

## PRIA 4 Interpretations

**TABLE 14. BIOPESTICIDES AND POLLUTION PREVENTION DIVISION - MICROBIAL AND BIOCHEMICAL PESTICIDES; AMENDMENTS**

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
B621	134	Amendment; Experimental Use Permit; no change to an established temporary tolerance or tolerance exemption(3)	<p>An application to amend an existing Experimental Use Permit for a microbial or biochemical pesticide. Amendments could include but are not limited to changing the uses, use sites, and/or acreage tested, and/or extending the length of time for completion of the experimental program. If a tolerance or tolerance exemption needs to be amended in connection with this action, you must add the cost of a petition (see B631 or B641, below, as appropriate).</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 amendment. 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</p>	7	5,363

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			prejudice.		
B622	135	Amendment; Experimental Use Permit; petition to amend an established or temporary tolerance or tolerance exemption. (3)	<p>An application to amend an existing Experimental Use Permit for a microbial or biochemical pesticide. This use requires a change/amendment to the existing tolerance/temporary tolerance or exemption for any U. S. registered active ingredient that currently has an approved tolerance/temporary tolerance or exemption for the proposed use.</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 amendment. 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>	11	13,403
B641	136	Amendment of an established tolerance or tolerance exemption.	A petition to amend an established tolerance for a microbial or biochemical pesticide, with supporting 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. This category includes amendments to temporary tolerances, such as those established in connection with an experimental use permit. In addition to the petition, there may be an application to register	13	13,403

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			<p>a product, or to amend an existing registered product or experimental use permit. 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 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>		
B680	137	Amendment; registered source of active ingredient(s); no new use(s); no changes to an established tolerance or tolerance exemption. Requires data	<p>An application to amend a registration is in this category when it contains data to support a change in the label (such as use patterns, use site changes) or to add an alternate formulation, or change the basic formulation of a currently registered product. These data include but are not limited to: toxicity data, product chemistry data, manufacturing process, non-target toxicity data, efficacy/product performance, child-resistant packaging data, and data to support a new pattern of use (e.g., increased application rate, different application methods) that changes the potential for human and/or environmental risks or exposure.</p> <p>EPA-initiated amendments shall not be charged fees. Label amendments submitted by notification under PR Notices, such as PR Notice 95-2 and PR Notice 98-10, continue under</p>	5	5,363

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		<p>submission. (2) (3)</p>	<p>PR Notice timelines and are not subject to PRIA fees.</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>(a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.</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 amendment. 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</p>		

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			application without prejudice.		
B681	138	Amendment; unregistered source of active ingredient(s). Requires data submission. (2) (3)	<p>An application to amend a registration is in this category when it contains data to support a change in the label (such as use patterns, use site changes) or to add an alternate formulation or change the basic formulation of a currently registered product. These data include but are not limited to: toxicity data, non-target toxicity data, efficacy/product performance, child-resistant packaging data, additional (unregistered) sources of the active ingredient with supporting chemistry data, manufacturing process, efficacy (if public health pests are claimed), and data to support a pattern of use (e.g., increased application rate, different application methods) that changes the potential for human and/or environmental risks or exposure.</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>(a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.</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 amendment. 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</p>	7	6,383

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			<p>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>		
B683	139	<p>Label amendment; requires review/update of previous risk assessment(s) without data submission (e.g., labeling changes to REI, PPE, PHI). (2) (3)</p>	<p>Modification in the label of a registered product that is not substantially similar to a currently registered product and that requires review and Agency determination of whether the existing database would support a change or modification to the amended label. Agency update of existing risk analysis/assessment may be required. No data is submitted to support this label amendment. Examples of actions in this category include: label changes to Directions for Use (including restricted entry intervals (REI), personal protective equipment (PPE), pre-harvest interval (PHI), application rate, application frequency, application timing, addition of aerial or chemigation application methods consistent with PR Notices 87-1 and 93-2, ground water or surface water advisory statements, etc. that require risk analysis by EPA.</p> <p>EPA-initiated amendments shall not be charged fees. Label amendments submitted by notification under PR Notices, such as and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees.</p> <p>(a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within</p>	6	5,363

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			<p>the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.</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 amendment. 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>		
B684	140	Amending non-food animal product that includes submission of target animal safety data; previously	<p>Generally modifying an existing, previously registered label by adding additional claims for use on adults or juveniles or breeding animals of the same species. An application to amend a registered end-use pesticide animal product. For example, spot-on and flea collar 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). This amendment would require the following:</p>	8	9,261

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		registered (2) (3)	<ul style="list-style-type: none"> <li>• A data matrix and data compensation forms are required with the application.</li> <li>• 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.</li> <li>• Same species of animal previously listed on registered label. If new efficacy claims are sought, then new pest efficacy data matching the claim(s) are required.</li> <li>• If the packing type has changed (e.g., spot-on vs. stripe-on) so that the dose volume is altered (new or different), new child resistant packaging data is required.</li> <li>• 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 on 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.</li> <li>• Proposed amended label for the end use product.</li> </ul> <p>EPA-initiated amendment shall not be charged fees. Label amendments submitted by notification under PR Notices, such as and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees.</p> <p>(a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in</p>		

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			<p>FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.</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 amendment. 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>		
B685	141 new	Amendment; add a new biochemical unregistered source of active	Amendment to add an unregistered source of active ingredient for a biochemical or to add a new production site for a microbial active ingredient. Applies to technical grade active ingredients and manufacturing use products only. Does not apply to an end-use product using a registered source of active ingredient. Does apply to an end-use product produced by an	5	5,363

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		<p>ingredient or a new microbial production site. Requires submission of analysis of samples data and source/production site-specific manufacturing process description (3)</p>	<p>Integrated System as defined in 40 CFR Part 158.300. Requires the submission of confirmatory analysis of samples data for the new source or production site, and an updated manufacturing process description specific to the source or production site, to ensure a comparable source or production.</p> <p>EPA-initiated amendments shall not be charged fees. Label amendments submitted by notification under PR Notices, such as and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees.</p> <p>(a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.</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.</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</p>		

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			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.		