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

EPA No.	New CR No.	Action	Interpretation	Decision Review Time (Months) (1)	FY'23 – FY'24 Registration Service Fee ($)
B630	128	First food use; petition to establish/amend a tolerance exemption. (2) (4) (5)	An application for registration of a first/new use for a microbial or biochemical pesticide where there is a reasonable expectation or certainty that residues of the active ingredient could occur in human food, animal feed, or in livestock from the proposed use. The proposed use requires that the applicant submit data to enable the Agency to conduct a dietary exposure assessment and requires that the applicant submit a petition to establish or amend a tolerance exemption for the active ingredient. All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee.	13	18,296
B640	129	First food use; petition to establish/amend a tolerance. (2) (4) (5)	An application for registration of a first/new food use for a microbial or biochemical pesticide where there is a reasonable expectation or certainty that residues of the active ingredient could occur in human food, animal feed, or in livestock from the proposed use. The proposed use requires the applicant to submit a petition to establish or amend a tolerance for the active ingredient for the proposed use, and to submit data to demonstrate that dietary exposures to residues of the active ingredient at the tolerance level meet the FFDCA standard of reasonable certainty of no harm. All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee.	19	27,443
B644	130	New use, no change to an established tolerance or	An application that proposes a new use for a microbial or biochemical pesticide for which establishment/amendment of a tolerance or	8	18,296

EPA No.	New CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23 – FY'24 Registration Service Fee ($)
		tolerance exemption (includes non-food uses). (3) (4) (5)	tolerance exemption under section 408 of the FFDCA is not needed. This category includes applications for food/feed uses that are already covered by an existing tolerance or tolerance exemption and applications for non-food uses (which can include first residential use, first aquatic use, first terrestrial use, first outdoor use, first forestry use, or any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms). A non-food use determination can be made in a pre-application conditional ruling under PRIA Category B616. All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee.		
B645	131	New use; Experimental Use Permit; petition to establish a permanent or temporary tolerance or tolerance exemption. (4) (5)	An Experimental Use Permit (EUP) application for a microbial or biochemical pesticide containing an active ingredient in a currently EPA-registered pesticide product, where the proposed use is considered a food use and requires the establishment or amendment of a permanent or temporary tolerance or tolerance exemption under section 408 of the FFDCA. The application submission must contain a petition to establish or amend tolerances or tolerance exemptions for all food/feed commodities covered by the proposed use application. All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee.	12	18,296
B646	132	New use; Experimental Use Permit; non-food use (includes crop destruct). (4) (5)	An Experimental Use Permit (EUP) application for a microbial or biochemical pesticide containing an active ingredient in a currently EPA-registered pesticide product, where the proposed use is a non-food use and does not require the establishment or amendment of a tolerance or tolerance exemption under section 408 of the FFDCA.	7	9,151

EPA No.	New CR No.	Action	Interpretation	Decision Review Time (Months) (1)	FY'23 – FY'24 Registration Service Fee ($)
			This category includes applications with an agreement to destroy, or use only for experimental purposes, any crops treated during the experimental program. This category also includes a change in use pattern such that the exposure to humans and the environment could be significantly increased (e.g., additional routes of exposure) and therefore must be evaluated for increased risks. A non-food use determination can be made in a pre-application conditional ruling under PRIA Category B616. All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own 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 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)(G)] 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.