Import and Other Tolerances

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
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R280	34	Establish import tolerance; new active ingredient or first food use ⁽²⁾	21	335,026
R290	35	Establish Import tolerance; Additional new food use	15	67,007
R291	36	Establish import tolerances; additional food uses; 6 or more crops submitted in one petition	15	402,031
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	47,609
R293	38	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated	12	56,158
R294	39	Establish tolerances for inadvertent residues; 6 or more crops submitted in one application; applicant-initiated	12	336,939
R295	40	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; submission of corresponding label amendments which specify the necessary plant-back restrictions; applicant-initiated ⁽³⁾⁽⁴⁾	15	69,431
R296	41	Establish tolerances for residues in rotational crops in response to a specific rotational crop petition; 6 or more crops submitted in one application; submission of corresponding label amendments which specify the necessary plant-back restrictions; applicant-initiated ⁽³⁾⁽⁴⁾	15	416,580
R297	42	Amend 6 or more established tolerances (e.g., decrease or increase) in one petition; domestic or import; applicant-initiated	11	285,639
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	61,494
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	299,525

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

²All 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.

³Where 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 applicant’s written or electronic confirmation of agreement to the Agency.

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

Table 4. Registration Division - New Products

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
R300	45	New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; no data review on acute toxicity, efficacy or CRP -- only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re- package of registered end use or	4	1,662

		manufacturing- use product that requires no data submission nor data matrix. ⁽²⁾⁽³⁾		
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	1,992
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: <ul style="list-style-type: none"> • product chemistry and/or • acute toxicity and/or • child resistant packaging and/or • pest(s) requiring efficacy – for up to 3 target pests⁽²⁾⁽³⁾⁽⁴⁾ 	7	7,667
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: <ul style="list-style-type: none"> • 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	9,058
R319	49 (new)	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	10	13,258

		<p>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:</p> <ul style="list-style-type: none"> • 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⁾ 		
R318	50 (new)	<p>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:</p> <ul style="list-style-type: none"> • product chemistry and/or • acute toxicity and/or • child resistant packaging and/or • pest(s) requiring efficacy – for up to 3 target pests⁽²⁾⁽³⁾⁽⁴⁾ 	9	13,915
R321	51 (new)	<p>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:</p> <ul style="list-style-type: none"> • 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	18,115
R315	52	<p>New end-use on-animal product, registered source of active ingredient(s) with submission of data and/or waivers for only:</p> <ul style="list-style-type: none"> • animal safety and • pest(s) requiring efficacy and/or • product chemistry and/or • acute toxicity and/or 	9	10,311

		• child resistant packaging ⁽²⁾⁽³⁾⁽⁴⁾		
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: <ul style="list-style-type: none"> • product chemistry and/or • acute toxicity and/or • child resistant packaging and/or • pest(s) requiring efficacy - for greater than 3 and up to 7 target pests⁽²⁾⁽³⁾⁽⁴⁾ 	9	11,867
R317	54 (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: <ul style="list-style-type: none"> • product chemistry and/or • acute toxicity and/or • child resistant packaging and/or • pest(s) requiring efficacy - for greater than 7 target pests⁽²⁾⁽³⁾⁽⁴⁾ 	10	16,067
R320	55	New product; new physical form; requires data review in science divisions ⁽²⁾⁽³⁾	12	13,888
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	2,657
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	297,376
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	20,830
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	24,255

¹A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be

extended to end on the next business day.

²An 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.

³Where 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.

⁴For 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 Ash Borer). This list may be updated/refined as invasive pest needs arise. To determine the number of pests for the PRIA categories, pests have been placed into groups (general; e.g., cockroaches) and pest specific (specifically a test species). If seeking a label claim against a pest group (general), use the group listing below and each group will count as 1. The general pests groups are: mites, dust mites, chiggers, ticks, hard ticks, soft ticks, cattle ticks, scorpions, spiders, centipedes, lice, fleas, cockroaches, keds, bot flies, screwworms, filth flies, blow flies, house flies, flesh flies, mosquitoes, biting flies, horse flies, stable flies, deer flies, sand flies, biting midges, black flies, true bugs, bed bugs, stinging bees, wasps, yellow jackets, hornets, ants (excluding carpenter ants), fire and harvester ants, wood destroying beetles, carpenter ants, termites, subterranean termites, dry wood termites, arboreal termites, damp wood termites and invasive species. If seeking a claim against a specific pest without a general claim then each specific pest will count as 1.

Table 5. Registration Division - Amendments

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
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	5,238
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⁾	6	6,288
R345	62	Amending on- animal products previously registered, with the submission of data and/or	7	9,261

		waivers for only: <ul style="list-style-type: none"> • animal safety and • pest(s) requiring efficacy and/or • product chemistry and/or • acute toxicity and/or • child resistant packaging⁽²⁾⁽³⁾⁽⁴⁾ 		
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	13,888
R351	64	Amendment adding a new unregistered source of active ingredient. ⁽²⁾⁽³⁾	8	13,888
R352	65	Amendment adding already approved uses; selective method of support; does not apply if the applicant owns all cited data ⁽²⁾⁽³⁾	8	13,888
R371	66	Amendment to Experimental Use Permit; (does not include extending a permit's time period) ⁽³⁾	6	10,595

¹A 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.

³Where 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.

⁴For 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 Ash Borer). This list may be updated/refined as invasive pest needs arise. To determine the number of pests for the PRIA categories, pests have been placed into groups (general; e.g., cockroaches) and pest specific (specifically a test species). If seeking a label claim against a pest group (general), use the group listing below and each group will count as 1. The general pests groups are: mites, dust mites, chiggers, ticks, hard ticks, soft ticks, cattle ticks, scorpions, spiders, centipedes,

lice, fleas, cockroaches, keds, bot flies, screwworms, filth flies, blow flies, house flies, flesh flies, mosquitoes, biting flies, horse flies, stable flies, deer flies, sand flies, biting midges, black flies, true bugs, bed bugs, stinging bees, wasps, yellow jackets, hornets, ants (excluding carpenter ants), fire and harvester ants, wood destroying beetles, carpenter ants, termites, subterranean termites, dry wood termites, arboreal termites, damp wood termites and invasive species. If seeking a claim against a specific pest without a general claim then each specific pest will count as 1.

Table 6. Registration Division - Other Actions

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
R124	67	Conditional Ruling on Pre-application Study Waivers; applicant-initiated	6	2,657
R272	68	Review of Study Protocol applicant- initiated; excludes DART, pre- registration conference, Rapid Response review, DNT protocol review, protocol needing HSRB review	3	2,657
R275	69	Rebuttal of agency reviewed protocol, applicant initiated	3	2,657
R370	70	Cancer reassessment; applicant-initiated	18	208,163

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

B. Antimicrobials Division (AD)

The Antimicrobials Division of OPP is responsible for the processing of pesticide applications and associated tolerances for conventional chemicals intended for antimicrobial uses, that is, uses that are defined under FIFRA section 2(mm)(1)(A), including products for use against bacteria, protozoa, non-agricultural fungi, and viruses. AD is also responsible for a selected set of conventional chemicals intended for other uses, including most wood preservatives and antifoulants. Tables 7 through 10 cover AD actions.

Table 7. Antimicrobials Division - New Active Ingredients

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
A380	71	New Active Ingredient; Indirect Food use; establish tolerance or tolerance exemption if required ⁽²⁾⁽³⁾	24	144,734
A390	72	New Active Ingredient; Direct Food use; establish	24	241,220

		tolerance or tolerance exemption if required ⁽²⁾⁽³⁾		
A410	73	New Active Ingredient Non-food use ⁽²⁾⁽³⁾	21	241,262
A431	74	New Active Ingredient, Non-food use; low-risk ⁽²⁾⁽³⁾	12	84,237

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

²All 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.

³Where 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) ⁽⁴⁾	FY'20 - FY'21 Fees (\$)
A440	75	New Use, Indirect Food Use, establish tolerance or tolerance exemption ⁽²⁾⁽³⁾⁽⁴⁾	21	33,506
A441	76 (new)	Additional Indirect food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application ⁽³⁾⁽⁴⁾⁽⁵⁾	21	120,614
A450	77	New use, Direct food use, establish tolerance or	21	100,511

		tolerance exemption ⁽²⁾⁽³⁾⁽⁴⁾		
A451	78 (new)	Additional Direct food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application ⁽³⁾⁽⁴⁾⁽⁵⁾	21	191,452
A500	79	New use, non-food ⁽⁴⁾⁽⁵⁾	12	33,506
A501	80	New use, non-food; 6 or more submitted in one application ⁽⁴⁾⁽⁵⁾	15	80,413

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

²All 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.

³If 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.

⁴Where 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.

⁵Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and

there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application.

Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screen, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

Table 9. Antimicrobials Division - New Products and Amendments

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
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	1,342
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	1,916
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	5,363
A540	84	New end use product; FIFRA §2(mm) uses only; up to 25 public health organisms ⁽²⁾⁽³⁾⁽⁵⁾⁽⁶⁾	5	5,363
A541	85 (new)	New end use product; FIFRA §2(mm) uses only; 26-50 public health organisms ⁽²⁾⁽³⁾⁽⁵⁾⁽⁶⁾	7	8,925
A542	86	New end use product; FIFRA §2(mm) uses only; ≥	10	15,750

	(new)	51 public health organisms ⁽²⁾⁽³⁾⁽⁵⁾		
A550	87	New end-use product; uses other than FIFRA §2(mm); non-FQPA product ⁽²⁾⁽³⁾⁽⁵⁾	9	13,888
A560	88	New manufacturing use product; registered active ingredient; selective data citation ⁽²⁾⁽³⁾	6	13,226
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	19,146
A570	90	Label amendment requiring data review; up to 25 public health organisms ⁽³⁾⁽⁴⁾⁽⁵⁾⁽⁶⁾	4	4,023
A573	91 (new)	Label amendment requiring data review; 26-50 public health organisms ⁽²⁾⁽³⁾⁽⁵⁾⁽⁷⁾	6	6,668
A574	92 (new)	Label amendment requiring data review; ≥ 51 public health organisms ⁽²⁾⁽³⁾⁽⁵⁾⁽⁷⁾	9	11,550
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	13,888

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

²An 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.

³Where 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.

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

⁶Once 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.

⁷Once 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⁾	FY'20 - FY'21 Fees (\$)
A520	94	Experimental Use Permit application, non-food use ⁽²⁾	9	6,703
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	4,963
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	12,764
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	160,814
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	100,511
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	96,772
A529	100	Amendment to Experimental Use Permit; requires data review or risk assessment ⁽²⁾	9	12,001
A523	101	Review of protocol other than a public health efficacy study (i.e., Toxicology or Exposure	9	12,764

		Protocols)		
A571	102	Science reassessment: Cancer risk, refined ecological risk, and/or endangered species; applicant-initiated.	18	100,511
A533	103 (new)	Exemption from the requirement of an Experimental Use Permit ⁽²⁾	4	2,607
A534	104 (new)	Rebuttal of agency reviewed protocol, applicant initiated	4	4,963
A535	105 (new)	Conditional Ruling on Pre-application Study Waiver or Data Bridging Argument; applicant-initiated	6	2,530
A536	106 (new)	Conditional Ruling on Pre-application Direct Food, Indirect Food, Nonfood use determination; applicant-initiated	4	2,607

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

²Where 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.

C. Biopesticides and Pollution Prevention Division (BPPD)

The Biopesticides and Pollution Prevention Division of OPP is responsible for the processing of pesticide applications for biochemical pesticides, microbial pesticides, and plant-incorporated protectants (PIPs).

The fee tables for BPPD actions are presented by type of pesticide rather than by type of action: Microbial and biochemical pesticides, straight chain lepidopteran pheromones (SCLPs), and PIPs. Within each table, the types of application are the same as those in other divisions.

Tables 11 through 17 cover BPPD actions.

Table 11. Biopesticides Division - New Active Ingredients

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
B580	107	New active ingredient; food use; petition to establish a tolerance ⁽²⁾⁽³⁾	20	53,606
B590	108	New active ingredient; food use; petition to establish a tolerance exemption ⁽²⁾⁽³⁾	18	33,506
B600	109	New active ingredient; non-food use ⁽²⁾⁽³⁾	13	20,104
B610	110	New active ingredient; Experimental Use Permit application; petition to establish a temporary tolerance or temporary tolerance exemption ⁽³⁾	10	13,403
B611	111	New active ingredient; Experimental Use Permit application; petition to establish permanent tolerance exemption ⁽³⁾	12	13,403
B612	112	New active ingredient; no change to a permanent tolerance exemption ⁽²⁾⁽³⁾	10	18,428
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	18,428
B620	114	New active ingredient; Experimental Use Permit application; non-food use including crop destruct ⁽³⁾	7	6,703

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

²All 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.

³Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms

associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

Table 12. Biopesticides Division - New Uses

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
B630	115	First food use; petition to establish a tolerance exemption ⁽²⁾⁽⁴⁾	13	13,403
B631	116	New food use; petition to amend an established tolerance ⁽³⁾⁽⁴⁾	12	13,403
B640	117	First food use; petition to establish a tolerance ⁽²⁾⁽⁴⁾	19	20,104
B643	118	New Food use; petition to amend tolerance exemption ⁽³⁾⁽⁴⁾	10	13,403
B642	119	First food use; indoor; food/food handling ⁽²⁾⁽⁴⁾	12	33,506
B644	120	New use, no change to an established tolerance or tolerance exemption ⁽³⁾⁽⁴⁾	8	13,403
B650	121	New use; non-food ⁽³⁾⁽⁴⁾	7	6,703
B645	122 (new)	New food use; Experimental Use Permit application; petition to amend or add a tolerance exemption ⁽⁴⁾	12	13,403
B646	123 (new)	New use; non-food use including crop destruct; Experimental Use Permit application ⁽⁴⁾	7	6,703

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

²All 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.

³Amendment 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.

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

Table 13. Biopesticides Division - New Products

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
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	13	13,403

		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⁾		
B660	125	New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption. No data review, or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data or authorization from data owner is demonstrated. Category includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission or data matrix. For microbial pesticides, the active ingredient(s) must not be re-isolated. ⁽²⁾⁽³⁾	4	1,342
B670	126	New product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption; requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. ⁽²⁾⁽³⁾	7	5,363
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	17	13,403

		scientifically-sound rationale explaining why the data requirement does not apply. ⁽²⁾⁽³⁾		
B672	128	New product; unregistered source of active ingredient(s); non-food use or food use with a tolerance or tolerance exemption previously established for the active ingredient(s); requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. ⁽²⁾⁽³⁾	13	9,574
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	5,363
B674	130	New product MUP; Repack of identical registered end-use product as a manufacturing-use product; same registered uses only. ⁽²⁾⁽³⁾	4	1,342
B675	131	New Product MUP; registered source of active ingredient; submission of completely new generic data package; registered uses only. ⁽²⁾⁽³⁾	10	9,574
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	9,574
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	10	9,261

		only: <ul style="list-style-type: none"> • product chemistry and/or • acute toxicity and/or • public health pest efficacy and/or • animal safety studies and/or • child resistant packaging⁽²⁾⁽³⁾ 		
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1A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

2An 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.

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

Table 14. Biopesticides Division - Amendments

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
B621	134	Amendment; Experimental Use Permit; no change to an established temporary tolerance or tolerance exemption. ⁽³⁾	7	5,363
B622	135	Amendment; Experimental Use Permit; petition to amend an established or temporary tolerance or tolerance exemption. ⁽³⁾	11	13,403
B641	136	Amendment of an established tolerance or tolerance exemption.	13	13,403
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	5,363
B681	138	Amendment; unregistered source of active ingredient(s). Requires data submission. ⁽²⁾⁽³⁾	7	6,383
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	5,363

B684	140	Amending non-food animal product that includes submission of target animal safety data; previously registered ⁽²⁾⁽³⁾	8	9,261
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	5,363

¹A 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.

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

Table 15. Biopesticides Division - SCLP

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
B690	142	New active ingredient; food or non-food use. ⁽²⁾⁽⁶⁾	7	2,682
B700	143	Experimental Use Permit application; new active ingredient or new use. ⁽⁶⁾	7	1,342
B701	144	Extend or amend Experimental Use Permit. ⁽⁶⁾	4	1,342
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	4	1,342

		or authorization from data owner is demonstrated. Category includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission or data matrix. ⁽³⁾⁽⁶⁾		
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	1,342
B721	147	New product; unregistered source of active ingredient. ⁽³⁾⁽⁶⁾	7	2,810
B722	148	New use and/or amendment; petition to establish a tolerance or tolerance exemption. ⁽⁴⁾⁽⁵⁾⁽⁶⁾	7	2,601
B730	149	Label amendment requiring data submission. ⁽⁴⁾⁽⁶⁾	5	1,342

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

²All 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.

³An 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.

⁵Amendment 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.

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

Table 16. Biopesticides Division - Other Actions

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
B614	150	Pre-application; Conditional Ruling on rationales for addressing a data requirement in lieu of data; applicant-initiated; applies to one (1) rationale at a time	3	2,657
B615	151	Rebuttal of agency reviewed protocol, applicant initiated	3	2,657
B682	152	Protocol review; applicant initiated; excludes time for HSRB review	3	2,554

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

Table 17. Biopesticides Division - PIP

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
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	100,511
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	167,515
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	134,012
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	201,017
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	134,012
B772	158	Application to amend or extend an Experimental Use Permit; no petition since the established	3	13,403

		tolerance/tolerance exemption for the active ingredient is unaffected. ⁽¹²⁾		
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	33,506
B780	160	Registration application; new ⁽²⁾ PIP; non-food/feed. ⁽¹²⁾	12	167,514
B790	161	Registration application; new ⁽²⁾ PIP; non-food/feed; SAP review. ⁽⁵⁾⁽¹²⁾	18	234,519
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	180,915
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	247,920
B820	164	Registration application; new ⁽²⁾ PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient. ⁽¹²⁾	15	214,419
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	281,424
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	134,012
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	40,205
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	33,506
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	15	100,511

		review. ⁽⁵⁾⁽⁶⁾⁽⁷⁾⁽¹²⁾		
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	201,017
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	134,012
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	167,514
B885	173	Registration application; registered ⁽²⁾ 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	33,506
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	234,519
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	67,007
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	134,012
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	13,403
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	80,407

B902	179	PIP Protocol review	3	6,703
B903	180	Inert ingredient tolerance exemption; e.g., a marker such as NPT II; reviewed in BPPD.	6	67,007
B904	181	Import tolerance or tolerance exemption; processed commodities/food only (inert or active ingredient).	9	134,012
B905	182 (new)	SAP Review	6	67,007
B906	183 (new)	Petition to establish a temporary tolerance/tolerance exemption for one or more active ingredients.	3	33,503
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	13,403
B908	185 (new)	Petition to establish a temporary tolerance/tolerance exemption for one or more active ingredients or inert ingredients	3	46,905

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

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

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

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

⁵The scientific data involved in this category are complex. EPA often seeks technical advice from the Scientific Advisory Panel (SAP) 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.

⁶Registered PIPs stacked through conventional breeding.

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

⁸The 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.

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

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

¹¹EPA-initiated amendments shall not be charged fees.

¹²Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c)

withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

Table 18. Inert Ingredients

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
I001	186	Approval of new food use inert ingredient ⁽²⁾⁽³⁾	13	28,350
I002	187	Amend currently approved inert ingredient tolerance or exemption from tolerance; new data ⁽²⁾	11	7,875
I003	188	Amend currently approved inert ingredient tolerance or exemption from tolerance; no new data ⁽²⁾	9	3,474
I004	189	Approval of new non-food use inert ingredient ⁽²⁾	6	11,577
I005	190	Amend currently approved non-food use inert ingredient with new use pattern; new data ⁽²⁾	6	5,789
I006	191	Amend currently approved non-food use inert ingredient with new use pattern; no new data ⁽²⁾	3	3,474
I007	192	Approval of substantially similar non-food use inert ingredients when original inert is compositionally similar with similar use pattern ⁽²⁾	4	1,737
I008	193	Approval of new or amended polymer inert ingredient, food use ⁽²⁾	5	3,937
I009	194	Approval of new or amended polymer inert ingredient, non-food use ⁽²⁾	4	3,242
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	1,737
I011	196 (new)	Approval of new food use safener with tolerance or exemption from tolerance ⁽²⁾⁽⁸⁾	24	627,568
I012	197 (new)	Approval of new non-food use safener ⁽²⁾⁽⁸⁾	21	436,004
I013	198 (new)	Approval of additional food use for previously approved safener with tolerance or exemption from tolerance ⁽²⁾	15	66,124
I014	199 (new)	Approval of additional non-food use for previously approved safener ⁽²⁾	15	26,427
I015	200 (new)	Approval of new generic data for previously approved food use safener ⁽²⁾	24	283,215
I016	201 (new)	Approval of amendment(s) to tolerance and label for previously approved safener ⁽²⁾	13	58,565

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

²If 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.

³If EPA data rules are amended to newly require clearance under section 408 of the FFDCFA 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.

⁴Any 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.

⁵Any 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.

⁶An 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.

⁷Where 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 applicant's written or electronic confirmation of agreement to the Agency.

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

Table 19. External Review and Miscellaneous Actions

EPA No.	New CR No.	Action	Decision Review Time (Months)⁽¹⁾	FY'20 - FY'21 Fees (\$)
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	8,335
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	8,335
M003	204	External technical peer review of new active	12	67,143

		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⁾		
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	67,143
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	23,153
M006	207	Request for up to 5 letters of certification (Gold Seal) for one actively registered product (excludes distributor products). ⁽⁸⁾	1	291
M007	208	Request to extend Exclusive Use of data as provided by FIFRA section 3(c)(1)(F)(ii).	12	5,789
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(II)(2) determination is required.	15	1,737
M009	210 (new)	Non-FIFRA Regulated Determination: Applicant initiated, per product.	4	2,482
M010	211 (new)	Conditional ruling on pre-application, product substantial similarity.	4	2,482
M011	212 (new)	Label amendment to add the DfE logo; requires data review; no other label changes. ⁽⁹⁾	4	3,831

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

²If 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.

³If 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.

⁴Any 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.

⁵Any 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.

⁶An 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.

⁷Where 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 applicant's written or electronic confirmation of agreement to the Agency.

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

⁹This category includes amendments the sole purpose of which are 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.

V. How to Pay Fees

Applicants must submit fee payments at the time of application, and EPA will reject any application that does not contain evidence that the fee has been paid. EPA has developed a website at <https://www.epa.gov/pria-fees/pria-4-fee-determination-decision-tree> to help applicants identify the fee category and the fee. All fees should be rounded up to the whole dollar. Due to changes mandated by the U.S. Department of the Treasury, checks, bank drafts and money orders are no longer acceptable as of September 30, 2015. Credit card payments are

only acceptable for amounts less than or equal to \$24,999. All payments equal to or above \$25,000 can be made by electronic funds transfer via the government payment website, <https://www.pay.gov/>.

More detailed instructions on how to make an application payment in association with a PRIA application are provided at the following website, <https://www.epa.gov/pria-fees/paying-pria-application-fees>.

VI. How to Submit Applications

Applicants are able to make PRIA submissions electronically via the Pesticide Submission Portal. The Portal is accessed through EPA's Central Data Exchange (CDX) network and requires user registration. Registrants currently submitting CDs or DVDs using the e-Dossier downloadable tool or their own builder tools using EPA's XML guidance can use the portal and forego courier delivery costs. Information on how to submit applications electronically via the Pesticide Submission Portal are provided at <https://www.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>.

Paper submissions to the Agency should be made at the address given in Unit VII. The applicant should attach documentation that the fee has been paid which in most cases will be pay.gov payment acknowledgement.

If the applicant is applying for a fee waiver, the applicant should provide sufficient documentation as described in FIFRA section 33(b)(7) and <https://www.epa.gov/pria-fees/pria-fee-waivers-small-businesses>. The fee waiver request should be easy to identify and separate from the rest of the application and submitted with documentation that at least 25% of the fee has been paid.

If evidence of fee payment (electronic acknowledgement) is not submitted with the

application, EPA will reject the application and will not process it further.

After EPA receives an application and payment, EPA performs a screen on the application to determine that the category is correct and that the proper fee amount has been paid. If either is incorrect, EPA will notify the applicant and require payment of any additional amount due. A refund will be provided in case of an overpayment. EPA will not process the application further until the proper fee has been paid for the category of application or a request for a fee waiver accompanies the application and the appropriate portion of the fee has been paid.

EPA will assign a unique identification number to each covered application for which payment has been made. EPA notifies the applicant of the unique identification number. This information is sent by email if EPA has either an email address on file or an email address is provided on the application.

VII. Addresses for Applications

New covered applications should be identified in the title line with the mail code REGFEE.

- By U.S. Postal Service mail. Document Processing Desk (REGFEE), Office of Pesticide Programs (7504P), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460-0001.

- By courier. Document Processing Desk (REGFEE), Office of Pesticide Programs, U.S. Environmental Protection Agency, Room S-4900, One Potomac Yard (South Bldg.), 2777 S. Crystal Drive, Arlington, VA 22202-4501.

Couriers and delivery personnel must present a valid picture identification card to gain access to the building. Hours of operation for the Document Processing Desk are 8 a.m. to 4:00 p.m., Monday through Friday, excluding Federal holidays.

List of Subjects: Environmental protection, Administrative practice and procedure,
Pesticides.

Dated: September 24, 2019.

Alexandra Dapolito Dunn,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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