TABLE 13. BIOPESTICIDES AND POLLUTION PREVENTION DIVISION - MICROBIAL AND BIOCHEMICAL PESTICIDES; NEW PRODUCTS

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
B652	124	New product; registered source of active ingredient; requires petition to amend established tolerance or tolerance exemption; requires 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government	An application for registration of a microbial or biochemical pesticide product that is not substantially similar or identical in its uses and formulation to a product currently registered and, which contains a registered source of active ingredient. If the proposed new product contains an unregistered source of active ingredient, then see category B671. The use requires a change to the tolerance or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to amend an existing tolerance(s) or exemption(s) from tolerance for food/feed commodities covered by the pending registration application. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient. 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 product 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	13	13,403

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
		expense; or 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 (2)(3)	applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA 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.		
B660	125	New product; registered source of active ingredient(s);	An application for registration of an end-use or a manufacturing use microbial or biochemical pesticide product that is substantially similar, identical in its uses and formulation, or that differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment to products that are currently registered and, which contains a	4	1,342

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
		identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption; no data review or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or authorization from data owner is demonstrated. Category also includes 100% re-package of registered end-use or	registered source of active ingredient. If the proposed new product contains an unregistered source of active ingredient, then see category B672. The applicant must identify the similar registered products for all active ingredients in the proposed product. All applications require the following: • A data matrix is required with the application if it is not a 100% re-packaged product. • Product chemistry data (Group A and B) unless the product is identical (e.g., 100% repackaged product). In some cases, product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. The active ingredient(s) must be currently registered and the CSF must include its EPA Registration Number(s). • In all cases, the registrant must identify the registered similar product for this category. • Acute toxicity requirements must be addressed by using: 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 The application is not in this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted and must be reviewed to support the application. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category. If the use pattern on the TGAI differs from the proposed products, then additional data are required and the application does not		

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		manufacturing-use product that requires no data submission or data matrix. For microbial pesticides, the active ingredient(s) must not be re-isolated. (2)(3)	fall within this category. Substantially similar: Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular), and substantially similar 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 end-use product. Manufacturing Use Product: A 100% re-package of a manufacturing use product that requires no data submission or data matrix is covered by this category. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient. 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 product 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 review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			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		
B670	126	New product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption; requires 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government	An application for registration of a microbial or biochemical pesticide product that is not substantially similar or identical in its uses and/or formulation to products that are currently registered and, which contains a registered source of active ingredient. If the proposed new product contains an unregistered source of active ingredient, then see category B672. These applications require product specific chemistry data, acute toxicity data and other Tier I mammalian and non-target toxicity data as determined by the general use patterns for the product. When public health pests are claimed, efficacy (product performance) data for the product must be submitted. Formulator's exemption for the data requirements can be claimed when the source of the TGAI is registered by another pesticide registrant. If the registered source of the active ingredient is owned by the current applicant, Formulator's exemption is not applicable. The data used to support the registered source is instead referenced on the applicant's data matrix. This category is not for a new use. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient. 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	7	5,363

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
		expense; or 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 (2)(3)	to be made in order to grant the requested new product 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 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.		
B671	127	New product; food use;	An application for registration of a microbial or biochemical pesticide product that is not substantially similar or identical in its uses and/or formulation to products that are currently	17	13,403

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
		unregistered source of active ingredient(s); requires a petition to amend an established tolerance or tolerance exemption; requires 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or	registered. These applications require product specific chemistry data, acute toxicity data and other Tier I mammalian and non-target toxicity data as determined by the general use patterns for the product. When public health pests are claimed, efficacy (product performance) data for the product must be submitted. This category includes products containing an active ingredient(s) that requires a change in, or establishment of, a tolerance or tolerance exemption and in those situations there must be a petition to establish or amend an existing tolerance or tolerance exemption for the active ingredient. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient. 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 product 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 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,		

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		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 (2)(3)	which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
B672	128	New product; unregistered source of active ingredient(s); non-food use or food use with a tolerance or tolerance exemption previously established for the active ingredient(s); requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or	An application for registration of a microbial or biochemical pesticide product that is not substantially similar or identical in its uses and/or formulation to products that are currently registered. These applications require product specific chemistry data, acute toxicity data and other Tier I mammalian and non-target toxicity data as determined by the general use patterns for the product. When public health pests are claimed, 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 of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient.	13	9,574

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
		citation of data generated at government expense; or 4) submission or citation of a 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. (2)(3)	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 product 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 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.		
B673	129	New product MUP/EP; unregistered source of active ingredient(s);	An application for registration of a new microbial or biochemical pesticide product (MUP or end use product) containing an unregistered source of a registered active ingredient for which the data cited to fulfill all TGAI data requirements has been previously reviewed and accepted by the Agency. If an update to the TGAI risk assessment is required, then this	10	5,363

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
		citation of Technical Grade Active Ingredient (TGAI) data previously reviewed and accepted by the Agency. Requires an Agency determination that the cited data supports the new product. (2)(3)	category does not apply. 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 of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient. 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 product 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 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.		

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B674	130	New product MUP; Repack of identical registered end-use product as a manufacturing-use product; same registered uses only (2)(3)	An application for registration of a new microbial or biochemical pesticide manufacturing use product that is identical in its formulation and uses to end use products that are currently registered. All applications require the following: • A formulator's exemption statement • The applicant must identify the registered identical product for this category • The active ingredient listed on the CSF must be an EPA registered product in order to satisfy the data requirements for the active ingredient. 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 applicable new use categories). An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient. 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 product 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 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	4	1,342

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			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.		
B675	131	New Product MUP; registered source of active ingredient; submission of completely new generic data package; registered uses only. (2)(3)	An application for registration of a new microbial or biochemical pesticide manufacturing use product (MUP) and, which contains a registered source of active ingredient. If the proposed new product contains an unregistered source of active ingredient, then see category B672. New manufacturing use product is any product intended (labeled) for formulation or repackaging into an end use formulated pesticide product. The active ingredient is not a new active ingredient, but one that claims to be substantially similar or identical to another active ingredient which is currently registered (as referenced by EPA registration number) and has the selective data citation used. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient. 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 product 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 review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a	10	9,574

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			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.		
B676	132	New product; more than one active ingredient where one active ingredient is an unregistered source; product chemistry data must be submitted; requires: 1) submission of product specific data, and 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-	An application for registration of a new microbial or biochemical pesticide product which contains more than one active ingredient where one active ingredient is derived from an unregistered source (i.e., does not have an EPA registration number) but is not a new active ingredient. The other active ingredient is derived from a registered source. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient. 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 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 product 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 review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a	13	9,574

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
		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. (2) (3)	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.		
B677	133	New end-use non-food animal product with submission of two or more target animal safety studies; includes data and/or waivers of data for only: • product chemistry and/or • acute toxicity and/or public health pest efficacy	An application for registration of a new microbial or biochemical pesticide end-use animal product that is not 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 is required with the application. • 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 not registered in this application; the decision review time line will be the longest of the associated application (see timeline for B672).	10	9,261

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
		and/or • animal safety studies and/or • child resistant packaging (2)(3)	• All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. In those cases where 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. • 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. • 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 breeding cats, then two companion animal studies are required: the first on 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. • Proposed label for the end use product. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient. 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 product 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 review time due date.		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			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.		