Editorial Notes

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 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)(B) 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) on completion of, where appropriate, the initial screening of the contents of the application or the preliminary technical screening 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 reg-

istration 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

(A) Data evaluation records

At the decision review time under a fee table specified in subparagraph (B) or as agreed upon under subsection (f)(5), for each covered application under a fee table specified in such subparagraph (B), the Administrator shall—

(i) complete data evaluation records for studies submitted by the applicant in support of the application; and

(ii) release those data evaluation records to the applicant, using appropriate protections for confidential business information.

(B) Schedule, actions, and 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 (RD) — 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)	36	1,079,356
R020	2	New Active Ingredient, Food use; reduced risk. (2)(3)	27	899,464
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)(4)	18	662,883
R060	4	New Active Ingredient, Non-food use; outdoor. (2)(3)	30	749,886
R070	5	New Active Ingredient, Non-food use; outdoor; reduced risk. (2)(3)	24	624,905
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)(4)	16	463,930
R110	7	New Active Ingredient, Non-food use; indoor. (2)(3)(4)	20	417,069
R120	8	New Active Ingredient, Non-food use; indoor; reduced risk. (2)(3)(4)	14	347,556
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)(4)	18	261,322
R122	10	Enriched isomer(s) of registered mixed-isomer active ingredient. (2)(3)	27	454,526
R123	11	New Active Ingredient, Seed treatment only; includes agricultural and non-agricultural seeds; non-food use, not requiring a tolerance. (2)(3)	27	676,296
R126	12 (new)	New Active Ingredient, Seed treatment only; limited uptake into raw agricultural commodities; use requiring a tolerance. (2)(3)	31	743,925
R125	13	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)(4)	16	463,930

(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 preliminary technical 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) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 2. — REGISTRATION DIVISION (RD) — NEW USES

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R130	14	First food use; indoor; food/food handling. (2)(3)(5)	23	274,388
R140	15	Additional food use; Indoor; food/food handling. (3)(4)(5)	17	64,028
R150	16	First food use. (2)(3)(5)	23	454,490
R155	17	First food use, Experimental Use Permit application; active ingredient registered for non-food use. (3)(4)(5)	21	378,742
R160	18	First food use; reduced risk. (2)(3)(5)	18	378,742
R170	19	Additional food use. (3)(4)(5)	17	113,728
R175	20	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)(5)	14	94,774
R180	21	Additional food use; reduced risk. (3)(4)(5)	12	94,774
R190	22	Additional food uses; 6 or more submitted in one application. (3)(4)(5)	17	682,357
R200	23	Additional Food Use; 6 or more submitted in one application; Reduced Risk. (3)(4)(5)	12	568,632
R210	24	Additional food use; Experimental Use Permit application; establish temporary tolerance; no credit toward new use registration. (3)(4)(5)	12	70,210
R220	25	Additional food use; Experimental Use Permit application; crop destruct basis; no credit toward new use registration. (3)(4)(5)	6	28,434
R230	26	Additional use; non-food; outdoor. (3)(4)(5)	16	45,453
R240	27	Additional use; non-food; outdoor; reduced risk. (3)(4)(5)	10	37,878

TABLE 2. — REGISTRATION DIVISION (RD) — NEW USES—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R250	28	Additional use; non-food; outdoor; Experimental Use Permit application; no credit toward new use registration. (3)(4)(5)	6	28,434
R251	29	Experimental Use Permit application which requires no changes to the tolerance(s); non-crop destruct basis. (3)(5)	8	28,434
R260	30	New use; non-food; indoor. (3)(4)(5)	12	21,954
R270	31	New use; non-food; indoor; reduced risk. (3)(4)(5)	9	18,296
R271	32	New use; non-food; indoor; Experimental Use Permit application; no credit toward new use registration. (3)(4)(5)	6	13,940
R273	33	Additional use; seed treatment only; use not requiring a new tolerance; includes crops with established tolerances (e.g., for soil or foliar application). (3)(4)(5)	12	72,302
R274	34	Additional use; seed treatment only; 6 or more submitted in one application; uses not requiring new tolerances; includes crops with established tolerances (e.g., for soil or foliar application). (3)(4)(5)	12	433,793
R276	35 (new)	Additional use, seed treatment only; limited uptake into raw agricultural commodities; use requiring a tolerance. (3)(4)(5)	14	79,560
R277	36 (new)	Additional use, seed treatment only; 6 or more submitted in one application; limited uptake into raw agricultural commodities; use requiring a tolerance. (3)(4)(5)	14	477,360

(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 preliminary technical 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 preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

(5) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 3. — REGISTRATION DIVISION (RD) — IMPORT AND OTHER TOLERANCES

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R280	37	Establish tolerances for residues in imported commodities; new active ingredient or first food use. (2)	22	457,311
R290	38	Establish tolerances for residues in imported commodities; Additional new food use.	16	91,465
R291	39	Establish tolerances for residues in imported commodities; additional food uses; 6 or more crops submitted in one petition.	16	548,773
R292	40	Amend an established tolerance (e.g., decrease or increase) and/or harmonize established tolerances with Codex Maximum Residue Limits; domestic or import; applicant-initiated.	12	64,987
R293	41	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated.	13	76,656
R294	42	Establish tolerances for inadvertent residues; 6 or more crops submitted in one application; applicant-initiated.	13	459,922
R295	43	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)	16	94,774
R296	44	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)	16	568,632
R297	45	Amend 6 or more established tolerances (e.g., decrease or increase) in one petition; domestic or import; applicant-initiated.	12	389,897
R298	46	Amend an established tolerance (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3)(4)	14	83,940
R299	47	Amend 6 or more established tolerances (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3)(4)	14	408,853

TABLE 3. — REGISTRATION DIVISION (RD) — IMPORT AND OTHER TOLERANCES—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R281	48 (new)	Establish tolerances for residues in imported commodities; additional new food use; submission of residue chemistry data review conducted by Codex or other competent national regulatory authority.	12	68,599
R282	49 (new)	Establish tolerances for residues in imported commodities; additional new food uses; 6 or more crops submitted in one petition; submission of residue chemistry data review conducted by Codex or other competent national regulatory authority.	12	411,580

(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 preliminary technical 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 (RD) — NEW PRODUCTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R300	50	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 child-resistant packaging — 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	2,270

TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R301	51	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	2,720
R310	52	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: 1. product chemistry and/or 2. acute toxicity and/or 4.[sic] Child-resistant packaging and/or 4. pest(s) requiring efficacy – for up to 3 target pests. (2)(3)(4)	7	10,466
R314	53	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: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. pest(s) requiring efficacy (4) for up to 3 target pests. (2)(3)	8	12,364
R319	54	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: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. pest(s) requiring efficacy (4) - for 4 to 7 target pests. (2)(3)	10	18,097

TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R318	55	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: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. pest(s) requiring efficacy – for up to 3 target pests. (2)(3)(4)	9	18,994
R321	56	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: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. pest(s) requiring efficacy (4) - for 4 to 7 target pests. (2)(3)	11	24,727
R315	57	New end-use on-animal product, registered source of active ingredient(s) with submission of data and/or waivers for only: 1. animal safety and 2. pest(s) requiring efficacy and/or 3. product chemistry and/or 4. acute toxicity and/or 5. child resistant packaging. (2)(3)(4)	9	14,075
R316	58	New end-use or manufacturing-use 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: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. pest(s) requiring efficacy - for 4 to 7 target pests. (2)(3)(4)	9	16,199
R317	59	New end-use or manufacturing-use 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: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. Pest(s) requiring efficacy - for greater than 7 target pests, (2)(3)(4)	10	21,932
R320	60	New product; new physical form; requires data review in science divisions. (2)(3)(5)	12	18,958

TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R331	61	New product; repack of identical registered end-use product as a manufacturing-use product; same registered uses only. (2)(3)	3	3,627
R332	62	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	405,919
R333	63	New product; manufacturing-use product 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)	11	28,434
R334	64	New product; manufacturing-use product or end-use product with unregistered source of the active ingredient; requires science data review; new physical form; etc. Selective data citation. (2)(3)	12	33,108
R361	65 (new)	New end-use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active 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: 1. product chemistry and/or 2. acute toxicity and/or 3. Child resistant packaging and/or 4. pest(s) requiring efficacy – for more than 7 target pests. (2)(3)(4)	12	23,400
R362	66 (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: 1. product chemistry and/or 2. acute toxicity and/or 3. Child resistant packaging and/or 4. pest(s) requiring efficacy – for more than 7 target pests. (2)(3)(4)	13	25,350
R363	67 (new)	New product; repack of identical registered manufacturing-use product as an end-use product; same registered uses only, with no additional data. (2)(3)	6	7,800

(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 both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, subpart R of part 158 of title 40, Code of Federal Regulations. This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in the Pesticide Registration Notice 2002-1. To determine the number of pests for the PRIA categories, pest groups, subgroups, and pest specific claims as listed in part 158 of title 40, Code of Federal Regulations, should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, etc.), each group will count as 1. If seeking a claim against a pest subgroup (e.g., small biting flies, filth flies, etc.) or specific pests (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each subgroup or specific pest will count as 1.

(5) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 5. — REGISTRATION DIVISION (RD) — AMENDMENTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R340	68	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	7,150
R341	69	Amendment requiring data review within RD (e.g., changes to precautionary label statements), includes adding/modifying pest(s) claims for greater than 2 target pests; excludes products requiring or citing an animal safety study. (2)(3)	6	8,584
R345	70	Amending on-animal products previously registered, with the submission of data and/or waivers for only: 1. animal safety and 2. pest(s) requiring efficacy and/or 3. product chemistry and/or 4. acute toxicity and/or 5. child resistant packaging. (2)(3)(4)	7	12,643
R350	71	Amendment requiring data review in science divisions (e.g., changes to Restricted Entry Interval, or Personal Protective Equipment, or Preharvest Interval, or use rate, or number of applications; or add aerial application; or modify Ground Water/Surface Water advisory statement). (2)(3)(5)	9	18,958
R351	72	Amendment adding a new unregistered source of active ingredient. (2)(3)	8	18,958
R352	73	Amendment adding already approved uses; selective method of support; does not apply if the applicant owns all cited data. (2)(3)	8	18,958
R371	74	Amendment to Experimental Use Permit; (does not include extending a permit's time period). (3)	6	14,463

(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 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 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 both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, subpart R of part 158 of title 40, Code of Federal Regulations. This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in the Pesticide Registration Notice 2002-1. To determine the number of pests for the PRIA categories, pest groups, subgroups, and pest specific claims as listed in part 158 of title 40, Code of Federal Regulations, should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, etc.), each group will count as 1. If seeking a claim against a pest subgroup (e.g., small biting flies, filth flies, etc.) or specific pests (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each subgroup or specific pest will count as 1.

(5) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 6. — REGISTRATION DIVISION (RD) — OTHER ACTIONS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
R124	75	Conditional Ruling on Pre-application Study Waivers; applicant-initiated.	6	3,627
R272	76	Review of Study Protocol applicant-initiated; excludes Data Analysis Reporting Tool, pre-registration conference, Rapid Response review, developmental neurotoxicity protocol review, protocol needing Human Studies Review Board review, companion animal safety protocol.	3	3,627
R275	77	Rebuttal of Agency reviewed protocol, applicant initiated.	3	3,627
R278	78 (new)	Review of Protocol for companion animal safety study.	5	4,927
R279	79 (new)	Comparative product determination for reduced risk submission, applicant initiated; submitted before application for reduced risk new active ingredient or reduced risk new use.	3	5,200

(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. — ANTIMICROBIAL DIVISION (AD) — NEW ACTIVE INGREDIENTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
A380	80	New Active Ingredient; Indirect Food use; establish tolerance or tolerance exemption if required. (2)(3)(4)	26	227,957
A390	81	New Active Ingredient; Direct Food use; establish tolerance or tolerance exemption if required. (2)(3)(4)	26	329,265
A410	82	New Active Ingredient Non-food use. (2)(3)(4)	23	278,659
A431	83	New Active Ingredient, Non-food use; low-risk. (2)(3)(4)	14	114,984

(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 preliminary technical 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) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 8. — ANTIMICROBIAL DIVISION (AD) — NEW USES

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
A440	84	New Use, Indirect Food Use, establish tolerance or tolerance exemption. (2)(3)(4)(6)	23	45,737
A441	85	Additional Indirect food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application. (3)(4)(5)(6)	23	164,639
A450	86	New use, Direct food use, establish tolerance or tolerance exemption. (2)(3)(4)(6)	23	137,198
A451	87	Additional Direct food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application. (3)(4)(5)(6)	22	261,333
A500	88	New use, non-food. (4)(5)(6)	15	45,737
A501	89	New use, non-food; 6 or more submitted in one application. (4)(5)(6)	17	109,764

(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 preliminary technical 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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) 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 preliminary technical screening, 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) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
A530	90	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	1,833
A531	91	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	2,616
A532	92	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	7,322
A550	93	New end-use product; uses other than FIFRA §2(mm); non-FQPA product. (2)(3)(5)	9	18,958
A560	94	New manufacturing-use product; registered active ingredient; selective data citation. (2)(3)	6	18,054
A565	95	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)	18	26,135
A572	96	New Product or amendment requiring data review for risk assessment by Science Branch (e.g., changes to Restricted Entry Interval, or Personal Protective Equipment, or use rate). (2)(3)(4)(7)	9	18,958

TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
A460	97 (new)	New end-use product; FIFRA §2(mm) uses only; 0 to 10 public health organisms. (2)(3)(5)(6)	5	7,322
A461	98 (new)	New end-use product; FIFRA §2(mm) uses only; 11 to 20 public health organisms. (2)(3)(5)(6)	6	10,158
A462	99 (new)	New end-use product; FIFRA §2(mm) uses only; 21 to 30 public health organisms. (2)(3)(5)(6)	7	12,995
A463	100 (new)	New end-use product; FIFRA §2(mm) uses only; 31 to 40 public health organisms. (2)(3)(5)(6)	9	15,831
A464	101 (new)	New end-use product; FIFRA §2(mm) uses only; 41 to 50 public health organisms. (2)(3)(5)(6)	10	18,668
A465	102 (new)	New end-use product; FIFRA §2(mm) uses only; 51 or more public health organisms. (2)(3)(5)(6)	11	21,505
A470	103 (new)	Label amendment requiring data review; 0 to 10 public health organisms. (3)(4)(5)(6)	4	5,493
A471	104 (new)	Label amendment requiring data review; 11 to 20 public health organisms. (3)(4)(5)(6)	5	8,506
A472	105 (new)	Label amendment requiring data review; 21 to 30 public health organisms. (3)(4)(5)(6)	6	10,219
A473	106 (new)	Label amendment requiring data review; 31 to 40 public health organisms. (3)(4)(5)(6)	7	11,933
A474	107 (new)	Label amendment requiring data review; 41 to 50 public health organisms. (3)(4)(5)(6)	8	13,646
A475	108 (new)	Label amendment requiring data review; 51 or more public health organisms. (3)(4)(5)(6)	9	15,766

(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 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 section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (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 an application for an amendment or a new product with public health organisms has been submitted and classified into any of categories A460 through A465 or A470 through A475, additional organisms submitted for the same product before the first application is granted will result in combination and reclassification of both the original and subsequent submissions into the appropriate new category based on the sum of the number of organisms in both submissions. Submission of additional organisms would result in a new PRIA start date and may require additional fees to meet the fee of a new category.

(7) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 10. — ANTIMICROBIAL DIVISION (AD) — EXPERIMENTAL USE PERMITS AND OTHER ACTIONS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
A520	109	Experimental Use Permit application, non-food use. (2)(3)	9	9,151
A521	110	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; applicant-initiated; Tier 1.	6	6,776
A522	111	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; applicant-initiated; Tier 2.	12	17,424
A537	112	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. (3)	18	219,512
A538	113	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. (3)	18	137,198
A539	114	New Active Ingredient/New Use, Experimental Use Permit application; Nonfood use. Credit 45% of fee toward new active ingredient/new use application that follows. (3)	15	132,094
A529	115	Amendment to Experimental Use Permit; requires data review or risk assessment. (2)(3)	9	16,383
A523	116	Review of protocol other than a public health efficacy study (i.e., Toxicology or Exposure Protocols).	9	17,424
A571	117	Science reassessment: refined ecological risk, and/or endangered species; applicant-initiated. (3)	18	137,198
A533	118	Exemption from the requirement of an Experimental Use Permit. (2)	4	3,559
A534	119	Rebuttal of Agency reviewed protocol, applicant initiated.	4	6,776
A535	120	Conditional ruling on pre-application study waiver or data bridging argument; applicant-initiated.	6	3,454
A536	121	Conditional ruling on pre-application direct food, indirect food, nonfood use determination; applicant-initiated.	4	3,559
A575	122 (new)	Efficacy similarity determination; if two products can be bridged or if confirmatory efficacy data are needed.	4	3,389

(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.

3) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 11. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW ACTIVE INGREDIENTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B580	123	New active ingredient; petition to establish a tolerance. (2)(3)(4)	22	73,173
B590	124	New active ingredient; petition to establish a tolerance exemption. (2)(3)(4)	20	45,737
B600	125	New active ingredient; no change to a permanent tolerance or tolerance exemption (includes non-food uses). (2)(3)(4)	15	27,443
B610	126	New active ingredient; Experimental Use Permit application; petition to establish a permanent or temporary tolerance or temporary tolerance exemption. (3)(4)	12	18,296
B620	127	New active ingredient; Experimental Use Permit application; non-food use (includes crop destruct). (3)(4)	9	9,151

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

(2) 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 preliminary technical 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) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 12. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW USES

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B630	128	First food use; petition to establish/amend a tolerance exemption. (2)(4)(5)	13	18,296
B640	129	First food use; petition to establish/amend a tolerance. (2)(4)(5)	19	27,443

TABLE 12. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW USES—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B644	130	New use, no change to an established tolerance or tolerance exemption (includes non-food uses). (3)(4)(5)	8	18,296
B645	131	New use; Experimental Use Permit; petition to establish a permanent or temporary tolerance or tolerance exemption. (4)(5)	12	18,296
B646	132	New use; Experimental Use Permit; non-food use (includes crop destruct). (4)(5)	7	9,151

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

(2) 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 preliminary technical 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 preliminary technical 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.

(5) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW PRODUCTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B660	133	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 submission or data matrix (or submission of product chemistry data only). (2)(3)	6	1,833

TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW PRODUCTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B670	134	New product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption; (including non-food); Must address Product-Specific Data Requirements. (2)(3)	9	7,322
B672	135	New product; unregistered source of at least one active ingredient (or registered source with new generic data package); no change in an established tolerance or tolerance exemption (including non-food); must address Product-Specific and Generic Data Requirements. (2)(3)	15	13,069
B673	136	New product; 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 support the new product. (2)(3)	12	7,322
B674	137	New product; repack of identical registered end-use product or repack of an end-use product as a manufacturing-use product; same registered uses only. (2)(3)	4	1,833
B677	138	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: 1. product chemistry and/or 2. acute toxicity and/or 3. public health pest efficacy and/or 4. animal safety studies and/or 5. child resistant packaging. (2)(3)	12	12,643

(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 AND POLLUTION PREVENTION DIVISION (BPPD) — AMENDMENTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B621	139	Amendment; Experimental Use Permit; no change to an established temporary or permanent tolerance or tolerance exemption. (3) (4)	7	7,322
B622	140	Amendment; Experimental Use Permit; petition to amend a permanent or temporary tolerance or tolerance exemption. (3)(4)	11	18,296
B641	141	Amendment; changes to an established tolerance or tolerance exemption. (4)	13	18,296
B680	142	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	7,322

TABLE 14. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — AMENDMENTS—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B681	143	Amendment; unregistered source of active ingredient(s); no change to an established tolerance or tolerance exemption; requires data submission. (2)(3)	7	8,714
B683	144	Amendment; no change to an established tolerance or tolerance exemption; requires review/update of previous risk assessment(s) without data submission (e.g., labeling changes to Restricted Entry Interval, Personal Protective Equipment, Preharvest Interval). (2)(3)	6	7,322
B684	145	Amending non-food animal product that includes submission of target animal safety data; previously registered. (2)(3)	8	12,643
B685	146	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	7,322

(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 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 section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (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) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 15. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — STRAIGHT-CHAIN LEPIDOPTERAN PHEROMONES (SCLP)

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B690	147	SCLP; new active ingredient; food or non-food use. (2)(6)(7)	7	3,662
B700	148	SCLP; Experimental Use Permit application; new active ingredient or new use. (6)(7)	7	1,833
B701	149	SCLP; Extend or amend Experimental Use Permit. (6)(7)	4	1,833
B710	150	SCLP; 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 submission or data matrix (or only product chemistry data); (Includes 100% re-pack; repack of registered end-use product as a manufacturing-use product). (3)(6)	4	1,833

TABLE 15. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — STRAIGHT-CHAIN LEPIDOPTERAN PHEROMONES (SCLP)—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B720	151	SCLP; new product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption (including non-food); Must address Product-Specific Data Requirements. (3)(6)	5	1,833
B721	152	SCLP: new product; unregistered source of active ingredient; no change in an established tolerance or tolerance exemption (including non-food); must address Product-Specific and Generic Data Requirements. (3)(6)	7	3,836
B722	153	SCLP; new use and/or amendment; petition to establish a tolerance or tolerance exemption. (4)(5)(6)(7)	7	3,552
B730	154	SCLP; amendment requiring data submission. (4)(6)	5	1,833

(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 preliminary technical 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 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 section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (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 preliminary technical screening, 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.

(7) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 16. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — OTHER ACTIONS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B614	155	Pre-application; Conditional Ruling on rationales for addressing a data requirement in lieu of data; applicant-initiated; applies to one (1) rationale at a time.	3	3,627
B682	156	Protocol review; applicant initiated; excludes time for Human Studies Review Board review (Includes rebuttal of protocol review).	3	3,487
B616	157 (new)	Pre-application; Conditional Ruling on a non-food use determination.	5	4,715
B617	158 (new)	Pre-application; biochemical classification determination.	5	4,715

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

TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B740	159	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; 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)(5)(12)	9	137,198
B750	160	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)	12	182,927
B771	161	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. (5)(12)	13	182,927
B772	162	Application to amend or extend a PIP Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active ingredient is unaffected. (12)	3	18,296
B773	163	Application to amend or extend a PIP Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient. (12)	9	45,737
B780	164	Registration application; new (2) PIP; non-food/feed or food/feed without tolerance petition based on an existing permanent tolerance exemption. (5)(12)(14)	16	228,657
B800	165	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. (5)(12)(14)	17	246,949
B820	166	Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient. (5)(12)(14)	19	292,682

TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B851	167	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	182,927
B870	168	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)(14)	9	54,881
B880	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). (5)(6)(7)(12)(14)	9	45,737
B883	170	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. (5)(8)(12)(14)	13	182,927
B884	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. (5)(8)(12)(14)	19	228,657
B885	172	Registration application; registered (2) PIP, seed increase; breeding stack of previously approved PIPs, same crop; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (9)(12)	6	45,737
B890	173	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). (5)(12)(14)	9	91,465
B900	174	Application to amend a registration, including actions such as modifying an IRM plan, or adding an insect to be controlled. (5)(10)(11)(12)	6	18,296
B902	175	PIP Protocol review.	3	9,151
B903	176	Inert ingredient permanent tolerance exemption; e.g., a marker such as NPT II; reviewed in BPPD.	12	91,465
B904	177	Import tolerance or tolerance exemption; processed commodities/food only (inert or active ingredient).	12	182,927
B905	178	FIFRA Scientific Advisory Panel Review.	6	91,465
B906	179	Petition to establish a temporary tolerance/tolerance exemption for one or more active ingredients.	9	45,733
B907	180	Petition to establish a permanent tolerance/tolerance exemption for one or more active ingredients based on an existing temporary tolerance/tolerance exemption.	9	18,296
B909	181 (new)	PIP tolerance exemption determination; applicant-initiated; request to determine if an existing tolerance exemption applies to a PIP.	6	18,296
B910	182 (new)	Biotechnology Notification for small-scale field testing of genetically engineered microbes.	3	9,151

TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B921	183 (new)	Experimental Use Permit application; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); non-food/feed. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. Credit 75% of B921 fee toward registration application for the new active ingredient that follows (B922). (5)(12)(13)	12	182,927
B922	184 (new)	Registration application; new active ingredient; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); non-food/feed. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. (5)(12)(13)(14)	16	228,657
B923	185 (new)	Experimental Use Permit application; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); with petition to establish a temporary or permanent tolerance/tolerance exemption of an active ingredient. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. Credit 75% of B923 fee toward registration application for the new active ingredient that follows (B924). (5)(12)(13)(14)	15	228,658
B924	186 (new)	Registration application; new active ingredient; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); with petition to establish a permanent tolerance/tolerance exemption of an active ingredient. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. (5)(12)(13)(14)	19	292,682
B925	187 (new)	Experimental Use Permit application; exogenous applications of RNA to elicit the RNA interference pathway in pests; non-food/feed; credit 75% of B925 fee toward registration application for the new active ingredient that follows (B926). (5)(12)	11	27,452
B926	188 (new)	Registration application; new active ingredient; exogenous applications of RNA to elicit the RNA interference pathway in pests; non-food/feed. (5)(12)(14)	17	82,329
B927	189 (new)	Experimental Use Permit application; exogenous applications of RNA to elicit the RNA interference pathway in pests; with petition to establish a temporary or permanent tolerance/tolerance exemption of an active ingredient; credit 75% of B927 fee toward registration application for the new active ingredient that follows (B928). (5)(12)	14	54,889
B928	190 (new)	Registration application; new active ingredient; exogenous applications of RNA to elicit the RNA interference pathway in pests; with petition to establish a permanent tolerance/tolerance exemption of an active ingredient. (5)(12)(14)	22	137,210

TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
B929	191 (new)	Registration application; new product, registered active ingredient; exogenous applications of RNA to elicit the RNA interference pathway in pests; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (5)(12)	10	7,322
B930	192 (new)	Application to amend or extend a non-PIP Emerging Technologies Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active ingredient is unaffected. (12)	3	18,296
B931	193 (new)	Application to amend or extend a non-PIP Emerging Technologies Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient. (12)	9	45,737
B932	194 (new)	Amendment; application to amend a non-PIP Emerging Technologies registration. (4)(5)(12)	6	18,296

(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'' means a PIP with an active ingredient that has not been registered.

(3) ''Registered PIP'' means 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) If, during review of the application, it is determined that review by the FIFRA Scientific Advisory Panel (SAP) is needed, the applicant will submit an application for category B905, which will be processed concurrently, and the decision review time for both applications will be the longer of the two associated applications. The scientific data involved in this category are complex. EPA often seeks technical advice from the SAP on risks that pesticides pose to wildlife, farm workers, pesticide applicators, non-target species, 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 Insecticide Resistance Management (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) (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 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 section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (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.

(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.

(13) This category does not include genetic modifications in animals not intended for use as a pesticide, e.g., genetic modifications in animals intended for food use or animals intended for use as companion animals.

(14) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

TABLE 18. — INERT INGREDIENTS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
I001	195	Approval of new food use inert ingredient. (2)(3)	15	38,698
I002	196	Amend currently approved inert ingredient tolerance or exemption from tolerance; new data. (2)	13	10,750
I003	197	Amend currently approved inert ingredient tolerance or exemption from tolerance; no new data. (2)	11	4,742
I004	198	Approval of new non-food use inert ingredient. (2)	6	15,803
I005	199	Amend currently approved non-food use inert ingredient with new use pattern; new data. (2)	6	7,903
I006	200	Amend currently approved non-food use inert ingredient with new use pattern; no new data. (2)	4	4,742
I007	201	Approval of substantially similar non-food use inert ingredients when original inert is compositionally similar with similar use pattern. (2)	5	2,371
I008	202	Approval of new or amended polymer inert ingredient, food use. (2)	7	5,374
I009	203	Approval of new or amended polymer inert ingredient, non-food use. (2)	4	4,427
I010	204	Petition to amend a single tolerance exemption descriptor, or single non-food use descriptor, to add ≤ 10 CASRNs; no new data. (2)	7	2,371
I011	205	Approval of new food use safener with tolerance or exemption from tolerance. (2)	26	856,631
I012	206	Approval of new non-food use safener. (2)	21	595,147
I013	207	Approval of additional food use for previously approved safener with tolerance or exemption from tolerance. (2)	17	90,260
I014	208	Approval of additional non-food use for previously approved safener. (2)	15	36,074
I015	209	Approval of new generic data for previously approved food use safener. (2)	26	386,589
I016	210	Approval of amendment(s) to tolerance and label for previously approved safener. (2)	15	79,942
I017	211 (new)	Add new source of previously approved safener.	8	18,958
I018	212 (new)	Petition to add one approved inert ingredient (CASRN) to the Commodity Inert Ingredient List; no data. (4)	3	2,371

(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 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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) 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) Due to low fee and short time frame this category is not eligible for small business waivers.

TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS

EPA No.	New CR No.	Action	Decision Review Time (Months)(1)	Registration Service Fee ($)
M001	213	Study protocol requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of a currently registered active ingredient.	14	11,378
M002	214	Completed study requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of an active ingredient. (2)	14	11,378
M003	215	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. (3)	12	91,651
M004	216	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. (3)	18	91,651
M005	217	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. (4)(5)(6)	9	31,604
M006	218	Request for up to 5 letters of certification (Gold Seal) for one actively registered product (excludes distributor products). (7)	1	398
M007	219	Request to extend Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(ii).	12	7,903
M008	220	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	2,371
M009	221	Non-FIFRA Regulated Determination; applicant-initiated, per product.	6	3,389
M010	222	Conditional ruling on pre-application, product substantial similarity.	4	3,389
M011	223	Label amendment to add the DfE logo; requires data review; no other label changes. (8)	4	5,230
M012	224 (new)	Request for up to 5 letters of certification (Certificate of Establishment) for one actively registered product or one product produced for export (excludes distributor products). (7)	1	398
M013	225 (new)	Cancer reassessment; applicant-initiated.	18	284,144
M014	227 (new)	Pre-application nano-particle determination.	8	17,424

(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) Any other covered application that is associated with and dependent on the review by the Human Studies Review Board 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.

(3) Any other covered application that is associated with and dependent on the FIFRA Scientific Advisory Panel 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.

(4) 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 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.

(5) 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.

(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.

(7) Due to low fee and short time frame this category is not eligible for small business waivers.

(8) This category includes amendments the sole purpose of which is to add ''Design for the Environment'' (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

Subject to the following sentence, effective for a covered application received during the period beginning on October 1, 2024, and ending on September 30, 2026, the Administrator may increase by 5 percent the registration service fee payable for the application under paragraph (3).[1] No adjustment may be made under the preceding sentence until the date on which the Administrator begins to implement clauses (i) and (ii) of subsection (k)(2)(A).

(B) Additional adjustment

Subject to the following sentence, effective for a covered application received on or after October 1, 2026, the Administrator may increase by an additional 5 percent the registration service fee in effect as of September 30, 2026. No adjustment may be made under the preceding sentence until the date on which the Administrator begins to implement any recommendations for process improvements contained in the report under subsection (c)(4), as appropriate.

(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 (including a Gold Seal letter and a Certificate of Establishment).

(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.

[1] See References in Text note below.

(iii) Inaccurate documentation

An application shall be subject to the applicable registration service fee payable under paragraph (3)(B) 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 covered registration service fees under this section.

(8) Refunds

(A) Early withdrawals

If, during the first 60 days after the beginning of the applicable decision time review period under subsection (f)(3), a covered 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)(B) 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)(B) 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

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

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).

(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) Endangered species review of outdoor use of pesticide products

(i) In general

The Administrator shall use the amounts made available in the Fund to develop, receive comments with respect to, and finalize, guidance to registrants regarding analysis necessary to support the review of outdoor uses of pesticide products under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.).

(ii) Deadlines for guidance

The Administrator shall issue final guidance required by clause (i) in accordance with the following:

(I) With respect to new active ingredients or any registration review decision proposed for 1 or more outdoor uses, not later than 9 months after December 29, 2022.

(II) With respect to new outdoor uses of a registered pesticide, not later than 1 year after December 29, 2022.

(III) With respect to antimicrobial pesticide products, not later than 3 years after December 29, 2022.

(C) Independent third party assessments

(i) In general

The Administrator shall use the amounts made available in the Fund to carry out the activities described in clauses (ii) and (iii).

(ii) Workforce assessment

(I) In general

The Administrator shall procure a competitive contract with a qualified, independent contractor with expertise in assessing public sector workforce data analysis and reporting to conduct an assessment of current methodologies and data or metrics available to represent the workforce implementing the Pesticide Registration Improvement Act of 2022 and the amendments made by that Act, including an assessment of filled and vacant positions and full-time equivalent employees relating to that implementation.

(II) Report

Not later than 2 years after December 29, 2022—

(aa) the contractor selected under subclause (I) shall submit to the Administrator a report describing—

(AA) the findings from the assessment under that subclause; and

(BB) recommendations for improved methodologies to represent full-time equivalent resources described in that subclause; and

(bb) the Administrator shall publish the report submitted under item (aa) on the website of the Environmental Protection Agency.

(iii) Process assessment

(I) In general

(aa) Contracts

Within 1 year of December 29, 2022, to the extent practicable, the Administrator shall issue a competitive contract to a private, independent consulting firm—

(AA) to conduct the assessment described in subclause (II); and

(BB) to submit to the Administrator a report describing the find-

ings of the assessment and the processes and performance of the Environmental Protection Agency relating to the implementation of the Pesticide Registration Improvement Act of 2022 and the amendments made by that Act.

(bb) Eligibility

The firm described in item (aa) shall be capable of performing the technical analysis, management assessment, and program evaluation tasks required to address the scope of the assessment under subclause (II).

(II) Assessment

(aa) In general

The Administrator, applicants, and registrants shall participate in a targeted assessment of the process for the review of applications submitted under this subchapter.

(bb) Consultation

The firm selected under subclause (I) shall consult with the Administrator and applicants at the start of the assessment under item (aa) and prior to submission of the report under subclause (I)(aa)(BB).

(cc) Requirements

The assessment under item (aa) shall evaluate and make recommendations regarding—

(AA) the initial content screen;

(BB) the preliminary technical screen;

(CC) performance, processes, and progress toward reducing renegotiation rates and the average length of renegotiations;

(DD) performance, processes, and progress toward eliminating the backlog of registrant submissions not covered by subsection (b)(3);

(EE) performance, processes, and progress toward ensuring that all registrant submissions not covered by subsection (b)(3) are completed by the applicable deadlines described in the notice of the Administrator entitled ''Pesticide Registration Notice (PR) 98–10: Notifications, Non-Notifications and Minor Formulation Amendments'' and dated October 22, 1998 (and any successor amendments to that notice) and described in subsections (c)(3)(B) and (h) of section 136a of this title;

(FF) compliance with the provisions of this subchapter relating to renegotiations and registrant submissions not covered by subsection (b)(3);

(GG) information technology systems;

(HH) recommended improvements to employee training;

(II) performance, progress, and processes in completing registration review; and

(JJ) other appropriate issues, such as submissions by inert suppliers and fast-track amendments under subsections (c)(3)(B) and (h) of section 136a of this title.

(III) Report to Congress

Not later than 1 year after the receipt of an assessment required under this section, the Administrator shall submit to the Committee on Agriculture, Nutrition, and Forestry of the Senate and the Committee on Agriculture of the House of Representatives—

(aa) a copy of each such assessment; and

(bb) the Administrator's evaluation of the findings and recommendations contained in each such assessment.

(IV) Recommendations

The Administrator shall include with the report submitted under subclause (III) a classification of each recommendation described in the report as—

(aa) can be implemented through administrative action of the Administrator; or

(bb) requires a statutory change.

(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;

(B) shall be available during periods in which Environmental Protection Agency employees are on shutdown or emergency furlough as a result of a lapse in appropriations; and

(C) 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 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 $166,000,000.

(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 and prevent double payment of registration fees

(1) Reduction of 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.

(2) Prevention of double payment of registration service fees

The Administrator shall develop and implement a process to determine the appropriate fee category or categories for an application that qualifies for more than one fee category in order to assist applicants and prevent unnecessary payment of fees for multiple categories for a single application.

(f) Decision time review periods

(1) In general

Not later than 30 days after the effective date of the Pesticide Registration Improvement Act of 2022, 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)(B) 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)(B).

(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)(B).

(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).

(III) Final fee category

The fee category of a covered application or other actions may not be changed, without providing the information to the applicant, after completion of the preliminary technical screening described in clause (iv).

(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 automate the process, to the maximum extent practicable, and 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—

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

(II) determine if 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;

(III) determine, if applicable, whether an application qualifies for a reduced risk determination under subsection (c)(10) or (h) of section 136a of this title;

(IV) grant or deny any data waiver requests submitted by the applicant with the application;

(V) verify and validate the accuracy of the fee category selected by the applicant; and

(VI) notify the applicant, in writing, if a new or different fee category is required and calculate the new decision review time based on the original submission date.

(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) Applications for reduced risk

(i) Fee

If an application for a reduced risk new active ingredient or a reduced risk new use is determined not to qualify as reduced risk, the applicant shall pay the difference in fee for the corresponding non-reduced risk application.

(ii) Decision review time period

After receipt by the Administrator of the original covered reduced risk application and fee, the decision time review period for the corresponding non-reduced risk application shall begin within the time periods described in subparagraph (A), based on the submission date of the original covered reduced risk application.

(5) Extension of decision time review period

(A) Notification

If the Administrator cannot meet a decision time review period under this subsection, the Administrator shall notify the applicant, in writing, of—

(i) the reasons why additional time is needed; and

(ii) the number of days needed that would allow the Administrator to make a regulatory decision.

(B) Extension by negotiation or mutual agreement

The Administrator, acting solely through the Director of the Office of Pesticide Programs, and the applicant may mutually agree, in writing, to extend a decision time review period under this subsection if—

(i) there is new or additional data or information from the applicant that is necessary for the Administrator to make a decision on the application that cannot be made available within the original decision time review period; or

(ii) a public comment period associated with the application generates significant comments that cannot be addressed within the original decision time review period.

(C) Priority

Once a decision time review period for a covered action described in subsection (b)(3)(B) is missed or extended, the Administrator shall make any action on the application a priority.

(g) Judicial review

(1) In general

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

(2) Scope

(A) In general

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

(B) Other actions

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

(3) Timing

(A) In general

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

(B) Meeting with Administrator

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

(4) Remedies

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

(h) Accounting

The Administrator shall—

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

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

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

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

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

(i) Auditing

(1) Financial statements of agencies

For the purpose of section 3515(c) of title 31, 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 and information technology

(1) Reports

(A) In general

Not later than 120 days after the last day of each of fiscal years 2023 through 2027, the Administrator shall publish an annual report describing—

(i) actions taken under this section;

(ii) registrant submissions not covered by subsection (b)(3)(B);

(iii) the initial content and preliminary technical screenings required in subsection (f)(4)(B); and

(iv) staffing relating to implementing the Pesticide Registration Improvement Act of 2022 and the amendments made by that Act.

(B) Contents

Each report published under subparagraph (A) shall include a summary of the following information:

(i) Actions under this section

To the extent practicable, data for each action taken under this section that is completed during the fiscal year covered by the report or pending at the conclusion of that fiscal year, organized by registering division, including—

(I) the Action Code;

(II) the application receipt date;

(III) the electronic portal tracking number assigned to the application at the time of submission to the electronic submission portal or the Environmental Protection Agency tracking number;

(IV) the original decision due date based on the Action Code;

(V) the dates of any renegotiations and the renegotiated due dates, if applicable;

(VI) the reasons for each renegotiation, if applicable;

(VII) if the submission had to be recoded, reassigned codes, if applicable;

(VIII) the date that the submission was recoded, if applicable;

(IX) the decision completion date, if the action has been completed;

(X) the status of the action, which may be—

(aa) failed initial content screen;

(bb) failed preliminary technical screen;

(cc) approved;

(dd) withdrawn;

(ee) denied;

(ff) do not grant; or

(gg) pending;

(XI) the reason for any denial or do not grant decision, if applicable;

(XII) a review of the progress made in carrying out each requirement of subsections (e) and (f), including, 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 the allowance and use of summaries of acute toxicity studies;

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

(aa)[3] the number of pesticides or pesticide cases reviewed and the number of registration review decisions completed, including—

(AA) the number of cases cancelled;

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

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

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

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

(XIV) a review of the progress made toward implementing enhancements to—

(aa) the electronic tracking of conditional registrations; and

(bb) the endangered species database;

(XV) 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);

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

(XVII) the number of the active ingredients approved, 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;

(XVIII) with respect to funds in the Reregistration and Expedited Processing Fund described under section 136a–1(k) of this title, a review that includes—

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

(AA) to carry out activities relating to worker protection under sub-

[3] So in original. There is no item (bb).

paragraphs (G) and (H) of section 136a–1(i)(1) of this title;

(BB) to award partnership grants under subparagraph (I) of such section; and

(CC) to carry out the pesticide safety education program under subparagraph (J) of such section;

(bb) an evaluation of the appropriateness and effectiveness of the activities, grants, and program under subparagraphs (G), (H), (I), and (J) of such section;

(cc) a description of how stakeholders are engaged in the decision to fund such activities, grants, and program in accordance with the stakeholder input provided under such subparagraphs; and

(dd) with respect to activities relating to worker protection carried out under subparagraphs (G) and (H) of section 136a–1(i)(1) of this title, a summary of the analyses from stakeholders, including from worker community-based organizations, on the appropriateness and effectiveness of such activities.

(XIX) beginning two years after enactment, report on the progress of meeting the deadlines listed in paragraph (5) of section 136a(f) of this title; and

(XX) a review of progress made in implementing the pesticide surveillance program referred to in paragraph (8) of section 136a–1(k) of this title.

(ii) Registrant submissions not covered by subsection (b)(3)(B)

Each registrant submission not covered by subsection (b)(3)(B), that is completed during the fiscal year covered by the report or pending at the conclusion of that fiscal year, organized by registering division, including—

(I) the submission date;

(II) the electronic portal tracking number assigned to the application at the time of the submission of the application to the electronic submission portal;

(III) the type of regulatory action, as defined by statute or guidance document, and the specific label action;

(IV) the status of the action;

(V) the due date;

(VI) the reason for the outcome; and

(VII) the completion date, if applicable.

(iii) Screening process

Data for the initial content screens and preliminary technical screens that are completed during the fiscal year covered by the report or pending at the conclusion of that fiscal year, organized by registering division, including—

(I) the number of applications successfully passing each type of screen;

(II) the number of applications that failed the screening process for each type of screen;

(III) the number of notifications issued by the Administrator under subsection (f)(4)(B)(ii)(II);

(IV) the number of notifications issued by the Administrator under subsection (f)(4)(B)(ii)(I) and the number of applications resulting in a rejection; and

(V) the number of notifications issued under section 152.105 of title 40, Code of Federal Regulations (or successor regulations), and to the extent practicable, the reasons for that issuance.

(iv) Staffing

Data on the staffing relating to work covered under the Pesticide Registration Improvement Act of 2022 and the amendments made by that Act, organized by registering division, including—

(I) the number of new hires and personnel departures;

(II) the number of full-time equivalents at the end of each fiscal year;

(III) the number of full-time equivalents working on registration review activities; and

(IV) the number of full-time equivalents working on registrant submissions not covered by subsection (b)(3)(B).

(C) Publication

The Administrator shall publish each report under subparagraph (A)—

(i) on the website of the Environmental Protection Agency; and

(ii) by such other methods as the Administrator determines to be the most effective for efficiently disseminating the report.

(2) Information technology

(A) System

Not later than 1 year after December 29, 2022, the Administrator shall establish an information technology system that—

(i) includes all registering divisions in the Office of Pesticide Programs;

(ii) provides a real-time, accurate, tracking system for all regulatory submissions to the Office of Pesticide Programs;

(iii) provides a[4] real-time, accessible information[4] that provides each applicant confidential, online access to the status and progress of the regulatory submissions of the applicant; and

(iv) updates the electronic submission portal—

(I) to ensure that label reviews are limited to current label changes, to the maximum extent practicable;

(II) to automate, to the extent practicable, minor, low risk regulatory actions; and

(III) to allow self-certification of certain regulatory actions, as determined by the Administrator.

(B) Access to registration data and decisions

The Administrator shall implement efforts to expand existing, and develop new, infor-

[4] So in original.

mation technology tools and databases to improve access by Environmental Protection Agency employees to data used to fulfill registrations, and public access to information about regulatory decisionmaking tools, including opportunities for—

(i) analysis of the impact of submitted studies on Environmental Protection Agency assessments and decisions;

(ii) facilitation of read-across or computational model development to help fill information gaps;

(iii) tracking and reporting submission and decision metrics relating to the use and acceptance of test methods; and

(iv) drafting and publication of policies communicating Environmental Protection Agency acceptance of novel technologies or approaches.

(*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, 2027.

(2) Phase out

(A) Fiscal year 2028

During fiscal year 2028, 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, 2027.

(B) Fiscal year 2029

During fiscal year 2029, 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, 2027.

(C) September 30, 2029

Effective September 30, 2029, 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, 2027, 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, 2027, 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; Pub. L. 117–328, div. HH, title VI, §§705, 706, Dec. 29, 2022, 136 Stat. 6008, 6018.)

Editorial Notes

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, 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.

Paragraph (3), referred to in subsec. (b)(6)(A), probably should be a reference to paragraph (3)(B). Amendment by section 705(a)(1)(B) of Pub. L. 117–328 substituting ''paragraph (3)(B)'' for ''paragraph (3)'' wherever appearing in subsec. (b) was followed by the general amendment of subsec. (b)(6)(A) by section 705(a)(1)(D)(i) of Pub. L. 117–328, which contained the reference to paragraph (3).

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 Endangered Species Act of 1973, referred to in subsec. (c)(3)(B)(i), is Pub. L. 93–205, Dec. 28, 1973, 87 Stat. 884, which is classified principally to chapter 35 (§1531 et seq.) of Title 16, Conservation. For complete classification of this Act to the Code, see Short Title note set out under section 1531 of Title 16 and Tables.

The Pesticide Registration Improvement Act of 2022, referred to in subsecs. (c)(3)(C)(ii)(I), (iii)(I)(aa)(BB) and (k)(1)(A)(iv), (B)(iv), is title VI (§701 et seq.) of div. HH of Pub. L. 117–328, Dec. 29, 2022, 136 Stat. 5996. For complete classification of this Act to the Code, see Short Title of 2022 Amendment note set out under section 136 of this title and Tables.

The effective date of the Pesticide Registration Improvement Extension Act of 2018, referred to in subsec. (e), means the effective date of Pub. L. 116–8, which was approved Mar. 8, 2019.

The effective date of the Pesticide Registration Improvement Act of 2022, referred to in subsec. (f)(1), means the effective date of title VI of div. HH of Pub. L. 117–263, which was approved Dec. 29, 2022.

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. 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.

Two years after enactment, referred to in subsec. (k)(1)(B)(i)(XIX), means two years after the enactment of section 136a(f)(5) of this title, as enacted by Pub. L. 117–328, which was approved Dec. 29, 2022.

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

2022—Subsec. (b). Pub. L. 117–328, §705(a)(1)(B), substituted ''paragraph (3)(B)'' for ''paragraph (3)'' wher-

ever appearing. Subsec. (b)(6)(A) was subsequently amended generally by Pub. L. 117–328, §705(a)(1)(D)(i), after which ''paragraph (3)'' appeared in text.

Subsec. (b)(2)(E)(iii). Pub. L. 117–328, §705(a)(1)(A), substituted ''on completion of, where appropriate, the initial screening of the contents of the application or the preliminary technical screening'' for ''after review''.

Subsec. (b)(3). Pub. L. 117–328, §705(a)(1)(C), designated existing provisions as subpar. (B), inserted heading, and added subpar. (A).

Subsec. (b)(3)(B). Pub. L. 117–328, §706, added subpar. (B) and struck out former subpar. (B), as designated by section 705(a)(1)(C) of Pub. L. 117–263, which set out the schedule of covered applications and other actions and their registration service fees.

Subsec. (b)(6)(A), (B). Pub. L. 117–328, §705(a)(1)(D), which directed amendment of subpars. (A) and (B) ''to read as follows'' but did not include subpar. designations or headings, was executed by amending the text only and retaining the existing designations and headings, to reflect the probable intent of Congress. Prior to amendment, subpars. (A) and (B) related to fee adjustment between Oct. 1, 2019, and Sept. 30, 2021, and an additional fee adjustment starting on Oct. 1, 2021.

Subsec. (b)(7)(A). Pub. L. 117–328, §705(a)(1)(E), substituted ''(including a Gold Seal letter and a Certificate of Establishment)'' for ''(commonly referred to as a Gold Seal letter)''.

Subsec. (c)(3)(B), (C). Pub. L. 117–328, §705(b)(1), added subpars. (B) and (C) and struck out former subpar. (B). Prior to amendment, text of subpar. (B) read as follows:

''(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.''

Subsec. (c)(4)(B), (C). Pub. L. 117–328, §705(b)(2), added subpar. (B) and redesignated former subpar. (B) as (C).

Subsec. (d)(2). Pub. L. 117–328, §705(c), struck out ''(as in existence in fiscal year 2012)'' after ''for the functions'' and substituted ''$166,000,000.'' for ''the amount of appropriations for covered functions for fiscal year 2012 (excluding the amount of any fees appropriated for the fiscal year).''

Subsec. (e). Pub. L. 117–328, §705(d), substituted ''Reforms to reduce decision time review periods and prevent double payment of registration fees'' for ''Reforms to reduce decision time review periods'' in subsec. heading, designated existing provisions as par. (1) and inserted par. heading, and added par. (2).

Subsec. (f). Pub. L. 117–328, §705(a)(2), substituted ''subsection (b)(3)(B)'' for ''subsection (b)(3)'' wherever appearing.

Subsec. (f)(1). Pub. L. 117–328, §705(e)(1), substituted ''Pesticide Registration Improvement Act of 2022'' for ''Pesticide Registration Improvement Extension Act of 2018''.

Subsec. (f)(4)(B)(i)(III). Pub. L. 117–328, §705(e)(2)(A)(i), added subcl. (III).

Subsec. (f)(4)(B)(iii). Pub. L. 117–328, §705(e)(2)(A)(ii), inserted ''automate the process, to the maximum extent practicable, and'' before ''determine'' in introductory provisions.

Subsec. (f)(4)(B)(iv). Pub. L. 117–328, §705(e)(2)(A)(iii), struck out ''determine if'' after ''shall'' in introductory provisions, inserted ''determine if'' at beginning of subcls. (I) and (II), and added subcls. (III) to (VI).

Subsec. (f)(4)(E). Pub. L. 117–328, §705(e)(2)(B), added subpar. (E) and struck out former subpar. (E). Prior to amendment, text read as follows: ''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.''

Subsec. (f)(5). Pub. L. 117–328, §705(e)(3), added par. (5) and struck out former par. (5). Prior to amendment, text read as follows: ''The Administrator and the applicant may mutually agree in writing to extend a decision time review period under this subsection.''

Subsec. (k). Pub. L. 117–328, §705(f), added subsec. (k) and struck out former subsec. (k) which related to publication of annual reports and submission of another report to Congress.

Subsec. (m). Pub. L. 117–328, §705(g)(1), substituted ''2027'' for ''2023'' wherever appearing.

Subsec. (m)(2)(A). Pub. L. 117–328, §705(g)(2)(A), substituted ''2028'' for ''2024'' in heading and text.

Subsec. (m)(2)(B), (C). Pub. L. 117–328, §705(g)(2)(B), substituted ''2029'' for ''2025'' in heading and text.

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 1/34 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.

Statutory Notes and Related Subsidiaries

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.

IMPLEMENTATION DATES WITH RESPECT TO FEES

Increases in registration service fees specified in this section, as amended by title VI of div. HH of Pub. L. 117–328, not effective until 60 days after Dec. 29, 2022, regardless of whether this section specifies such increases to be effective for fiscal year 2023, see section 708(a)(1) of Pub. L. 117–328, set out in a note under section 136a–1 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, formerly 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, extended the authority provided by this section until Sept. 30, 2018.

§ 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.)

Editorial Notes

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.

Statutory Notes and Related Subsidiaries

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.)

Editorial Notes

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.''

1985—Pub. L. 99–198 substituted provisions authorizing appropriations of $68,604,200 for fiscal year 1986 of which not more than $11,993,100 shall be available for research for former provisions which had authorized appropriations for fiscal years 1973 through 1984.

1983—Pub. L. 98–201 authorized necessary appropriations for period beginning Oct. 1, 1983, and ending Sept. 30, 1984, not in excess of $64,200,000.

1980—Pub. L. 96–539 inserted provisions authorizing appropriations for period beginning Oct. 1, 1979, and ending Sept. 30, 1980, and for period beginning Oct. 1, 1980, and ending Sept. 30, 1981.

1978—Pub. L. 95–396, § 25, substituted appropriations authorization of $46,636,000 for period beginning Oct. 1, 1976, and ending Sept. 30, 1977, for prior authorization of $23,600,000 for period beginning Oct. 1, 1976, and ending Mar. 31, 1977, and authorized appropriations of $54,500,000 for period beginning Oct. 1, 1977, and ending Sept. 30, 1978, and such sums as may be necessary, limited to $70,000,000, for period beginning Oct. 1, 1978, and ending Sept. 30, 1979.

1975—Pub. L. 94–140 authorized appropriation of $47,868,000 to carry out provisions of this subchapter for period beginning Oct. 1, 1975, and ending Sept. 30, 1976, and $23,600,000 for period beginning Oct. 1, 1976, and ending Mar. 31, 1977.

Pub. L. 94–109 inserted provisions authorizing appropriation of $5,983,500 for period beginning Oct. 1, 1975 and ending Nov. 15, 1975.

Pub. L. 94–51 authorized appropriation of $11,967,000 to carry out provisions of this subchapter for period beginning July 1, 1975, and ending Sept. 30, 1975.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100–532, title VII, § 701, Oct. 25, 1988, 102 Stat. 2679, provided that amendment made by Pub. L. 100–532 is effective Oct. 1, 1988.

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.

CHAPTER 6A—NATIONAL LABORATORY ACCREDITATION

§ 138. Definitions

As used in this chapter:

(1) Agricultural product

The term ''agricultural product'' means any fresh fruit or vegetable or any commodity or