TABLE 11. BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) - MICROBIAL AND BIOCHEMICAL PESTICIDES; NEW ACTIVE INGREDIENTS

EPA No.	New CR No.	Action	Interpretation	Decision Review Time (Months) (1)	FY'23 – FY'24 Registration Service Fee ($)
B580	123	New active ingredient; petition to establish a tolerance. (2) (3) (4)	An application that proposes a food use for a microbial or biochemical pesticide active ingredient that is not currently an active ingredient in any EPA-registered pesticide product. The proposed use requires the establishment of a permanent tolerance under section 408 of the FFDCA. This category includes applications for conversion of an existing temporary tolerance or tolerance exemption to a permanent tolerance under section 408 of the FFDCA. The application must contain a petition to establish a tolerance for all food/feed commodities covered by the pending registration application. Some examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. 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.	22	73,173
B590	124	New active ingredient; petition to establish a tolerance exemption. (2) (3) (4)	An application that proposes a food use for a microbial or biochemical pesticide active ingredient that is not currently an active ingredient in any EPA-registered pesticide product. The proposed use requires the establishment of a permanent tolerance exemption under section 408 of the FFDCA. This category includes applications for conversion of an existing temporary tolerance exemption to a permanent tolerance exemption under section 408 of the FFDCA. The application must contain a petition to establish a tolerance	20	45,737

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			exemption for all food/feed commodities covered by the pending registration application. Some examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. 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.		
B600	125	New active ingredient; no change to a permanent tolerance or tolerance exemption (includes non-food uses). (2) (3) (4)	An application that proposes uses for a microbial or biochemical pesticide active ingredient that is not currently an active ingredient in any EPA-registered pesticide product for which establishment/amendment of a tolerance or 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. A non-food use determination can be made in a pre-application conditional ruling under the 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.	15	27,443
B610	126	New active ingredient; Experimental Use Permit application; petition to establish a permanent or temporary tolerance	An Experimental Use Permit (EUP) application that proposes a food use for a microbial or biochemical pesticide product containing an active ingredient that is not an active ingredient in any currently EPA-registered pesticide product. The use requires the establishment of a permanent or temporary tolerance or a tolerance exemption	12	18,296

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		or temporary tolerance exemption. (3) (4)	under section 408 of the FFDCA. The application must contain a petition to establish permanent or temporary tolerance(s) or exemption(s) from tolerances for all food/feed commodities covered by the pending registration application. Increases in exposure such as a dosage rate increase or different method of application that will result in a temporary tolerance increase belong to this category. Some examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. The Agency will not accept a certification for crop destruct once the review clock has started (the "clock" or decision review timeframe starts 21 days after the Agency receives the application and the required fees or approves a fee waiver or fee exemption). A change to a crop destruct application would require the applicant to withdraw their application and start the application process anew. 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.		
B620	127	New active ingredient; Experimental Use Permit application; non-food use (includes crop destruct). (3) (4)	An application for an Experimental Use Permit (EUP) that proposes a non-food use for a microbial or biochemical pesticide product containing an active ingredient that is not an active ingredient in any currently EPA-registered pesticide product. This category includes applications with an agreement to destroy, or use only for experimental purposes, any crops treated during the experimental program. All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the	9	9,151

EPA No.	New CR No.	Action	Interpretation	Decision Review Time (Months) (1)	FY'23 – FY'24 Registration Service Fee ($)
			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) 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)(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.