TABLE 16. BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) - OTHER ACTIONS

EPA No.	New CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25 – FY'26 Registration Service Fee ($)
B614	155	Pre-application; Conditional Ruling on rationales for addressing a data requirement in lieu of data; applicant-initiated; applies to one (1) rationale at a time	A pre-application request for an active ingredient, new use, or new product. The request is for review of a study waiver associated with any of the above pre-applications. The fee for this category is multiplied by each additional waiver request submitted for review. The study waiver request must include a written rationale for the study waiver and the identity of the new active ingredient (chemical structure). The submission of the full application package follows after the Agency has made a ruling on the study waiver(s). The decision on the waiver is conditional upon the review of the formal registration application and the data accompanying the application. Formal decisions or formal feedback on study waivers will not be made in meetings such as pre-registration conferences or any other pre-registration meeting with the Agency.	3	3,809
B682	156	Protocol review; applicant initiated; excludes time for Human Studies Review Board review (Includes rebuttal of protocol review)	An application for approval of a study protocol. Applicant provides a written copy of the protocol along with any specific questions about the protocol. The fee for this category is multiplied by each additional protocol submitted for review. Includes an application or submission to the EPA rebutting the conclusion(s) reached by the EPA for a previously submitted study protocol request (except HSRB protocol reviews). The science review of the study protocol is considered the completed PRIA decision on the protocol review request, so any written response contesting the conclusions in the review is considered to be a separate action and subject to a separate fee under PRIA.	3	3,662
B616	157 (new)	Pre-application; Conditional Ruling on a non-food determination	A pre-application request for a determination that an active ingredient when applied to food, whether directly or indirectly, is not likely to result in residues in or on food per 40 CFR 180.2020. Non-food determinations are made on a case-by-case basis and depend on the active ingredient and its use and/or use pattern in a particular product. Requires the submission of data (e.g., residue	5	4,951

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			data, environmental fate data [such as, but not limited to, soil degradation, photodegradation, or hydrolysis data], physical & chemical properties data [such as, but not limited to, vapor pressure or partition coefficient], etc.)		
B617	158 (new)	Pre-application; biochemical classification determination	A pre-application request for the determination of a substance (active ingredient) classification as a biochemical pesticide. The substance must meet all three criteria: (i) Is a naturally-occurring substance or structurally similar and functionally identical to a naturally-occurring substance; (ii) Has a history of exposure to humans and the environment demonstrating minimal toxicity, or in the case of a synthetically-derived biochemical pesticides, is equivalent to a naturally-occurring substance that has such a history; and (iii) Has a non-toxic mode of action to the target pest(s). Requires the submission of information to support each criterion: (1) Evidence of natural occurrence, or evidence that the compounds are structurally similar **and** functionally identical to naturally occurring compounds; (2) Evidence of a history of safe exposure to humans and to the environment. Information must be scientifically valid, peer reviewed (if applicable) and data-driven (e.g. quantifiable); and (3) Evidence of a non-toxic mode of action against the target pest. Referenced materials must be included in the application package.	5	4,951

(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.