TABLE 19. EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 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	An application for review of a study protocol submitted to EPA in support of an active ingredient with currently registered product(s), which proposes research involving intentional exposure of a human subject, as those terms are defined in 40 CFR §§ 26.1102(d), (k), and (l). Worker exposure studies and skin-applied insect repellent efficacy studies are the most common types of studies submitted to OPP that may meet the regulatory definition of "research involving intentional exposure." A protocol that describes research that would provide data to populate a generic database such as the Agricultural Handler Exposure Database (AHED) or the Biocide Handler Exposure Database (BHED) will not be considered a PRIA action because the data from this type of research are intended to support many active ingredients, and the resulting study would not be submitted in support of a particular active ingredient. EPA will review both the scientific and ethical aspects of a protocol covered by this category. If EPA determines that the protocol is of sufficiently high quality, EPA will submit its review of the protocol, together with the available supporting materials, to the Human Studies Review Board (HSRB). The HSRB will provide comment on both the scientific and ethical aspects of the protocol. EPA will consider the HSRB's advice in determining whether to approve the protocol.	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)	An application for review of a completed study submitted to EPA, in support of an active ingredient, which reports research involving intentional exposure of a human subject, as those terms are defined in 40 CFR §§ 26.1102(d), (k), and (l). Worker exposure studies and skin-applied insect repellent efficacy studies are the most common types of studies submitted to OPP that may meet the regulatory definition of "research involving intentional exposure." A study conducted to generate data to populate a generic database such as the Agricultural Handler Exposure Database (AHED) or the Biocide Handler Exposure Database (BHED) will not be considered a PRIA action because the data are not intended to be used to support a particular active ingredient. EPA will review both the scientific and ethical aspects of a completed study covered by this	14	11,378

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			category. EPA will submit its review of the completed study, together with the available supporting materials, to the Human Studies Review Board (HSRB). The HSRB will provide comment on both the scientific and ethical aspects of the study. EPA will consider the HSRB's advice in determining whether to rely on the study. Any other covered application that is associated with and dependent upon the HSRB review will be subject to its separate fee. The decision review time for the associated action will run concurrently with that of the HSRB review but will end at the date of the latest review time.		
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)	An application for external peer review of a new active ingredient, new product, or amendment of a registered product, for an action with a decision review timeframe of less than 12 months. Covered applications with PRIA decision time frames of less than 12 months, when the Agency submits to an advisory panel for comment, evaluation, and recommendations concerning the impact on health and the environment of a covered application. Examples include pesticide active ingredients, products or amendments, and uses that are based upon new or evolving technology or risks. Any covered application that is associated with and dependent upon the SAP review will be subject to its separate fee. The decision review time for the associated action will be extended by the decision review time for the SAP review.	12	91,651

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M004	216	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of greater than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA § 25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (3)	An application for external peer review of a new active ingredient, new product, or amendment of a registered product, for an action with a decision review timeframe greater than or equal to 12 months. Covered applications with PRIA decision time frames greater than or equal to 12 months, if the Agency submits to an advisory panel for comment, evaluation, and recommendations concerning the impact on health and the environment of a covered application. Examples include pesticide active ingredients, products or amendments, and uses that are based upon new or evolving technology or risks. Any covered application that is associated with and dependent upon the SAP review will be subject to its separate fee. The decision review time for the associated action will be extended by the decision review time for the SAP review.	18	91,651
M005	217	New Product: Combination, Contains a combination of active ingredients from a registered and/or unregistered source; conventional, antimicrobial, and/or	An application for registration of a new end-use product that contains more than one registered conventional, antimicrobial or biopesticide active ingredient. The active ingredients have never been registered as this combination before. The proposed label has the same uses as those found on the registered product labels for the single active ingredients. Each active ingredient may use a registered or unregistered source of active ingredient. If using an unregistered source of any of the active ingredients, the application for the source product would reside in the respective division for processing. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert petition submitted within the package for the applicable uses (food or nonfood). The decision review time for the pending products will carry the longest of the pending products associated with all of the actions (i.e. the source product or the inert petition timeframes). All applications require the following:	9	31,604

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		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)	• Certification with Respect to Citation of Data and a data matrix • Product chemistry data • If applicable, acute toxicity, efficacy, and or child resistant packaging data requirements must be addressed by using; (1) the cite-all method; (2) selective data citation. A rationale for a waiver or bridging of these data can be submitted. A determination on whether data can be bridged or translated to other formulation types (for the individual active ingredients) will not be done in this category. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new combination product registration.		
M006	218	Request for up to 5 letters of certification (Gold Seal) for one actively registered product (excludes distributor products) (7)	A request for a Certificate of Registration, commonly known as a "gold seal letter". The gold seal letter certifies that the product being exported is legally registered in the U.S. with the Agency. The company must submit a written request to the Agency, identify the company name, the EPA Registration Number and the country(ies) in which the product will be exported. The fee for this category will cover up to five (5) gold seal letters for one product. Distributor products are not eligible for Gold Seal letters. Due to the low fee and short time frame for this category, this category is NOT eligible for small business waivers.	1	398
M007	219	Request to extend Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(ii)	FIFRA Section 3(c)(1)(F)(ii) sets forth the criteria to be met for extending the exclusive use period. The threshold requirement is that the new minor use must be registered within the first 7 years of the commencement of the exclusive use period. FIFRA Section 3(c)(1)(F)(ii) states, in part: 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 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 – 1. there are insufficient efficacious alternative registered pesticides available for the use; 2. the alternatives to the minor use pesticide pose greater risks to the environment or human health;	12	7,903

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			3. the minor use pesticide plays or will play a significant part in managing pest resistance; or 4. the minor use pesticide plays or will play a significant part in an integrated pest management program. FIFRA Section 2(ll) states, in part: The term "minor use" means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where— 1. the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or 2. the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and a. there are insufficient efficacious alternative registered pesticides available for the use; b. the alternatives to the pesticide use pose greater risks to the environment or human health; c. the minor use pesticide plays or will play a significant part in managing pest resistance; or d. the minor use pesticide plays or will play a significant part in an integrated pest management program."		
M008	220	Request to grant Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(vi) for a minor use, when a FIFRA Section 2(ll)(2) determination is required	FIFRA Section 3(c)(1)(F)(vi) applies to data submitted to add a minor use to an existing registration after the initial data exclusivity period expires. It provides for a new exclusive use period for data generated by an applicant or registrant to register a new minor use. It allows registrants to request at the time they submit their application for a new minor use (the use does not have exclusive use protected data) that the data be given exclusive use protection. FIFRA Section 2(ll) states, in part: "The term "minor use" means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where: 1. the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or 2. the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant,	15	2,371

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			the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and a. there are insufficient efficacious alternative registered pesticides available for the use; b. the alternatives to the pesticide use pose greater risks to the environment or human health; c. the minor use pesticide plays or will play a significant part in managing pest resistance; or d. the minor use pesticide plays or will play a significant part in an integrated pest management program."		
M009	221	Non-FIFRA Regulated Determination: applicant initiated, per product	A voluntary request that EPA determine (1) whether and how a product is regulated under FIFRA (*e.g.*, a Section 3 pesticide, an exempt treated article, a pesticidal device, or excluded plant nutrient, plant inoculant, soil amendment); (2) whether a specific substance is eligible for inclusion as an active ingredient and/or inert ingredient permitted in exempted minimum risk pesticide products under 40 CFR § 152.25(f)(1); or (3) whether a plant-incorporated protectant is eligible for FIFRA exemption under 40 CFR Part 174 subpart E. Each M009 application can request a determination for only one product or substance (*i.e.*, different products or multiple substances would require multiple M009 applications). Each M009 determination is based on the particular facts about the product available at the time EPA considers the M009 application. If an applicant subsequently makes changes to the product (or its claims), a previous M009 determination may no longer be applicable to the changed product. Applicants may submit a new M009 application if they want EPA to reassess the product and the impacts of any changes. Applicants must submit sufficient information to allow EPA to make a jurisdictional determination on the product. Failure to provide this information may result in the EPA not being able to make the determination or delays in review. This may include the following materials, to the extent necessary to make EPA's jurisdictional determination. • A cover letter requesting a specific type of FIFRA determination (e.g., device, exempt treated article, barrier). • A clear description of the product, including manufacturing methods and formulation, if appropriate. Generally, formulation information may include:	6	3,389

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			• Whether the product contains an EPA registered pesticide; • Identity and CAS numbers, if available, for each ingredient and any known impurities; • Genus, species, and any strain/isolate identifier for any microorganism(s) and information on whether the microorganism(s) are naturally occurring or intergeneric; and • Purpose of each ingredient including the scientific and theoretical basis when applicable. • A clear description of (1) how the product is used, including, where relevant, application methods, application rate(s), and directions for use; (2) any claims made for the product (*e.g.*, proposed label or labeling claims, web-based content, print or other advertising); (3) precautionary statements, warnings, or caution statements, if any; and (4) the complete brand name(s) of the product. Generally, this should include: • A complete copy of the product label and/or manual(s); and • Any materials distributed about the product (including pamphlets, brochures, advertising materials and/or website materials). • A clear description of how the product works (e.g., how the product does or does not kill, destroy, repel, trap, or mitigate a pest). Where appropriate, this description should include: • Specifications used in the operation of the product • Any input or output substances (identified by common name and CAS number) associated with the product • Any schematic diagram, engineering drawings, diagrams, flow diagrams, or patent application information. Generally, patent application information (for both United States or international patents), should include the application number(s), the corresponding patent office, and any pre-grant publication or issued patent. (Primarily for Device Determinations) • Digital copies of photographs of the product from all sides. (Primarily for Device Determinations) Information claimed as confidential must be clearly marked. EPA will consider any information not so marked as not subject to a claim of confidentiality and may make the information publicly available without further notice, except as limited by FIFRA section 10(g). Additional information that may be helpful to include for a FIFRA determination for products containing microbes can be found at the following link: Pesticide Determination Requests for		

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			Microbial Products. The M009 category also covers exemption eligibility determinations under EPA's "Exemptions of Certain Plant-Incorporated Protectants Derived from Newer Technologies" rule. Additional information that may be helpful to include for applicants submitting a request for this type of determination is available in the preamble and regulatory text for that rule (88 FR 34756; 40 CFR § 174 subpart E).		
M010	222	Conditional ruling on pre-application, product substantial similarity.	An application for conditional ruling by EPA on the substantial similarity between a cited, registered product and a not-yet submitted new product or product amendment. The EPA response for this category is a letter indicating agreement/disagreement that the product cited by the applicant is substantially similar to the proposed new product or amendment, such that cited acute toxicity and/or product chemistry studies would adequately address product specific guideline requirements for the new product or amendment application when submitted. This is a conditional ruling, and should the actual registration or amendment application, once submitted, differ from the pre-application in formulation, labeling, or cited studies, it may be that the Similarity Clinic determination for the actual application will not match the pre-application conditional ruling. **Substantially similar**: Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular), and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the proposed product bears the same use patterns. Adding use patterns or changing existing use patterns (other than deleting them) would exclude the proposed product from treatment as a substantially similar product. Deleting use patterns is acceptable. The submission of a pre-application conditional ruling application does not replace the Similarity Clinic screen conducted for the new product registration or amendment application. This category does not contemplate multiple iterations of substantial similarity requests or rebuttal of the pre-conditional ruling on substantial similarity under the same application. Any new proposal for citation to a different registered product must be submitted as a separate M010 application. This category does not contemplate multiple products being submitted for consideration of substantial similarity as part of one application. This determination is not required by the Agency as a pre-condition of a registration application, and such a request is at the discretion of the applicant.	4	3,389

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M011	223	Label amendment to add the DfE logo; requires data review; no other label changes. (8)	Application to add the Design for the Environment (DfE) logo to a registered pesticide label via an amendment application. Registrants are required to obtain DfE certification prior to requesting label amendment to add the logo. Documentation of the DfE approval/certification must be submitted with the label amendment application.	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)	A request for a Certificate of Establishment (COE) confirming that a pesticide-producing establishment is registered with the Agency under FIFRA §7(b), and that production of the specified product at that establishment has been reported to the Agency under FIFRA §7(c). The application should include: • the EPA Product Registration Number (or product name if there is no EPA Product Registration Number) • the name, address, and EPA establishment number of the pesticide-producing establishment • The country(ies) for which the COE is being requested. The submitted request is not expected to contain confidential business information. The fee for this category will cover up to five (5) COEs for one product and/or establishment. The COE will reflect the information in the Agency's records at the time the COE is issued. COEs do not certify that a particular establishment is in compliance with FIFRA regulations. The COE does not certify that a particular product batch or container was produced at a specific pesticide-producing establishment or that the product was distributed or sold in compliance with FIFRA. EPA assumes no responsibility to notify the applicant for the COE or the country receiving the COE of any subsequent change in the registration status of the product or the establishment addressed in a COE after the COE is issued outside a separate M012 application. Due to the low fee and short timeframe, this category is not eligible for small business waivers. Distributor products (also known as "supplemental registrations") are not eligible for COEs.	1	398
M013	225 (new)	Cancer reassessment; applicant initiated	An application which requests to change the cancer classification of a pesticide active or inert ingredient; applicant-initiated.	18	284,144
M014	226 (new)	Pre-application nano-particle determination	A request for a pre-application nanoparticle determination. This determination is not required by the Agency, and such a request is at the discretion of the applicant.	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 Science 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') logo 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.