

PRIA 4 Interpretations

TABLE 12. BIOPESTICIDES AND POLLUTION PREVENTION DIVISION - MICROBIAL AND BIOCHEMICAL PESTICIDES; NEW USES

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
B630	115	First food use; petition to establish tolerance exemption (2)(4)	<p>An application for registration of a new use for a microbial or biochemical pesticide, where the proposed first food use meets the definition of a food use, requires that the applicant submit data to enable the Agency to conduct a dietary exposure assessment and requires that the applicant submit a petition for an exemption from the requirement of a tolerance for the active ingredient.</p> <p>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.</p> <p>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 first food use application 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 first food use decision review time.</p> <p>Until the first food use 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 first food use service fee and decision review timeframe.</p> <p>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</p>	13	13,403

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			<p>charged an additional 25% of the full registration service fee for the first food use 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 first food use 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.</p> <p>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.</p>		
B631	116	New food use; petition to amend an established tolerance (3)(4)	<p>A petition to amend an existing tolerance for a microbial or biochemical pesticide active ingredient where the proposed use meets the definition of a food use and requires that the applicant submit data to enable the Agency to conduct a dietary exposure assessment and that the applicant submit a petition for a tolerance for the active ingredient. This category includes amendments to temporary tolerances and other time-limited tolerances. In addition to the petition, there may be an application to amend an existing registered product or experimental use permit.</p> <p>All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.</p> <p>Amendment applications to add new use(s) to registered product labels are covered by the</p>	12	13,403

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			<p>base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception is if the new use(s) are to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses.</p> <p>Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time.</p> <p>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 use application.</p> <p>Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.</p> <p>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 food use 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.</p>		

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			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.		
B640	117	First food use; petition to establish tolerance (2)(4)	<p>An application for registration of a new use for a microbial or biochemical pesticide where there is a reasonable expectation or certainty that residues of the active ingredient could occur in human food, animal feed, or in livestock from the proposed use. The first food use requires the applicant to submit a petition to establish a tolerance for the active ingredient for the proposed use, and to submit data 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.</p> <p>All uses included in any original application or petition for a first food use that otherwise satisfy the conditions for the category are covered by the base fee for that application.</p> <p>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.</p> <p>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 first food use 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 first food use decision review time.</p> <p>Until the first food use 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 first food use service fee and decision review timeframe.</p>	19	20,104

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			<p>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 first food use application.</p> <p>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 first food use 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.</p> <p>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.</p>		
B643	118	New Food use; petition to amend an established tolerance exemption (3)(4)	An application that proposes a new/additional food use for a microbial or biochemical pesticide active ingredient. New/additional food use includes a proposed use of any U. S. registered active ingredient for which there is no registered "food use". The use requires the amendment of the existing exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to amend tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s).	10	13,403

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			<p>All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.</p> <p>Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception is if the new use(s) are to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses.</p> <p>Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time.</p> <p>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 use application.</p> <p>Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.</p> <p>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 food use registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time</p>		

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			<p>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.</p> <p>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.</p>		
B642	119	First food use; indoor; food/food handling (2)(4)	<p>An application for a microbial or biochemical pesticide that proposes the first indoor, food/food handling use. First food use includes a proposed use of any U. S. registered active ingredient for which there is no registered "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 tolerances or exemptions from tolerance for all food/feed commodities covered by the pending registration application(s). Indoor means that the proposed use is for use inside of manmade structures. All indoor food uses included in any original application or petition for the first food use are covered by the base fee for the application in this category if submitted within the original application.</p> <p>Some examples of indoor food uses include: use in a food handling and/or processing establishment and use on food crops in a greenhouse. 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.</p> <p>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 first food use application package is subject to the registration service</p>	12	33,506

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			<p>fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to first food use decision review time.</p> <p>Until the first food use 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 first food use service fee and decision review timeframe.</p> <p>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 first food use application.</p> <p>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 food use 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.</p> <p>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.</p>		

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B644	120	New use, no change to an established tolerance or tolerance exemption (3)(4)	<p>An application that proposes a new use for a microbial or biochemical pesticide active ingredient. New use (indoor/outdoor/food handling) includes a proposed use of any U.S. registered active ingredient for which there is no registered use. The use does not require an amendment to the established tolerance or 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.</p> <p>All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.</p> <p>Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception is if the new use(s) are to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses.</p> <p>Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time.</p> <p>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 use application.</p> <p>Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the</p>	8	13,403

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			<p>longest decision review time applies to all of the new uses requested in the application.</p> <p>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 use 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.</p> <p>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.</p>		
B650	121	New use; non-food (3)(4)	<p>An application for registration of a new use for a microbial or biochemical pesticide, with uses that do not fall under the definition of a food use. This category also includes a change in use pattern such that the exposure to humans and the environment could be significantly increased (e.g., additional routes of exposure) and therefore must be evaluated for increased risks.</p> <p>All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.</p> <p>Amendment applications to add new use(s) to registered product labels are covered by the</p>	7	6,703

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			<p>base fee for this category as long as they are all submitted in the same package. Each application for a new product and/or new inert approval submitted in this package, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses.</p> <p>Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time.</p> <p>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 use application.</p> <p>Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.</p> <p>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 use 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.</p>		

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			<p>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.</p>		
B645	122 new	New food use; Experimental Use Permit application; petition to amend or add a tolerance exemption (4)	<p>An Experimental Use Permit (EUP) application for a microbial or biochemical pesticide product containing an already registered active ingredient, where the proposed use meets the definition of a new food use. New food use includes a proposed use of any U. S. registered active ingredient for which there is no registered "food use". The use requires the establishment or amendment of the existing exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to add or amend tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s).</p> <p>All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.</p> <p>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</p>	12	13,403

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			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.		
B646	123 new	New use; non-food use including crop destruct; Experimental use Permit application (4)	<p>An application for an Experimental Use Permit (EUP) for a microbial or biochemical pesticide for an already registered active ingredient, where the proposed use does not fall under the definition of a food use, or with an agreement to destroy or use only for experimental uses purposes any crops treated during the experimental program. This category also includes a change in use pattern such that the exposure to humans and the environment could be significantly increased (e.g., additional routes of exposure) and therefore must be evaluated for increased risks.</p> <p>All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.</p> <p>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</p>	7	6,703

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
			(c) withdraw the application without prejudice.		