PRIA 4 Interpretations

TABLE 19. EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
M001	202	Study protocol requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of an active ingredient (4)	This category includes study protocols submitted to EPA, in support of an active ingredient, which propose research involving intentional exposure of a human subject, as those terms are defined in 40 CFR parts 26.1102(d), (e), and (i). Worker exposure studies and insect repellant 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 protocols 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.	9	8,335
M002	203	Completed study requiring Human Studies Review	This category includes completed studies submitted to EPA, in support of an active ingredient, which report research involving intentional exposure of a human subject, as those terms are defined in 40 CFR parts 26.1102(d), (e), and (i). Worker exposure studies and insect repellant	9	8,335

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		Board review as defined in 40 CFR Part 26 in support of an active ingredient (4)	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 completed studies covered by this 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	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	Covered applications include microbial and biochemical pesticide products 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	67,143

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
		initiated request based on a requirement of the Administrator, as defined by FIFRA § 25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (5)			
M004	205	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of greater than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA § 25(d), in support	Covered applications include microbial and biochemical pesticide products 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	67,143

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
		of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (5)			
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	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 approved or pending with the Agency for the applicable uses. 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: • 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	9	23,153

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		each active ingredient in the combination product. (6) (7)	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. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
M006	207	Request for up to 5 letters of certification (Gold Seal) for one actively registered product. (excludes distributor products (8)	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 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	291
M007	208	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	12	5,789

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			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. 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	209	Request to grant Exclusive Use of	FIFRA Section 3(c)(1)(F)(vi) applies to data submitted to add a minor use to an existing	15	1,737

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		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	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, 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	210 new	Non-FIFRA regulated determination: applicant initiated, per product	A request for a determination of whether FIFRA registration is required for a proposed product. Includes but is not limited to determinations for treated articles exemptions, FIFRA 25(b) minimum risk pesticides, and pesticidal device(s). This determination is not required by the Agency, and such a request is at the discretion of the applicant.	4	2,482

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
M010	211 new	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	2,482
M011	212 new	Label amendment to	Application to add the DfE logo. Registrants are required to obtain DfE certification prior to requesting logo. Documentation of the DfE	4	3,831

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		add DfE logo; requires data review; no other label changes (3)	approval/certification must be submitted with the label amendment.		