Comparative Print: Changes in Existing Law for Bill number:

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Summary

(1) 51 amendments.
(2) 1 automated notification.

Current Law(s) being amended

1. Federal Insecticide Fungicide and Rodenticide Act
2. Federal Food Drug and Cosmetic Act

Comparative Print: Changes in Existing Law

1. Federal Insecticide Fungicide and Rodenticide Act

[As Amended Through P.L. 116–8, Enacted March 08, 2019]

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Sec. 3. REGISTRATION OF PESTICIDES.

(a) **Requirement of Registration.—** Except as provided by this Act, no person in any State may distribute or sell to any person any pesticide that is not registered under this Act. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this Act and that is not the subject of an experimental use permit under section 5 or an emergency exemption under section 18.

(b) **Exemptions.—** A pesticide which is not registered with the Administrator may be transferred if —

(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

(c) **Procedure for Registration.—**

(1) **Statement required.—** Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this Act after the date of enactment of the Federal Pesticide Act of 1978 **[**September 30, 1978**]** , data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data.

(ii) The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after the date of enactment of this clause **[**Aug. 3, 1996**]** and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that—

(I) there are insufficient efficacious alternative registered pesticides available for the use;

(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;

(III) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this

clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

(iii) Except as otherwise provided in clause (i), with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this Act, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation.

(iv) After expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under clauses (i), (ii), and (iii), the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data.

(v) The period of exclusive use provided under clause (ii) shall not take effect until 1 year after enactment of this clause [Aug. 3, 1996] , except where an applicant or registrant is applying for the registration of a pesticide containing an active ingredient not previously registered.

(vi) With respect to data submitted after the date of enactment of this clause [Aug. 3, 1996] by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of a pesticide, such data shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. The applicant or registrant at the time the new minor use is requested shall notify the Administrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph. If the minor use registration which is supported by data submitted pursuant to this subsection is voluntarily canceled or if such data are subsequently used to support a nonminor use, the data shall no longer be subject to the exclusive use provisions of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.

(G) If the applicant is requesting that the registration or amendment to the registration of a pesticide be expedited, an explanation of the basis for the request must be submitted, in accordance with paragraph (10) of this subsection.

(2) **Data in support of registration.—**

(A) **In general.—** The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter the Administrator requires any additional kind of information under subparagraph (B) of this paragraph, the Administrator shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, the public health and agricultural need for such minor use, and the level and degree of potential beneficial or adverse effects on man and the environment. The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this Act, any field residue data from a geographic area where the pesticide will not be registered for such use. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 10, within 30 days after the Administrator registers a pesticide under this Act the Administrator shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the Administrator's decision.

(B) **Additional data.—** (i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iv) Notwithstanding any other provision of this Act, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 6(d) of this Act. The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this Act, a hearing shall be held and a

determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of paragraph (1)(D). Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.

(vi) Upon the request of a registrant the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under section 4 for the other uses of the pesticide established as of the date of enactment of the Food Quality Protection Act of 1996 [Aug. 3, 1996] , if—

(I) the data to support other uses of the pesticide on a food are being provided;

(II) the registrant, in submitting a request for such an extension, provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(III) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under section 4; and

(IV) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment.[6] If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this clause, the Administrator may take action to modify or revoke the extension under this clause if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide, in writing to the registrant, a notice revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date established by the Administrator for the submission of the data.

6

Indentation of the following sentences of this clause is so in original (as added by sec. 201(c)(1) of P.L. 104–170). Probably should be indented the same as flush matter of this clause.

(vii) If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this clause in regard to such unsupported minor use until the final deadline established as of the date of enactment of the Food Quality Protection Act of 1996 **[**Aug. 3, 1996**]** , for the submission of data under section 4 for the supported uses identified pursuant to this clause unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 6(f)(1). If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of this subparagraph regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 6(f)(2). Notwithstanding the provisions of this clause, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(viii) (I) If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant.

(II) The Administrator may enter into a cooperative agreement with a State to carry out subclause (I).

(III) Not later than 1 year after the date of enactment of this clause **[**Aug. 3, 1996**]** , the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.

(C) **Simplified procedures.—** Within nine months after the date of enactment of this subparagraph **[**September 30, 1978**]** , the Administrator shall, by regulation, prescribe simplified

procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

(D) **Exemption.—** No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to—

(i) submit or cite data pertaining to such purchased product; or

(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

(E) **Minor use waiver.—** In handling the registration of a pesticide for a minor use, the Administrator may waive otherwise applicable data requirements if the Administrator determines that the absence of such data will not prevent the Administrator from determining—

(i) the incremental risk presented by the minor use of the pesticide; and

(ii) that such risk, if any, would not be an unreasonable adverse effect on the environment.

(3) **Time for acting with respect to Application.—**

(A) **In general.—** The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of the Administrator's determination that it does not comply with the provisions of the Act in accordance with paragraph (6).

(B) **Identical or substantially similar.—** (i) The Administrator shall, as expeditiously as possible, review and act on any application received by the Administrator that—

(I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or

(II) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data.

(ii) In expediting the review of an application for an action described in clause (i), the Administrator shall—

(I) review the application in accordance with section 33(f)(4)(B) and, if the application is found to be incomplete, reject the application;

(II) not later than the applicable decision review time established pursuant to section 33(f)(4)(B), or, if no review time is established, not later than 90 days after receiving a complete application, notify the registrant if the application has been granted or denied; and

(III) if the application is denied, notify the registrant in writing of the specific reasons for the denial of the application.

(C) **Minor use registration.—**

(i) The Administrator shall, as expeditiously as possible, review and act on any complete application—

(I) that proposes the initial registration of a new pesticide active ingredient if the active ingredient is proposed to be registered solely for minor uses, or proposes a registration amendment solely for minor uses to an existing registration; or

(II) for a registration or a registration amendment that proposes significant minor uses.

(ii) For the purposes of clause (i)—

(I) the term "as expeditiously as possible" means that the Administrator shall, to the greatest extent practicable, complete a review and evaluation of all data, submitted with a complete application, within 12 months after the submission of the complete application, and the failure of the Administrator to complete such a review and evaluation under clause (i) shall not be subject to judicial review; and

(II) the term "significant minor uses" means 3 or more minor uses proposed for every nonminor use, a minor use that would, in the judgment of the Administrator, serve as a replacement for any use which has been canceled in the 5 years preceding the receipt of the application, or a minor use that in the opinion of the Administrator would avoid the reissuance of an emergency exemption under section 18 for that minor use.

(D) **Adequate time for submission of minor use data.—** If a registrant makes a request for a minor use waiver, regarding data required by the Administrator, pursuant to paragraph (2)(E), and if the Administrator denies in whole or in part such data waiver request, the registrant shall have a full-time period for providing such data. For purposes of this subparagraph, the term "full-time period" means the time period originally established by the Administrator for submission of such data, beginning with the date of receipt by the registrant of the Administrator's notice of denial.

(4) **Notice of application.—** The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

(5) **Approval of registration.—** The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d)—

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this Act;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 24(c) of this Act, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

(6) **Denial of registration.—** If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, the Administrator shall notify the applicant for registration of the Administrator's determination and of the Administrator's reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of the Administrator's decision and of the Administrator's reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 6.

(7) **Registration under special circumstances.—** Notwithstanding the provisions of paragraph (5)—

(A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this Act.

(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provisions of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations issued under this Act, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this Act.

(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator

receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this Act, and on such other conditions as the Administrator may prescribe. A conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

(8) **Interim administrative review.—** Notwithstanding any other provision of this Act, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this Act, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms "validated test" and "other significant evidence" as used herein shall be published by the Administrator in the Federal Register.

(9) **Labeling.—**

(A) **Additional statements.—** Subject to subparagraphs (B) and (C), it shall not be a violation of this Act for a registrant to modify the labeling of an antimicrobial pesticide product to include relevant information on product efficacy, product composition, container composition or design, or other characteristics that do not relate to any pesticidal claim or pesticidal activity.

(B) **Requirements.—** Proposed labeling information under subparagraph (A) shall not be false or misleading, shall not conflict with or detract from any statement required by law or the Administrator as a condition of registration, and shall be substantiated on the request of the Administrator.

(C) **Notification and disapproval.—**

(i) **Notification.—** A registration may be modified under subparagraph (A) if —

(I) the registrant notifies the Administrator in writing not later than 60 days prior to distribution or sale of a product bearing the modified labeling; and

(II) the Administrator does not disapprove of the modification under clause (ii).

(ii) **Disapproval.—** Not later than 30 days after receipt of a notification under clause (i), the Administrator may disapprove the modification by sending the registrant notification in writing stating that the proposed language is not acceptable and stating the reasons why the Administrator finds the proposed modification unacceptable.

(iii) **Restriction on sale.—** A registrant may not sell or distribute a product bearing a disapproved modification.

(iv) **Objection.—** A registrant may file an objection in writing to a disapproval under clause (ii) not later than 30 days after receipt of notification of the disapproval.

(v) **Final action.—** A decision by the Administrator following receipt and consideration of an objection filed under clause (iv) shall be considered a final agency action.

(D) **Use dilution.—** The label or labeling required under this Act for an antimicrobial pesticide that is or may be diluted for use may have a different statement of caution or protective measures for use of the recommended diluted solution of the pesticide than for use of a concentrate of the pesticide if the Administrator determines that —

(i) adequate data have been submitted to support the statement proposed for the diluted solution uses; and

(ii) the label or labeling provides adequate protection for exposure to the diluted solution of the pesticide.

(10) **Expedited registration of pesticides.—**

(A) Not later than 1 year after the date of enactment of this paragraph [Aug. 3, 1996] , the Administrator shall, utilizing public comment, develop procedures and guidelines, and expedite the review of an application for registration of a pesticide or an amendment to a registration that satisfies such guidelines.

(B) Any application for registration or an amendment, including biological and conventional pesticides, will be considered for expedited review under this paragraph. An application for registration or an amendment shall qualify for expedited review if use of the pesticide proposed by the application may reasonably be expected to accomplish 1 or more of the following:

(i) Reduce the risks of pesticides to human health.

(ii) Reduce the risks of pesticides to nontarget organisms.

(iii) Reduce the potential for contamination of groundwater, surface water, or other valued environmental resources.

(iv) Broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective.

(C) The Administrator, not later than 30 days after receipt of an application for expedited review, shall notify the applicant whether the application is complete. If it is found to be incomplete, the Administrator may either reject the request for expedited review or ask the applicant for additional information to satisfy the guidelines developed under subparagraph (A).

(11) **Interagency working group.—**

(A) **Definition of covered agency.—** In this paragraph, the term "covered agency" means any of the following:

(i) The Department of Agriculture.

(ii) The Department of Commerce.

(iii) The Department of the Interior.

(iv) The Council on Environmental Quality.

(v) The Environmental Protection Agency.

(B) **Establishment.—** The Administrator shall establish an interagency working group, to be comprised of representatives from each covered agency, to provide recommendations regarding, and to implement a strategy for improving, the consultation process required under section 7 of the Endangered Species Act of 1973 (16 U.S.C. 1536) for pesticide registration and registration review.

(C) **Duties.—** The interagency working group established under subparagraph (B) shall—

(i) analyze relevant Federal law (including regulations) and case law for purposes of providing an outline of the legal and regulatory framework for the consultation process referred to in that subparagraph, including—

(I) requirements under this Act and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.);

(II) Federal case law regarding the intersection of this Act and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.); and

(III) Federal regulations relating to the pesticide consultation process;

(ii) provide advice regarding methods of—

(I) defining the scope of actions of the covered agencies that are subject to the consultation requirement referred to in subparagraph (B); and

(II) properly identifying and classifying effects of actions of the covered agencies with respect to that consultation requirement;

(iii) identify the obligations and limitations under Federal law of each covered agency for purposes of providing a legal and regulatory framework for developing the recommendations referred to in subparagraph (B);

(iv) review practices for the consultation referred to in subparagraph (B) to identify problem areas, areas for improvement, and best practices for conducting that consultation among the covered agencies;

(v) develop scientific and policy approaches to increase the accuracy and timeliness of the process for that consultation, in accordance with requirements of this Act and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.), including—

(I) processes to efficiently share data and coordinate analyses among the Department of Agriculture, the Department of Commerce, the Department of the Interior, and the Environmental Protection Agency;

(II) a streamlined process for identifying which actions require no consultation, informal consultation, or formal consultation;

(III) an approach that will provide clarity with respect to what constitutes the best scientific and commercial data available in the fields of pesticide use and ecological risk assessment, pursuant to section 7(a)(2) of the Endangered Species Act of 1973 (16 U.S.C. 1536(a)(2)); and

(IV) approaches that enable the Environmental Protection Agency to better assist the Department of the Interior and the Department of Commerce in carrying out obligations under that section in a timely and efficient manner; and

(vi) propose and implement a strategy to implement approaches to consultations under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.) and document that strategy in a memorandum of understanding, revised regulations, or another appropriate format to promote durable cooperation among the covered agencies.

(D) **Reports.—**

(i) **Progress reports.—**

(I) **In general.—** Not later than 18 months after the date of enactment of this paragraph, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing the progress of the working group in developing the recommendations under subparagraph (B).

(II) **Requirements.—** The report under this clause shall—

(aa) reflect the perspectives of each covered agency; and

(bb) identify areas of new consensus and continuing topics of disagreement and debate.

(ii) **Results.—**

(I) **In general.—** Not later than 1 year after the date of enactment of this paragraph, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing—

(aa) the recommendations developed under subparagraph (B); and

(bb) plans for implementation of those recommendations.

(II) **Requirements.—** The report under this clause shall—

(aa) reflect the perspectives of each covered agency; and

(bb) identify areas of consensus and continuing topics of disagreement and debate, if any.

(iii) **Implementation.—** Not later than 1 year after the date of submission of the report under clause (i), the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing—

(I) the implementation of the recommendations referred to in that clause;

(II) the extent to which that implementation improved the consultation process referred to in subparagraph (B); and

(III) any additional recommendations for improvements to the process described in subparagraph (B).

(iv) **Other reports.—** Not later than the date that is 180 days after the date of submission of the report under clause (iii), and not less frequently than once every 180 days thereafter during the 5-year period beginning on that date, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing—

(I) the implementation of the recommendations referred to in that clause;

(II) the extent to which that implementation improved the consultation process referred to in subparagraph (B); and

(III) any additional recommendations for improvements to the process described in subparagraph (B).

(E) **Consultation with private sector.—** In carrying out the duties under this paragraph, the working group shall, as appropriate—

(i) consult with, representatives of interested industry stakeholders and nongovernmental organizations; and

(ii) take into consideration factors, such as actual and potential differences in interest between, and the views of, those stakeholders and organizations.

(F) **Federal advisory committee act.—** The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the working group established under this paragraph.

(G) **Savings clause.—** Nothing in this paragraph supersedes any provision of—

(i) this Act; or

(ii) the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.), including the requirements under section 7 of that Act (16 U.S.C. 1536).

(d) **Classification of Pesticides.—**

(1) **Classification for general use, restricted use, or both.—**

(A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use. If the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, the Administrator shall classify it for both general use and restricted use. Pesticide uses may be classified by regulation on the initial classification and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are classified for general use and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses. The Administrator may require that its packaging and labeling for restricted uses shall be clearly distinguishable from its packaging and labeling for general uses.

(B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment, the Administrator will classify the pesticide, or the particular use or uses of the pesticide to which the determination applies, for general use.

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, the Administrator shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use:

(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.

(ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.

(2) **Change in classification.—** If the Administrator determines that a change in the classification of any use of a pesticide from general use to restricted use is necessary to prevent unreasonable adverse effects on the environment, the Administrator shall notify the registrant of such pesticide of such determination at least forty-five days before making the change and shall publish the proposed change in the Federal Register. The registrant, or other interested person with the concurrence of the registrant, may seek relief from such determination under section 6(b).

(3) **Change in classification from restricted use to general use.—** The registrant of any pesticide with one or more uses classified for restricted use may petition the Administrator to change any such classification from restricted to general use. Such petition shall set out the basis for the registrant's position that restricted use classification is unnecessary because classification of the pesticide for general use would not cause unreasonable adverse effects on the environment. The Administrator, within sixty days after receiving such petition, shall notify the registrant whether the

petition has been granted or denied. Any denial shall contain an explanation therefor and any such denial shall be subject to judicial review under section 16 of this Act.

(e) **Products With Same Formulation and Claims.—** Products which have the same formulation, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same pesticide may be registered as a single pesticide; and additional names and labels shall be added to the registration by supplemental statements.

(f) **Miscellaneous.—**

(1) **Effect of change of labeling or formulation.—** If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this Act.

(2) **Registration not a defense.—** In no event shall registration of an article be construed as a defense for the commission of any offense under this Act. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the Act.

(3) **Authority to consult other federal agencies.—** In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency.

(4) **Mixtures of nitrogen stabilizers and fertilizer products.—** Any mixture or other combination of—

(A) 1 or more nitrogen stabilizers registered under this Act; and

(B) 1 or more fertilizer products,

shall not be subject to the provisions of this section or sections 4, 5, 7, 15, and 17(a)(2) if the mixture or other combination is accompanied by the labeling required under this Act for the nitrogen stabilizer contained in the mixture or other combination, the mixture or combination is mixed or combined in accordance with such labeling, and the mixture or combination does not contain any active ingredient other than the nitrogen stabilizer.

(5) BILINGUAL LABELING.—

(A) REQUIREMENT.—

(i) IN GENERAL.— Subject to clause (ii), not later than the applicable deadline described in subparagraph (B), each registered pesticide product released for shipment shall include —

(I) the translation of the parts of the labeling contained in the Spanish Translation Guide described in subparagraph (G) on the product container; or

(II) a link to such translation via scannable technology or other electronic methods readily accessible on the product label.

(ii) EXCEPTIONS.— Notwithstanding clause (i)—

(I) an antimicrobial pesticide product may, in lieu of including a translation or a link under clause (i), provide a link to the safety data sheets in Spanish via scannable technology or other electronic methods readily accessible on the product label; or

(II) a non-agricultural pesticide product that is not classified by the Administrator as restricted use under subsection (d)(1)(A) may, in lieu of including a translation or a link under clause (i), provide a link to the safety data sheets in Spanish via scannable technology or other electronic methods readily accessible on the product label.

(B) DEADLINES FOR BILINGUAL LABELING.—

(i) PESTICIDE PRODUCTS CLASSIFIED AS RESTRICTED USE.— In the case of pesticide products classified by the Administrator as restricted use under subsection (d)(1)(A), the deadline specified in this subparagraph is the date that is 3 years following the date of enactment of this paragraph.

(ii) PESTICIDE PRODUCTS NOT CLASSIFIED AS RESTRICTED USE.— In the case of pesticide products not classified by the Administrator as restricted use under subsection (d)(1)(A), the deadline specified in this subparagraph shall be as follows:

(I) AGRICULTURAL.—

(aa) ACUTE TOXICITY CATEGORY I.— For agricultural pesticides classified as Acute Toxicity Category I, the date that is 3 years after the date of enactment of this paragraph.

(bb) ACUTE TOXICITY CATEGORY II.— For agricultural pesticides classified as Acute Toxicity Category II, the date that is 5 years after the date of enactment of this paragraph.

(II) ANTIMICROBIAL AND NON-AGRICULTURAL.—

(aa) ACUTE TOXICITY CATEGORY I.— For antimicrobial and non-agricultural pesticide products classified as Acute Toxicity Category I, the date that is 4 years after the date of enactment of this paragraph.

(bb) ACUTE TOXICITY CATEGORY II.— For antimicrobial and non-agricultural pesticide products classified as Acute Toxicity Category II, the date that is 6 years after the date of enactment of this paragraph.

(III) OTHER PESTICIDE PRODUCTS.— With respect to pesticide products not described in subclause (I) or (II), the date that is 8 years after the date of enactment of this paragraph.

(C) IMPLEMENTATION.—

(i) NON-NOTIFICATION.—

(I) IN GENERAL.— In carrying out this paragraph, the Administrator shall allow translations of the parts of the label of a pesticide contained in the Spanish Translation Guide described in subparagraph (G) and scannable technology or other electronic methods to be added using non-notification procedures.

(II) NON-NOTIFICATION PROCEDURE DEFINED.— In this clause, the term '"non-notification procedure"' refers to a procedure under which a change may be made to a pesticide label without notifying the Administrator.

(ii) COOPERATION AND CONSULTATION.— In carrying out this paragraph, the Administrator shall cooperate and consult with State lead agencies for pesticide regulation for the purpose of implementing bilingual labeling as provided in this paragraph as expeditiously as possible.

(iii) END USE LABELING.— The labeling requirements of this paragraph shall apply to end use product labels.

(iv) INCORPORATION TIMEFRAME.— After initial translation deadlines provided in subparagraph (B), updates to the Spanish Translation Guide described in subparagraph (G) shall be incorporated into labeling on the earlier of—

(I) in the case of agricultural use pesticide labels, as determined by the Administrator—

(aa) 1 year after the date of publication of the updated Spanish Label Translation Guide described in subparagraph (G); or

(bb) the released for shipment date specified on the EPA Stamped Approved Label after the pesticide label is next changed or amended following the date of publication of the updated Spanish Label Translation Guide described in subparagraph (G); and

(II) in the case of antimicrobial and non-agricultural use pesticide labels, as determined by the Administrator—

(aa) 2 years after the date of publication of the updated Spanish Label Translation Guide described in subparagraph (G); or

(bb) the released for shipment date specified on the EPA Stamped Approved Label after the pesticide label is next changed or amended following the date of publication of the updated Spanish Label Translation Guide described in subparagraph (G).

(v) NOTIFICATION OF UPDATES TO THE SPANISH TRANSLATION GUIDE FOR PESTICIDE LABELING.— Not later than 10 days after updating the Spanish Translation Guide described in subparagraph (G), the Administrator shall notify registrants of the update to such guide.

(D) ACCESSIBILITY OF BILINGUAL LABELING FOR FARM WORKERS.— Not later than 180 days after the date of enactment of this paragraph, to the maximum extent practicable, the Administrator shall seek stakeholder input on ways to make bilingual labeling required under this paragraph accessible to farm workers.

(E) PLAN.— Not later than 3 years after the date of enactment of this paragraph, the Administrator shall implement a plan to ensure that farm workers have access to the bilingual labeling required under this paragraph.

(F) REPORTING.— Not later than 2 years after the date of enactment of this paragraph, the Administrator shall develop and implement, and make publicly available, a plan for tracking the adoption of the bilingual labeling required under this paragraph.

(G) SPANISH TRANSLATION GUIDE DESCRIBED.— The Spanish Translation Guide described in this subparagraph is the Spanish Translation Guide for Pesticide Labeling issued in October 2019, as in effect on the date of enactment of the Pesticide Registration Improvement Act of 2022, and any successor guides or amendments to such guide.

(g) **Registration Review.—**

(1) (A) **General rule.—**

(i) **In general.—** The registrations of pesticides are to be periodically reviewed.

(ii) **Regulations.—** In accordance with this subparagraph, the Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations.

(iii) **Initial registration review.—** The Administrator shall complete the registration review of each pesticide or pesticide case, which may be composed of 1 or more active ingredients and the products associated with the active ingredients, not later than the later of—

(I) October 1, 2022; or

(II) the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered.

(iv) **Subsequent registration review.—** Not later than 15 years after the date on which the initial registration review is completed under clause (iii) and each 15 years thereafter, the Administrator shall complete a subsequent registration review for each pesticide or pesticide case.

(v) **Cancellation.—** No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 6.

(B) **Docketing.—**

(i) **In general.—** Subject to clause (ii), after meeting with 1 or more individuals that are not government employees to discuss matters relating to a registration review, the Administrator shall place in the docket minutes of the meeting, a list of attendees, and any documents exchanged at the meeting, not later than the earlier of—

(I) the date that is 45 days after the meeting; or

(II) the date of issuance of the registration review decision.

(ii) **Protected information.—** The Administrator shall identify, but not include in the docket, any confidential business information the disclosure of which is prohibited by section 10.

(C) **Limitation.—** Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide pursuant to this Act.

(2) (A) **Data.—** The Administrator shall use the authority in subsection (c)(2)(B) to require the submission of data when such data are necessary for a registration review.

(B) **Data submission, compensation, and exemption.—** For purposes of this subsection, the provisions of subsections (c)(1), (c)(2)(B), and (c)(2)(D) shall be utilized for and be applicable to any data required for registration review.

(h) **Registration Requirements for Antimicrobial Pesticides.—**

(1) **Evaluation of process.—** To the maximum extent practicable consistent with the degrees of risk presented by an antimicrobial pesticide and the type of review appropriate to evaluate the risks, the Administrator shall identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of the date of enactment of this subsection **[**Aug. 3, 1996**]** for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products, including—

(A) new antimicrobial active ingredients;

(B) new antimicrobial end-use products;

(C) substantially similar or identical antimicrobial pesticides; and

(D) amendments to antimicrobial pesticide registrations.

(2) **Review time period reduction goal.—** Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete application, consistent with the degree of risk, to a period of not more than—

(A) 540 days for a new antimicrobial active ingredient pesticide registration;

(B) 270 days for a new antimicrobial use of a registered active ingredient;

(C) 120 days for any other new antimicrobial product;

(D) 90 days for a substantially similar or identical antimicrobial product;

(E) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(F) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this paragraph.

(3) **Implementation.—**

(A) **Proposed rulemaking.—**

(i) **Issuance.—** Not later than 270 days after the date of enactment of this subsection [Aug. 3, 1996] , the Administrator shall publish in the Federal Register proposed regulations to accelerate and improve the review of antimicrobial pesticide products designed to implement, to the extent practicable, the goals set forth in paragraph (2).

(ii) **Requirements.—** Proposed regulations issued under clause (i) shall—

(I) define the various classes of antimicrobial use patterns, including household, industrial, and institutional disinfectants and sanitizing pesticides, preservatives, water treatment, and pulp and paper mill additives, and other such products intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime;

(II) differentiate the types of review undertaken for antimicrobial pesticides;

(III) conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this Act, considering the use patterns of the product, toxicity, expected exposure, and product type;

(IV) ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made; and

(V) implement effective and reliable deadlines for process management.

(iii) **Comments.—** In developing the proposed regulations, the Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

(B) **Final regulations.—**

(i) **Issuance.—** The Administrator shall issue final regulations not later than 240 days after the close of the comment period for the proposed regulations.

(ii) **Failure to meet goal.—** If a goal described in paragraph (2) is not met by the final regulations, the Administrator shall identify the goal, explain why the goal was not attained, describe the element of the regulations included instead, and identify future steps to attain the goal.

(iii) **Requirements.—** In issuing final regulations, the Administrator shall—

(I) consider the establishment of a certification process for regulatory actions involving risks that can be responsibly managed, consistent with the degree of risk, in the most cost-efficient manner;

(II) consider the establishment of a certification process by approved laboratories as an adjunct to the review process;

(III) use all appropriate and cost-effective review mechanisms, including—

(aa) expanded use of notification and non-notification procedures;

(bb) revised procedures for application review; and

(cc) allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations; and

(IV) clarify criteria for determination of the completeness of an application.

(C) **Expedited review.—** This subsection does not affect the requirements or extend the deadlines or review periods contained in subsection (c)(3).

(D) **Alternative review periods.—** If the final regulations to carry out this paragraph are not effective 630 days after the date of enactment of this subsection **[**Aug. 3, 1996**]** , until the final regulations become effective, the review period, beginning on the date of receipt by the Agency of a complete application, shall be—

(i) 2 years for a new antimicrobial active ingredient pesticide registration;

(ii) 1 year for a new antimicrobial use of a registered active ingredient;

(iii) 180 days for any other new antimicrobial product;

(iv) 90 days for a substantially similar or identical antimicrobial product;

(v) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(vi) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this subparagraph.

(E) **Wood preservatives.—** An application for the registration, or for an amendment to the registration, of a wood preservative product for which a claim of pesticidal activity listed in section 2(mm) is made (regardless of any other pesticidal claim that is made with respect to the product) shall be reviewed by the Administrator within the same period as that established under this paragraph for an antimicrobial pesticide product application, consistent with the degree of risk posed by the use of the wood preservative product, if the application requires the applicant to satisfy the same data requirements as are required to support an application for a wood preservative product that is an antimicrobial pesticide.

(F) **Notification.—**

(i) **In general.—** Subject to clause (iii), the Administrator shall notify an applicant whether an application has been granted or denied not later than the final day of the appropriate review period under this paragraph, unless the applicant and the Administrator agree to a later date.

(ii) **Final decision.—** If the Administrator fails to notify an applicant within the period of time required under clause (i), the failure shall be considered an agency action unlawfully withheld or unreasonably delayed for purposes of judicial review under chapter 7 of title 5, United States Code.

(iii) **Exemption.—** This subparagraph does not apply to an application for an antimicrobial pesticide that is filed under subsection (c)(3)(B) prior to 90 days after the date of enactment of this subsection **[**Aug. 3, 1996.**]**

(iv) **Limitation.—** Notwithstanding clause (ii), the failure of the Administrator to notify an applicant for an amendment to a registration for an antimicrobial pesticide shall not be judicially reviewable in a Federal or State court if the amendment requires scientific review of data within—

(I) the time period specified in subparagraph (D)(vi), in the absence of a final regulation under subparagraph (B); or

(II) the time period specified in paragraph (2)(F), if adopted in a final regulation under subparagraph (B).

(4) **Annual report.—**

(A) **Submission.—** Beginning on the date of enactment of this subsection **[**Aug. 3, 1996**]** and ending on the date that the goals under paragraph (2) are achieved, the Administrator shall, not later than March 1 of each year, prepare and submit an annual report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(B) **Requirements.—** A report submitted under subparagraph (A) shall include a description of—

(i) measures taken to reduce the backlog of pending registration applications;

(ii) progress toward achieving reforms under this subsection; and

(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations.

Sec. 4. REREGISTRATION OF REGISTERED PESTICIDES.

(a) **General Rule.—** The Administrator shall reregister, in accordance with this section, each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984, except for any pesticide as to which the Administrator has determined, after November 1, 1984, and before the effective date of this section **[**December 24, 1988**]** , that—

(1) there are no outstanding data requirements; and

(2) the requirements of section 3(c)(5) have been satisfied.

(b) **Reregistration Phases.—** Reregistrations of pesticides under this section shall be carried out in the following phases:

(1) The first phase shall include the listing under subsection (c) of the active ingredients of the pesticides that will be reregistered.

(2) The second phase shall include the submission to the Administrator under subsection (d) of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants to replace such missing or inadequate data within the applicable time period.

(3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (e).

(4) The fourth phase shall include an independent, initial review by the Administrator under subsection (f) of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requests for additional data.

(5) The fifth phase shall include the review by the Administrator under subsection (g) of data submitted for reregistration and appropriate regulatory action by the Administrator.

(c) **Phase One.—**

(1) **Priority for reregistration.—** For purposes of the reregistration of the pesticides described in subsection (a), the Administrator shall list the active ingredients of pesticides and shall give

priority to, among others, active ingredients (other than active ingredients for which registration standards have been issued before the effective date of this section [December 24, 1988]) that—

(A) are in use on or in food or feed and may result in postharvest residues;

(B) may result in residues of potential toxicological concern in potable ground water, edible fish, or shellfish;

(C) have been determined by the Administrator before the effective date of this section [December 24, 1988] to have significant outstanding data requirements; or

(D) are used on crops, including in greenhouses and nurseries, where worker exposure is most likely to occur.

(2) **Reregistration lists.—** For purposes of reregistration under this section, the Administrator shall by order—

(A) not later than 70 days after the effective date of this section [December 24, 1988] , list pesticide active ingredients for which registration standards have been issued before such effective date;

(B) not later than 4 months after such effective date, list the first 150 pesticide active ingredients, as determined under paragraph (1);

(C) not later than 7 months after such effective date, list the second 150 pesticide active ingredients, as determined under paragraph (1); and

(D) not later than 10 months after such effective date, list the remainder of the pesticide active ingredients, as determined under paragraph (1).

Each list shall be published in the Federal Register.

(3) **Judicial review.—** The content of a list issued by the Administrator under paragraph (2) shall not be subject to judicial review.

(4) **Notice to registrants.—** On the publication of a list of pesticide active ingredients under paragraph (2), the Administrator shall send by certified mail to the registrants of the pesticides containing such active ingredients a notice of the time by which the registrants are to notify the Administrator under subsection (d) whether the registrants intend to seek or not to seek reregistration of such pesticides.

(d) **Phase Two.—**

(1) **In general.—** The registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) shall submit to the Administrator, within the time period prescribed by paragraph (4), the notice described in paragraph (2) and any information, commitment, or offer described in paragraph (3).

(2) **Notice of intent to seek or not to seek reregistration.—**

(A) The registrant of a pesticide containing an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) shall notify the Administrator by certified mail whether the registrant intends to seek or does not intend to seek reregistration of the pesticide.

(B) If a registrant submits a notice under subparagraph (A) of an intention not to seek reregistration of a pesticide, the Administrator shall publish a notice in the Federal Register stating that such a notice has been submitted.

(3) **Missing or inadequate data.—** Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) and for which the registrant submitted a notice under paragraph (2) of an intention to seek reregistration of such pesticide shall submit to the Administrator—

(A) in accordance with regulations issued by the Administrator under section 3, an identification of—

(i) all data that are required by regulation to support the registration of the pesticide with respect to such active ingredient;

(ii) data that were submitted by the registrant previously in support of the registration of the pesticide that are inadequate to meet such regulations; and

(iii) data identified under clause (i) that have not been submitted to the Administrator; and

(B) either—

(i) a commitment to replace the data identified under subparagraph (A)(ii) and submit the data identified under subparagraph (A)(iii) within the applicable time period prescribed by paragraph (4)(B); or

(ii) an offer to share in the cost to be incurred by a person who has made a commitment under clause (i) to replace or submit the data and an offer to submit to arbitration as described by section 3(c)(2)(B) with regard to such cost sharing.

For purposes of a submission by a registrant under subparagraph (A)(ii), data are inadequate if the data are derived from a study with respect to which the registrant is unable to make the certification prescribed by subsection (e)(1)(G) that the registrant possesses or has access to the raw data used in or generated by such study. For purposes of a submission by a registrant under such subparagraph, data shall be considered to be inadequate if the data are derived from a study submitted before January 1, 1970, unless it is demonstrated to the satisfaction of the Administrator that such data should be considered to support the registration of the pesticide that is to be reregistered.

(4) **Time periods.—**

(A) A submission under paragraph (2) or (3) shall be made—

(i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B), not later than 3 months after the date of publication of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C), not later than 3 months after the date of publication of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D), not later than 3 months after the date of publication of the listing of such active ingredient.

On application, the Administrator may extend a time period prescribed by this subparagraph if the Administrator determines that factors beyond the control of the registrant prevent the registrant from complying with such period.

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (3)(B) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the

pesticide established as of the date of enactment of the Food Quality Protection Act of 1996 [Aug. 3, 1996] if—

(i) the data to support other uses of the pesticide on a food are being provided;

(ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(iii) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under this section; and

(iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment.[7] If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 3(c)(2)(B) or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

[7] Indentation of the following sentences of this subparagraph is so in original (as added by sec. 201(c)(2) of P.L. 104–170). Probably should be indented the same as flush matter of this subparagraph.

(5) **Cancellation and removal.—**

(A) If the registrant of a pesticide does not submit a notice under paragraph (2) or (3) within the time prescribed by paragraph (4)(A), the Administrator shall issue a notice of intent to cancel the registration of such registrant for such pesticide and shall publish the notice in the Federal Register and allow 60 days for the submission of comments on the notice. On expiration of such 60 days, the Administrator, by order and without a hearing, may cancel the registration or take such other action, including extension of applicable time periods, as may be necessary to enable reregistration of such pesticide by another person.

(B) (i) If—

(I) no registrant of a pesticide containing an active ingredient listed under subsection (c)(2) notifies the Administrator under paragraph (2) that the registrant intends to seek reregistration of any pesticide containing that active ingredient;

(II) no such registrant complies with paragraph (3)(A); or

(III) no such registrant makes a commitment under paragraph (3)(B) to replace or submit all data described in clauses (ii) and (iii) of paragraph (3)(A);

the Administrator shall publish in the Federal Register a notice of intent to remove the active ingredient from the list established under subsection (c)(2) and a notice of intent to cancel the registrations of all pesticides containing such active ingredient and shall provide 60 days for comment on such notice.

(ii) After the 60-day period has expired, the Administrator, by order, may cancel any such registration without hearing, except that the Administrator shall not cancel a registration under this subparagraph if—

(I) during the comment period a person acquires the rights of the registrant in that registration;

(II) during the comment period that person furnishes a notice of intent to reregister the pesticide in accordance with paragraph (2); and

(III) not later than 120 days after the publication of the notice under this subparagraph, that person has complied with paragraph (3) and the fee prescribed by this section has been paid.

(6) **Suspensions and penalties.—** The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 3(c)(2)(B)(iv) if the Administrator determines that (A) progress is insufficient to ensure the submission of the data required for such pesticide under a commitment made under paragraph (3)(B) within the time period prescribed by paragraph (4)(B) or (B) the registrant has not submitted such data to the Administrator within such time period. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this paragraph in regard to such unsupported minor use until the final deadline established as of the date of enactment of the Food Quality Protection Act of 1996 **[**Aug. 3, 1996**]** , for the submission of data under this section for the supported uses identified pursuant to this paragraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a determination the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 6(f)(1). If the Administrator grants an extension under this paragraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 3(c)(2)(B)(iv) regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 6(f)(2). Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(e) **Phase Three.—**

(1) **Information about studies.—** Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) who has submitted a notice under subsection (d)(2) of an intent to seek the reregistration of such pesticide shall submit, in accordance with the guidelines issued under paragraph (4), to the Administrator—

(A) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient and considered by the registrant to be adequate to meet the requirements of section 3 and the regulations issued under such section;

(B) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient that may not comply with the requirements of section 3 and the regulations issued under such section but which the registrant asserts should be deemed to comply with such requirements and regulations;

(C) a reformat of the data from each study summarized under subparagraph (A) or (B) by the registrant concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, teratogenicity, or residue chemistry of the active ingredient that were submitted to the Administrator before January 1, 1982;

(D) where data described in subparagraph (C) are not required for the active ingredient by regulations issued under section 3, a reformat of acute and subchronic dosing data submitted by the registrant to the Administrator before January 1, 1982, that the registrant considers to be adequate to meet the requirements of section 3 and the regulations issued under such section;

(E) an identification of data that are required to be submitted to the Administrator under section 6(a)(2) indicating an adverse effect of the pesticide;

(F) an identification of any other information available that in the view of the registrant supports the registration;

(G) a certification that the registrant or the Administrator possesses or has access to the raw data used in or generated by the studies that the registrant summarized under subparagraph (A) or (B);

(H) either—

(i) a commitment to submit data to fill each outstanding data requirement identified by the registrant; or

(ii) an offer to share in the cost of developing such data to be incurred by a person who has made a commitment under clause (i) to submit such data, and an offer to submit to arbitration as described by section 3(c)(2)(B) with regard to such cost sharing; and

(I) evidence of compliance with section 3(c)(1)(D)(ii) and regulations issued thereunder with regard to previously submitted data as if the registrant were now seeking the original registration of the pesticide.

A registrant who submits a certification under subparagraph (G) that is false shall be considered to have violated this Act and shall be subject to the penalties prescribed by section 14.

(2) **Time periods.—**

(A) The information required by paragraph (1) shall be submitted to the Administrator—

(i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B), not later than 12 months after the date of publication of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C), not later than 12 months after the date of publication of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D), not later than 12 months after the date of publication of the listing of such active ingredient.

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (1)(H) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment under such paragraph. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of the date of enactment of the Food Quality Protection Act of 1996 [Aug. 3, 1996] if—

(i) the data to support other uses of the pesticide on a food are being provided;

(ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(iii) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under this section; and

(iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment.[8] If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 3(c)(2)(B) or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

[8] Indentation of the following sentences of this subparagraph is so in original (as added by sec. 201(c)(2) of P.L. 104–170). Probably should be indented the same as flush matter of this subparagraph.

(3) **Cancellation.—**

(A) If the registrant of a pesticide fails to submit the information required by paragraph (1) within the time prescribed by paragraph (2), the Administrator, by order and without hearing, shall cancel the registration of such pesticide. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this subparagraph in regard to such unsupported minor use until the final deadline established as of the date of enactment of the Food Quality Protection Act of 1996 **[**Aug. 3, 1996**]** , for the submission of data under this section for the supported uses identified pursuant to this subparagraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 6(f)(1). If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 3(c)(2)(B)(iv) regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 6(f)(2). Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(B) (i) If the registrant of a pesticide submits the information required by paragraph (1) within the time prescribed by paragraph (2) and such information does not conform to the guidelines for submissions established by the Administrator, the Administrator shall determine whether the registrant made a good faith attempt to conform its submission to such guidelines.

(ii) If the Administrator determines that the registrant made a good faith attempt to conform its submission to such guidelines, the Administrator shall provide the registrant a reasonable period of time to make any necessary changes or corrections.

(iii) (I) If the Administrator determines that the registrant did not make a good faith attempt to conform its submission to such guidelines, the Administrator may issue a notice of intent to cancel the registration. Such a notice shall be sent to the registrant by certified mail.

(II) The registration shall be canceled without a hearing or further notice at the end of 30 days after receipt by the registrant of the notice unless during that time a request for a hearing is made by the registrant.

(III) If a hearing is requested, a hearing shall be conducted under section 6(d), except that the only matter for resolution at the hearing shall be whether the registrant made a good faith attempt to conform its submission to such guidelines. The hearing shall be held and a determination made within 75 days after receipt of a request for hearing.

(4) **Guidelines.—**

(A) Not later than 1 year after the effective date of this section [December 24, 1988] , the Administrator, by order, shall issue guidelines to be followed by registrants in—

(i) summarizing studies;

(ii) reformatting studies;

(iii) identifying adverse information; and

(iv) identifying studies that have been submitted previously that may not meet the requirements of section 3 or regulations issued under such section,

under paragraph (1).

(B) Guidelines issued under subparagraph (A) shall not be subject to judicial review.

(5) **Monitoring.—** The Administrator shall monitor the progress of registrants in acquiring and submitting the data required under paragraph (1).

(f) **Phase Four.—**

(1) **Independent review and identification of outstanding data requirements.—**

(A) The Administrator shall review the submissions of all registrants of pesticides containing a particular active ingredient under subsections (d)(3) and (e)(1) to determine if such submissions identified all the data that are missing or inadequate for such active ingredient. To assist the review of the Administrator under this subparagraph, the Administrator may require a registrant seeking reregistration to submit complete copies of studies summarized under subsection (e)(1).

(B) The Administrator shall independently identify and publish in the Federal Register the outstanding data requirements for each active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (c)(2) and that is contained in a pesticide to be reregistered under this section. The Administrator, at the same time, shall issue a notice under section 3(c)(2)(B) for the submission of the additional data that are required to meet such requirements.

(2) **Time periods.—**

(A) The Administrator shall take the action required by paragraph (1)—

(i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B), not later than 18 months after the date of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C), not later than 24 months after the date of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D), not later than 33 months after the date of the listing of such active ingredient.

(B) If the Administrator issues a notice to a registrant under paragraph (1)(B) for the submission of additional data, the registrant shall submit such data within a reasonable period of time, as determined by the Administrator, but not to exceed 48 months after the issuance of such notice. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of the date of enactment of the Food Quality Protection Act of 1996 [Aug. 3, 1996] if—

(i) the data to support other uses of the pesticide on a food are being provided;

(ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(iii) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under this section; and

(iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment.[9] If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 3(c)(2)(B) or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

[9] Indentation of the following sentences of this subparagraph is so in original (as added by sec. 201(c)(2) of P.L. 104–170). Probably should be indented the same as flush matter of this subparagraph.

(3) **Suspensions and penalties.—** The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 3(c)(2)(B)(iv) if the Administrator determines that (A) tests necessary to fill an outstanding data requirement for such pesticide have not been initiated within 1 year after the issuance of a notice under paragraph (1)(B), or (B) progress is insufficient to ensure submission of the data referred to in clause (A) within the time period prescribed by paragraph (2)(B) or the required data have not been submitted to the Administrator within such time period. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this paragraph in regard to such unsupported minor use until the final deadline established as of the date of enactment of the Food Quality Protection Act of 1996 **[**Aug. 3, 1996**]** , for the submission of data under this section for the supported uses identified pursuant to this paragraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a determination the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 6(f)(1). If the Administrator grants an extension under this paragraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of

such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 3(c)(2)(B)(iv) regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 6(f)(2). Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(g) **Phase Five.—**

(1) **Data review.—** The Administrator shall conduct a thorough examination of all data submitted under this section concerning an active ingredient listed under subsection (c)(2) and of all other available data found by the Administrator to be relevant.

(2) **Reregistration and other actions.—**

(A) **In general.—** The Administrator shall make a determination as to eligibility for reregistration—

(i) for all active ingredients subject to reregistration under this section for which tolerances or exemptions from tolerances are required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), not later than the last date for tolerance reassessment established under section 408(q)(1)(C) of that Act (21 U.S.C. 346a(q)(1)(C)); and

(ii) for all other active ingredients subject to reregistration under this section, not later than October 3, 2008.

(B) **Product-specific data.—**

(i) **In general.—** Before reregistering a pesticide, the Administrator shall obtain any needed product-specific data regarding the pesticide by use of section 3(c)(2)(B) and shall review such data within 90 days after its submission.

(ii) **Timing.—**

(I) **In general.—** Subject to subclause (II), the Administrator shall require that data under this subparagraph be submitted to the Administrator not later than 8 months after a determination of eligibility under subparagraph (A) has been made for each active ingredient of the pesticide, unless the Administrator determines that a longer period is required for the generation of the data.

(II) **Extraordinary circumstances.—** In the case of extraordinary circumstances, the Administrator may provide such a longer period, of not more than 2 additional years, for submission of data to the Administrator under this subparagraph.

(C) After conducting the review required by paragraph (1) for each active ingredient of a pesticide and the review required by subparagraph (B) of this paragraph, the Administrator shall determine whether to reregister a pesticide by determining whether such pesticide meets the requirements of section 3(c)(5). If the Administrator determines that a pesticide is eligible to be reregistered, the Administrator shall reregister such pesticide within 6 months after the submission of the data concerning such pesticide under subparagraph (B).

(D) **Determination to not reregister.—**

(i) **In general.—** If after conducting a review under paragraph (1) or subparagraph (B) of this paragraph the Administrator determines that a pesticide should not be reregistered, the Administrator shall take appropriate regulatory action.

(ii) **Timing for regulatory action.—** Regulatory action under clause (i) shall be completed as expeditiously as possible.

(E) As soon as the Administrator has sufficient information with respect to the dietary risk of a particular active ingredient, but in any event no later than the time the Administrator makes a determination under subparagraph (C) or (D) with respect to pesticides containing a particular active ingredient, the Administrator shall—

(i) reassess each associated tolerance and exemption from the requirement for a tolerance issued under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a);

(ii) determine whether such tolerance or exemption meets the requirements of that Act;

(iii) determine whether additional tolerances or exemptions should be issued;

(iv) publish in the Federal Register a notice setting forth the determinations made under this subparagraph; and

(v) commence promptly such proceedings under this Act and section 408 of the Federal Food, Drug, and Cosmetic Act as are warranted by such determinations.

(h) **Compensation of Data Submitter.—** If data that are submitted by a registrant under subsection (d), (e), (f), or (g) are used to support the application of another person under section 3, the registrant who submitted such data shall be entitled to compensation for the use of such data as prescribed by section 3(c)(1)(D). In determining the amount of such compensation, the fees paid by the registrant under this section shall be taken into account.

(i) **Fees.—**

(1) **Maintenance fee.—**

(A) **In general.—** Subject to other provisions of this paragraph, each registrant of a pesticide shall pay an annual fee by January 15 of each year for each registration, except that no fee shall be charged for more than 200 registrations held by any registrant.

(B) In the case of a pesticide that is registered for a minor agricultural use, the Administrator may reduce or waive the payment of the fee imposed under this paragraph if the Administrator determines that the fee would significantly reduce the availability of the pesticide for the use.

(C) **Total amount of fees.—** The amount of each fee prescribed under subparagraph (A) shall be adjusted by the Administrator to a level that will result in the collection under this paragraph of, to the extent practicable, an average amount of $31,000,000 for each of fiscal years 2019 through ~~2023~~ *2022, and $42,000,000 for each of fiscal years 2023 through 2027*.

(D)[10] **Maximum amount of fees for registrants.—** The maximum annual fee payable under this paragraph by—

[10] Title II of the Emergency Wartime Supplemental Appropriations Act, 2003, P.L. 108–11, 117 Stat. 603, provided that "Within 30 days of enactment of this Act, the Administrator of the Environmental Protection Agency shall adjust each'maximum annual fee payable'pursuant to 7 U.S.C. 136a–1(i)(5)(D) and (E) in a manner such that maintenance fee collections made to reach the level authorized in division K of Public Law 108–7 shall be established in

the same proportion as those maintenance fee collections authorized in Public Law 107–73.”.

(i) a registrant holding not more than 50 pesticide registrations shall be $129,400 for each of fiscal years 2019 through ~~2023~~ *2022, and $172,000 for each of fiscal years 2023 through 2027*; and

(ii) a registrant holding over 50 registrations shall be $207,000 for each of fiscal years 2019 through ~~2023~~ *2022, and $277,200 for each of fiscal years 2023 through 2027*.

(E) **Maximum amount of fees for small businesses.—**

(i) **In general.—** For a small business, the maximum annual fee payable under this paragraph by—

(I) a registrant holding not more than 50 pesticide registrations shall be $79,100 for each of fiscal years 2019 through ~~2023~~ *2022, and $105,000 for each of fiscal years 2023 through 2027*; and

(II) a registrant holding over 50 pesticide registrations shall be $136,800 for each of fiscal years 2019 through ~~2023~~ *2022, and $184,800 for each of fiscal years 2023 through 2027*.

(ii) **Definition of small business.—**

(I) **In general.—** In clause (i), the term “small business” means a corporation, partnership, or unincorporated business that—

(aa) has 500 or fewer employees; and

(bb) during the 3-year period prior to the most recent maintenance fee billing cycle, had an average annual global gross revenue from pesticides that did not exceed $60,000,000.

(II) **Affiliates.—**

(aa) **In general.—** In the case of a business entity with 1 or more affiliates, the gross revenue limit under subclause (I)(bb) shall apply to the gross revenue for the entity and all of the affiliates of the entity, including parents and subsidiaries, if applicable.

(bb) **Affiliated persons.—** For the purpose of item (aa), persons are affiliates of each other if, directly or indirectly, either person controls or has the power to control the other person, or a third person controls or has the power to control both persons.

(cc) **Indicia of control.—** For the purpose of item (aa), indicia of control include interlocking management or ownership, identity of interests among family members, shared facilities and equipment, and common use of employees.

(F) **Fee reduction for certain small businesses.—**

(i) **Definition.—** In this subparagraph, the term “qualified small business entity” means a corporation, partnership, or unincorporated business that—

(I) has 500 or fewer employees;

(II) during the 3-year period prior to the most recent maintenance fee billing cycle, had an average annual global gross revenue from all sources that did not exceed $10,000,000; and

(III) holds not more than 5 pesticide registrations under this paragraph.

(ii) **Waiver.—** Except as provided in clause (iii), the Administrator shall waive 25 percent of the fee under this paragraph applicable to the first registration of any qualified small business entity under this paragraph.

(iii) **Limitation.—** The Administrator shall not grant a waiver under clause (ii) to a qualified small business entity if the Administrator determines that the entity has been formed or manipulated primarily for the purpose of qualifying for the waiver.

(G) FARM WORKER TRAINING AND EDUCATION GRANTS.—

(i) SET-ASIDE.— In addition to amounts otherwise available, for fiscal years 2023 through 2027, the Administrator shall use not more than $7,500,000 of the amounts collected under this paragraph to provide grants to organizations described in clause (ii) for purposes of facilitating—

(I) training of farm workers;

(II) education of farm workers with respect to—

(aa) rights of farm workers relating to pesticide safety; and

(bb) the worker protection standard under part 170 of title 40, Code of Federal Regulations (or successor regulations);

(III) the development of new informational materials;

(IV) the development of training modules; and

(V) the development of innovative methods of delivery of such informational materials and training modules.

(ii) ELIGIBILITY.— To be eligible to receive a grant under this subparagraph, an organization shall have demonstrated experience in—

(I) providing training and education services for farm workers or handlers of pesticides; or

(II) developing informational materials for farm workers or handlers of pesticides.

(iii) COMMUNITY-BASED ORGANIZATIONS.—

(I) COMMUNITY-BASED NON-PROFIT FARM WORKER ORGANIZATION GRANTS.— The Administrator shall use funds available under clause (i) to provide grants to community-based non-profit farm worker organizations.

(II) APPLICATION OF FUNDS.— The Administrator shall apply the unspent balance of funds available (up to $1,800,000) under clause (i) in fiscal years 2025 through 2027 to carry out subclause (I).

(iv) INTERIM FUNDING.— In addition to amounts otherwise available, the Administrator may use not more than $1,200,000 in fiscal years 2023 and 2024 to fund existing cooperative agreements that were authorized under section 33(c)(3)(B), as such section was in effect as of March 8, 2019.

(v) PARTNERSHIPS.— Organizations described in clause (ii) may apply for a grant under this subparagraph as a partnership with another organization, provided such organizations, at the time of application, have entered into an agreement designating—

(I) a member of the partnership that will enter into the assistance agreement with the Environmental Protection Agency for the purposes of accountability for the proper expenditure of Federal funds;

(II) performance of the assistance agreement;

(III) liability for claims for recovery of unallowable costs incurred under the agreement; and

(IV) specifying roles in performing the proposed scope of work for the assistance agreement.

(H) HEALTH CARE PROVIDER TRAINING.—

(i) SET-ASIDE.— In addition to other amounts available, for the period of fiscal years 2023 through 2027, the Administrator shall use not more than $2,500,000 of the amounts collected under this paragraph to provide grants to nonprofit organizations described in clause (ii) for purposes of facilitating—

(I) technical assistance and training of health care providers relating to the recognition, treatment, and management of pesticide-related injuries and illnesses;

(II) the development of informational materials for technical assistance and training described in subclause (I); and

(III) the development of outreach and delivery methods relating to the recognition, treatment, and management of pesticide-related illnesses.

(ii) ELIGIBILITY.— To be eligible to receive a grant under this subparagraph, a nonprofit organization shall have demonstrated experience in providing technical assistance and training to health care providers who serve farm worker populations.

(iii) PARTNERSHIPS.— Organizations described in clause (ii) may apply for a grant under this subparagraph as a partnership with another organization, provided such organizations, at the time of application, have entered into an agreement designating—

(I) a member of the partnership that will enter into the assistance agreement with the Environmental Protection Agency for the purposes of accountability for the proper expenditure of Federal funds;

(II) performance of the assistance agreement;

(III) liability for claims for recovery of unallowable costs incurred under the agreement; and

(IV) roles in performing the proposed scope of work for the assistance agreement.

(I) PARTNERSHIP GRANTS.— In addition to funds otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than $500,000 of the amounts collected under this paragraph for partnership grants.

(J) PESTICIDE SAFETY EDUCATION PROGRAM.— In addition to amounts otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than $500,000 of the amounts collected under this paragraph to carry out the pesticide safety education program.

(K) TECHNICAL ASSISTANCE TO GRANTEES.—

(i) SET-ASIDE.— In addition to other amounts available, for fiscal years 2023 through 2027, the Administrator shall use not more than $1,750,000 of the amounts collected under this paragraph to provide grants to nonprofit organizations, subject to such conditions as the Administrator establishes to prevent conflicts of interest, to provide easily accessible technical assistance to grantees receiving, and potential grantees applying for, grants under subparagraphs (G) and (H).

(ii) CONSIDERATIONS.— In evaluating requests for grants under this subparagraph, the Administrator shall consider, at a minimum, the extent to which—

(I) the organization applying for the grant has experience providing technical assistance to farm worker or clinician-training organizations; and

(II) the proposed project would make specific technical assistance available to organizations seeking information and assistance concerning—

(aa) the grant application process;

(bb) the drafting of grant applications; and

(cc) compliance with grant management and reporting requirements.

(iii) NO SUITABLE ORGANIZATION.— If no suitable organization requests a grant under this subparagraph, the Administrator shall provide technical assistance described in clause (i) using the amounts made available by that clause.

(iv) STAKEHOLDER INPUT.— In formulating requests for proposals for grants under subparagraphs (G) and (H) for a fiscal year, the Administrator shall solicit and consider, in an open and transparent manner that does not provide a competitive advantage to any person or persons, input from persons who conduct farm worker education and training, or technical assistance and training of clinicians, regarding the request for proposals.

(~~G~~ *L*) The Administrator shall exempt any public health pesticide from the payment of the fee prescribed under this paragraph if, in consultation with the Secretary of Health and Human Services, the Administrator determines, based on information supplied by the registrant, that the economic return to the registrant from sales of the pesticide does not support the registration or reregistration of the pesticide.

(~~H~~ *M*) If any fee prescribed by this paragraph with respect to the registration of a pesticide is not paid by a registrant by the time prescribed, the Administrator, by order and without hearing, may cancel the registration.

(~~I~~ *N*) The authority provided under this paragraph shall terminate on September 30, ~~2023~~ *2027*.

(2) **Other fees.—** Except as provided in section 33, during the period beginning on the effective date of ~~the Pesticide Registration Improvement Extension Act of 2018 and ending on September 30, 2025~~ *the Pesticide Registration Improvement Act of 2022 and ending on September 30, 2029*, the Administrator may not levy any other fees for the registration of a pesticide under this Act or any other action covered under a table specified in ~~section 33(b)(3)~~ *section 33(b)(3)(B)*, except as provided in paragraph (1).

(j) **Exemption of Certain Registrants.—** The requirements of subsections (d), (e), (f), and (i) (other than subsection (i)(1)) regarding data concerning an active ingredient and fees for review of such data shall not apply to any person who is the registrant of a pesticide to the extent that, under section 3(c)(2)(D), the person would not be required to submit or cite such data to obtain an initial registration of such pesticide.

(k) **Reregistration and Expedited Processing Fund.—**

(1) **Establishment.—** There shall be established in the Treasury of the United States a reregistration and expedited processing fund which shall be known as the Reregistration and Expedited Processing Fund.[11]

[11] Sec. 501(b) of P.L. 104–170 amended sec. 4(k)(1) (7 U.S.C. 136a–1(k)(1)) by inserting "which shall be known as the Reregistration and Expedited Processing

Fund", without specifying the Act that was being amended. The amendment was executed to this Act to effectuate the probable intent of Congress.

(2)[12] **Source and use.—**

[12] Sec. 501(c) of P.L. 104–170 amended sec. 4(k)(2) (7 U.S.C. 136a–1(k)(2)) to read as provided above, without specifying the Act that was being amended. The amendment was executed to this Act to effectuate the probable intent of Congress.

(A) All moneys derived from fees collected by the Administrator under subsection (i) shall be deposited in the Reregistration and Expedited Processing Fund and shall be available to the Administrator, without fiscal year limitation,*including, to the maximum extent practicable, during periods in which Environmental Protection Agency employees are on shutdown or emergency furlough as a result of a lapse in appropriations,* specifically to offset the costs of reregistration and expedited processing of the applications specified in paragraph (3), to offset the costs of registration review under section 3(g), including the costs associated with any review under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.) required as part of the registration review, to offset the costs associated with tracking and implementing registration review decisions, including registration review decisions designed to reduce risk, for the purposes specified in paragraphs (4) and (5), and to enhance the information systems capabilities to improve the tracking of pesticide registration decisions. The Administrator shall, prior to expending any such moneys derived from fees—

(i) effective October 1, 1997, adopt specific and cost accounting rules and procedures as approved by the General Accounting Office and the Inspector General of the Environmental Protection Agency to ensure that moneys derived from fees are allocated solely for the purposes specified in the first sentence of this subparagraph;

(ii) prohibit the use of such moneys derived from fees to pay for any costs other than those necessary to achieve the purposes specified in the first sentence of this subparagraph; and

(iii) ensure that personnel and facility costs associated with the functions to be carried out under this paragraph do not exceed agency averages for comparable personnel and facility costs.

(B) The Administrator shall also—

(i) complete the review of unreviewed reregistration studies required to support the reregistration eligibility decisions scheduled for completion in accordance with subsection (l)(2); and

(ii) contract for such outside assistance as may be necessary for review of required studies, using a generally accepted competitive process for the selection of vendors of such assistance.

~~(3) **Review of inert ingredients; expedited processing of similar applications.—**~~

~~(A) For each of fiscal years 2018 through 2023, the Administrator shall use between 1/9 and 1/8 of the maintenance fees collected in such fiscal year to obtain sufficient personnel and resources—~~

~~(i) to review and evaluate inert ingredients; and~~

~~(ii) to ensure the expedited processing and review of any application that—~~

(I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from any such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment;

(II) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data; or

(III) proposes the initial or amended registration of an end use pesticide that, if registered as proposed, would be used for a public health pesticide.

(B) Any amounts made available under subparagraph (A) shall be used to obtain sufficient personnel and resources to carry out the activities described in such subparagraph that are in addition to the personnel and resources available to carry out such activities on the date of enactment of this section [October 25, 1988.]

(C)[13] So long as the Administrator has not met the time frames specified in clause (ii) of section 3(c)(3)(B) with respect to any application subject to section 3(c)(3)(B) that was received prior to the date of enactment of the Food Quality Protection Act of 1996 [Aug. 3, 1996] , the Administrator shall use the full amount of the fees specified in subparagraph (A) for the purposes specified therein. Once all applications subject to section 3(c)(3)(B) that were received prior to such date of enactment have been acted upon, no limitation shall be imposed by the preceding sentence of this subparagraph so long as the Administrator meets the time frames specified in clause (ii) of section 3(c)(3)(B) on 90 percent of affected applications in a fiscal year. Should the Administrator not meet such time frames in a fiscal year, the limitations imposed by the first sentence of this subparagraph shall apply until all overdue applications subject to section 3(c)(3)(B) have been acted upon.

[13]

Sec. 501(d)(2) of P.L. 104–170 added subpara. (C) to sec. 4(k)(3) (7 U.S.C. 136a–1(k)(3)), without specifying the Act that was being amended. The amendment was executed to this Act to effectuate the probable intent of Congress.

(4) **Expedited rulemaking and guidance development for certain product performance data requirements.—**

(A) **Set-aside.—** For each of fiscal years 2018 through 2023, the Administrator shall use not more than $500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

(B) **Products claiming efficacy against invertebrate pests of significant public health or economic importance.—** The Administrator shall use amounts made available under subparagraph (A) to develop, receive comments with respect to, finalize, and implement the necessary rulemaking and guidance for product performance data requirements to evaluate products claiming efficacy against the following invertebrate pests of significant public health or economic importance (in order of importance):

(i) Bed bugs.

(ii) Premise (including crawling insects, flying insects, and baits).

~~(iii) Pests of pets (including pet pests controlled by spot-ons, collars, shampoos, powders, or dips).~~

~~(iv) Fire ants.~~

~~(C) **Deadlines for guidance.—** The Administrator shall develop, and publish guidance required by subparagraph (B), with respect to claims of efficacy against pests described in such subparagraph as follows:~~

~~(i) With respect to bed bugs, issue final guidance not later than 30 days after the effective date of the Pesticide Registration Improvement Extension Act of 2018.~~

~~(ii) With respect to pests specified in clause (ii) of such subparagraph—~~

~~(I) submit draft guidance to the Scientific Advisory Panel and for public comment not later than June 30, 2018; and~~

~~(II) complete any response to comments received with respect to such draft guidance and finalize the guidance not later than September 30, 2019.~~

~~(iii) With respect to pests specified in clauses (iii) and (iv) of such subparagraph—~~

~~(I) submit draft guidance to the Scientific Advisory Panel and for public comment not later than June 30, 2019; and~~

~~(II) complete any response to comments received with respect to such draft guidance and finalize the guidance not later than March 31, 2021.~~

~~(D) **Revision.—** The Administrator shall revise the guidance required by subparagraph (B) from time to time, but shall permit applicants and registrants sufficient time to obtain data that meet the requirements specified in such revised guidance.~~

~~(E) **Deadline for product performance data requirements.—** The Administrator shall, not later than September 30, 2021, issue regulations prescribing product performance data requirements for any pesticide intended for preventing, destroying, repelling, or mitigating any invertebrate pest of significant public health or economic importance specified in clauses (i) through (iv) of subparagraph (B).~~

(3) REVIEW OF REGISTRANT SUBMISSIONS NOT COVERED BY SECTION 33(B)(3)(B).—

(A) DEFINITION OF SUBMISSION NOT COVERED BY SECTION 33(B)(3)(B).— In this paragraph, the term '"submission not covered by section 33(b)(3)(B)" ' means any submission filed by a registrant with the Administrator relating to a registration that is not covered by a fee table under section 33(b)(3)(B).

(B) SET-ASIDE.—

(i) IN GENERAL.— In addition to amounts otherwise available for each of fiscal years 2023 through 2027, the Administrator shall use approximately 1/8 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in clause (ii).

(ii) ACTIVITIES.— In addition to amounts otherwise available, the Administrator shall use amounts made available under clause (i) to obtain sufficient personnel and resources to process submissions not covered by section 33(b)(3)(B) to meet the applicable deadlines described in—

(I) 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 such notice); and

(II) subsections (c)(3)(B) and (h) of section 3.

(4) DEVELOPMENT OF PUBLIC HEALTH PERFORMANCE STANDARDS FOR ANTIMICROBIAL PESTICIDE DEVICES.—

(A) SET-ASIDE.— In addition to amounts otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than $500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

(B) ANTIMICROBIAL PESTICIDE DEVICES.— The Administrator shall use amounts made available under subparagraph (A) to develop efficacy test methods for antimicrobial pesticide devices making public health claims.

(5) **Good laboratory practices inspections.—**

(A) **Set-aside.—** For each of fiscal years ~~2018 through 2023~~ *2023 through 2027*, the Administrator shall use not more than $500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

(B) **Activities.—** The Administrator shall use amounts made available under subparagraph (A) for enhancements to the good laboratory practices standards compliance monitoring program established under part 160 of title 40 of the Code of Federal Regulations (or successor regulations), with respect to laboratory inspections and data audits conducted in support of pesticide product registrations under this Act. As part of such monitoring program, the Administrator shall make available to each laboratory inspected under such program in support of such registrations a preliminary summary of inspection observations not later than 60 days after the date on which such an inspection is completed.

(6) AGENCY TRAINING AND STAFF.—

(A) SET-ASIDE.— In addition to amounts otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than $500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

(B) ACTIVITIES.— The Administrator shall use amounts made available under subparagraph (A) to carry out the following activities:

(i) TRAINING FOR AGENCY EMPLOYEES.— The Administrator shall administer training and education programs for employees of the Environmental Protection Agency, relating to the regulatory responsibilities and policies established by this Act, including programs—

(I) for improving the scientific, technical, and administrative skills of officers and employees authorized to administer programs under this Act;

(II) to align competencies identified by the Administrator for mission accomplishment;

(III) for addressing best practices for operational performance and improvement;

(IV) for improving administrative processes and procedures and addressing efficiency issues;

(V) to promote consistent regulatory decision-making; and

(VI) for educating registrants and regulated stakeholders on regulatory procedures.

(ii) AGREEMENTS WITH INSTITUTIONS OF HIGHER EDUCATION.— Not later than 1 year, to the maximum extent practicable, after the date of enactment of the Pesticide Registration Improvement Act of 2022, the Administrator shall establish a competitive grant program to

develop training curricula and programs in accordance with clause (i) through financial assistance agreements with 1 or more of the following institutions of higher education:

(I) Non-land-grant colleges of agriculture (as defined in section 1404 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3103)).

(II) Land-grant colleges and universities (as defined in section 1404 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3103)).

(III) 1994 Institutions (as defined in section 532 of the Equity in Educational Land-Grant Status Act of 1994 (7 U.S.C. 301 note; Public Law 103–382)).

(7) VECTOR EXPEDITED REVIEW VOUCHERS.—

(A) SET-ASIDE.— In addition to amounts otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than $500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund to establish and carry out the Vector Expedited Review Voucher program in accordance with subparagraph (B).

(B) VECTOR EXPEDITED REVIEW VOUCHER PROGRAM.—

(i) DEFINITIONS.— In this subparagraph:

(I) PROGRAM.— The term ‘“program”’ means the Vector Expedited Review Voucher program established under clause (ii).

(II) VOUCHER.— The term ‘“voucher”’ means a voucher—

(aa) issued under the program by the Administrator to a pesticide registration applicant that entitles the holder to an expedited review described under clause (vi) of a single different pesticide registration action; and

(bb) the entitlement to which may be transferred (including by sale) by the holder of the voucher, without limitation on the number of times the voucher may be transferred, before the voucher is redeemed.

(ii) ESTABLISHMENT.— Not later than one year after the date of enactment of the Pesticide Registration Improvement Act of 2022, the Administrator, acting though the Office of Pesticide Programs, shall establish a program to be known as the Vector Expedited Review Voucher program.

(iii) PURPOSE.— The purpose of the program is to incentivize the development of new insecticides to control and prevent the spread of vector borne disease by expediting reviews by decreasing decision review times provided in section 33(b)(3)(B).

(iv) ISSUANCE OF VOUCHERS.—

(I) IN GENERAL.— For each of fiscal years 2023 through 2027, the Administrator shall issue a voucher to a pesticide registration applicant for a new active ingredient if the applicant submits and has successfully registered a mosquito-control product that —

(aa) demonstrates a proven efficacy against pyrethroid or other insecticide-resistant mosquitoes;

(bb) prevents, mitigates, destroys, or repels pyrethroid or other insecticide-resistant mosquitoes, with a novel or unique mechanism or mode of action, different from other insecticides already registered by the Administrator for mosquito control;

(cc) targets mosquitoes capable of spreading such diseases as Malaria, Dengue, Zika, Chikungunya, St. Louis encephalitis, Eastern encephalitis, Western encephalitis, West Nile encephalitis, Cache Valley encephalitis, LaCrosse encephalitis, and Yellow Fever;

(dd) the registrant has submitted a global access plan that will be made publicly available for the active ingredient and that includes—

(AA) manufacturing locations, including any licensed third-party manufacturers;

(BB) distribution and procurement processes for malaria vector control programs in selected countries; and

(CC) the prices for common quantities of the product;

(ee) meets the appropriate guidelines as being effective in the primary vector control intervention areas, including insecticide-treated nets and indoor residual spray;

(ff) is made accessible for use in—

(AA) the United States, including territories or possessions of the United States; and

(BB) countries where mosquito-borne diseases, such as malaria, are prevalent;

(gg) meets registration requirements for human health and environmental effects, labeling, and presents no unreasonable adverse effects to the environment;

(hh) broadens the adoption of integrated pest management strategies, such as insecticide resistance management, or makes those strategies more effective;

(ii) is not contained in any pesticide product registered by the Administrator as of the date of the enactment of the Pesticide Registration Improvement Act of 2022; or

(jj) does not contain as attested to by the registrant, an active ingredient approved in the 2-year period preceding the date of registration by any global stringent regulatory authority for the same uses, vectors, and applications.

(II) MOSQUITO VECTOR PRIORITY.— For each of fiscal years 2023 through 2027, the focus of the program shall be to incentivize the development of insecticides to control and prevent the spread of mosquitoes bearing diseases described in subclause (I)(cc).

(III) EXCEPTION.— If the Administrator determines that there is a significant public health benefit, an active ingredient that is registered for agricultural use that is repurposed and submitted for control of mosquitoes and that otherwise meets the requirements of subclause (I) (excluding items (bb) and (jj)) as determined necessary by the Administrator, shall be considered a mosquito control product meeting the criteria specified in such subclause.

(IV) ELIGIBILITY CRITERIA MODIFICATIONS.—

(aa) IN GENERAL.— Beginning in fiscal year 2028, the Administrator shall review the program and recommend—

(AA) modifications to the requirements described in subclause (I); and

(BB) additional vectors to be included in the program, prioritizing vectors that pose the most significant population health risks.

(bb) PUBLIC INVOLVEMENT.— In carrying out item (aa), the Administrator shall solicit the involvement of registrants, nongovernmental organizations, and governmental agencies engaged in vector-borne disease mitigation and treatment.

(v) REDEMPTION OF VOUCHERS.— To redeem a voucher, the holder shall—

(I) notify the Administrator of the intent of the holder to submit a pesticide application with a voucher for expedited review not less than 90 days before the submission of the application; and

(II) pay the applicable registration service fee under section 33(b).

(vi) EXPEDITED REVIEW.— On redemption of a voucher, in furtherance of the purpose described in clause (iii), the Administrator shall expedite decision review times as follows:

(I) 6 months less than the decision review time for Category R010, New Active Ingredient, Food use.

(II) 6 months less than the decision review time for Category R020, New Active Ingredient, Food use; reduced risk.

(III) 6 months less than the decision review time for Category R060, New Active Ingredient, Non-food use; outdoor.

(IV) 6 months less than the decision review time for Category R110, New Active Ingredient, Non-food use; indoor.

(V) 4 months less than the decision review time for Category R070, New Active Ingredient, Non-food use; outdoor; reduced risk.

(VI) 2 months less than the decision review time for Category R120, New Active Ingredient, Non-food use; indoor; reduced risk.

(vii) REPORTS.— Not later than September 30, 2025, and not later than September 30 of each year thereafter, the Administrator shall issue a report on the program, including—

(I) the number of submissions seeking a voucher;

(II) the total time in review for each such submission;

(III) the number of such vouchers awarded;

(IV) the number of such vouchers redeemed; and

(V) with respect to each such redeemed voucher—

(aa) the decision review time for the pesticide application for which the voucher was redeemed; and

(bb) the average standard decision review time for the applicable pesticide category.

(C) UNUSED AMOUNTS.— Any unused amounts made available under this paragraph at the end of each fiscal year shall be made available to the Administrator to carry out other activities for which amounts in the Reregistration and Expedited Processing Fund are authorized to be used.

(8) PESTICIDE SURVEILLANCE PROGRAM.— In addition to amounts otherwise available, for each of fiscal years 2023 through 2027, the Administrator shall use not more than $500,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund to support

the interagency agreement with the National Institute for Occupational Safety and Health to support the Sentinel Event Notification System for Occupational Risk pesticides program—

(A) with a goal of increasing the number of participating States, prioritizing expansion in States with the highest numbers of agricultural workers; and

(B) to improve reporting by participating States.

(~~6~~ 9) **Unused funds.—** Money in the fund not currently needed to carry out this section shall be —

(A) maintained on hand or on deposit;

(B) invested in obligations of the United States or guaranteed thereby; or

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

(~~7~~ *10*)[14] **Accounting and performance.—** The Administrator shall take all steps necessary to ensure that expenditures from fees authorized by subsection (i)(1)(C)(ii) are used only for the purposes described in paragraphs ~~(2), (3), (4), and (5)~~ *(2) through (8)* and to carry out the goals established under subsection (l). The Reregistration and Expedited Processing Fund shall be designated as an Environmental Protection Agency component for purposes of section 3515(c) of title 31, United States Code. The annual audit required under section 3521 of such title of the financial statements of activities under this Act under section 3515(b) of such title shall include an audit of the fees collected under subsection (i)(1)(C) and disbursed, of the amount appropriated to match such fees, and of the Administrator's attainment of performance measures and goals established under subsection (l). Such an audit shall also include a review of the reasonableness of the overhead allocation and adequacy of disclosures of direct and indirect costs associated with carrying out the reregistration and expedited processing of the applications specified in paragraph (3), and the basis for and accuracy of all costs paid with moneys derived from such fees. The Inspector General shall conduct the annual audit and report the findings and recommendations of such audit to the Administrator and to the Committees on Agriculture of the House of Representatives and the Senate. The cost of such audit shall be paid for out of the fees collected under subsection (i)(1)(C).

[14] Sec. 501(e) of P.L. 104–170 amended sec. 4(k)(5) (7 U.S.C. 136a–1(k)(5)) to read as provided above, without specifying the Act that was being amended. The amendment was executed to this Act to effectuate the probable intent of Congress.

(l)[15] **Performance Measures and Goal.—** The Administrator shall establish and publish annually in the Federal Register performance measures and goals. Such measures and goals shall include—

[15] Sec. 501(f) of P.L. 104–170 amended sec. 4 (7 U.S.C. 136a–1) by redesignating subsecs. (l) and (m) as subsecs. (m) and (n), respectively, and inserting a new subsec. (l), without specifying the Act that was being amended. The amendments were executed to this Act to effectuate the probable intent of Congress.

(1) the number of products reregistered, canceled, or amended, the status of reregistration, the number and type of data requests under section 3(c)(2)(B) issued to support product reregistration by active ingredient, the progress in reducing the number of unreviewed, required reregistration studies,

the aggregate status of tolerances reassessed, and the number of applications for registration submitted under subsection (k)(3) that were approved or disapproved;

(2) the future schedule for reregistrations, including the projection for such schedules that will be issued under subsection (g)(2)(A) and (B) in the current fiscal year and the succeeding fiscal year; and

(3) the projected year of completion of the reregistrations under this section.

(m) **Judicial Review.—** Any failure of the Administrator to take any action required by this section shall be subject to judicial review under the procedures prescribed by section 16(b).

(n) **Authorization of Funds To Develop Public Health Data.—**

(1) **Definition.—** For the purposes of this section, "Secretary" means the Secretary of Health and Human Services, acting through the Public Health Service.

(2) **Consultation.—** In the case of a pesticide registered for use in public health programs for vector control or for other uses the Administrator determines to be human health protection uses, the Administrator shall, upon timely request by the registrant or any other interested person, or on the Administrator's own initiative may, consult with the Secretary prior to taking final action to suspend registration under section 3(c)(2)(B)(iv), or cancel a registration under section 4, 6(e), or 6(f). In consultation with the Secretary, the Administrator shall prescribe the form and content of requests under this section.

(3) **Benefits to support family.—** The Administrator, after consulting with the Secretary, shall make a determination whether the potential benefits of continued use of the pesticide for public health or health protection purposes are of such significance as to warrant a commitment by the Secretary to conduct or to arrange for the conduct of the studies required by the Administrator to support continued registration under section 3 or reregistration under section 4.

(4) **Additional time.—** If the Administrator determines that such a commitment is warranted and in the public interest, the Administrator shall notify the Secretary and shall, to the extent necessary, amend a notice issued under section 3(c)(2)(B) to specify additional reasonable time periods for submission of the data.

(5) **Arrangements.—** The Secretary shall make such arrangements for the conduct of required studies as the Secretary finds necessary and appropriate to permit submission of data in accordance with the time periods prescribed by the Administrator. Such arrangements may include Public Health Service intramural research activities, grants, contracts, or cooperative agreements with academic, public health, or other organizations qualified by experience and training to conduct such studies.

(6) **Support.—** The Secretary may provide for support of the required studies using funds authorized to be appropriated under this section, the Public Health Service Act, or other appropriate authorities. After a determination is made under subsection (d), the Secretary shall notify the Committees on Appropriations of the House of Representatives and the Senate of the sums required to conduct the necessary studies.

(7) **Authorization of appropriations.—** There is authorized to be appropriated to carry out the purposes of this section $12,000,000 for fiscal year 1997, and such sums as may be necessary for succeeding fiscal years.

Sec. 33. 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 Act 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)~~ *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) ~~after review~~ *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 registration service fee) by the date that is 30 days after the fee is due, the fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(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),*~~

(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

		New Active Ingredient, Seed treatment only; includes agricultural and non-agricultural seeds; non-food use, not requiring a tolerance.	*27*	
R123	*11*	*(2) (3)*		*676,296*
	12	*New Active Ingredient, Seed treatment only; limited uptake into raw agricultural commodities; use requiring a*	*31*	
R126	*(new)*	*tolerance. (2) (3)*		*743,925*
		New Active Ingredient, Seed treatment; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that	*16*	
R125	*13*	*follows. (3) (4)*		*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	21		378,742

		ingredient registered for non-food use. (3) (4) (5)		
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*
R250	*28*	*Additional use; non-food; outdoor; Experimental Use Permit application; no credit toward new use registration. (3) (4) (5)*	*6*	*28,434*

		Experimental Use Permit application which requires no changes to the tolerance(s); non-	*8*	
R251	*29*	*crop destruct basis. (3) (5)*		*28,434*
		New use; non-food; indoor.	*12*	
R260	*30*	*(3) (4) (5)*		*21,954*
		New use; non-food; indoor;	*9*	
R270	*31*	*reduced risk. (3) (4) (5)*		*18,296*
		New use; non-food; indoor; Experimental Use Permit application; no credit toward	*6*	
R271	*32*	*new use registration. (3) (4) (5)*		*13,940*
		Additional use; seed treatment only; use not requiring a new tolerance; includes crops with established tolerances (e.g., for soil or foliar application). (3)	*12*	
R273	*33*	*(4) (5)*		*72,302*
		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)	*12*	
R274	*34*	*(5)*		*433,793*
		Additional use, seed treatment only; limited uptake	*14*	
	35	*into raw agricultural commodities; use requiring a*		
R276	*(new)*	*tolerance. (3) (4) (5)*		*79,560*
		Additional use, seed treatment only; 6 or more submitted in one application;	*14*	
	36	*limited uptake into raw agricultural commodities; use*		
R277	*(new)*	*requiring a tolerance. (3) (4) (5)*		*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;	12	389,897

		domestic or import; applicant-initiated.		
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*
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.

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"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
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	4	2,720

		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)			
		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. Child-resistant packaging and/or* *4. pest(s) requiring efficacy – for up to 3 target pests. (2) (3) (4)*	*7*		
R310	*52*	*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*	*8*	*10,466*	
R314	*53*			*12,364*	

		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)*			
		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*		
R319	*54*			*18,097*	

		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*		
R318	*55*			*18,994*	
		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;	*11*		
R321	*56*	*requires review of data package*		*24,727*	

		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)*			
		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*		
R315	*57*	*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:*	*9*	*14,075*	
R316	*58*			*16,199*	

		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)*			
		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*		
R317	*59*	*New product; new physical form; requires data review in science divisions. (2) (3) (5)*	*12*	*21,932*	
R320	*60*	*New product; repack of identical registered end-use product as a manufacturing-use product; same registered uses only. (2) (3)*	*3*	*18,958*	
R331	*61*			*3,627*	

		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	*24*	
R332	*62*	*science divisions. (2) (3)*		*405,919*
		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	*11*	
R333	*63*	*required data. (2) (3)*		*28,434*
		New product; manufacturing-use product or end-use product with unregistered source of the active ingredient; requires science data review; new physical form; etc.	*12*	
R334	*64*	*Selective data citation. (2) (3)*		*33,108*
		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;	*12*	
	65	*includes data and/or waivers of data for only:*		
R361	*(new)*			*23,400*

		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)*			
		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*		
R362	*66 (new)*	*New product; repack of identical registered manufacturing-use product as an end-use product; same registered*	*6*	*25,350*	
R363	*67 (new)*			*7,800*	

		uses only, with no additional data. (2) (3)		

(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*	*7*	*12,643*

		5. child resistant packaging. (2) (3) (4)		
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	5	7,322	

		product chemistry; product chemistry data submitted. (2) (3)		
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
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	10	18,668

		public health organisms. (2) (3) (5) (6)		
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*

		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-	*6*	
A521	*110*	*initiated; Tier 1.*		*6,776*
		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;	*12*	
A522	*111*	*Tier 2.*		*17,424*
		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	*18*	
A537	*112*	*that follows. (3)*		*219,512*
		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	*18*	
A538	*113*	*that follows. (3)*		*137,198*
		New Active Ingredient/New Use, Experimental Use Permit application; Nonfood use. Credit 45% of fee toward new active ingredient/new use	*15*	
A539	*114*	*application that follows. (3)*		*132,094*
		Amendment to	*9*	
A529	*115*	*Experimental Use Permit;*		*16,383*

		requires data review or risk assessment. (2) (3)		
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
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*

		New product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption; (including non-food); Must address Product-Specific	*9*		
B670	*134*	*Data Requirements. (2) (3)*		*7,322*	
		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)	*15*		
B672	*135*	*(3)*		*13,069*	
		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	*12*		
B673	*136*	*product. (2) (3)*		*7,322*	
		New product; repack of identical registered end-use product or repack of an end-use product as a manufacturing-use product; same registered uses	*4*		
B674	*137*	*only. (2) (3)*		*1,833*	
		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*	*12*		
B677	*138*	*2. acute toxicity and/or*		*12,643*	

		3. public health pest efficacy and/or *4. animal safety studies and/or* *5. child resistant packaging. (2) (3)*		

(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*	*7*	*7,322*	

		established temporary or permanent tolerance or tolerance exemption. (3) (4)		
		Amendment; Experimental Use Permit; petition to amend a permanent or temporary tolerance or tolerance	11	
B622	140	exemption. (3) (4)		18,296
		Amendment; changes to an established tolerance or	13	
B641	141	tolerance exemption. (4)		18,296
		Amendment; registered sources of active ingredient(s); no new use(s); no changes to an established tolerance or tolerance exemption; requires	5	
B680	142	data submission. (2) (3)		7,322
		Amendment; unregistered source of active ingredient(s); no change to an established tolerance or tolerance exemption; requires data	7	
B681	143	submission. (2) (3)		8,714
		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).	6	
B683	144	(2) (3)		7,322
		Amending non-food animal product that includes submission of target animal safety data;	8	
B684	145	previously registered. (2) (3)		12,643
		Amendment; add a new biochemical unregistered source of active ingredient or a new	5	
B685	146	microbial production site;		7,322

		requires submission of analysis of samples data and source/ production site-specific manufacturing process description. (3)		

(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
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	7		3,552

		tolerance or tolerance exemption. (4) (5) (6) (7)		
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 ($)	

		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*	*9*		
B740	*159*	*intended use(s). (4) (5) (12)*		*137,198*	
		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.	*12*		
B750	*160*	*(4) (12)*		*182,927*	
		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	*13*		
B771	*161*	*ingredient that follows. (5) (12)*		*182,927*	
		Application to amend or extend a PIP Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active	*3*		
B772	*162*	*ingredient is unaffected. (12)*		*18,296*	

		Application to amend or extend a PIP Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active	*9*	
B773	*163*	*ingredient. (12)*		*45,737*
		Registration application; new (2) PIP; non-food/feed or food/feed without tolerance petition based on an existing permanent tolerance exemption.	*16*	
B780	*164*	*(5) (12) (14)*		*228,657*
		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)	*17*	
B800	*165*	*(14)*		*246,949*
		Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient. (5) (12)	*19*	
B820	*166*	*(14)*		*292,682*
		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	*9*	
B851	*167*	*ingredient(s). (12)*		*182,927*
		Registration application; registered (3) PIP; new product; new use; no petition since a permanent tolerance/ tolerance exemption is already established for the active	*9*	
B870	*168*	*ingredient(s). (4) (12) (14)*		*54,881*

		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*	
B880	*169*			*45,737*
		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*	
B883	*170*			*182,927*
		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*	
B884	*171*			*228,657*
		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*	
B885	*172*			*45,737*
		Application to amend a seed increase registration; converts registration to commercial registration; no petition since permanent	*9*	
B890	*173*			*91,465*

		tolerance/tolerance exemption is already established for the active ingredient(s). (5) (12) (14)		
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*
B921	*183*	*Experimental Use Permit application; genetic*	*12*	*182,927*

		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).			
	(new)	*(5) (12) (13)*			
		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)	*16*		
	184				
B922	*(new)*	*(14)*		*228,657*	
		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	*15*		
	185				
B923	*(new)*			*228,658*	

		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)			
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*	

		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*		
B927	*189 (new)*			*54,889*	
		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*		
B928	*190 (new)*			*137,210*	
		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*		
B929	*191 (new)*			*7,322*	
		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*		
B930	*192 (new)*			*18,296*	
		Application to amend or extend a non-PIP Emerging Technologies Experimental Use	*9*		
B931	*193 (new)*			*45,737*	

		Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient. (12)		
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	18		91,651

		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)			
		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*		
M005	*217*			*31,604*	
		Request for up to 5 letters of certification (Gold Seal) for one actively registered product (excludes distributor products). (7)	*1*		
M006	*218*			*398*	
		Request to extend Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(ii).	*12*		
M007	*219*			*7,903*	
		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*		
M008	*220*			*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.

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

TABLE 1. — REGISTRATION DIVISION — NEW ACTIVE INGREDIENTS

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

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day. (2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application. (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

R010 1 New Active Ingredient, Food use. (2)(3) 24 753,082 R020 2 New Active Ingredient, Food use; reduced risk. (2)(3) 18 627,568 R040 3 New Active Ingredient, Food use; Experimental Use Permit application; establish temporary tolerance; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3) 18 462,502 R060 4 New Active Ingredient, Non-food use; outdoor. (2)(3) 21 523,205 R070 5 New Active Ingredient, Non-food use; outdoor; reduced risk. (2)(3) 16 436,004 R090 6 New Active Ingredient, Non-food use; outdoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3) 16 323,690 R110 7 New Active Ingredient, Non-food use; indoor. (2)(3) 20 290,994 R120 8 New Active Ingredient, Non-food use; indoor; reduced risk. (2)(3) 14 242,495 R121 9 New Active Ingredient, Non-food use; indoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3) 18 182,327 R122 10 Enriched isomer(s) of registered mixed-isomer active ingredient. (2)(3) 18 317,128 R123 11 New Active Ingredient, Seed treatment only; includes agricultural and non-agricultural seeds; residues not expected in raw agricultural commodities. (2)(3) 18 471,861 R125 12 New Active Ingredient, Seed treatment; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3) 16 323,690

TABLE 2. — REGISTRATION DIVISION — NEW USES	*EPA No. New CR No. Action Decision Review Time (Months)*(1)	*Registration Service Fee ($)*

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day. (2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application. (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency. (4) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes agri-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

R130 13 First food use; indoor; food/food handling. (2) (3) 21 191,444 R140 14 Additional food use; Indoor; food/food handling. (3) (4) 15 44,672 R150 15 First food use. (2)(3) 21 317,104 R155 16 (new) First food use, Experimental Use Permit application; a.i. registered for non-food outdoor use. (3)(4) 21 264,253 R160 17 First food use; reduced risk. (2)(3) 16 264,253 R170 18 Additional food use. (3) (4) 15 79,349 R175 19 Additional food uses covered within a crop group resulting from the conversion of existing approved crop group(s) to one or more revised crop groups. (3)(4) 10 66,124 R180 20 Additional food use; reduced risk. (3)(4) 10 66,124 R190 21 Additional food uses; 6 or more submitted in one application. (3)(4) 15 476,090 R200 22 Additional Food Use; 6 or more submitted in one application; Reduced Risk. (3)(4) 10 396,742 R210 23 Additional food use; Experimental Use Permit application; establish temporary tolerance; no credit toward new use registration. (3)(4) 12 48,986 R220 24 Additional food use; Experimental Use Permit application; crop destruct basis; no credit toward new use registration. (3)(4) 6 19,838 R230 25 Additional use; non-food; outdoor. (3) (4) 15 31,713 R240 26 Additional use; non-food; outdoor; reduced risk. (3)(4) 10 26,427 R250 27 Additional use; non-food; outdoor; Experimental Use Permit application; no credit toward new use registration. (3)(4) 6 19,838 R251 28 Experimental Use Permit application which requires no changes to the tolerance(s); non-crop destruct basis. (3) 8 19,838 R260 29 New use; non-food; indoor. (3) (4) 12 15,317 R270 30 New use; non-food; indoor; reduced risk. (3)(4) 9 12,764 R271 31 New use; non-food; indoor; Experimental Use Permit application; no credit toward new use registration. (3)(4) 6 9,725 R273 32 Additional use; seed treatment; limited uptake into Raw Agricultural Commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food and/or non-food uses. (3)(4) 12 50,445 R274 33 Additional uses; seed treatment only; 6 or more submitted in one application; limited uptake into raw agricultural commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food and/or non-food uses. (3)(4) 12 302,663

TABLE 3. — REGISTRATION DIVISION — IMPORT AND OTHER TOLERANCES

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

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day. (2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application. (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency. (4) Amendment applications to add the revised use pattern(s) to registered product labels are covered by the base fee for the category. All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the amendment application package is subject to the registration service fee for a new product or a new inert approval. However, if an amendment application only proposes to register the amendment for a new product and there are no amendments in the application, then review of one new product application is covered by the base fee. All such associated applications that are submitted together will be subject to the category decision review time.

R280 34 Establish import tolerance; new active ingredient or first food use. (2) 21 319,072 R290 35 Establish Import tolerance; Additional new food use. 15 63,816 R291 36 Establish import tolerances; additional food uses; 6 or more crops submitted in one petition. 15 382,886 R292 37 Amend an established tolerance (e.g., decrease or increase) and/or harmonize established tolerances with Codex MRLs; domestic or import; applicant-initiated. 11 45,341 R293 38 Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated. 12 53,483 R294 39 Establish tolerances for inadvertent residues; 6 or more crops submitted in one application; applicant-initiated. 12 320,894 R295 40 Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; submission of corresponding label amendments which specify the necessary plant-back restrictions; applicant-initiated. (3) (4) 15 66,124 R296 41 Establish tolerances for residues in rotational crops in response to a specific rotational crop petition; 6 or more crops submitted in one application; submission of corresponding label amendments which specify the necessary plant-back restrictions; applicant-initiated. (3) (4) 15 396,742 R297 42 Amend 6 or more established tolerances (e.g., decrease or increase) in one petition; domestic or import; applicant-initiated. 11 272,037 R298 43 Amend an established tolerance (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3) (4) 13 58,565 R299 44 Amend 6 or more established tolerances (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3) (4) 13 285,261

TABLE 4. — REGISTRATION DIVISION — NEW PRODUCTS

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

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day. (2) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient. (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency. (4) For the purposes of classifying proposed registration actions into PRIA categories, pest(s) requiring efficacy" are: public health pests listed in PR Notice 2002–1, livestock pests (e.g. Horn flies, Stable flies), wood-destroying pests (e.g. termites, carpenter ants, wood-boring beetles) and certain invasive species (e.g. Asian Longhorned beetle, Emerald Ashborer). This list may be updated/refined as invasive pest needs arise. To determine the number of pests for the PRIA categories, pests have been placed into groups (general; e.g., cockroaches) and pest specific (specifically a test species). If seeking a label claim against a pest group (general), use the group listing below and each group will count as 1. The general pests groups are: mites, dust mites, chiggers, ticks, hard ticks, soft ticks, cattle ticks, scorpions, spiders, centipedes, lice, fleas, cockroaches, keds, bot flies, screwworms, filth flies, blow flies, house flies, flesh flies, mosquitoes, biting flies, horse flies, stable flies, deer flies, sand flies, biting midges, black flies, true bugs, bed bugs, stinging bees, wasps, yellow jackets, hornets, ants (excluding carpenter ants), fire and harvester ants, wood destroying beetles, carpenter ants, termites, subterranean termites, dry wood termites, arboreal termites, damp wood termites and invasive species. If seeking a claim against a specific pest without a general claim then each specific pest will count as 1.

R300 45 New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; no data review on acute toxicity, efficacy or CRP – only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix. (2)(3) 4 1,582 R301 46 New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy (identical data citation and claims to cited product(s)), where applicant does not own all required data and does not have a specific authorization letter from data owner. (2)(3) 4 1,897 R310 47 New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:

• product chemistry and/or
• acute toxicity and/or
• child resistant packaging and/or
• pest(s) requiring efficacy (4) - for up to 3 target pests. (2)(3) 7 7,301 R314 48 New end use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:

• product chemistry and/or
• acute toxicity and/or
• child resistant packaging and/or
• pest(s) requiring efficacy (4) - for up to 3 target pests. (2)(3) 8 8,626 R319 49 New end use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the

TABLE 5. — REGISTRATION DIVISION — AMENDMENTS

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

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day. (2) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees. (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency. (4) For the purposes of classifying proposed registration actions into PRIA categories, "pest(s) requiring efficacy" are: public health pests listed in PR Notice 2002–1, livestock pests (e.g. Horn flies, Stable flies), wood-destroying pests (e.g. termites, carpenter ants, wood-boring beetles) and certain invasive species (e.g. Asian Longhorned beetle, Emerald Ashborer). This list may be updated/refined as invasive pest needs arise. To determine the number of pests for the PRIA categories, pests have been placed into groups (general; e.g., cockroaches) and pest specific (specifically a test species). If seeking a label claim against a pest group (general), use the group listing below and each group will count as 1. The general pests groups are: mites, dust mites, chiggers, ticks, hard ticks, soft ticks, cattle ticks, scorpions, spiders, centipedes, lice, fleas, cockroaches, keds, bot flies, screwworms, filth flies, blow flies, house flies, flesh flies, mosquitoes, biting flies, horse flies, stable flies, deer flies, sand flies, biting midges, black flies, true bugs, bed bugs, stinging bees, wasps, yellow jackets, hornets, ants (excluding carpenter ants), fire and harvester ants, wood destroying beetles, carpenter ants, termites, subterranean termites, dry wood termites, arboreal termites, damp wood termites and invasive species. If seeking a claim against a specific pest without a general claim then each specific pest will count as 1.

R340 60 Amendment requiring data review within RD (e.g., changes to precautionary label statements); includes adding/modifying pest(s) claims for up to 2 target pests, excludes products requiring or citing an animal safety study. (2)(3)(4) 4 4,988 R341 61 (New) Amendment requiring data review within RD (e.g., changes to precautionary label statements), includes adding/modifying pest(s) claims for greater than 2 target pests, excludes products requiring or citing an animal safety study. (2)(3)(4) 6 5,988 R345 62 Amending on-animal products previously registered, with the submission of data and/or waivers for only:

- animal safety and
- pest(s) requiring efficacy (4) and/or
- product chemistry and/or
- acute toxicity and/or
- child resistant packaging. (2)(3) 7 8,820 R350 63 Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement). (2)(3) 9 13,226 R351 64 Amendment adding a new unregistered source of active ingredient. (2)(3) 8 13,226 R352 65 Amendment adding already approved uses; selective method of support; does not apply if the applicant owns all cited data. (2) (3) 8 13,226 R371 66 Amendment to Experimental Use Permit; (does not include extending a permit's time period). (3) 6 10,090

TABLE 6. — REGISTRATION DIVISION — OTHER ACTIONS

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

(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.

R124 67 Conditional Ruling on Pre-application Study Waivers; applicant-initiated. 6 2,530 R272 68 Review of Study Protocol applicant-initiated; excludes DART, pre-registration conference, Rapid Response review, DNT protocol review, protocol needing HSRB review. 3 2,530 R275 69 Rebuttal of agency reviewed protocol, applicant initiated. 3 2,530 R370 70 Cancer reassessment; applicant-initiated. 18 198,250

TABLE 7. — ANTIMICROBIALS DIVISION — NEW ACTIVE INGREDIENTS

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

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day. (2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application. (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

A380 71 New Active Ingredient; Indirect Food use; establish tolerance or tolerance exemption if required. (2)(3) 24 137,841 A390 72 New Active Ingredient; Direct Food use; establish tolerance or tolerance exemption if required. (2)(3) 24 229,733 A410 73 New Active Ingredient Non-food use.(2)(3) 21 229,733 A431 74 New Active Ingredient, Non-food use; low-risk. (2)(3) 12 80,225

TABLE 8. — ANTIMICROBIALS DIVISION — NEW USES

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

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day. (2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application. (3) If EPA data rules are amended to newly require clearance under section 408 of the FFDCA for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule. (4) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency. (5) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the

A440 75 New Use, Indirect Food Use, establish tolerance or tolerance exemption. (2)(3)(4) 21 31,910 A441 76 Additional Indirect food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application. (3)(4)(5) 21 114,870 A450 77 New use, Direct food use, establish tolerance or tolerance exemption. (2)(3)(4) 21 95,724 A451 78 Additional Direct food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application. (3)(4)(5) 21 182,335 A500 79 New use, non-food. (4)(5) 12 31,910 A501 80 New use, non-food; 6 or more submitted in one application. (4)(5) 15 76,583

TABLE 9. — ANTIMICROBIALS DIVISION — NEW PRODUCTS AND AMENDMENTS

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

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day. (2) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient. (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency. (4)(a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees. (5) The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements. (6) Once a submission for a new product with public health organisms has been submitted and classified in either A540 or A541, additional organisms submitted for the same product before expiration of the first submission's original decision review time period will result in reclassification of both the original and subsequent submission into the appropriate new category based on the sum of the number of organisms in both submissions. A reclassification would result in a new PRIA start date and require additional fees to meet the fee of the new category. (7) Once a submission for a label amendment with public health organisms has been submitted and classified in either A570 or A573, additional organisms submitted for the same product before expiration of the first submission's original decision review time period will result in reclassification of both the original and subsequent submission into the appropriate new category based on the sum of the number of organisms in both submissions. A reclassification would result in a new PRIA start date and require additional fees to meet the fee of the new category.

A530 81 New product, identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite all data citation or selective data citation where applicant owns all required data; or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing use product that requires no data submission nor data matrix. (2)(3) 4 1,278 A531 82 New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient: selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner. (2)(3) 4 1,824 A532 83 New product; identical or substantially similar in composition and use to a registered product; registered active ingredient; unregistered source of active ingredient; cite-all data citation except for product chemistry; product chemistry data submitted. (2)(3) 5 5,107 A540 84 New end use product; FIFRA §2(mm) uses only; up to 25 public health organisms. (2)(3)(5)(6) 5 5,107 A541 85 (new) New end use product; FIFRA §2(mm) uses only; 26–50 public health organisms. (2)(3)(5)(6) 7 8,500 A542 86 (new) New end use product; FIFRA §2(mm) uses only; 51 public health organisms. (2)(3)(5) 10 15,000 A550 87 New end-use product; uses other than FIFRA §2(mm); non-FQPA product. (2)(3)(5) 9 13,226 A560 88 New manufacturing use product; registered active ingredient; selective data citation. (2)(3) 6 12,596 A565 89 (new) New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of new generic data package; registered uses only; requires science review. (2)(3) 12 18,234 A570 90 Label amendment requiring data review; up to 25 public health organisms. (3)(4)(5)(6) 4 3,831 A573 91 (new) Label amendment requiring data review; 26–50 public health organisms. (2)(3)(5)(7) 6 6,350 A574 92 (new) Label amendment requiring data review; 51 public health organisms. (2)(3)(5)(7) 9 11,000 A572 93 New Product or amendment requiring data review for risk assessment by Science Branch (e.g., changes to REI, or PPE, or use rate). (2)(3)(4) 9 13,226

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

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

(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.

A520 94 Experimental Use Permit application, non-food use. (2) 9 6,383 A521 95 Review of public health efficacy study protocol within AD, per AD Internal Guidance for the Efficacy Protocol Review Process; Code will also include review of public health efficacy study protocol and data review for devices making pesticidal claims; applicant-initiated; Tier 1. 4 4,726 A522 96 Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; Code will also include review of public health efficacy study protocol and data review for devices making pesticidal claims; applicant-initiated; Tier 2. 12 12,156 A537 97 (new) New Active Ingredient/New Use, Experimental Use Permit application; Direct food use; Establish tolerance or tolerance exemption if required. Credit 45% of fee toward new active ingredient/new use application that follows. 18 153,156 A538 98 (new) New Active Ingredient/New Use, Experimental Use Permit application; Indirect food use; Establish tolerance or tolerance exemption if required Credit 45% of fee toward new active ingredient/new use application that follows. 18 95,724 A539 99 (new) New Active Ingredient/New Use, Experimental Use Permit application; Nonfood use. Credit 45% of fee toward new active ingredient/new use application that follows. 15 92,163 A529 100 Amendment to Experimental Use Permit; requires data review or risk assessment. (2) 9 11,429 A523 101 Review of protocol other than a public health efficacy study (i.e., Toxicology or Exposure Protocols). 9 12,156 A571 102 Science reassessment: Cancer risk, refined ecological risk, and/or endangered species; applicant-initiated. 18 95,724 A533 103 (new) Exemption from the requirement of an Experimental Use Permit. (2) 4 2,482 A534 104 (new) Rebuttal of agency reviewed protocol, applicant initiated. 4 4,726 A535 105 (new) Conditional Ruling on Pre-application Study Waiver or Data Bridging Argument; applicant-initiated. 6 2,409 A536 106 (new) Conditional Ruling on Pre-application Direct Food, Indirect Food, Nonfood use determination; applicant-initiated. 4 2,482

TABLE 11. — BIOPESTICIDES DIVISION — NEW ACTIVE INGREDIENTS

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

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day. (2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application. (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

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

TABLE 12. — BIOPESTICIDES DIVISION — NEW USES	EPA No. New CR No. Action Decision Review Time (Months)(1)	Registration Service Fee ($)

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day. (2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application. (3) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screen, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application. (4) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with

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

TABLE 13. — BIOPESTICIDES DIVISION — NEW PRODUCTS

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

(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.

B652	124	New product; registered source of active ingredient; requires petition to amend established tolerance or tolerance exemption; requires 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply.	(2)(3) 13	12,764
B660	125	New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product. No data review, or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data or authorization from data owner is demonstrated. Category includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission or data matrix. For microbial pesticides, the active ingredient(s) must not be re-isolated.	(2)(3) 4	1,278
B670	126	New product; registered source of active ingredient(s); requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply.	(2)(3) 7	5,107
B671	127	New product; unregistered source of active ingredient(s); requires a petition to amend an established tolerance or tolerance exemption; requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply.	(2)(3) 17	12,764
B672	128	New product; unregistered source of active ingredient(s); non-food use or food use requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply.	(2)(3) 13	9,118
B673	129	New product MUP/EP; unregistered source of active ingredient(s); citation of Technical Grade Active Ingredient (TGAI) data previously reviewed and accepted by the Agency. Requires an Agency determination that the cited data supports the new product.	(2)(3) 10	5,107
B674	130	New product MUP; Repack of identical registered end-use product as a manufacturing-use product; same registered uses only.	(2)(3) 4	1,278
B675	131	New Product MUP; registered source of active ingredient; submission of completely new generic data package; registered uses only.	(2)(3) 10	9,118

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B676	132	New product; more than one active ingredient where one active ingredient is an unregistered source; product chemistry data must be submitted; requires: 1) submission of product specific data, and 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply.	(2)(3) 13	9,118
B677	133	New end-use non-food animal product with submission of two or more target animal safety studies; includes data and/or waivers of data for only: • product chemistry and/or • acute toxicity and/or • public health pest efficacy and/or • animal safety studies and/or • child resistant packaging	(2)(3) 10	8,820

TABLE 14. — BIOPESTICIDES DIVISION — AMENDMENTS

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

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day. (2) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees. (3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

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

TABLE 15. — BIOPESTICIDES DIVISION — SCLP	EPA No.	New CR	No. Action Decision Review Time (Months)(1)	Registration Service Fee ($)

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day. (2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application. (3) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient. (4) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees. (5) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screen, and (c) is not itself a covered registration

B690 142 New active ingredient; food or non-food use. (2)(6) 7 2,554 B700 143 Experimental Use Permit application; new active ingredient or new use. (6) 7 1,278 B701 144 Extend or amend Experimental Use Permit. (6) 4 1,278 B710 145 New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption. No data review, or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data or authorization from data owner is demonstrated. Category includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission or data matrix. (3)(6) 4 1,278 B720 146 New product; registered source of active ingredient(s); requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (3)(6) 5 1,278 B721 147 New product; unregistered source of active ingredient. (3)(6) 7 2,676 B722 148 New use and/or amendment; petition to establish a tolerance or tolerance exemption. (4)(5)(6) 7 2,477 B730 149 Label amendment requiring data submission. (4)(6) 5 1,278

TABLE 16. — BIOPESTICIDES DIVISION — OTHER ACTIONS

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

(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.

B614 150 Pre-application; Conditional Ruling on rationales for addressing a data requirement in lieu of data; applicant-initiated; applies to one rationale at a time. 3 2,530 B615 151 Rebuttal of agency reviewed protocol, applicant initiated. 3 2,530 B682 152 Protocol review; applicant initiated; excludes time for HSRB review. 3 2,432

TABLE 17. — BIOPESTICIDES DIVISION — PIP	*EPA No. New CR No. Action Decision Review Time (Months)*(1)	*Registration Service Fee ($)*

(1) A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day. (2) New PIP = a PIP with an active ingredient that has not been registered. (3) Registered PIP = a PIP with an active ingredient that is currently registered. (4) Transfer registered PIP through conventional breeding for new food/feed use, such as from field corn to sweet corn. (5) The scientific data involved in this category are complex. EPA often seeks technical advice from the Scientific Advisory Panel on risks that pesticides pose to wildlife, farm workers, pesticide applicators, non-target species, as well as insect resistance, and novel scientific issues surrounding new technologies. The scientists of the SAP neither make nor recommend policy decisions. They provide advice on the science used to make these decisions. Their advice is invaluable to the EPA as it strives to protect humans and the environment from risks posed by pesticides. Due to the time it takes to schedule and prepare for meetings with the SAP, additional time and costs are needed. (6) Registered PIPs stacked through conventional breeding. (7) Deployment of a registered PIP with a different IRM plan (e.g., seed blend). (8) The negotiated acreage cap will depend upon EPA's determination of the potential environmental exposure, risk(s) to non-target organisms, and the risk of targeted pest developing resistance to the pesticidal substance. The uncertainty of these risks may reduce the allowable acreage, based upon the quantity and type of non-target organism data submitted and the lack of insect resistance management data, which is usually not required for seed-increase registrations. Registrants are encouraged to consult with EPA prior to submission of a registration application in this category. (9) Application can be submitted prior to or concurrently with an application for commercial registration. (10) For example, IRM plan modifications that are applicant-initiated. (11) EPA-initiated amendments shall not be charged fees. (12) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant’s written or electronic confirmation of agreement to the Agency.

B740 153 Experimental Use Permit application; no petition for tolerance/tolerance exemption. Includes:
1. non-food/feed use(s) for a new (2) or registered (3) PIP (12);
2. food/feed use(s) for a new or registered PIP with crop destruct (12);
3. food/feed use(s) for a new or registered PIP in which an established tolerance/tolerance exemption exists for the intended use(s). (4)(12) 6 95,724 B741 154 (new) Experimental Use Permit application; no petition for tolerance/tolerance exemption. Includes:
1. non-food/feed use(s) for a new (2) or registered (3) PIP;
2. food/feed use(s) for a new or registered PIP with crop destruct;
3. food/feed use(s) for a new or registered PIP in which an established tolerance/tolerance exemption exists for the intended use(s);
SAP Review. (12) 12 159,538 B750 155 Experimental Use Permit application; with a petition to establish a temporary or permanent tolerance/tolerance exemption for the active ingredient. Includes new food/feed use for a registered (3) PIP. (4)(12) 9 127,630 B770 156 Experimental Use Permit application; new (2) PIP; with petition to establish a temporary tolerance/tolerance exemption for the active ingredient; credit 75% of B771 fee toward registration application for a new active ingredient that follows; SAP review. (5)(12) 15 191,444 B771 157 Experimental Use Permit application; new (2) PIP; with petition to establish a temporary tolerance/tolerance exemption for the active ingredient; credit 75% of B771 fee toward registration application for a new active ingredient that follows. (12) 10 127,630 B772 158 Application to amend or extend an Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active ingredient is unaffected. (12) 3 12,764 B773 159 Application to amend or extend an Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient. (12) 5 31,910 B780 160 Registration application; new (2) PIP; non-food/feed. (12) 12 159,537 B790 161 Registration application; new (2) PIP; non-food/feed; SAP review. (5)(12) 18 223,351 B800 162 Registration application; new (2) PIP; with petition to establish permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. (12) 13 172,300 B810 163 Registration application; new (2) PIP; with petition to establish permanent tolerance/tolerance exemption for the active

TABLE 18. — INERT INGREDIENTS

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

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

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

TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS

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

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

M001 202 Study protocol requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of an active ingredient. (4) 9 7,938 M002 203 Completed study requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of an active ingredient. (4) 9 7,938 M003 204 External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of less than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA § 25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (5) 12 63,945 M004 205 External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of greater than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA § 25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (5) 18 63,945 M005 206 New Product: Combination, Contains a combination of active ingredients from a registered and/or unregistered source; conventional, antimicrobial and/or biopesticide. Requires coordination with other regulatory divisions to conduct review of data, label and/or verify the validity of existing data as cited. Only existing uses for each active ingredient in the combination product. (6)(7) 9 22,050 M006 207 Request for up to 5 letters of certification (Gold Seal) for one actively registered product (excludes distributor products). (8) 1 277 M007 208 Request to extend Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(ii). 12 5,513 M008 209 Request to grant Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(vi) for a minor use, when a FIFRA Section 2(ll)(2) determination is required. 15 1,654 M009 210 (new) Non-FIFRA Regulated Determination: Applicant initiated, per product. 4 2,363 M010 211 (new) Conditional ruling on pre-application, product substantial similarity. 4 2,363 M011 212 (new) Label amendment to add the DfE logo; requires data review; no other label changes. (9) 4 3,648

(4) **Pending pesticide registration applications.—**

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

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

(C) **Documentation.—** An application for which a voluntary registration service fee is paid under this paragraph shall be submitted with documentation certifying—

(i) payment of the registration service fee; or

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

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

(6) **Fee adjustment.—**

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

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

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 ~~(commonly referred to as a Gold Seal letter)~~ *(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.

(iii) **Inaccurate documentation.—** An application shall be subject to the applicable registration service fee payable under ~~paragraph (3)~~ *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)); 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 4(i)(1)(E)(ii)) 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 4(i)(1)(E)(ii)) at the time of application; and

(II) has average annual global gross revenues described in section 4(i)(1)(E)(ii)(I)(bb) 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 4(i)(1)(E)(ii)) 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 4(i)(1)(E)(ii)(I)(bb) 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.[18] of the total registration service fee payable under ~~paragraph (3)~~ *paragraph (3)(B)* for the application.

[18]

So in original. The period probably should not appear.

(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)~~ *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 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) **Worker protection, partnership grants, and pesticide safety education.—**~~

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

~~(ii) **Partnership grants.—** Of the amounts in the Fund, the Administrator shall use for partnership grants, for each of fiscal years 2013 through 2023, $500,000.~~

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

(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 the date of enactment of the Pesticide Registration Improvement Act of 2022.

(II) With respect to new outdoor uses of a registered pesticide, not later than 1 year after the date of enactment of the Pesticide Registration Improvement Act of 2022.

(III) With respect to antimicrobial pesticide products, not later than 3 years after the date of enactment of the Pesticide Registration Improvement Act of 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 the date of enactment of the Pesticide Registration Improvement Act of 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 the date of enactment of the Pesticide Registration Improvement Act of 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 findings 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 Act.

(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 3;

(FF) compliance with the provisions of this Act 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 3.

(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; ~~and~~

(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

(~~B~~ *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)[19] maintained readily available or on deposit;

[19] Indentation of clauses (i) through (iii) is so in original (as amended by sec. 5(e)(3)(A) of Public Law 110–94). Clauses probably should be indented.

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

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

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

(d) **Assessment of Fees.—**

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

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

(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

~~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 Act 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 Extension Act of 2018~~ *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)~~ *subsection (b)(3)(B)* and corresponding registration service fees under this Act.

(2) **Report.—** The schedule shall be the same as the applicable schedule provided under ~~subsection (b)(3)~~ *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)~~ *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 determine if—~~ *shall—*

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

(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 Act, 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 3;

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

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

(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, United States Code, the Fund shall be considered a component of an executive agency.

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

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

(B) compliance with subsection (f);

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

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

(3) **Inspector general.—** The Inspector General of the Environmental Protection Agency shall —

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

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

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

~~(k) **Reports.—**~~

~~(1) **In general.—** Not later than March 1, 2005, and each March 1 thereafter through March 1, 2023, the Administrator shall publish an annual report describing actions taken under this section.~~

~~(2) **Contents.—** The report shall include—~~

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

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

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

~~(iii) the amount of money from the Reregistration and Expedited Processing Fund used to carry out inert ingredient review and review of similar applications under section 4(k)(3);~~

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) a review of the progress in meeting the timeline requirements of section 4(g);

(D) a review of the progress in carrying out section 3(g), including—

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

(I) the number of cases cancelled;

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

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

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

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

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

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

(I) process improvements in the handling of registration review under section 3(g);

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

(III) streamlining the registration review process, consistent with section 3(g);

(E) a review of the progress in meeting the timeline requirements for the review of antimicrobial pesticide products under section 3(h);

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

(G) a review of the progress made toward—

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

(ii) implementing enhancements to—

(I) the electronic tracking of covered applications;

(II) the electronic tracking of conditional registrations;

(III) the endangered species database;

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

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

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

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

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

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

(K) a review of the progress made in developing, updating, and implementing product performance test guidelines for pesticide products that are intended to control invertebrate pests of significant public health importance and, by regulation, prescribing product performance data requirements for such pesticide products registered under section 3;

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

(M) a review of the progress made in implementing enhancements to the good laboratory practices standards compliance monitoring program established under part 160 of title 40 of the Code of Federal Regulations (or successor regulations);

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

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

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

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

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

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

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

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

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

~~(3) **Method.—** The Administrator shall publish a report required by this subsection by such method as the Administrator determines to be the most effective for efficiently disseminating the report, including publication of the report on the Internet site of the Environmental Protection Agency.~~

~~(4) **Other report.—**~~

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

~~(i) 10 or fewer employees; and~~

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

~~(B) **Information required.—** In conducting the analysis described in subparagraph (A), the Administrator shall collect, and include in the report under that subparagraph, information on—~~

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

~~(ii) the number of registrations each company holds.~~

(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 3(g), including—

(aa) 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 4(k), 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 subparagraphs (G) and (H) of section 4(i)(1);

(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 4(i)(1), 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 3(f); and

(XX) a review of progress made in implementing the pesticide surveillance program referred to in paragraph (8) of section 4(k).

(ii) REGISTRANT SUBMISSIONS NOT COVERED BY SECTION 33(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 the date of enactment of the Pesticide Registration Improvement Act of 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 real-time, accessible information 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, information 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 Act, including the right to judicial review of duties, obligations, or authorities established by any other section of this Act.

(m) **Termination of Effectiveness.—**

(1) **In general.—** Except as provided in paragraph (2), the authority provided by this section terminates on September 30, ~~2023~~ *2027*.

(2) **Phase out.—**

(A) **Fiscal year ~~2024~~ *2028*.—** During fiscal year ~~2024~~ *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, ~~2023~~ *2027*.

(B) **Fiscal year ~~2025~~.—** During fiscal year ~~2025~~ *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, ~~2023~~ *2027*.

(C) **September 30, ~~2025~~ *2029*.—** Effective September 30, ~~2025~~ *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, ~~2023~~ *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, ~~2023~~ *2027*, subsection (f) shall not apply to the application.

2. Federal Food Drug and Cosmetic Act

[As Amended Through P.L. 117–180, Enacted September 30, 2022]

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CHAPTER IV—FOOD

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Sec. 408.[42] TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

(a) **Requirement for Tolerance or Exemption.—**

42

See footnote for section 406.

(1) **General rule.—** Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 402(a)(2)(B) unless—

(A) a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

(B) an exemption from the requirement of a tolerance is in effect under this section for the pesticide chemical residue.

For the purposes of this section, the term "food", when used as a noun without modification, shall mean a raw agricultural commodity or processed food.

(2) **Processed food.—** Notwithstanding paragraph (1)—

(A) if a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B) despite the lack of a tolerance for the pesticide chemical residue in or on the processed food if the pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section, such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

(B) if an exemption for the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B).

(3) **Residues of degradation products.—** If a pesticide chemical residue is present in or on a food because it is a metabolite or other degradation product of a precursor substance that itself is a pesticide chemical or pesticide chemical residue, such a residue shall not be considered to be unsafe within the meaning of section 402(a)(2)(B) despite the lack of a tolerance or exemption from the need for a tolerance for such residue in or on such food if—

(A) the Administrator has not determined that the degradation product is likely to pose any potential health risk from dietary exposure that is of a different type than, or of a greater significance than, any risk posed by dietary exposure to the precursor substance;

(B) either—

(i) a tolerance is in effect under this section for residues of the precursor substance in or on the food, and the combined level of residues of the degradation product and the precursor substance in or on the food is at or below the stoichiometrically equivalent level that would be permitted by the tolerance if the residue consisted only of the precursor substance rather than the degradation product; or

(ii) an exemption from the need for a tolerance is in effect under this section for residues of the precursor substance in or on the food; and

(C) the tolerance or exemption for residues of the precursor substance does not state that it applies only to particular named substances and does not state that it does not apply to residues of the degradation product.

(4) **Effect of tolerance or exemption.—** While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, the food shall not by reason of bearing or containing any amount of such a residue be considered to be adulterated within the meaning of section 402(a)(1).

(b) **Authority and Standard for Tolerance.—**

(1) **Authority.—** The Administrator may issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food—

(A) in response to a petition filed under subsection (d); or

(B) on the Administrator's own initiative under subsection (e).

As used in this section, the term "modify" shall not mean expanding the tolerance to cover additional foods.

(2) **Standard.—**

(A) **General rule.—**

(i) **Standard.—** The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

(ii) **Determination of safety.—** As used in this section, the term "safe", with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(iii) **Rule of construction.—** With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

(B) **Tolerances for eligible pesticide chemical residues.—**

(i) **Definition.—** As used in this subparagraph, the term "eligible pesticide chemical residue" means a pesticide chemical residue as to which—

(I) the Administrator is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health (referred to in this section as a "nonthreshold effect");

(II) the lifetime risk of experiencing the nonthreshold effect is appropriately assessed by quantitative risk assessment; and

(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to in this section as a "threshold effect"), the Administrator determines that the level of aggregate exposure is safe.

(ii) **Determination of tolerance.—** Notwithstanding subparagraph (A)(i), a tolerance for an eligible pesticide chemical residue may be left in effect or modified under this subparagraph if—

(I) at least one of the conditions described in clause (iii) is met; and

(II) both of the conditions described in clause (iv) are met.

(iii) **Conditions regarding use.—** For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) Use of the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue.

(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.

(iv) **Conditions regarding risk.—** For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that would be allowed under subparagraph (A) for such effect.

(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect.

(v) **Review.—** Five years after the date on which the Administrator makes a determination to leave in effect or modify a tolerance under this subparagraph, and thereafter as the Administrator deems appropriate, the Administrator shall determine, after notice and opportunity for comment, whether it has been demonstrated to the Administrator that a condition described in clause (iii)(I) or clause (iii)(II) continues to exist with respect to the tolerance and that the yearly and lifetime risks from aggregate exposure to such residue continue to comply with the limits specified in clause (iv). If the Administrator determines by such date that such demonstration has not been made, the Administrator shall, not later than 180 days after the date of such determination, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

(vi) **Infants and children.—** Any tolerance under this subparagraph shall meet the requirements of subparagraph (C).

(C) **Exposure of infants and children.—** In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator—

(i) shall assess the risk of the pesticide chemical residue based on—

(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population;

(II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

(III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity; and

(ii) shall—

(I) ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and

(II) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.

The Secretary of Health and Human Services and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children. In the case of threshold effects, for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.

(D) **Factors.—** In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall consider, among other relevant factors—

(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue;

(ii) the nature of any toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies;

(iii) available information concerning the relationship of the results of such studies to human risk;

(iv) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);

(v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;

(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;

(viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects; and

(ix) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

(E) **Data and information regarding anticipated and actual residue levels.—**

(i) **Authority.—** In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and information on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by the Food and Drug Administration.

(ii) **Requirement.—** If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) require that data be provided five years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1), or an order under subsection (f)(2), as appropriate, to modify or revoke the tolerance.

(F) **Percent of food actually treated.—** In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator—

(i) finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;

(ii) finds that the exposure estimate does not understate exposure for any significant subpopulation group;

(iii) finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator; and

(iv) provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

(3) **Detection methods.—**

(A) **General rule.—** A tolerance for a pesticide chemical residue in or on a food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

(B) **Detection limit.—** A tolerance for a pesticide chemical residue in or on a food shall not be established at or modified to a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (A).

(4) **International standards.—** In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

(c) **Authority and Standard for Exemptions.—**

(1) **Authority.—** The Administrator may issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food—

(A) in response to a petition filed under subsection (d); or

(B) on the Administrator's initiative under subsection (e).

(2) **Standard.—**

(A) **General rule.—**

(i) **Standard.—** The Administrator may establish or leave in effect an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the exemption is safe. The Administrator shall modify or revoke an exemption if the Administrator determines it is not safe.

(ii) **Determination of safety.—** The term "safe", with respect to an exemption for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(B) **Factors.—** In making a determination under this paragraph, the Administrator shall take into account, among other relevant considerations, the considerations set forth in subparagraphs (C) and (D) of subsection (b)(2).

(3) **Limitation.—** An exemption from the requirement for a tolerance for a pesticide chemical residue in or on food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary—

(A) that there is a practical method for detecting and measuring the levels of such pesticide chemical residue in or on food; or

(B) that there is no need for such a method, and states the reasons for such determination in issuing the regulation establishing or modifying the exemption.

(d) **Petition for Tolerance or Exemption.—**

(1) **Petitions and petitioners.—** Any person may file with the Administrator a petition proposing the issuance of a regulation—

(A) establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food; or

(B) establishing, modifying, or revoking an exemption from the requirement of a tolerance for such a residue.

(2) **Petition contents.—**

(A) **Establishment.—** A petition under paragraph (1) to establish a tolerance or exemption for a pesticide chemical residue shall be supported by such data and information as are specified in regulations issued by the Administrator, including—

(i) (I) an informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition; and

(II) a statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice of filing of the petition to be published under this subsection and as part of a proposed or final regulation issued under this section;

(ii) the name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the residue;

(iii) data showing the recommended amount, frequency, method, and time of application of that pesticide chemical;

(iv) full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations;

(v) full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the analytical methods used;

(vi) a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed;

(vii) a proposed tolerance for the pesticide chemical residue, if a tolerance is proposed;

(viii) if the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing method(s) used to produce that food;

(ix) such information as the Administrator may require to make the determination under subsection (b)(2)(C);

(x) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects;

(xi) information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue;

(xii) practical methods for removing any amount of the residue that would exceed any proposed tolerance; and

(xiii) such other data and information as the Administrator requires by regulation to support the petition.

If information or data required by this subparagraph is available to the Administrator, the person submitting the petition may cite the availability of the information or data in lieu of submitting it. The Administrator may require a petition to be accompanied by samples of the pesticide chemical with respect to which the petition is filed.

(B) **Modification or revocation.—** The Administrator may by regulation establish the requirements for information and data to support a petition to modify or revoke a tolerance or to modify or revoke an exemption from the requirement for a tolerance.

(3) **Notice.—** A notice of the filing of a petition that the Administrator determines has met the requirements of paragraph (2) shall be published by the Administrator within 30 days after such determination. The notice shall announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue

with respect to which the petition is filed or shall set forth the petitioner's statement of why such a method is not needed. The notice shall include the summary required by paragraph (2)(A)(i)(I).

(4) **Actions by the administrator.—**

(A) **In general.—** The Administrator shall, after giving due consideration to a petition filed under paragraph (1) and any other information available to the Administrator—

(i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance (which final regulation shall be issued without further notice and without further period for public comment);

(ii) issue a proposed regulation under subsection (e), and thereafter issue a final regulation under such subsection; or

(iii) issue an order denying the petition.

(B) **Priorities.—** The Administrator shall give priority to petitions for the establishment or modification of a tolerance or exemption for a pesticide chemical residue that appears to pose a significantly lower risk to human health from dietary exposure than pesticide chemical residues that have tolerances in effect for the same or similar uses.

(C) **Expedited review of certain petitions.—**

(i) **Date certain for review.—** If a person files a complete petition with the Administrator proposing the issuance of a regulation establishing a tolerance or exemption for a pesticide chemical residue that presents a lower risk to human health than a pesticide chemical residue for which a tolerance has been left in effect or modified under subsection (b)(2)(B), the Administrator shall complete action on such petition under this paragraph within 1 year.

(ii) **Required determinations.—** If the Administrator issues a final regulation establishing a tolerance or exemption for a safer pesticide chemical residue under clause (i), the Administrator shall, not later than 180 days after the date on which the regulation is issued, determine whether a condition described in subclause (I) or (II) of subsection (b)(2)(B)(iii) continues to exist with respect to a tolerance that has been left in effect or modified under subsection (b)(2)(B). If such condition does not continue to exist, the Administrator shall, not later than 180 days after the date on which the determination under the preceding sentence is made, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

(e) **Action on Administrator's Own Initiative.—**

(1) **General rule.—** The Administrator may issue a regulation—

(A) establishing, modifying, suspending under subsection (l)(3), or revoking a tolerance for a pesticide chemical or a pesticide chemical residue;

(B) establishing, modifying, suspending under subsection (l)(3), or revoking an exemption of a pesticide chemical residue from the requirement of a tolerance; or

(C) establishing general procedures and requirements to implement this section.

(2) **Notice.—** Before issuing a final regulation under paragraph (1), the Administrator shall issue a notice of proposed rulemaking and provide a period of not less than 60 days for public comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

(f) **Special Data Requirements.—**

(1) **Requiring submission of additional data.—** If the Administrator determines that additional data or information are reasonably required to support the continuation of a tolerance or exemption that is in effect under this section for a pesticide chemical residue on a food, the Administrator shall —

(A) issue a notice requiring the person holding the pesticide registrations associated with such tolerance or exemption to submit the data or information under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act;

(B) issue a rule requiring that testing be conducted on a substance or mixture under section 4 of the Toxic Substances Control Act; or

(C) publish in the Federal Register, after first providing notice and an opportunity for comment of not less than 60 days' duration, an order—

(i) requiring the submission to the Administrator by one or more interested persons of a notice identifying the person or persons who will submit the required data and information;

(ii) describing the type of data and information required to be submitted to the Administrator and stating why the data and information could not be obtained under the authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act or section 4 of the Toxic Substances Control Act;

(iii) describing the reports of the Administrator required to be prepared during and after the collection of the data and information;

(iv) requiring the submission to the Administrator of the data, information, and reports referred to in clauses (ii) and (iii); and

(v) establishing dates by which the submissions described in clauses (i) and (iv) must be made.

The Administrator may under subparagraph (C) revise any such order to correct an error. The Administrator may under this paragraph require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

(2) **Noncompliance.—** If a submission required by a notice issued in accordance with paragraph (1)(A), a rule issued under paragraph (1)(B), or an order issued under paragraph (1)(C) is not made by the time specified in such notice, rule, or order, the Administrator may by order published in the Federal Register modify or revoke the tolerance or exemption in question. In any review of such an order under subsection (g)(2), the only material issue shall be whether a submission required under paragraph (1) was not made by the time specified.

(g) **Effective Date, Objections, Hearings, and Administrative Review.—**

(1) **Effective date.—** A regulation or order issued under subsection (d)(4), (e)(1), or (f)(2) shall take effect upon publication unless the regulation or order specifies otherwise. The Administrator may stay the effectiveness of the regulation or order if, after issuance of such regulation or order, objections are filed with respect to such regulation or order pursuant to paragraph (2).

(2) **Further proceedings.—**

(A) **Objections.—** Within 60 days after a regulation or order is issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C), any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed

objectionable and stating reasonable grounds therefor. If the regulation or order was issued in response to a petition under subsection (d)(1), a copy of each objection filed by a person other than the petitioner shall be served by the Administrator on the petitioner.

(B) **Hearing.—** An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Administrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections. The presiding officer in such a hearing may authorize a party to obtain discovery from other persons and may upon a showing of good cause made by a party issue a subpoena to compel testimony or production of documents from any person. The presiding officer shall be governed by the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, such a subpoena may be enforced by a Federal district court.

(C) **Final decision.—** As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted. If a hearing was held under subparagraph (B), such order and any revision to the regulation or prior order shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at such hearing, and shall set forth in detail the findings of facts and the conclusions of law or policy upon which the order or regulation is based.

(h) **Judicial Review.—**

(1) **Petition.—** In a case of actual controversy as to the validity of any regulation issued under subsection (e)(1)(C), or any order issued under subsection (f)(1)(C) or (g)(2)(C), or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

(2) **Record and jurisdiction.—** A copy of the petition under paragraph (1) shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title 28, United States Code. Upon the filing of such a petition, the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part. As to orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.

(3) **Additional evidence.—** If a party applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the proceeding before the Administrator, the court may order that the additional evidence (and evidence in rebuttal thereof) shall be taken before the Administrator in the manner and upon the terms and conditions the court deems proper. The Administrator may modify prior findings as to the facts by reason of the additional evidence so taken and may modify the order or regulation accordingly. The Administrator shall file with the court any such modified finding, order, or regulation.

(4) **Final judgment; supreme court review.—** The judgment of the court affirming or setting aside, in whole or in part, any regulation or any order and any regulation which is the subject of such

an order shall be final, subject to review by the Supreme Court of the United States as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

(5) **Application.—** Any issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law.

(i) **Confidentiality and Use of Data.—**

(1) **General rule.—** Data and information that are or have been submitted to the Administrator under this section or section 409 in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act.

(2) **Exceptions.—**

(A) **In general.—** Data and information that are entitled to confidential treatment under paragraph (1) may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

(i) employees of the United States authorized by the Administrator to examine such data and information in the carrying out of their official duties under this Act or other Federal statutes intended to protect the public health; or

(ii) contractors with the United States authorized by the Administrator to examine such data and information in the carrying out of contracts under this Act or such statutes.

(B) **Congress.—** This subsection does not authorize the withholding of data or information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(3) **Summaries.—** Notwithstanding any provision of this subsection or other law, the Administrator may publish the informative summary required by subsection (d)(2)(A)(i) and may, in issuing a proposed or final regulation or order under this section, publish an informative summary of the data relating to the regulation or order.

(j) **Status of Previously Issued Regulations.—**

(1) **Regulations under section 406.—** Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in accordance with section 701(e), under the authority of section 406(a) upon the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsections (d) and (e), and shall be subject to review under subsection (q).

(2) **Regulations under section 409.—** Regulations that established tolerances for substances that are pesticide chemical residues in or on processed food, or that otherwise stated the conditions under which such pesticide chemicals could be safely used, and that were issued under section 409 on or before the date of the enactment of this paragraph, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsection (d) or (e), and shall be subject to review under subsection (q).

(3) **Regulations under section 408.—** Regulations that established tolerances or exemptions under this section that were issued on or before the date of the enactment of this paragraph shall remain in effect unless modified or revoked under subsection (d) or (e), and shall be subject to review under subsection (q).

(4) **Certain substances.—** With respect to a substance that is not included in the definition of the term "pesticide chemical" under section 201(q)(1) but was so included on the day before the date of the enactment of the Antimicrobial Regulation Technical Corrections Act of 1998, the following applies as of such date of enactment:

(A) Notwithstanding paragraph (2), any regulation applying to the use of the substance that was in effect on the day before such date, and was on such day deemed in such paragraph to have been issued under this section, shall be considered to have been issued under section 409.

(B) Notwithstanding paragraph (3), any regulation applying to the use of the substance that was in effect on such day and was issued under this section (including any such regulation issued before the date of the enactment of the Food Quality Protection Act of 1996) is deemed to have been issued under section 409.

(k) **Transitional Provision.—** If, on the day before the date of the enactment of this subsection, a substance that is a pesticide chemical was, with respect to a particular pesticidal use of the substance and any resulting pesticide chemical residue in or on a particular food—

(1) regarded by the Administrator or the Secretary as generally recognized as safe for use within the meaning of the provisions of subsection (a) or section 201(s) as then in effect; or

(2) regarded by the Secretary as a substance described by section 201(s)(4);

such a pesticide chemical residue shall be regarded as exempt from the requirement for a tolerance, as of the date of enactment of this subsection. The Administrator shall by regulation indicate which substances are described by this subsection. Any exemption under this subsection may be modified or revoked as if it had been issued under subsection (c).

(l) **Harmonization With Action Under Other Laws.—**

(1) **Coordination with fifra.—** To the extent practicable and consistent with the review deadlines in subsection (q), in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act.

(2) **Revocation of tolerance or exemption following cancellation of associated registrations. —** If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, cancels the registration of each pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit its use in connection with the production, storage, or transportation of such food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall revoke any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A revocation under this paragraph shall become effective not later than 180 days after—

(A) the date by which each such cancellation of a registration has become effective; or

(B) the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

(3) **Suspension of tolerance or exemption following suspension of associated registrations. —**

(A) **Suspension.—** If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, suspends the use of each registered pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the

Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

(B) **Effect of suspension.—** The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. While a suspension of a tolerance or exemption is effective the tolerance or exemption shall not be considered to be in effect. If the suspension of use of the pesticide under that Act is terminated, leaving the registration of the pesticide for such use in effect under that Act, the Administrator shall rescind any associated suspension of tolerance or exemption.

(4) **Tolerances for unavoidable residues.—** In connection with action taken under paragraph (2) or (3), or with respect to pesticides whose registrations were suspended or canceled prior to the date of the enactment of this paragraph under the Federal Insecticide, Fungicide, and Rodenticide Act, if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue. In establishing such a tolerance, the Administrator shall take into account both the factors set forth in subsection (b)(2) and the unavoidability of the residue. Subsection (e) shall apply to the establishment of such tolerance. The Administrator shall review any such tolerance periodically and modify it as necessary so that it allows no greater level of the pesticide chemical residue than is unavoidable.

(5) **Pesticide residues resulting from lawful application of pesticide.—** Notwithstanding any other provision of this Act, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that—

(A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act; and

(B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this Act;

unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e), the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

(6) **Tolerance for use of pesticides under an emergency exemption.—** If the Administrator grants an exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136p) for a pesticide chemical, the Administrator shall establish a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue. Such a tolerance or exemption from a tolerance shall have an expiration date. The Administrator may establish such a tolerance or exemption without providing notice or a period for comment on the tolerance or exemption. The Administrator shall promulgate regulations within 365 days after the date of the enactment of this paragraph governing the establishment of tolerances and exemptions under this paragraph. Such regulations shall be consistent with the safety standard under subsections (b)(2) and (c)(2) and with section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

(m)[43] **Fees.—**

43

Section 501(d)(2) of division G of Public Law 108–199 (118 Stat. 422) provides as follows:

(2) Tolerance fees.—Notwithstanding section 408(m)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(m)(1)), during the period beginning on October 1, 2003, and ending on September 30, 2008, the Administrator of the Environmental Protection Agency shall not collect any tolerance fees under that section.

(1) **Amount.—** The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section. Under the regulations, the performance of the Administrator's services or other functions under this section, including—

(A) the acceptance for filing of a petition submitted under subsection (d);

(B) establishing, modifying, leaving in effect, or revoking a tolerance or establishing, modifying, leaving in effect, or revoking an exemption from the requirement for a tolerance under this section;

(C) the acceptance for filing of objections under subsection (g); or

(D) the certification and filing in court of a transcript of the proceedings and the record under subsection (h);

may be conditioned upon the payment of such fees. The regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purposes of this subsection.

(2) **Deposit.—** All fees collected under paragraph (1) shall be deposited in the Reregistration and Expedited Processing Fund created by section 4(k) of the Federal Insecticide, Fungicide, and Rodenticide Act. Such fees shall be available to the Administrator, without fiscal year limitation, for the performance of the Administrator's services or functions as specified in paragraph (1).

(3) **Prohibition.—** During the period beginning on the effective date of ~~the Pesticide Registration Improvement Renewal Act and ending on September 30, 2023~~ *the Pesticide Registration Improvement Act of 2022 and ending on September 30, 2027*, the Administrator shall not collect any tolerance fees under paragraph (1).

(n) **National Uniformity of Tolerances.—**

(1) **Qualifying pesticide chemical residue.—** For purposes of this subsection, the term "qualifying pesticide chemical residue" means a pesticide chemical residue resulting from the use, in production, processing, or storage of a food, of a pesticide chemical that is an active ingredient and that—

(A) was first approved for such use in a registration of a pesticide issued under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act on or after April 25, 1985, on the basis of data determined by the Administrator to meet all applicable requirements for data prescribed by regulations in effect under that Act on April 25, 1985; or

(B) was approved for such use in a reregistration eligibility determination issued under section 4(g) of that Act on or after the date of enactment of this subsection.

(2) **Qualifying federal determination.—** For purposes of this subsection, the term "qualifying Federal determination" means a tolerance or exemption from the requirement for a tolerance for a qualifying pesticide chemical residue that—

(A) is issued under this section after the date of the enactment of this subsection and determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption); or

(B) (i) pursuant to subsection (j) is remaining in effect or is deemed to have been issued under this section, or is regarded under subsection (k) as exempt from the requirement for a tolerance; and

(ii) is determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption).

(3) **Limitation.—** The Administrator may make the determination described in paragraph (2)(B)(ii) only by issuing a rule in accordance with the procedure set forth in subsection (d) or (e) and only if the Administrator issues a proposed rule and allows a period of not less than 30 days for comment on the proposed rule. Any such rule shall be reviewable in accordance with subsections (g) and (h).

(4) **State authority.—** Except as provided in paragraphs (5), (6), and (8) no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of such pesticide chemical residue in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination. A State or political subdivision shall be deemed to establish or enforce a regulatory limit on a pesticide chemical residue in or on a food if it purports to prohibit or penalize the production, processing, shipping, or other handling of a food because it contains a pesticide residue (in excess of a prescribed limit).

(5) **Petition procedure.—**

(A) **In general.—** Any State may petition the Administrator for authorization to establish in such State a regulatory limit on a qualifying pesticide chemical residue in or on any food that is not identical to the qualifying Federal determination applicable to such qualifying pesticide chemical residue.

(B) **Petition requirements.—** Any petition under subparagraph (A) shall—

(i) satisfy any requirements prescribed, by rule, by the Administrator; and

(ii) be supported by scientific data about the pesticide chemical residue that is the subject of the petition or about chemically related pesticide chemical residues, data on the consumption within such State of food bearing the pesticide chemical residue, and data on exposure of humans within such State to the pesticide chemical residue.

(C) **Authorization.—** The Administrator may, by order, grant the authorization described in subparagraph (A) if the Administrator determines that the proposed State regulatory limit—

(i) is justified by compelling local conditions; and

(ii) would not cause any food to be a violation of Federal law.

(D) **Treatment.—** In lieu of any action authorized under subparagraph (C), the Administrator may treat a petition under this paragraph as a petition under subsection (d) to modify or revoke a tolerance or an exemption. If the Administrator determines to treat a petition under this paragraph as a petition under subsection (d), the Administrator shall thereafter act on the petition pursuant to subsection (d).

(E) **Review.—** Any order of the Administrator granting or denying the authorization described in subparagraph (A) shall be subject to review in the manner described in subsections (g) and (h).

(6) **Urgent petition procedure.—** Any State petition to the Administrator pursuant to paragraph (5) that demonstrates that consumption of a food containing such pesticide residue level during the period of the food's likely availability in the State will pose a significant public health threat from acute exposure shall be considered an urgent petition. If an order by the Administrator to grant or deny the requested authorization in an urgent petition is not made within 30 days of receipt of the petition, the petitioning State may establish and enforce a temporary regulatory limit on a qualifying pesticide chemical residue in or on the food. The temporary regulatory limit shall be validated or terminated by the Administrator's final order on the petition.

(7) **Residues from lawful application.—** No State or political subdivision may enforce any regulatory limit on the level of a pesticide chemical residue that may appear in or on any food if, at the time of the application of the pesticide that resulted in such residue, the sale of such food with such residue level was lawful under this section and under the law of such State, unless the State demonstrates that consumption of the food containing such pesticide residue level during the period of the food's likely availability in the State will pose an unreasonable dietary risk to the health of persons within such State.

(8) **Savings.—** Nothing in this Act preempts the authority of any State or political subdivision to require that a food containing a pesticide chemical residue bear or be the subject of a warning or other statement relating to the presence of the pesticide chemical residue in or on such food.

(o) **Consumer Right To Know.—** Not later than 2 years after the date of the enactment of the Food Quality Protection Act of 1996, and annually thereafter, the Administrator shall, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, publish in a format understandable to a lay person, and distribute to large retail grocers for public display (in a manner determined by the grocer), the following information, at a minimum:

(1) A discussion of the risks and benefits of pesticide chemical residues in or on food purchased by consumers.

(2) A listing of actions taken under subparagraph (B) of subsection (b)(2) that may result in pesticide chemical residues in or on food that present a yearly or lifetime risk above the risk allowed under subparagraph (A) of such subsection, and the food on which the pesticide chemicals producing the residues are used.

(3) Recommendations to consumers for reducing dietary exposure to pesticide chemical residues in a manner consistent with maintaining a healthy diet, including a list of food that may reasonably substitute for food listed under paragraph (2).

Nothing[44] in this subsection shall prevent retail grocers from providing additional information.

44

Indentation is so in law. Beginning of sentence probably should be moved to left.

(p) **Estrogenic substances screening program.—**

(1) **Development.—** Not later than 2 years after the date of enactment of this section, the Administrator shall in consultation with the Secretary of Health and Human Services develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.

(2) **Implementation.—** Not later than 3 years after the date of enactment of this section, after obtaining public comment and review of the screening program described in paragraph (1) by the scientific advisory panel established under section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act or the science advisory board established by section 8 of the Environmental Research, Development, and Demonstration[45] Act of 1978 (42 U.S.C. 4365), the Administrator shall implement the program.

45

So in law. The word "Authorization" probably should appear after "Demonstration".

(3) **Substances.—** In carrying out the screening program described in paragraph (1), the Administrator—

(A) shall provide for the testing of all pesticide chemicals; and

(B) may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such substance.

(4) **Exemption.—** Notwithstanding paragraph (3), the Administrator may, by order, exempt from the requirements of this section a biologic substance or other substance if the Administrator determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen.

(5) **Collection of information.—**

(A) **In general.—** The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to a person who manufactures or imports a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program described in paragraph (1), and submit information obtained from the testing to the Administrator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information.

(B) **Procedures.—** To the extent practicable the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information.

(C) **Failure of registrants to submit information.—**

(i) **Suspension.—** If a registrant of a substance referred to in paragraph (3)(A) fails to comply with an order under subparagraph (A) of this paragraph, the Administrator shall issue a notice of intent to suspend the sale or distribution of the substance by the registrant. Any suspension proposed under this paragraph shall become final at the end of the 30-day period beginning on the date that the registrant receives the notice of intent to suspend, unless during that period a person adversely affected by the notice requests a hearing or the Administrator determines that the registrant has complied fully with this paragraph.

(ii) **Hearing.—** If a person requests a hearing under clause (i), the hearing shall be conducted in accordance with section 554 of title 5, United States Code. The only matter for resolution at the hearing shall be whether the registrant has failed to comply with an order under subparagraph (A) of this paragraph. A decision by the Administrator after completion of a hearing shall be considered to be a final agency action.

(iii) **Termination of suspensions.—** The Administrator shall terminate a suspension under this subparagraph issued with respect to a registrant if the Administrator determines that the registrant has complied fully with this paragraph.

(D) **Noncompliance by other persons.—** Any person (other than a registrant) who fails to comply with an order under subparagraph (A) shall be liable for the same penalties and sanctions as are provided under section 16 of the Toxic Substances Control Act (15 U.S.C. 2601 and following) in the case of a violation referred to in that section. Such penalties and sanctions shall be assessed and imposed in the same manner as provided in such section 16.

(6) **Agency action.—** In the case of any substance that is found, as a result of testing and evaluation under this section, to have an endocrine effect on humans, the Administrator shall, as appropriate, take action under such statutory authority as is available to the Administrator, including consideration under other sections of this Act, as is necessary to ensure the protection of public health.

(7) **Report to congress.—** Not later than 4 years after the date of enactment of this section, the Administrator shall prepare and submit to Congress a report containing—

(A) the findings of the Administrator resulting from the screening program described in paragraph (1);

(B) recommendations for further testing needed to evaluate the impact on human health of the substances tested under the screening program; and

(C) recommendations for any further actions (including any action described in paragraph (6)) that the Administrator determines are appropriate based on the findings.

(q) **Schedule for Review.—**

(1) **In general.—** The Administrator shall review tolerances and exemptions for pesticide chemical residues in effect on the day before the date of the enactment of the Food Quality Protection Act of 1996, as expeditiously as practicable, assuring that—

(A) 33 percent of such tolerances and exemptions are reviewed within 3 years of the date of enactment of such Act;

(B) 66 percent of such tolerances and exemptions are reviewed within 6 years of the date of enactment of such Act; and

(C) 100 percent of such tolerances and exemptions are reviewed within 10 years of the date of enactment of such Act.

In conducting a review of a tolerance or exemption, the Administrator shall determine whether the tolerance or exemption meets the requirements of subsections[46] (b)(2) or (c)(2) and shall, by the deadline for the review of the tolerance or exemption, issue a regulation under subsection (d)(4) or (e)(1) to modify or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements.

46

So in law. Probably should be "subsection".

(2) **Priorities.—** In determining priorities for reviewing tolerances and exemptions under paragraph (1), the Administrator shall give priority to the review of the tolerances or exemptions that appear to pose the greatest risk to public health.

(3) **Publication of schedule.—** Not later than 12 months after the date of the enactment of the Food Quality Protection Act of 1996, the Administrator shall publish a schedule for review of

tolerances and exemptions established prior to the date of the enactment of the Food Quality Protection Act of 1996. The determination of priorities for the review of tolerances and exemptions pursuant to this subsection is not a rulemaking and shall not be subject to judicial review, except that failure to take final action pursuant to the schedule established by this paragraph shall be subject to judicial review.

(r) **Temporary Tolerance or Exemption.—** The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon the Administrator's own initiative, establish a temporary tolerance or exemption for the pesticide chemical residue for the uses covered by the permit. Subsections (b)(2), (c)(2), (d), and (e) shall apply to actions taken under this subsection.

(s) **Savings Clause.—** Nothing in this section shall be construed to amend or modify the provisions of the Toxic Substances Control Act or the Federal Insecticide, Fungicide, and Rodenticide Act.

Summary

(1) 51 amendments.
(2) 1 automated notification.

1 Automated Notification

Automated notifications with target identifiers: 0.
Automated notifications without target identifiers: 1.

Automated Notification: This amendment could not be executed programmatically.
Details:

- Amendment number 49
- Amendment target identifier:
- Amendment target category:
- Operations on nodes of type not supported yet.
- The portion of law being amended could not be found.

AMENDMENT:

TITLE TITLE VI—PESTICIDES

SUBTITLE Subtitle A—Pesticide Registration Improvement Act of 2022

SEC. 705. PESTICIDE REGISTRATION SERVICE FEES.

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

(2) in paragraph (2)—

(B) in each of subparagraphs (B) and (C)—

(i) in the subparagraph heading, by striking " 2025 " each place it appears and inserting " 2029 "; and

About this report
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