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

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
B580	107	New active ingredient; food use; establish tolerance (2)(3)	An application that proposes a food use for a microbial or biochemical pesticide active ingredient that is not currently an active ingredient in any U.S. registered pesticide product. The use requires the establishment of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish a tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted within the original 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 of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time.	20	53,606

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			Until the 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 charged a new active ingredient service fee and decision review timeframe. If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
B590	108	New active ingredient; food	An application that proposes a food use for a microbial or biochemical pesticide active ingredient that is not currently contained as an active ingredient in any U.S. registered	18	33,506

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		use; petition to establish tolerance exemption (2)(3)	pesticide product. The use requires the establishment of a tolerance exemption under section 408 of the FFDCA. The application submission must contain a petition to establish a tolerance exemption for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted within the original 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 of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Until the 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 charged a new active ingredient service fee and decision review timeframe. If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening,		

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			and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
B600	109	New active ingredient; non-food use (2)(3)	An application that proposes a non-food use for a microbial or biochemical pesticide active ingredient that is not currently an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories above. Outdoor use means any use that is not indoor and could include treatment of ornamentals in a shade house and turf uses. Indoor means that the proposed use is for use inside of manmade structures. All indoor non-food uses included in the application are covered by the base fee for the application in this category if submitted within the original application. Some examples of indoor uses are termiticide structural protection, and indoor residential treatments (i.e. cockroach treatments). All non-food uses included in the	13	20,104

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			application are covered by the base fee for the application in this category if submitted simultaneously. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Until the 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 charged a new active ingredient service fee and decision review timeframe. If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application. The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date		

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			time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
B610	110	New active ingredient; Experimental Use Permit application; petition to establish temporary tolerance or temporary tolerance exemption (3)	An Experimental Use Permit (EUP) application where the proposed use meets the definition of a food use. The use requires the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish temporary tolerances or exemption from tolerances for all food/feed commodities covered by the pending registration application(s). 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.	10	13,403

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			All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient EUP. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been *agreed upon*, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
B611	111	New active ingredient; Experimental Use Permit application; petition to establish permanent tolerance exemption	An Experimental Use Permit (EUP) application for a microbial or biochemical pesticide product containing an active ingredient that is not an active ingredient in any currently U.S. registered pesticide product. The application proposes a food use. The use requires the establishment of an exemption from the requirement of a tolerance under section 408 of the FFDCA. The application must contain a petition to establish an exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). 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. A change to a crop	12	13,403

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			destruct application would require the applicant to withdraw their application and start the application process anew. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient EUP. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
B612	112	New active ingredient; no change to a permanent tolerance exemption (2)(3)	An application that proposes a food use for a microbial or biochemical pesticide active ingredient that is not currently an active ingredient in any U.S. registered pesticide product. The use does not require the establishment/amendment of a tolerance exemption under section 408 of the FFDCA. The application contains uses for food/feed commodities that are all currently covered by an existing tolerance or tolerance exemption. All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted within the original application. Some examples of food uses include: use on foods, for example, corn or apples; aquatic uses	10	18,428

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			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 of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
B613	113	New active ingredient; petition to	An application that proposes a food use for a microbial or biochemical pesticide active ingredient that is not currently an active ingredient in any U.S. registered pesticide product. The use requires the conversion of an existing temporary/tolerance or exemption to a	11	18,428

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		convert a temporary tolerance or a temporary tolerance exemption to a permanent tolerance or tolerance exemption (2)(3)	permanent tolerance under section 408 of the FFDCA. The application contains uses for food/feed commodities that are all currently covered by an existing tolerance or tolerance exemption and must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The petition will not contain new data for review in this category. The agency will assess the risks associated with the conversion of the commodities. If conversion of a crop group or subgroup or commodities requires submission of new data, the action does not belong in this category. The appropriate category will be one of the food use categories (e.g.B580). All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted within the original 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 of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time.		

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			Until the 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 charged a new active ingredient service fee and decision review timeframe. If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
B620	114	New active ingredient; Experimental Use Permit	An application for an Experimental Use Permit for a microbial or biochemical pesticide, with uses that do not fall under the definition of a food use, or with an agreement to destroy or use only for experimental purposes any crops treated during the experimental program.	7	6,703

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		application; Non-Food Use including crop destruct; (3)	All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new active ingredient EUP. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		