TABLE 13. BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) - NEW PRODUCTS

EPA No.	New CR No.	Action	Interpretation	Decision Review Time (Months) (1)	FY'25 – FY'26 Registration Service Fee ($)
B660	133	New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption; no data submission or data matrix (or submission of product chemistry data only) (2) (3)	An application for registration of an end-use or a manufacturing-use microbial or biochemical pesticide product which contains a registered source of active ingredient (i.e., the active ingredient in the proposed product is derived from an EPA-registered product), and the product is identical, or substantially similar, in its uses and formulation to products that are currently registered and for which the Agency must make a determination of similarity to a registered product. If a review of data other than product chemistry is needed, the application does not fall in this category. For proposed new products for which product-specific data or waiver requests beyond product chemistry (e.g., efficacy, acute toxicity, companion animal safety, and/or child resistant packaging), must be submitted and reviewed to support the application, see category B670. For proposed new products containing an unregistered source of active ingredient or new generic (active ingredient) data, see category B672. For 100% repacks, see category B674. All applications require the following: • The active ingredient in the proposed product must be derived from an EPA-registered product. • The applicant must identify the currently registered similar product, and this must be accurately reflected on the CSF. • A data matrix (if data are cited or submitted) • Product chemistry data (Group A and B). In some cases, product chemistry data can be	6	1,925

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			satisfied as outlined in Pesticide Registration Notice 98-1. • Acute toxicity requirements must be addressed by using only: (1) the cite-all method, (2) selective data citation where the applicant owns all required data, or (3) applicant submits specific authorization letter from the data owner. A formulator's exemption for generic data requirements can be claimed when the registered source of the active ingredient is owned by another pesticide registrant. If the registered source of the active ingredient is owned by the current applicant, a formulator's exemption is not applicable, and the generic data used to support the active ingredient is instead referenced on the applicant's data matrix. **Substantially similar:** Product must have the same active ingredient, in substantially the same proportion, same chemical form (solid, liquid, granular), and substantially similar composition (inert ingredients) as the already registered product. In addition, substantially similar means that the proposed product bears the same use pattern. Adding to or changing existing use patterns excludes the proposed product from treatment as a substantially similar product. Deleting use patterns is acceptable. **Identical:** Same composition and use patterns as a currently registered product.		
B670	134	New product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption; (including non-food); Must address Product-Specific Data Requirements (2) (3)	An application for registration of an end-use or manufacturing-use microbial or biochemical pesticide product which contains a registered source of active ingredient (i.e., the active ingredient in the proposed product is derived from an EPA-registered product), and the product is not substantially similar or identical in its	9	7,689

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			uses and/or formulation to products that are currently registered. This category only includes applications that require product-specific data review (e.g., product chemistry, acute toxicity, and/or efficacy). For proposed new products containing an unregistered source of active ingredient or new generic (active ingredient) data, see category B672. For proposed new products containing new uses, see Table 12. Product-specific data requirements can be addressed with a combination of 1) submission of product-specific data; 2) citation of previously reviewed and accepted data; 3) submission or citation of data generated at government expense; 4) submission or citation of scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. When uses against public health pests are proposed, efficacy (product performance) data for the product must be submitted. A formulator's exemption for generic data requirements can be claimed when the registered source of the active ingredient is owned by another pesticide registrant. If the registered source of the active ingredient is owned by the current applicant, a formulator's exemption is not applicable, and the generic data used to support the		

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			active ingredient is instead referenced on the applicant's data matrix. 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.		
B672	135	New product; unregistered source of at least one active ingredient (or registered source with new generic data package); no change in an established tolerance or tolerance exemption (including non-food); must address Product-Specific and Generic Data Requirements (2) (3)	An application for registration of an end-use or a manufacturing-use microbial or biochemical pesticide product which contains an unregistered source of active ingredient (i.e., the active ingredient in the proposed product is not derived from an EPA-registered product) or a registered source of active ingredient with new generic (active ingredient) data. This category only includes applications that require both product-specific (e.g., product chemistry, acute toxicity, and efficacy) and generic (e.g., mammalian and nontarget organism) data/waiver review. For proposed new products containing an unregistered source of active ingredient and for which all data cited to fulfill generic data requirements have been previously reviewed and accepted by the Agency, see category B673. Generic and product-specific data requirements can be addressed with a combination of 1) submission of data; 2) citation of previously reviewed and accepted data; 3) submission or citation of data generated at government expense; 4) submission or citation of scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-	15	13,723

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			sound rationale explaining why the data requirement does not apply. When uses against public health pests are proposed, efficacy (product performance) data for the product must be submitted. This category does not include products containing an active ingredient(s) that requires a change in, or establishment of, a tolerance or tolerance exemption or require the Agency to conduct a dietary risk assessment. 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.		
B673	136	New product; unregistered source of active ingredient(s); citation of Technical Grade Active Ingredient (TGAI) data previously reviewed and accepted by the Agency; requires an Agency determination that the cited data support the new product (2) (3)	An application for registration of an end-use or a manufacturing use microbial or biochemical pesticide product containing an unregistered source of an active ingredient (i.e., the active ingredient in the proposed product is not derived from an EPA-registered product) for which the data cited to fulfill all generic (active ingredient) data requirements have been previously reviewed and accepted by the Agency. If new generic data/waiver review is required, see category B672. For microbial pesticides this category does not apply when data to demonstrate similarity is needed to bridge to previously reviewed and accepted data, see Table 11 (New Active Ingredients). 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	12	7,689

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			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.		
B674	137	New product; repack of identical registered end-use product or repack of an end-use product as a manufacturing-use product; same registered uses only (2) (3)	An application for registration of an end-use or a manufacturing-use microbial or biochemical pesticide product that is a 100% repack of a registered end-use product, a 100% repack of a registered manufacturing-use product, or a repack of a registered end-use product as a manufacturing-use product. All applications require the following: • A formulator's exemption statement (or if the registered source of the active ingredient is owned by the current applicant, the data used to support the registered source must be referenced on a data matrix). • The applicant must identify the currently registered product being repacked for this application in a CSF listing the original product in Box 10, the EPA registration number in Box 12, and "100% repack" in Box 13. Submission of data or requests to waive data is not allowed in this category. Products that require a "substantially similar" determination fall under PRIA Category B660. If the use pattern for the proposed product differs from the currently registered product, then additional data are required and the application does not fall within this category (see Table 12 for applicable new use categories).	4	1,925
B677	138	New end-use non-food animal product with submission of two or more target animal safety	An application for registration of a new microbial or biochemical pesticide end-use animal product that is not	12	13,276

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		studies; includes data and/or waivers of data for only: 1. product chemistry and/or 2. acute toxicity and/or 3. public health pest efficacy and/or 4. animal safety studies and/or child resistant packaging (2) (3)	substantially similar or identical in its uses and formulation to a product currently registered. For example, spot-on and flea collars 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). All applications require the following: • A data matrix. • Product chemistry data (Group A and B) and CSF. In some cases, product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. If the source of the active ingredient is unregistered in this application, the decision review timeline will be the longest of the associated applications (see timeline for B672) and will be considered an application for a new product with an unregistered source of an active ingredient • Acute toxicity, public health pest efficacy, child resistant packaging data, companion animal safety data and/or requirements must be addressed by using: 1) the cite-all method, or 2) selective data citation which includes submitting required data. A rationale for a waiver or bridging of these data falls within this category. • The required companion animal safety studies are 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 breeding cats, then two companion animal studies are required: the first on kittens ≥ 12		

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			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. • Proposed label for the end-use product. 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 in the end-use 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) 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.

(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.