TABLE 14. BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) - AMENDMENTS

EPA No.	New CR No.	Action	Interpretation	Decision Review Time (Months) (1)	FY'25 – FY'26 Registration Service Fee ($)
B621	139	Amendment; Experimental Use Permit; no change to an established temporary or permanent tolerance or tolerance exemption (3) (4)	An application to amend an existing Experimental Use Permit for a microbial or biochemical pesticide. Amendments could include but are not limited to changing the acreage tested, and/or extending the length of time for completion of the experimental program. This category does not include New Uses (see B645 or B646) or actions for which a tolerance or tolerance exemption needs to be amended (see B622).	7	7,689
B622	140	Amendment; Experimental Use Permit; petition to amend a permanent or temporary tolerance or tolerance exemption (3) (4)	An application to amend an existing Experimental Use Permit for a microbial or biochemical pesticide with a change/amendment to an existing permanent/temporary tolerance or tolerance exemption. This category does not include New Uses (see B645 or B646).	11	19,211
B641	141	Amendment; changes to an established tolerance or tolerance exemption. (4)	A petition to amend an established tolerance or tolerance exemption for a microbial or biochemical pesticide to support a new or existing product registration, with supporting data/information 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. This category does not include New Uses (see Table 12). 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	19,211

EPA No.	New CR No.	Action	Interpretation	Decision Review Time (Months) (1)	FY'25 – FY'26 Registration Service Fee ($)
B680	142	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)	An application to amend a registration for a product with a registered source of active ingredient (i.e., the active ingredient in the proposed product is derived from an EPA-registered product). Applications included in this category contain data to support a change in the label (e.g., adjusting precautionary statements, addition of public health pest claims, changes to Directions for Use that do not qualify as New Uses), or to add an alternate formulation, or change the basic formulation. These data include but are not limited to: toxicity data, product chemistry data, manufacturing process, non-target toxicity data, efficacy/product performance, and child-resistant packaging data. 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.	5	7,689
B681	143	Amendment; unregistered source of active ingredient(s); no change to an established tolerance or tolerance exemption; requires data submission (2) (3)	An application to amend a product registration with an unregistered source of active ingredient (i.e., the active ingredient in the proposed product is not derived from an EPA-registered product). Applications included in this category contain data to support a change in the label (e.g., adjusting precautionary statements, addition of public health pest claims, changes to Directions for Use that do not qualify as New Uses), or to add an alternate formulation, or change the basic formulation. These data include but are not limited to: toxicity data, product chemistry data, manufacturing process, non-target toxicity data, efficacy/product performance, and child-resistant packaging data.	7	9,150

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			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.		
B683	144	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) (2) (3)	Modification in the label of a registered product that is not substantially similar to a currently registered product and that requires review and Agency determination of whether the existing database would support a change or modification to the amended label. Agency update of existing risk analysis/assessment may be required. No data is submitted to support this label amendment. Examples of label changes or modifications in this category include: label changes to Directions for Use (including restricted entry intervals (REI), personal protective equipment (PPE), pre-harvest interval (PHI), application rate, application frequency, application timing, addition of aerial or chemigation application methods consistent with PR Notices 87-1 and 93-2, ground water or surface water advisory statements, etc. that require risk analysis by EPA.	6	7,689
B684	145	Amending non-food animal product that includes submission of target animal safety data; previously registered (2) (3)	An application to amend a registered end-use pesticide animal product by adding additional claims for use on adult animals, juvenile animals, or breeding animals of the same species. For example, spot-on and flea collar products are generally labeled species specific, in that a product is labeled for dogs or cats, but not generally both, while shampoos and sprays may be labeled for both species (dogs and cats). This amendment would require the following: proposed amended label for the end-use product, a data matrix, data compensation forms, and	8	13,276

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			supporting data (animal safety and possibly efficacy and/or child-resistant packaging, see below). If new efficacy claims are proposed for the same species of animal currently on the product label, efficacy data to support the proposed claims are required. If the packaging type has changed (e.g., spot-on vs. stripe-on) so that the dose volume is altered (new or different), new child resistant packaging data are required. Which companion animal safety studies are required is based upon the specific label claims in the proposed label. For example, if the proposed end use product label claim is to use the product on 12-week-old kittens weighing ≥ 3 lbs and on breeding cats, then two companion animal studies are required: the first one using kittens ≥ 12 weeks of age and weighing at least 3 lbs. and a second study on pregnant and nursing adult cats. Each of these studies must demonstrate an adequate margin of safety. 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. If the product relies upon a pending inert clearance, the new companion animal studies must be conducted with the pending inert in the tested product as it is intended to be marketed and sold as the end use product.		
B685	146	Amendment; add a new biochemical unregistered source of active ingredient or a new microbial production site; requires submission of analysis of samples data and	An amendment to add an unregistered source of active ingredient (Integrated System as defined in 40 CFR Part 158.300) for a biochemical or to add a new production site for any microbial product containing an unregistered source of active ingredient (Integrated System as defined	5	7,689

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		source/production site-specific manufacturing process description (3)	in 40 CFR Part 158.300). Data needed to support a new microbial active ingredient production site for products with an unregistered source are 1) an analysis of samples study generated at the new production site and, 2) a thorough description of the manufacturing process with specific attention given to any minor modifications made to the process used at the new production site. Such minor modifications may be made only if they are required for production at the new site and have no significant effect on the toxicological (mammalian or ecological) or pesticidal status of the resulting product.		

(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 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)(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.