PRIOR PROVISIONS

A prior section 31 of act June 25, 1947, ch. 125, was renumbered section 35 and is classified to section 136y of this title.

§ 136w–7. Department of Agriculture minor use program

(a) In general

The Secretary of Agriculture (hereinafter in this section referred to as the ''Secretary'') shall assure the coordination of the responsibilities of the Department of Agriculture related to minor uses of pesticides, including—

(1) carrying out the Inter-Regional Project Number 4 (IR–4) as described in section 2 of Public Law 89–106 (7 U.S.C. 450i(e))[1] and the national pesticide resistance monitoring program established under section 1651[1] of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5882);

(2) supporting integrated pest management research;

(3) consulting with growers to develop data for minor uses; and

(4) providing assistance for minor use registrations, tolerances, and reregistrations with the Environmental Protection Agency.

(b) Minor use pesticide data and revolving fund

(1) Minor use pesticide data

(A) Grant authority

The Secretary, in consultation with the Administrator, shall establish a program to make grants for the development of data to support minor use pesticide registrations and reregistrations. The amount of any such grant shall not exceed ½ of the cost of the project for which the grant is made.

(B) Applicants

Any person who wants to develop data to support minor use pesticide registrations and reregistrations may apply for a grant under subparagraph (A). Priority shall be given to an applicant for such a grant who does not directly receive funds from the sale of pesticides registered for minor uses.

(C) Data ownership

Any data that is developed under a grant under subparagraph (A) shall be jointly owned by the Department of Agriculture and the person who received the grant. Such a person shall enter into an agreement with the Secretary under which such person shall share any fee paid to such person under section 136a(c)(1)(F) of this title.

(2) Minor Use Pesticide Data Revolving Fund

(A) Establishment

There is established in the Treasury of the United States a revolving fund to be known as the Minor Use Pesticide Data Revolving Fund. The Fund shall be available without fiscal year limitation to carry out the authorized purposes of this subsection.

(B) Contents of the Fund

There shall be deposited in the Fund—

(i) such amounts as may be appropriated to support the purposes of this subsection; and

(ii) fees collected by the Secretary for any data developed under a grant under paragraph (1)(A).

(C) Authorizations of appropriations

There are authorized to be appropriated for each fiscal year to carry out the purposes of this subsection $10,000,000 to remain available until expended.

(June 25, 1947, ch. 125, § 32, as added Pub. L. 104–170, title II, § 210(j), Aug. 3, 1996, 110 Stat. 1501.)

REFERENCES IN TEXT

Section 2 of Public Law 89–106, referred to in subsec. (a)(1), was formerly classified to secton 450i of this title prior to editorial reclassification and renumbering as section 3157 of this title.

Section 1651 of the Food, Agriculture, Conservation, and Trade Act of 1990, referred to in subsec. (a)(1), was classified to section 5882 of this title prior to repeal by Pub. L. 104–127, title VIII, § 862(a), Apr. 4, 1996, 110 Stat. 1174.

§ 136w–8. Pesticide registration service fees

(a) Definition of costs

In this section, the term ''costs'', when used with respect to review and decisionmaking pertaining to an application for which registration service fees are paid under this section, means—

(1) costs to the extent that—

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

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

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

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

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

(b) Fees

(1) In general

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

(2) Covered applications

(A) In general

An application for the registration of a pesticide covered by this subchapter that is

[1] See References in Text note below.

received by the Administrator on or after the effective date of the Pesticide Registration Improvement Act of 2003 or for any other action covered by a table specified in paragraph (3) shall be subject to a registration service fee under this section.

(B) Existing applications

(i) In general

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

(ii) Tolerance or exemption fees

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

(C) Documentation

An application subject to a registration service fee under this section shall be submitted with documentation certifying—

(i) payment of the registration service fee; or

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

(D) Payment

The registration service fee required under this subsection shall be due upon submission of the application.

(E) Applications subject to additional fees

An application may be subject to additional fees if—

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

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

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

(F) Effect of failure to pay fees

The Administrator shall reject any application submitted without the required registration service fee.

(G) Non-refundable portion of fees

(i) In general

The Administrator shall retain 25 percent of the applicable registration service fee.

(ii) Limitation

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

(H) Collection of unpaid fees

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

(3) Schedule of covered applications and other actions and their registration service fees

Subject to paragraph (6), the schedule of registration applications and other covered actions and their corresponding registration service fees shall be as follows:

TABLE 1. — REGISTRATION DIVISION — NEW ACTIVE INGREDIENTS

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

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

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R090	6	New Active Ingredient, Non-food use; outdoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)	16	323,690
R110	7	New Active Ingredient, Non-food use; indoor. (2)(3)	20	290,994
R120	8	New Active Ingredient, Non-food use; indoor; reduced risk. (2)(3)	14	242,495
R121	9	New Active Ingredient, Non-food use; indoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)	18	182,327
R122	10	Enriched isomer(s) of registered mixed-isomer active ingredient. (2)(3)	18	317,128
R123	11	New Active Ingredient, Seed treatment only; includes agricultural and non-agricultural seeds; residues not expected in raw agricultural commodities. (2)(3)	18	471,861
R125	12	New Active Ingredient, Seed treatment; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3)	16	323,690

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

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

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

TABLE 2. — REGISTRATION DIVISION — NEW USES

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

TABLE 2. — REGISTRATION DIVISION — NEW USES—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R155	16 (new)	First food use, Experimental Use Permit application; a.i. registered for non-food outdoor use. (3)(4)	21	264,253
R160	17	First food use; reduced risk. (2)(3)	16	264,253
R170	18	Additional food use. (3) (4)	15	79,349
R175	19	Additional food uses covered within a crop group resulting from the conversion of existing approved crop group(s) to one or more revised crop groups. (3)(4)	10	66,124
R180	20	Additional food use; reduced risk. (3)(4)	10	66,124
R190	21	Additional food uses; 6 or more submitted in one application. (3)(4)	15	476,090
R200	22	Additional Food Use; 6 or more submitted in one application; Reduced Risk. (3)(4)	10	396,742
R210	23	Additional food use; Experimental Use Permit application; establish temporary tolerance; no credit toward new use registration. (3)(4)	12	48,986
R220	24	Additional food use; Experimental Use Permit application; crop destruct basis; no credit toward new use registration. (3)(4)	6	19,838
R230	25	Additional use; non-food; outdoor. (3) (4)	15	31,713
R240	26	Additional use; non-food; outdoor; reduced risk. (3)(4)	10	26,427
R250	27	Additional use; non-food; outdoor; Experimental Use Permit application; no credit toward new use registration. (3)(4)	6	19,838
R251	28	Experimental Use Permit application which requires no changes to the tolerance(s); non-crop destruct basis. (3)	8	19,838
R260	29	New use; non-food; indoor. (3) (4)	12	15,317
R270	30	New use; non-food; indoor; reduced risk. (3)(4)	9	12,764
R271	31	New use; non-food; indoor; Experimental Use Permit application; no credit toward new use registration. (3)(4)	6	9,725
R273	32	Additional use; seed treatment; limited uptake into Raw Agricultural Commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food and/or non-food uses. (3)(4)	12	50,445
R274	33	Additional uses; seed treatment only; 6 or more submitted in one application; limited uptake into raw agricultural commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food and/or non-food uses. (3)(4)	12	302,663

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

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

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

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

TABLE 3. — REGISTRATION DIVISION — IMPORT AND OTHER TOLERANCES

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R280	34	Establish import tolerance; new active ingredient or first food use. (2)	21	319,072
R290	35	Establish Import tolerance; Additional new food use.	15	63,816
R291	36	Establish import tolerances; additional food uses; 6 or more crops submitted in one petition.	15	382,886
R292	37	Amend an established tolerance (e.g., decrease or increase) and/or harmonize established tolerances with Codex MRLs; domestic or import; applicant-initiated.	11	45,341
R293	38	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated.	12	53,483
R294	39	Establish tolerances for inadvertent residues; 6 or more crops submitted in one application; applicant-initiated.	12	320,894
R295	40	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; submission of corresponding label amendments which specify the necessary plant-back restrictions; applicant-initiated. (3) (4)	15	66,124

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

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R296	41	Establish tolerances for residues in rotational crops in response to a specific rotational crop petition; 6 or more crops submitted in one application; submission of corresponding label amendments which specify the necessary plant-back restrictions; applicant-initiated. (3) (4)	15	396,742
R297	42	Amend 6 or more established tolerances (e.g., decrease or increase) in one petition; domestic or import; applicant-initiated.	11	272,037
R298	43	Amend an established tolerance (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3) (4)	13	58,565
R299	44	Amend 6 or more established tolerances (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3) (4)	13	285,261

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

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

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

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

TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R300	45	New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; no data review on acute toxicity, efficacy or CRP – only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix. (2)(3)	4	1,582
R301	46	New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy (identical data citation and claims to cited product(s)), where applicant does not own all required data and does not have a specific authorization letter from data owner. (2)(3)	4	1,897
R310	47	New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: • product chemistry and/or • acute toxicity and/or • child resistant packaging and/or • pest(s) requiring efficacy (4) - for up to 3 target pests. (2)(3)	7	7,301
R314	48	New end use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: • product chemistry and/or • acute toxicity and/or • child resistant packaging and/or • pest(s) requiring efficacy (4) - for up to 3 target pests. (2)(3)	8	8,626
R319	49	New end use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: • product chemistry and/or • acute toxicity and/or • child resistant packaging and/or • pest(s) requiring efficacy (4) - for 4 to 7 target pests. (2)(3)	10	12,626

TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R318	50 (new)	New end use product containing four or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: • product chemistry and/or • acute toxicity and/or • child resistant packaging and/or • pest(s) requiring efficacy (4) - for up to 3 target pests. (2)(3)	9	13,252
R321	51 (new)	New end use product containing four or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: • product chemistry and/or • acute toxicity and/or • child resistant packaging and/or • pest(s) requiring efficacy (4) - for 4 to 7 target pests. (2)(3)	11	17,252
R315	52	New end-use, on-animal product, registered source of active ingredient(s), with the submission of data and/or waivers for only: • animal safety and • pest(s) requiring efficacy (4) and/or • product chemistry and/or • acute toxicity and/or • child resistant packaging. (2) (3)	9	9,820
R316	53 (new)	New end-use or manufacturing product with registered source(s) of active ingredient(s) including products containing two or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; and requires review of data and/or waivers for only: • product chemistry and/or • acute toxicity and/or • child resistant packaging and/or • pest(s) requiring efficacy (4) - for greater than 3 and up to 7 target pests. (2)(3)	9	11,301
R317	54 (new)	New end-use or manufacturing product with registered source(s) of active ingredient(s) including products containing 2 or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; and requires review of data and/or waivers for only: • product chemistry and/or • acute toxicity and/or • child resistant packaging and/or • pest(s) requiring efficacy (4) - for greater than 7 target pests. (2)(3)	10	15,301
R320	55	New product; new physical form; requires data review in science divisions. (2)(3)	12	13,226

TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R331	56	New product; repack of identical registered end-use product as a manufacturing-use product, or identical registered manufacturing-use product as an end use product; same registered uses only. (2)(3)	3	2,530
R332	57	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of completely new generic data package; registered uses only; requires review in RD and science divisions. (2)(3)	24	283,215
R333	58	New product; MUP or End use product with unregistered source of active ingredient; requires science data review; new physical form; etc. Cite-all or selective data citation where applicant owns all required data. (2)(3)	10	19,838
R334	59	New product; MUP or End use product with unregistered source of the active ingredient; requires science data review; new physical form; etc. Selective data citation. (2)(3)	11	23,100

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

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

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

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

TABLE 5. — REGISTRATION DIVISION — AMENDMENTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R340	60	Amendment requiring data review within RD (e.g., changes to precautionary label statements); includes adding/modifying pest(s) claims for up to 2 target pests, excludes products requiring or citing an animal safety study. (2)(3)(4)	4	4,988
R341	61 (New)	Amendment requiring data review within RD (e.g., changes to precautionary label statements), includes adding/modifying pest(s) claims for greater than 2 target pests, excludes products requiring or citing an animal safety study. (2)(3)(4)	6	5,988

TABLE 5. — REGISTRATION DIVISION — AMENDMENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R345	62	Amending on-animal products previously registered, with the submission of data and/or waivers for only: • animal safety and • pest(s) requiring efficacy (4) and/or • product chemistry and/or • acute toxicity and/or • child resistant packaging. (2)(3)	7	8,820
R350	63	Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement). (2)(3)	9	13,226
R351	64	Amendment adding a new unregistered source of active ingredient. (2)(3)	8	13,226
R352	65	Amendment adding already approved uses; selective method of support; does not apply if the applicant owns all cited data. (2) (3)	8	13,226
R371	66	Amendment to Experimental Use Permit; (does not include extending a permit's time period). (3)	6	10,090

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

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

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

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

TABLE 6. — REGISTRATION DIVISION — OTHER ACTIONS

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

TABLE 6. — REGISTRATION DIVISION — OTHER ACTIONS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R370	70	Cancer reassessment; applicant-initiated.	18	198,250

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

TABLE 7. — ANTIMICROBIALS DIVISION — NEW ACTIVE INGREDIENTS

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

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

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

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

TABLE 8. — ANTIMICROBIALS DIVISION — NEW USES

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

TABLE 8. — ANTIMICROBIALS DIVISION — NEW USES—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
A500	79	New use, non-food. (4)(5)	12	31,910
A501	80	New use, non-food; 6 or more submitted in one application. (4)(5)	15	76,583

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

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

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

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

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

TABLE 9. — ANTIMICROBIALS DIVISION — NEW PRODUCTS AND AMENDMENTS

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

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

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
A531	82	New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient: selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner. (2)(3)	4	1,824
A532	83	New product; identical or substantially similar in composition and use to a registered product; registered active ingredient; unregistered source of active ingredient; cite-all data citation except for product chemistry; product chemistry data submitted. (2)(3)	5	5,107
A540	84	New end use product; FIFRA §2(mm) uses only; up to 25 public health organisms. (2)(3)(5)(6)	5	5,107
A541	85 (new)	New end use product; FIFRA §2(mm) uses only; 26–50 public health organisms. (2)(3)(5)(6)	7	8,500
A542	86 (new)	New end use product; FIFRA §2(mm) uses only; ≥51 public health organisms. (2)(3)(5)	10	15,000
A550	87	New end-use product; uses other than FIFRA §2(mm); non-FQPA product. (2)(3)(5)	9	13,226
A560	88	New manufacturing use product; registered active ingredient; selective data citation. (2)(3)	6	12,596
A565	89 (new)	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of new generic data package; registered uses only; requires science review. (2)(3)	12	18,234
A570	90	Label amendment requiring data review; up to 25 public health organisms. (3)(4)(5)(6)	4	3,831
A573	91 (new)	Label amendment requiring data review; 26–50 public health organisms. (2)(3)(5)(7)	6	6,350
A574	92 (new)	Label amendment requiring data review; ≥51 public health organisms. (2)(3)(5)(7)	9	11,000
A572	93	New Product or amendment requiring data review for risk assessment by Science Branch (e.g., changes to REI, or PPE, or use rate). (2)(3)(4)	9	13,226

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

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

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

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

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

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

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

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

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
A520	94	Experimental Use Permit application, non-food use. (2)	9	6,383
A521	95	Review of public health efficacy study protocol within AD, per AD Internal Guidance for the Efficacy Protocol Review Process; Code will also include review of public health efficacy study protocol and data review for devices making pesticidal claims; applicant-initiated; Tier 1.	4	4,726
A522	96	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; Code will also include review of public health efficacy study protocol and data review for devices making pesticidal claims; applicant-initiated; Tier 2.	12	12,156
A537	97 (new)	New Active Ingredient/New Use, Experimental Use Permit application; Direct food use; Establish tolerance or tolerance exemption if required. Credit 45% of fee toward new active ingredient/new use application that follows.	18	153,156
A538	98 (new)	New Active Ingredient/New Use, Experimental Use Permit application; Indirect food use; Establish tolerance or tolerance exemption if required Credit 45% of fee toward new active ingredient/new use application that follows.	18	95,724
A539	99 (new)	New Active Ingredient/New Use, Experimental Use Permit application; Nonfood use. Credit 45% of fee toward new active ingredient/new use application that follows.	15	92,163
A529	100	Amendment to Experimental Use Permit; requires data review or risk assessment. (2)	9	11,429
A523	101	Review of protocol other than a public health efficacy study (i.e., Toxicology or Exposure Protocols).	9	12,156
A571	102	Science reassessment: Cancer risk, refined ecological risk, and/or endangered species; applicant-initiated.	18	95,724
A533	103 (new)	Exemption from the requirement of an Experimental Use Permit. (2)	4	2,482
A534	104 (new)	Rebuttal of agency reviewed protocol, applicant initiated.	4	4,726
A535	105 (new)	Conditional Ruling on Pre-application Study Waiver or Data Bridging Argument; applicant-initiated.	6	2,409
A536	106 (new)	Conditional Ruling on Pre-application Direct Food, Indirect Food, Nonfood use determination; applicant-initiated.	4	2,482

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

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

TABLE 11. — BIOPESTICIDES DIVISION — NEW ACTIVE INGREDIENTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B580	107	New active ingredient; food use; petition to establish a tolerance. (2)(3)	20	51,053
B590	108	New active ingredient; food use; petition to establish a tolerance exemption. (2)(3)	18	31,910
B600	109	New active ingredient; non-food use. (2)(3)	13	19,146
B610	110	New active ingredient; Experimental Use Permit application; petition to establish a temporary tolerance or temporary tolerance exemption. (3)	10	12,764
B611	111	New active ingredient; Experimental Use Permit application; petition to establish permanent tolerance exemption. (3)	12	12,764
B612	112	New active ingredient; no change to a permanent tolerance exemption. (2)(3)	10	17,550
B613	113	New active ingredient; petition to convert a temporary tolerance or a temporary tolerance exemption to a permanent tolerance or tolerance exemption. (2)(3)	11	17,550
B620	114	New active ingredient; Experimental Use Permit application; non-food use including crop destruct. (3)	7	6,383

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

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

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

TABLE 12. — BIOPESTICIDES DIVISION — NEW USES

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B630	115	First food use; petition to establish a tolerance exemption. (2)(4)	13	12,764
B631	116	New food use; petition to amend an established tolerance. (3)(4)	12	12,764
B640	117	First food use; petition to establish a tolerance. (2)(4)	19	19,146
B643	118	New Food use; petition to amend an established tolerance exemption. (3)(4)	10	12,764
B642	119	First food use; indoor; food/food handling. (2)(4)	12	31,910
B644	120	New use, no change to an established tolerance or tolerance exemption. (3)(4)	8	12,764
B650	121	New use; non-food. (3)(4)	7	6,383
B645	122 (new)	New food use; Experimental Use Permit application; petition to amend or add a tolerance exemption. (4)	12	12,764
B646	123 (new)	New use; non-food use including crop destruct; Experimental Use Permit application. (4)	7	6,383

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

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

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

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

TABLE 13. — BIOPESTICIDES DIVISION — NEW PRODUCTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B652	124	New product; registered source of active ingredient; requires petition to amend established tolerance or tolerance exemption; requires 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (2)(3)	13	12,764
B660	125	New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product. No data review, or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data or authorization from data owner is demonstrated. Category includes 100% repackage of registered end-use or manufacturing-use product that requires no data submission or data matrix. For microbial pesticides, the active ingredient(s) must not be re-isolated. (2)(3)	4	1,278
B670	126	New product; registered source of active ingredient(s); requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (2)(3)	7	5,107
B671	127	New product; unregistered source of active ingredient(s); requires a petition to amend an established tolerance or tolerance exemption; requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (2)(3)	17	12,764
B672	128	New product; unregistered source of active ingredient(s); non-food use or food use requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (2)(3)	13	9,118

TABLE 13. — BIOPESTICIDES DIVISION — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B673	129	New product MUP/EP; unregistered source of active ingredient(s); citation of Technical Grade Active Ingredient (TGAI) data previously reviewed and accepted by the Agency. Requires an Agency determination that the cited data supports the new product. (2)(3)	10	5,107
B674	130	New product MUP; Repack of identical registered end-use product as a manufacturing-use product; same registered uses only. (2)(3)	4	1,278
B675	131	New Product MUP; registered source of active ingredient; submission of completely new generic data package; registered uses only. (2)(3)	10	9,118
B676	132	New product; more than one active ingredient where one active ingredient is an unregistered source; product chemistry data must be submitted; requires: 1) submission of product specific data, and 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (2)(3)	13	9,118
B677	133	New end-use non-food animal product with submission of two or more target animal safety studies; includes data and/or waivers of data for only: • product chemistry and/or • acute toxicity and/or • public health pest efficacy and/or • animal safety studies and/or • child resistant packaging. (2)(3)	10	8,820

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

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

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

TABLE 14. — BIOPESTICIDES DIVISION — AMENDMENTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B621	134	Amendment; Experimental Use Permit; no change to an established temporary tolerance or tolerance exemption. (3)	7	5,107
B622	135	Amendment; Experimental Use Permit; petition to amend an established or temporary tolerance or tolerance exemption. (3)	11	12,764

TABLE 14. — BIOPESTICIDES DIVISION — AMENDMENTS—Continued

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

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

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

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

TABLE 15. — BIOPESTICIDES DIVISION — SCLP

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B690	142	New active ingredient; food or non-food use. (2)(6)	7	2,554
B700	143	Experimental Use Permit application; new active ingredient or new use. (6)	7	1,278
B701	144	Extend or amend Experimental Use Permit. (6)	4	1,278
B710	145	New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption. No data review, or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data or authorization from data owner is demonstrated. Category includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission or data matrix. (3)(6)	4	1,278

TABLE 15. — BIOPESTICIDES DIVISION — SCLP—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B720	146	New product; registered source of active ingredient(s); requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (3)(6)	5	1,278
B721	147	New product; unregistered source of active ingredient. (3)(6)	7	2,676
B722	148	New use and/or amendment; petition to establish a tolerance or tolerance exemption. (4)(5)(6)	7	2,477
B730	149	Label amendment requiring data submission. (4)(6)	5	1,278

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

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

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

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

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

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

TABLE 16. — BIOPESTICIDES DIVISION — OTHER ACTIONS

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

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

TABLE 17. — BIOPESTICIDES DIVISION — PIP

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B740	153	Experimental Use Permit application; no petition for tolerance/tolerance exemption. Includes: 1. non-food/feed use(s) for a new (2) or registered (3) PIP (12); 2. food/feed use(s) for a new or registered PIP with crop destruct (12); 3. food/feed use(s) for a new or registered PIP in which an established tolerance/tolerance exemption exists for the intended use(s). (4)(12)	6	95,724
B741	154 (new)	Experimental Use Permit application; no petition for tolerance/tolerance exemption. Includes: 1. non-food/feed use(s) for a new (2) or registered (3) PIP; 2. food/feed use(s) for a new or registered PIP with crop destruct; 3. food/feed use(s) for a new or registered PIP in which an established tolerance/tolerance exemption exists for the intended use(s); SAP Review. (12)	12	159,538
B750	155	Experimental Use Permit application; with a petition to establish a temporary or permanent tolerance/tolerance exemption for the active ingredient. Includes new food/feed use for a registered (3) PIP. (4)(12)	9	127,630
B770	156	Experimental Use Permit application; new (2) PIP; with petition to establish a temporary tolerance/tolerance exemption for the active ingredient; credit 75% of B771 fee toward registration application for a new active ingredient that follows; SAP review. (5)(12)	15	191,444
B771	157	Experimental Use Permit application; new (2) PIP; with petition to establish a temporary tolerance/tolerance exemption for the active ingredient; credit 75% of B771 fee toward registration application for a new active ingredient that follows. (12)	10	127,630
B772	158	Application to amend or extend an Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active ingredient is unaffected. (12)	3	12,764
B773	159	Application to amend or extend an Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient. (12)	5	31,910

TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B780	160	Registration application; new (2) PIP; non-food/feed. (12)	12	159,537
B790	161	Registration application; new (2) PIP; non-food/feed; SAP review. (5)(12)	18	223,351
B800	162	Registration application; new (2) PIP; with petition to establish permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. (12)	13	172,300
B810	163	Registration application; new (2) PIP; with petition to establish permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. SAP review. (5)(12)	19	236,114
B820	164	Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient. (12)	15	204,208
B840	165	Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient. SAP review. (5)(12)	21	268,022
B851	166	Registration application; new event of a previously registered PIP active ingredient(s); no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s). (12)	9	127,630
B870	167	Registration application; registered (3) PIP; new product; new use; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (4) (12)	9	38,290
B880	168	Registration application; registered (3) PIP; new product or new terms of registration; additional data submitted; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (6) (7) (12)	9	31,910
B881	169	Registration application; registered (3) PIP; new product or new terms of registration; additional data submitted; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). SAP review. (5)(6)(7)(12)	15	95,724
B882	170 (new)	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption; SAP Review. (8)(12)	15	191,444
B883	171	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. (8) (12)	9	127,630
B884	172	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient. (8)(12)	12	159,537

TABLE 17. — BIOPESTICIDES DIVISION — PIP—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B885	173	Registration application; registered (3) PIP, seed increase; breeding stack of previously approved PIPs, same crop; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (9)(12)	6	31,910
B886	174 (new)	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient. SAP Review. (8) (12)	18	223,351
B890	175	Application to amend a seed increase registration; converts registration to commercial registration; no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s). (12)	9	63,816
B891	176	Application to amend a seed increase registration; converts registration to a commercial registration; no petition since a permanent tolerance/tolerance exemption already established for the active ingredient(s); SAP review. (5)(12)	15	127,630
B900	177	Application to amend a registration, including actions such as extending an expiration date, modifying an IRM plan, or adding an insect to be controlled. (10)(11)(12)	6	12,764
B901	178	Application to amend a registration, including actions such as extending an expiration date, modifying an IRM plan, or adding an insect to be controlled. SAP review. (10) (11) (12)	12	76,578
B902	179	PIP Protocol review.	3	6,383
B903	180	Inert ingredient tolerance exemption; e.g., a marker such as NPT II; reviewed in BPPD.	6	63,816
B904	181	Import tolerance or tolerance exemption; processed commodities/food only (inert or active ingredient).	9	127,630
B905	182 (new)	SAP Review.	6	63,816
B906	183 (new)	Petition to establish a temporary tolerance/tolerance exemption for one or more active ingredients.	3	31,907
B907	184 (new)	Petition to establish a temporary tolerance/tolerance exemption for one or more active ingredients based on an existing temporary tolerance/tolerance exemption.	3	12,764
B908	185 (new)	Petition to establish a temporary tolerance/tolerance exemption for one or more active ingredients or inert ingredients.	3	44,671

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

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

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

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

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

(6) Registered PIPs stacked through conventional breeding.

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

(8) The negotiated acreage cap will depend upon EPA's determination of the potential environmental exposure, risk(s) to non-target organisms, and the risk of targeted pest developing resistance to the pesticidal substance. The uncertainty of these risks may reduce the allowable acreage, based upon the quantity and type of non-target organism data submitted and the lack of insect resistance management data, which is usually not required for seed-increase registrations. Registrants are encouraged to consult with EPA prior to submission of a registration application in this category.
(9) Application can be submitted prior to or concurrently with an application for commercial registration.
(10) For example, IRM plan modifications that are applicant-initiated.
(11) EPA-initiated amendments shall not be charged fees.
(12) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

TABLE 18. — INERT INGREDIENTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
I001	186	Approval of new food use inert ingredient. (2)(3)	13	27,000
I002	187	Amend currently approved inert ingredient tolerance or exemption from tolerance; new data. (2)	11	7,500
I003	188	Amend currently approved inert ingredient tolerance or exemption from tolerance; no new data. (2)	9	3,308
I004	189	Approval of new non-food use inert ingredient. (2)	6	11,025
I005	190	Amend currently approved non-food use inert ingredient with new use pattern; new data. (2)	6	5,513
I006	191	Amend currently approved non-food use inert ingredient with new use pattern; no new data. (2)	3	3,308
I007	192	Approval of substantially similar non-food use inert ingredients when original inert is compositionally similar with similar use pattern. (2)	4	1,654
I008	193	Approval of new or amended polymer inert ingredient, food use. (2)	5	3,749
I009	194	Approval of new or amended polymer inert ingredient, non-food use. (2)	4	3,087
I010	195	Petition to amend a single tolerance exemption descriptor, or single non-food use descriptor, to add ≤ 10 CASRNs; no new data. (2)	6	1,654
I011	196 (new)	Approval of new food use safener with tolerance or exemption from tolerance. (2)(8)	24	597,683
I012	197 (new)	Approval of new non-food use safener. (2)(8)	21	415,241
I013	198 (new)	Approval of additional food use for previously approved safener with tolerance or exemption from tolerance. (2)	15	62,975
I014	199 (new)	Approval of additional non-food use for previously approved safener. (2)	15	25,168
I015	200 (new)	Approval of new generic data for previously approved food use safener. (2)	24	269,728
I016	201 (new)	Approval of amendment(s) to tolerance and label for previously approved safener. (2)	13	55,776

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.
(2) If another covered application is submitted that depends upon an application to approve an inert ingredient, each application will be subject to its respective registration service fee. The decision review time line for both submissions will be the longest of the associated applications. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.

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

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

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

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

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

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

TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
M001	202	Study protocol requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of an active ingredient. (4)	9	7,938
M002	203	Completed study requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of an active ingredient. (4)	9	7,938
M003	204	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of less than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA §25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (5)	12	63,945
M004	205	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of greater than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA §25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (5)	18	63,945
M005	206	New Product: Combination, Contains a combination of active ingredients from a registered and/or unregistered source; conventional, antimicrobial and/or biopesticide. Requires coordination with other regulatory divisions to conduct review of data, label and/or verify the validity of existing data as cited. Only existing uses for each active ingredient in the combination product. (6)(7)	9	22,050
M006	207	Request for up to 5 letters of certification (Gold Seal) for one actively registered product (excludes distributor products). (8)	1	277
M007	208	Request to extend Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(ii).	12	5,513

TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

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

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.
(2) If another covered application is submitted that depends upon an application to approve an inert ingredient, each application will be subject to its respective registration service fee. The decision review time line for both submissions will be the longest of the associated applications. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.
(3) If EPA data rules are amended to newly require clearance under section 408 of the FFDCA for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.
(4) Any other covered application that is associated with and dependent on the HSRB review will be subject to its separate registration service fee. The decision review times for the associated actions run concurrently, but will end at the date of the latest review time.
(5) Any other covered application that is associated with and dependent on the SAP review will be subject to its separate registration service fee. The decision review time for the associated action will be extended by the decision review time for the SAP review.
(6) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.
(7) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.
(8) Due to low fee and short time frame this category is not eligible for small business waivers. Gold seal applies to one registered product.
(9) This category includes amendments the sole purpose of which is to add DfE (or equivalent terms that do not use ''safe'' or derivatives of ''safe'') logos to a label. DfE is a voluntary program. A label bearing a DfE logo is not considered an Agency endorsement because the ingredients in the qualifying product must meet objective, scientific criteria established and widely publicized by EPA.

(4) Pending pesticide registration applications

(A) In general

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

(B) Voluntary fee

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

(C) Documentation

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

(i) payment of the registration service fee; or

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

(5) Resubmission of covered applications

If a covered application is submitted by a person that paid the fee for the application under paragraph (2), is determined by the Administrator to be complete, and is not approved or is withdrawn (without a waiver or refund), the submission of the same covered application by the same person (or a licensee, assignee, or successor of the person) shall not be subject to a fee under paragraph (2).

(6) Fee adjustment

(A) In general

Effective for a covered application received during the period beginning on October 1, 2019, and ending on September 30, 2021, the Administrator shall increase by 5 percent the registration service fee payable for the application under paragraph (3).

(B) Additional adjustment

Effective for a covered application received on or after October 1, 2021, the Administrator shall increase by an additional 5 percent the registration service fee in effect as of September 30, 2021.

(C) Publication

The Administrator shall publish in the Federal Register the service fee schedules revised pursuant to this paragraph.

(7) Waivers and reductions

(A) In general

An applicant for a covered application may request the Administrator to waive or reduce the amount of a registration service fee payable under this section under the circumstances described in subparagraphs (D) through (G), except that no waiver or fee reduction shall be provided in connection with a request for a letter of certification (commonly referred to as a Gold Seal letter).

(B) Documentation

(i) In general

A request for a waiver from or reduction of the registration service fee shall be accompanied by appropriate documentation demonstrating the basis for the waiver or reduction.

(ii) Certification

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

(iii) Inaccurate documentation

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

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

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

(C) Determination to grant or deny request

As soon as practicable, but not later than 60 days, after the date on which the Administrator receives a request for a waiver or reduction of a registration service fee under this paragraph, the Administrator shall—

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

(ii) notify the applicant of the determination.

(D) Minor uses

(i) In general

The Administrator may exempt from, or waive a portion of, the registration service fee for an application for minor uses for a pesticide.

(ii) Supporting documentation

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

(E) IR–4 exemption

The Administrator shall exempt an application from the registration service fee if the Administrator determines that—

(i) the application is solely associated with a tolerance petition submitted in connection with the Inter-Regional Project Number 4 (IR–4) as described in section 2 of Public Law 89–106 (7 U.S.C. 450i(e));[1] and

(ii) the exemption is in the public interest.

(F) Small businesses

(i) In general

The Administrator shall waive 50 percent of the registration service fees payable by an entity for a covered application under this section if the entity is a small business (as defined in section 136a–1(i)(1)(E)(ii) of this title) at the time of application.

(ii) Waiver of fees

The Administrator shall waive 75 percent of the registration service fees payable by an entity under this section if the entity—

(I) is a small business (as defined in section 136a–1(i)(1)(E)(ii) of this title) at the time of application; and

(II) has average annual global gross revenues described in section 136a–1(i)(1)(E)(ii)(I)(bb) of this title that does not exceed $10,000,000, at the time of application.

(iii) Formation for waiver

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

(iv) Documentation

An entity requesting a waiver under this subparagraph shall provide to the Administrator—

(I) documentation demonstrating that the entity is a small business (as defined in section 136a–1(i)(1)(E)(ii) of this title) at the time of application; and

(II) if the entity is requesting a waiver of 75 percent of the applicable registration service fees payable under this section, documentation demonstrating that the entity has an average annual global gross revenue described in section 136a–1(i)(1)(E)(ii)(I)(bb) of this title that does not exceed $10,000,000, at the time of application.

(G) Federal and State agency exemptions

An agency of the Federal Government or a State government shall be exempt from cov-

[1] See References in Text note below.

ered registration service fees under this section.

(8) Refunds

(A) Early withdrawals

If, during the first 60 days after the beginning of the applicable decision time review period under subsection (f)(3), a covered application is withdrawn by the applicant, the Administrator shall refund all but 25 percent.[2] of the total registration service fee payable under paragraph (3) for the application.

(B) Withdrawals after the first 60 days of decision review time period

(i) In general

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

(ii) Timing

The Administrator shall—

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

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

(C) Discretionary refunds

(i) In general

In the case of a covered application that has been filed with the Administrator and has not been withdrawn by the applicant, but for which the Administrator has not yet made a final determination, the Administrator may refund a portion of a covered registration service fee if the Administrator determines that the refund is justified.

(ii) Basis

The Administrator may provide a refund for an application under this subparagraph—

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

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

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

(D) Credited fees

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

[2] So in original. The period probably should not appear.

(c) Pesticide Registration Fund

(1) Establishment

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

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

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

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

(2) Deposits in Fund

Subject to paragraph (4), the Administrator shall deposit fees collected under this section in the Fund.

(3) Expenditures from Fund

(A) In general

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

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

(ii) to otherwise carry out this section.

(B) Worker protection, partnership grants, and pesticide safety education

(i) In general

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

(ii) Partnership grants

Of the amounts in the Fund, the Administrator shall use for partnership grants, for each of fiscal years 2013 through 2023, $500,000.

(iii) Pesticide safety education program

Of the amounts in the Fund, the Administrator shall use $500,000 for each of fiscal years 2013 through 2023 to carry out the pesticide safety education program.

(4) Collections and appropriations Acts

The fees authorized by this section and amounts deposited in the Fund—

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

(B) shall be available without fiscal year limitation.

(5) Unused funds

(A) In general

Amounts in the Fund not currently needed to carry out this section shall be—

(i) maintained readily available or on deposit;

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

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

(B) Use of investment income

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

(d) Assessment of fees

(1) Definition of covered functions

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

(2) Minimum amount of appropriations

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

(3) Use of fees

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

(4) Subsequent authority

If the Administrator does not assess registration service fees under subsection (b) during any portion of a fiscal year as the result of paragraph (2) and is subsequently permitted to assess the fees under subsection (b) during the fiscal year, the Administrator shall assess and collect the fees, without any modification in rate, at any time during the fiscal year, notwithstanding any provisions of subsection (b) relating to the date fees are to be paid.

(e) Reforms to reduce decision time review periods

To the maximum extent practicable consistent with the degrees of risk presented by pesticides and the type of review appropriate to evaluate risks, the Administrator shall identify and evaluate reforms to the pesticide registration process under this subchapter with the goal of reducing decision review periods in effect on the effective date of the Pesticide Registration Improvement Extension Act of 2018 for pesticide registration actions for covered pesticide registration applications (including reduced risk applications). Such reforms shall include identifying opportunities for streamlining review processes for applications for a new active ingredient or a new use and providing prompt feedback to applicants during such review process.

(f) Decision time review periods

(1) In general

Not later than 30 days after the effective date of the Pesticide Registration Improvement Extension Act of 2018, the Administrator shall make publicly available a schedule of decision review periods for covered pesticide registration actions or for any other action covered by a table specified in subsection (b)(3) and corresponding registration service fees under this subchapter.

(2) Report

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

(3) Applications subject to decision time review periods

The decision time review periods specified in paragraph (1) shall apply to—

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

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

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

(4) Start of decision time review period

(A) In general

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

(B) Initial content and preliminary technical screenings

(i) Screenings

(I) Initial content

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

(II) Preliminary technical screening

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

(aa) not later than 45 days after the date on which the decision time review

period begins (for applications with decision time review periods of not more than 180 days); and

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

(ii) Rejection

(I) In general

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

(II) Written notification

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

(iii) Requirements of initial content screening

In conducting an initial content screening of an application, the Administrator shall determine whether—

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

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

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

(iv) Requirements of preliminary technical screening

In conducting a preliminary technical screening of an application, the Administrator shall determine if—

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

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

(C) Applications with waiver or reduction requests

(i) In general

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

(ii) Request granted with no additional fees required

If the Administrator grants the waiver or reduction request and no additional fee is required, the decision time review period begins on the earlier of—

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

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

(iii) Request granted with additional fees required

If the Administrator grants the waiver or reduction request, in whole or in part, but an additional registration service fee is required, the decision time review period begins on the date on which the Administrator receives certification of payment of the applicable registration service fee.

(iv) Request denied

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

(D) Pending applications

(i) In general

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

(ii) Applications

Clause (i) applies to—

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

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

(E) 2003 work plan

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

(5) Extension of decision time review period

The Administrator and the applicant may mutually agree in writing to extend a decision time review period under this subsection.

(g) Judicial review

(1) In general

Any applicant adversely affected by the failure of the Administrator to make a deter-

mination on the application of the applicant for registration of a new active ingredient or new use for which a registration service fee is paid under this section may obtain judicial review of the failure solely under this section.

(2) Scope

(A) In general

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

(B) Other actions

No other action authorized or required under this section shall be judicially reviewable by a Federal or State court.

(3) Timing

(A) In general

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

(B) Meeting with Administrator

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

(4) Remedies

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

(h) Accounting

The Administrator shall—

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

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

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

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

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

(i) Auditing

(1) Financial statements of agencies

For the purpose of section 3515(c) of title 31, the Fund shall be considered a component of an executive agency.

(2) Components

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

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

(B) compliance with subsection (f);

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

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

(3) Inspector General

The Inspector General of the Environmental Protection Agency shall—

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

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

(j) Personnel levels

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

(k) Reports

(1) In general

Not later than March 1, 2005, and each March 1 thereafter through March 1, 2023, the Administrator shall publish an annual report describing actions taken under this section.

(2) Contents

The report shall include—

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

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

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

(iii) the amount of money from the Reregistration and Expedited Processing Fund used to carry out inert ingredient review and review of similar applications under section 136a–1(k)(3) of this title;

(iv) the number of applications completed for identical or substantially similar applications under section 136a(c)(3)(B) of this title, including the number of such applications completed within 90 days pursuant to that section;

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

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

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

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

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

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

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

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

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

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

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

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

(C) a review of the progress in meeting the timeline requirements of section 136a–1(g) of this title;

(D) a review of the progress in carrying out section 136a(g) of this title, including—

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

(I) the number of cases cancelled;

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

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

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

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

(ii) a description of the staffing and resources relating to the costs associated with the review and decision making relating to reregistration and registration review for compliance with the deadlines specified in this subchapter;

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

(I) process improvements in the handling of registration review under section 136a(g) of this title;

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

(III) streamlining the registration review process, consistent with section 136a(g) of this title;

(E) a review of the progress in meeting the timeline requirements for the review of antimicrobial pesticide products under section 136a(h) of this title;

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

(G) a review of the progress made toward—

(i) carrying out paragraphs (4) and (5) of section 136a–1(k) of this title and the amounts from the Reregistration and Expedited Processing Fund used for the purposes described in such paragraphs;

(ii) implementing enhancements to—

(I) the electronic tracking of covered applications;

(II) the electronic tracking of conditional registrations;

(III) the endangered species database;

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

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

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

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

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

(J) an assessment of the public availability of summary pesticide usage data;

(K) a review of the progress made in developing, updating, and implementing product performance test guidelines for pesticide products that are intended to control invertebrate pests of significant public health importance and, by regulation, prescribing product performance data requirements for such pesticide products registered under section 136a of this title;

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

(M) a review of the progress made in implementing enhancements to the good laboratory practices standards compliance

monitoring program established under part 160 of title 40 of the Code of Federal Regulations (or successor regulations);

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

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

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

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

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

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

(ii) an evaluation of the appropriateness and effectiveness of the activities, grants, and program described in clause (i);

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

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

(3) Method

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

(4) Other report

(A) Scope

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

(i) 10 or fewer employees; and

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

(B) Information required

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

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

(ii) the number of registrations each company holds.

***(l)* Savings clause**

Nothing in this section affects any other duties, obligations, or authorities established by any other section of this subchapter, including the right to judicial review of duties, obligations, or authorities established by any other section of this subchapter.

(m) Termination of effectiveness

(1) In general

Except as provided in paragraph (2), the authority provided by this section terminates on September 30, 2023.

(2) Phase out

(A) Fiscal year 2024

During fiscal year 2024, the requirement to pay and collect registration service fees applies, except that the level of registration service fees payable under this section shall be reduced 40 percent below the level in effect on September 30, 2023.

(B) Fiscal year 2025

During fiscal year 2025, the requirement to pay and collect registration service fees applies, except that the level of registration service fees payable under this section shall be reduced 70 percent below the level in effect on September 30, 2023.

(C) September 30, 2025

Effective September 30, 2025, the requirement to pay and collect registration service fees terminates.

(D) Decision review periods

(i) Pending applications

In the case of an application received under this section before September 30, 2023, the application shall be reviewed in accordance with subsection (f).

(ii) New applications

In the case of an application received under this section on or after September 30, 2023, subsection (f) shall not apply to the application.

(June 25, 1947, ch. 125, §33, as added Pub. L. 108–199, div. G, title V, §501(f)(2), Jan. 23, 2004, 118 Stat. 422; amended Pub. L. 110–94, §5, Oct. 9, 2007, 121 Stat. 1002; Pub. L. 110–193, §1(a), Mar. 6, 2008, 122 Stat. 649; Pub. L. 112–177, §2(a)(2)(B), (b), Sept. 28, 2012, 126 Stat. 1328, 1330; Pub. L. 116–8, §§5, 6, Mar. 8, 2019, 133 Stat. 487, 491.)

REFERENCES IN TEXT

The effective date of the Pesticide Registration Improvement Act of 2003, and the effective date of this section, referred to in text, is the effective date of section 501 of Pub. L. 108–199, which is the date that is 60 days after Jan. 23, 2004, unless otherwise provided, see section 501(h) of Pub. L. 108–199, set out as an Effective Date of 2004 Amendment note under section 136a of this title.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(2)(B)(ii), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Section 2 of Public Law 89–106, referred to in subsec. (b)(7)(E)(i), was formerly classified to secton 450i of this title prior to editorial reclassification and renumbering as section 3157 of this title.

The effective date of the Pesticide Registration Improvement Extension Act of 2018, referred to in subsecs.

(e) and (f)(1), means the effective date of Pub. L. 116–8, which was approved Mar. 8, 2019.

The Chief Financial Officers Act of 1990, referred to in subsec. (h)(1)(A), is Pub. L. 101–576, Nov. 15, 1990, 104 Stat. 2838. For complete classification of this Act to the Code, see Short Title of 1990 Amendment note set out under section 501 of Title 31, Money and Finance, and Tables.

The Government Management Reform Act of 1994, referred to in subsec. (h)(1)(B), is Pub. L. 103–356, Oct. 13, 1994, 108 Stat. 3410, as amended. For complete classification of this Act to the Code, see Short Title of 1994 Amendment note set out under section 3301 of Title 31, Money and Finance, and Tables.

PRIOR PROVISIONS

A prior section 33 of act June 25, 1947, ch. 125, was renumbered section 34 and is classified to section 136x of this title.

AMENDMENTS

2019—Subsec. (b)(2). Pub. L. 116–8, §5(a)(1)(A), struck out ''pesticide registration'' after ''Covered'' in heading.

Subsec. (b)(2)(A). Pub. L. 116–8, §5(a)(1)(B), inserted ''or for any other action covered by a table specified in paragraph (3)'' after ''Pesticide Registration Improvement Act of 2003''.

Subsec. (b)(3). Pub. L. 116–8, §6, amended par. (3) generally. Prior to amendment, par. (3) related to schedule of covered applications and registration service fees.

Subsec. (b)(5). Pub. L. 116–8, §5(a)(2), substituted ''covered applications'' for ''pesticide registration applications'' in heading and ''covered application'' for ''pesticide registration application'' in two places in text.

Subsec. (b)(6)(A). Pub. L. 116–8, §5(a)(3)(A), struck out ''pesticide registration'' after ''Effective for a covered'' and substituted ''October 1, 2019, and ending on September 30, 2021'' for ''October 1, 2013, and ending on September 30, 2015''.

Subsec. (b)(6)(B). Pub. L. 116–8, §5(a)(3)(B), struck out ''pesticide registration'' after ''Effective for a covered'' and substituted ''2021'' for ''2015'' in two places.

Subsec. (b)(6)(C). Pub. L. 116–8, §5(a)(3)(C), substituted ''service fee schedules revised pursuant to this paragraph'' for ''revised registration service fee schedules''.

Subsec. (b)(7)(A). Pub. L. 116–8, §5(a)(4)(A), substituted ''covered application'' for ''covered pesticide registration'' and inserted before period at end '', except that no waiver or fee reduction shall be provided in connection with a request for a letter of certification (commonly referred to as a Gold Seal letter)''.

Subsec. (b)(7)(F)(i). Pub. L. 116–8, §5(a)(4)(B), struck out ''pesticide registration'' after ''for a covered''.

Subsec. (b)(8)(A). Pub. L. 116–8, §5(a)(5)(A), struck out ''pesticide registration'' after ''a covered''.

Subsec. (b)(8)(B)(i). Pub. L. 116–8, §5(a)(5)(B), struck out ''pesticide registration'' after ''If a covered''.

Subsec. (b)(8)(C)(i). Pub. L. 116–8, §5(a)(5)(C)(i), substituted ''case of a covered'' for ''case of a pesticide registration''.

Subsec. (b)(8)(C)(ii)(I). Pub. L. 116–8, §5(a)(5)(C)(ii), substituted ''covered'' for ''pesticide registration''.

Subsec. (c)(3)(B). Pub. L. 116–8, §5(b)(1), inserted '', partnership grants, and pesticide safety education'' after ''Worker protection'' in heading.

Subsec. (c)(3)(B)(i). Pub. L. 116–8, §5(b)(2), substituted ''2023'' for ''2017'' and inserted before period at end '', with an emphasis on field-worker populations in the United States''.

Subsec. (c)(3)(B)(ii). Pub. L. 116–8, §5(b)(3), substituted ''2023'' for ''2017''.

Subsec. (c)(3)(B)(iii). Pub. L. 116–8, §5(b)(4), substituted ''2023'' for ''2017''.

Subsec. (e). Pub. L. 116–8, §5(c), substituted ''Pesticide Registration Improvement Extension Act of 2018'' for ''Pesticide Registration Improvement Extension Act of 2012'' and inserted at end ''Such reforms shall include identifying opportunities for streamlining review processes for applications for a new active ingredient or a new use and providing prompt feedback to applicants during such review process.''

Subsec. (f)(1). Pub. L. 116–8, §5(d)(1), substituted ''Pesticide Registration Improvement Extension Act of 2018'' for ''Pesticide Registration Improvement Extension Act of 2012'' and inserted ''or for any other action covered by a table specified in subsection (b)(3)'' after ''covered pesticide registration actions''.

Subsec. (f)(3)(C). Pub. L. 116–8, §5(d)(2), added subpar. (C) and struck out former subpar. (C) which read as follows: ''covered pesticide registration applications listed in the Registration Division 2003 Work Plan of the Office of Pesticide Programs of the Environmental Protection Agency.''

Subsec. (f)(4)(A). Pub. L. 116–8, §5(d)(3), substituted ''a covered application'' for ''a pesticide registration application'' and ''the covered application'' for ''the covered pesticide registration application''.

Subsec. (k)(1). Pub. L. 116–8, §5(e)(1), substituted ''2023'' for ''2017''.

Subsec. (k)(2)(D)(i). Pub. L. 116–8, §5(e)(2)(A), added cl. (i) and struck out former cl. (i) which read as follows: ''the number of pesticides or pesticide cases reviewed;''.

Subsec. (k)(2)(G)(i). Pub. L. 116–8, §5(e)(2)(B)(i), substituted ''paragraphs (4) and (5) of section 136a–1(k) of this title'' for ''section 136a–1(k)(4) of this title'' and ''such paragraphs'' for ''that section''.

Subsec. (k)(2)(G)(ii) to (vii). Pub. L. 116–8, §5(e)(2)(B)(ii)–(iv), added cl. (ii), redesignated cl. (vii) as (iii), and struck out former cls. (ii) to (vi) which read as follows:

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

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

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

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

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

Subsec. (k)(2)(K) to (O). Pub. L. 116–8, §5(e)(2)(C)–(E), added subpars. (K) to (O).

Subsec. (m)(1). Pub. L. 116–8, §5(f)(1), substituted ''2023'' for ''2017''.

Subsec. (m)(2)(A). Pub. L. 116–8, §5(f)(2)(A), in heading, substituted ''Fiscal year 2024'' for ''Fiscal year 2018'' and in text, substituted ''2024'' for ''2018'' and ''2023'' for ''2017''.

Subsec. (m)(2)(B). Pub. L. 116–8, §5(f)(2)(B), in heading, substituted ''Fiscal year 2025'' for ''Fiscal year 2019'' and in text, substituted ''2025'' for ''2019'' and ''2023'' for ''2017''.

Subsec. (m)(2)(C). Pub. L. 116–8, §5(f)(2)(C), substituted ''2025'' for ''2019'' in heading and text.

Subsec. (m)(2)(D). Pub. L. 116–8, §5(f)(2)(D), substituted ''2023'' for ''2017'' in cls. (i) and (ii).

2012—Subsec. (b)(3). Pub. L. 112–177, §2(b)(1)(A), added par. (3) and struck out former par. (3) which related to schedule of covered applications and registration service fees.

Subsec. (b)(6)(A). Pub. L. 112–177, §2(b)(1)(B)(i), substituted ''October 1, 2013'' for ''October 1, 2008'' and ''September 30, 2015'' for ''September 30, 2010''.

Subsec. (b)(6)(B). Pub. L. 112–177, §2(b)(1)(B)(ii), substituted ''October 1, 2015'' for ''October 1, 2010'' and ''September 30, 2015'' for ''September 30, 2010''.

Subsec. (b)(7)(F)(i). Pub. L. 112–177, §2(a)(2)(B)(i), substituted ''section 136a–1 (i)(1)(E)(ii)'' for ''section 136a–1(i)(5)(E)(ii)''.

Subsec. (b)(7)(F)(ii). Pub. L. 112–177, §2(a)(2)(B)(i), (ii), substituted ''section 136a–1 (i)(1)(E)(ii)'' for ''section 136a–1(i)(5)(E)(ii)'' in subcl. (I) and ''section 136a–1(i)(1)(E)(ii)(I)(bb)'' for ''136a–1(i)(5)(E)(ii)(I)(bb)'' in subcl. (II).

Subsec. (b)(7)(F)(iv)(I). Pub. L. 112–177, §2(a)(2)(B)(i), substituted ''section 136a–1 (i)(1)(E)(ii)'' for ''section 136a–1(i)(5)(E)(ii)''.

Subsec. (b)(7)(F)(iv)(II). Pub. L. 112–177, §2(a)(2)(B)(ii), (iii), substituted ''applicable'' for ''applicable.'', ''revenue'' for ''revenues'', and ''section 136a–1(i)(1)(E)(ii)(I)(bb)'' for ''section 136a–1(i)(5)(E)(ii)(I)(bb)''.

Subsec. (b)(8)(C)(ii)(III). Pub. L. 112–177, §2(b)(1)(C), added subcl. (III).

Subsec. (c)(3)(B)(i). Pub. L. 112–177, §2(b)(2)(A), substituted ''2013 through 2017'' for ''2008 through 2012''.

Subsec. (c)(3)(B)(ii). Pub. L. 112–177, §2(b)(2)(B), substituted ''grants, for each of fiscal years 2013 through 2017, $500,000.'' for ''grants—

''(I) for each of fiscal years 2008 and 2009, $750,000; and

''(II) for each of fiscal years 2010 through 2012, $500,000.''

Subsec. (c)(3)(B)(iii). Pub. L. 112–177, §2(b)(2)(C), substituted ''2013 through 2017'' for ''2008 through 2012''.

Subsec. (d)(2). Pub. L. 112–177, §2(b)(3)(A), substituted ''2012'' for ''2002'' in two places.

Subsec. (d)(4), (5). Pub. L. 112–177, §2(b)(3)(B), (C), redesignated par. (5) as (4) and struck out former par. (4). Prior to amendment, text of par. (4) read as follows: ''The requirements of paragraph (2) shall have been considered to have been met for any fiscal year if the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2002) of the Office of Pesticide Programs of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) is not more than 3 percent below the amount of appropriations for covered functions for fiscal year 2002 (excluding the amount of any fees appropriated for the fiscal year).''

Subsec. (e). Pub. L. 112–177, §2(b)(4), substituted ''Pesticide Registration Improvement Extension Act of 2012'' for ''Pesticide Registration Improvement Act of 2003''.

Subsec. (f)(1). Pub. L. 112–177, §2(b)(5)(A), substituted ''Pesticide Registration Improvement Extension Act of 2012, the Administrator shall make publicly available'' for ''Pesticide Registration Improvement Renewal Act, the Administrator shall publish in the Federal Register''.

Subsec. (f)(2). Pub. L. 112–177, §2(b)(5)(B), substituted ''provided under subsection (b)(3).'' for ''appearing in the Congressional Record on pages S10409 through S10411, dated July 31, 2007.''

Subsec. (f)(4)(A). Pub. L. 112–177, §2(b)(5)(C)(i), inserted ''and fee'' before period at end.

Subsec. (f)(4)(B). Pub. L. 112–177, §2(b)(5)(C)(ii)(I), substituted ''Initial content and preliminary technical screenings'' for ''Completeness of application'' in heading.

Subsec. (f)(4)(B)(i). Pub. L. 112–177, §2(b)(5)(C)(ii)(I), (II), substituted ''Screenings'' for ''In general'' in cl. heading, designated existing provisions as subcl. (I) and inserted subcl. heading, and added subcl. (II).

Subsec. (f)(4)(B)(ii). Pub. L. 112–177, §2(b)(5)(C)(ii)(III), added cl. (ii) and struck out former cl. (ii). Prior to amendment, text read as follows: ''If the Administrator determines under clause (i) that the application does not pass the initial screening and cannot be corrected within the 21-day period, the Administrator shall reject the application not later than 10 days after making the determination.''

Subsec. (f)(4)(B)(iii). Pub. L. 112–177, §2(b)(5)(C)(ii)(IV), inserted ''initial content'' before ''screening'' in heading, ''content'' before ''screening'' in introductory provisions, and substituted ''appears to contain'' for ''contains'' in subcl. (II).

Subsec. (f)(4)(B)(iv). Pub. L. 112–177, §2(b)(5)(C)(ii)(V), added cl. (iv).

Subsec. (k)(1). Pub. L. 112–177, §2(b)(6)(A), substituted ''March 1, 2017'' for ''March 1, 2014''.

Subsec. (k)(2)(A)(viii). Pub. L. 112–177, §2(b)(6)(B)(i), added cl. (viii).

Subsec. (k)(2)(G) to (J). Pub. L. 112–177, §2(b)(6)(B)(ii)–(iv), added subpars. (G) to (J).

Subsec. (k)(4). Pub. L. 112–177, §2(b)(6)(C), added par. (4).

Subsec. (m)(1). Pub. L. 112–177, §2(b)(7)(A), substituted ''2017'' for ''2012''.

Subsec. (m)(2)(A). Pub. L. 112–177, §2(b)(7)(B)(i), substituted ''2018'' for ''2013'' in heading and ''2018,'' for ''2013,'' and ''September 30, 2017'' for ''September 30, 2012'' in text.

Subsec. (m)(2)(B). Pub. L. 112–177, §2(b)(7)(B)(ii), substituted ''2019'' for ''2014'' in heading and ''2019,'' for ''2014,'' and ''September 30, 2017'' for ''September 30, 2012'' in text.

Subsec. (m)(2)(C). Pub. L. 112–177, §2(b)(7)(B)(iii), substituted ''2019'' for ''2014'' in heading and ''September 30, 2019'' for ''September 30, 2014'' in text.

Subsec. (m)(2)(D). Pub. L. 112–177, §2(b)(7)(B)(iv), substituted ''2017'' for ''2012'' in cls. (i) and (ii).

2008—Subsec. (b)(7)(D)(i). Pub. L. 110–193, §1(a)(1)(A)(i), added cl. (i) and struck out former cl. (i). Prior to amendment, text read as follows: ''The Administrator may waive or reduce a registration service fee for an application for minor uses for a pesticide.''

Subsec. (b)(7)(D)(ii). Pub. L. 110–193, §1(a)(1)(A)(ii), inserted ''or exemption'' after ''waiver''.

Subsec. (b)(7)(E). Pub. L. 110–193, §1(a)(1)(B)(ii), substituted ''exempt an application from the registration service fee'' for ''waive the registration service fee for an application'' in introductory provisions.

Pub. L. 110–193, §1(a)(1)(B)(i), substituted ''exemption'' for ''waiver'' in heading.

Subsec. (b)(7)(E)(ii). Pub. L. 110–193, §1(a)(1)(B)(iii), substituted ''exemption'' for ''waiver''.

Subsec. (m)(2)(A), (B). Pub. L. 110–193, §1(a)(2), substituted ''2012'' for ''2008''.

2007—Subsec. (b)(2)(C)(ii). Pub. L. 110–94, §5(a)(1), added cl. (ii) and struck out former cl. (ii) which read as follows: ''a request for a waiver from or reduction of the registration service fee.''

Subsec. (b)(2)(D) to (H). Pub. L. 110–94, §5(a)(2), added subpars. (D) to (H).

Subsec. (b)(3)(A). Pub. L. 110–94, §5(b)(1)(A), substituted ''Pesticide Registration Improvement Renewal Act'' for ''Pesticide Registration Improvement Act of 2003''.

Subsec. (b)(3)(B). Pub. L. 110–94, §5(b)(1)(B), substituted ''S10409 through S10411, dated July 31, 2007.'' for ''S11631 through S11633, dated September 17, 2003.''

Subsec. (b)(6). Pub. L. 110–94, §5(b)(2), added par. (6) and struck out former par. (6). Prior to amendment, text of par. (6) read as follows: ''Effective for a covered pesticide registration application received on or after October 1, 2005, the Administrator shall—

''(A) increase by 5 percent the service fee payable for the application under paragraph (3); and

''(B) publish in the Federal Register the revised registration service fee schedule.''

Subsec. (b)(7)(F)(ii). Pub. L. 110–94, §5(c)(1), substituted ''75 percent'' for ''all'' in introductory provisions.

Subsec. (b)(7)(F)(iv)(II). Pub. L. 110–94, §5(c)(2), substituted ''75 percent of the applicable.'' for ''all''.

Subsec. (b)(8)(A). Pub. L. 110–94, §5(d), substituted ''25 percent.'' for ''10 percent''.

Subsec. (c)(1)(B). Pub. L. 110–94, §5(e)(1), substituted ''paragraph (5)'' for ''paragraph (4)''.

Subsec. (c)(3)(B). Pub. L. 110–94, §5(e)(2)(A), added subpar. (B) and struck out former subpar. (B). Prior to amendment, text of subpar. (B) read as follows: ''For each of fiscal years 2004 through 2008, the Administrator shall use approximately 1/17 of the amount in the Fund (but not more than $1,000,000, and not less than $750,000, for any fiscal year) to enhance current scientific and regulatory activities related to worker protection.''

Subsec. (c)(3)(C). Pub. L. 110–94, §5(e)(2)(B), struck out subpar. (C). Text read as follows: ''For each of fiscal years 2004 and 2005, the Administrator shall use approximately ¼ of the amount in the Fund (but not to exceed $500,000 for any fiscal year) for the review and evaluation of new inert ingredients.''

Subsec. (c)(5). Pub. L. 110–94, §5(e)(3), designated existing provisions as subpar. (A), inserted heading, redesignated former subpars. (A) to (C) as cls. (i) to (iii), respectively, of subpar. (A) and added subpar. (B).

Subsec. (d)(2). Pub. L. 110–94, §5(f), which directed substitution of ''Registration'' for ''For fiscal years 2004, 2005 and 2006 only, registration'', was executed by making the substitution for text which contained a comma after ''2005'' to reflect the probable intent of Congress.

Subsec. (f)(1). Pub. L. 110–94, §5(g)(1), substituted ''Pesticide Registration Improvement Renewal Act'' for ''Pesticide Registration Improvement Act of 2003''.

Subsec. (f)(2). Pub. L. 110–94, §5(g)(2), substituted ''S10409 through S10411, dated July 31, 2007.'' for ''S11631 through S11633, dated September 17, 2003.''

Subsec. (f)(4)(B). Pub. L. 110–94, §5(g)(3), added subpar. (B) and struck out former subpar. (B) which provided criteria for determining completeness of pesticide registration applications.

Subsec. (k)(1). Pub. L. 110–94, §5(h)(1), substituted ''March 1, 2014'' for ''March 1, 2009''.

Subsec. (k)(2)(A)(ii) to (v). Pub. L. 110–94, §5(h)(2)(A)(i), (ii), added cls. (ii) to (iv) and redesignated former cl. (ii) as (v). Former cls. (iii) and (iv) redesignated (vi) and (vii), respectively.

Subsec. (k)(2)(A)(vi). Pub. L. 110–94, §5(h)(2)(A)(i), (iii), redesignated cl. (iii) as (vi) and added subcls. (IV) and (V).

Subsec. (k)(2)(A)(vii). Pub. L. 110–94, §5(h)(2)(A)(i), redesignated cl. (iv) as (vii).

Subsec. (k)(2)(D) to (F). Pub. L. 110–94, §5(h)(2)(B)–(D), added subpars. (D) to (F).

Subsec. (m)(1). Pub. L. 110–94, §5(i)(1), substituted ''2012'' for ''2008''.

Subsec. (m)(2)(A). Pub. L. 110–94, §5(i)(2)(A), substituted ''2013'' for ''2009'' in heading and text.

Subsec. (m)(2)(B), (C). Pub. L. 110–94, §5(i)(2)(B), substituted ''2014'' for ''2010'' in headings and text.

Subsec. (m)(2)(D). Pub. L. 110–94, §5(i)(2)(C), substituted ''2012'' for ''2008'' in two places.

EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by Pub. L. 112–177 effective Oct. 1, 2012, see section 2(c) of Pub. L. 112–177, set out as a note under section 136a–1 of this title.

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110–193, §1(b), Mar. 6, 2008, 122 Stat. 650, provided that: ''The amendments made by subsection (a) [amending this section] take effect on October 1, 2007.''

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 110–94 effective Oct. 1, 2007, see section 6 of Pub. L. 110–94, set out as a note under section 136a of this title.

EFFECTIVE DATE

Section effective on the date that is 60 days after Jan. 23, 2004, except as otherwise provided, see section 501(h) of Pub. L. 108–199, set out as an Effective Date of 2004 Amendment note under section 136a of this title.

EXTENSION OF LIMITATIONS ON FEE AMOUNTS AND USAGE OF FEES

Subsection (c)(3)(B) of this section to continue in effect through Sept. 30, 2018, see section 401(a) of Pub. L. 115–141, set out as a note under section 136a–1 of this title.

Pub. L. 115–141, div. M, title IV, §401(b)(2), Mar. 23, 2018, 132 Stat. 1050, provided that: ''Notwithstanding section 33(m)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w–8(m)(2)), section 33(m)(1) of such Act (7 U.S.C. 136w–8(m)(1)) shall be applied by substituting 'September 30, 2018' for 'September 30, 2017'.''

§ 136x. Severability

If any provision of this subchapter or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this subchapter which can be given effect without regard to the invalid provision or application, and to this end the provisions of this subchapter are severable.

(June 25, 1947, ch. 125, §34, formerly §26, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 998; renumbered §30, Pub. L. 95–396, §24(1), Sept. 30, 1978, 92 Stat. 836; renumbered §33, Pub. L. 104–170, title I, §121(1), Aug. 3, 1996, 110 Stat. 1492; renumbered §34, Pub. L. 108–199, div. G, title V, §501(f)(1), Jan. 23, 2004, 118 Stat. 422.)

PRIOR PROVISIONS

A prior section 34 of act June 25, 1947, ch. 125, was renumbered section 35 and is classified to section 136y of this title.

EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92–516, set out as a note under section 136 of this title.

§ 136y. Authorization of appropriations

There is authorized to be appropriated to carry out this subchapter (other than section 136u(a) of this title)—

(1) $83,000,000 for fiscal year 1989, of which not more than $13,735,500 shall be available for research under this subchapter;

(2) $95,000,000 for fiscal year 1990, of which not more than $14,343,600 shall be available for research under this subchapter; and

(3) $95,000,000 for fiscal year 1991, of which not more than $14,978,200 shall be available for research under this subchapter.

(June 25, 1947, ch. 125, §35, formerly §27, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 998; amended Pub. L. 94–51, July 2, 1975, 89 Stat. 257; Pub. L. 94–109, Oct. 10, 1975, 89 Stat. 571; Pub. L. 94–140, §3, Nov. 28, 1975, 89 Stat. 752; renumbered §31 and amended Pub. L. 95–396, §§24(1), 25, Sept. 30, 1978, 92 Stat. 836, 838; Pub. L. 96–539, §3, Dec. 17, 1980, 94 Stat. 3195; Pub. L. 98–201, §2, Dec. 2, 1983, 97 Stat. 1380; Pub. L. 99–198, title XVII, §1768, Dec. 23, 1985, 99 Stat. 1656; Pub. L. 100–532, title VII, §701, Oct. 25, 1988, 102 Stat. 2679; renumbered §34, Pub. L. 104–170, title I, §121(1), Aug. 3, 1996, 110 Stat. 1492; renumbered §35, Pub. L. 108–199, div. G, title V, §501(f)(1), Jan. 23, 2004, 118 Stat. 422.)

CODIFICATION

Another section 1768 of Pub. L. 99–198 enacted sections 154a and 159 and amended sections 151, 154, and 157 of Title 21, Food and Drugs.

AMENDMENTS

1988—Pub. L. 100–532 amended section generally. Prior to amendment, section read as follows: ''There is authorized to be appropriated to carry out this subchapter for the period beginning October 1, 1985, and ending September 30, 1986, $68,604,200 of which not more than $11,993,100 shall be available for research under this subchapter.''