

PRIA 5 Interpretations

TABLE 17. BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) - PLANT-INCORPORATED PROTECTANTS

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) ⁽¹⁾	FY'23 - FY'24 Registration Service Fee (\$)
B740	159	<p>Experimental Use Permit application; no petition for tolerance/tolerance exemption; includes: 1. non-food/feed use(s) for a new (2) or registered (3) PIP (12); 2. food/feed use(s) for a new or registered PIP with crop destruct; 3. food/feed use(s) for a new or registered PIP in which an established tolerance/tolerance exemption exists for the intended use(s). (4) (5) (12)</p>	<p>An application for a EUP using a new or registered PIP active ingredient, without food or feed uses, or with an agreement to destroy, or use only for experimental purposes, any crops treated during the experimental program. This category also applies to PIPs for which a tolerance exemption has been previously established.</p> <p>Example: transfer existing PIP trait by traditional breeding, such as from field corn to sweet corn.</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 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</p>	9	137,198

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) ⁽¹⁾	FY'23 - FY'24 Registration Service Fee (\$)
			changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
B750	160	Experimental Use Permit application; with a petition to establish a temporary or permanent tolerance/tolerance exemption for the active ingredient. Includes new food/feed use for a registered (3) PIP. (4) (12)	<p>An application for a EUP to allow a registered PIP active ingredient to be used under controlled, field or actual use conditions so that the data required to support a federal registration can be developed to evaluate the PIP's efficacy and potential for adverse effects on human health and the environment. A temporary tolerance or exemption is set for an appropriate period of time to allow the harvest of any treated food or feed commodities during the experimental period.</p> <p>Example: transfer existing PIP trait by traditional breeding, such as from field corn to sweet corn.</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 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</p>	12	182,927

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) ⁽¹⁾	FY'23 - FY'24 Registration Service Fee (\$)
			changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
B771	161	Experimental Use Permit application; new (2) PIP; with petition to establish a temporary tolerance/tolerance exemption for the active ingredient; credit 75% of B771 fee toward registration application for a new active ingredient that follows. (5) (12)	<p>An application for a EUP to allow a new PIP active ingredient to be used under controlled, field or actual use conditions so that data required for a federal registration can be developed to evaluate its efficacy and/or potential for adverse effects on humans and the environment. A temporary tolerance or exemption will be established for an appropriate period of time to allow the harvest of any treated food or feed commodities during the experimental period.</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 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.</p>	13	182,927

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) ⁽¹⁾	FY'23 - FY'24 Registration Service Fee (\$)
B772	162	Application to amend or extend a PIP Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active ingredient is unaffected (12)	<p>An amendment making minor changes to or to extend the test period of an existing PIP EUP. This category does not apply to EUPs issued under categories B921, B923, B925, or B927 (i.e., non-PIP EUPs) in Table 17.</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 EUP 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 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.</p>	3	18,296
B773	163	Application to amend or extend a PIP Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient (12)	<p>An amendment making minor changes to or to extend the test period of an existing PIP EUP; an extension of an existing temporary tolerance/tolerance exemption is needed. This category does not apply to EUPs issued under categories B921, B923, B925, or B927 (i.e., non-PIP EUPs) in Table 17.</p>	9	45,737

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) ⁽¹⁾	FY'23 - FY'24 Registration Service Fee (\$)
			<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 EUP 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 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.</p>		
B780	164	<p>Registration application; new (2) PIP; non-food/feed or food/feed without tolerance petition based on an existing permanent tolerance exemption (5) (12) (14)</p>	<p>An application for a new PIP active ingredient for either (a) a non-food/feed use; or (b) a food use that is currently covered by an existing permanent tolerance exemption.</p> <p>This category is used for full commercial registration; a seed increase registration can be obtained under B883, B884, or B885.</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 PIP. 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</p>	16	228,657

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) ⁽¹⁾	FY'23 - FY'24 Registration Service Fee (\$)
			<p>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.</p>		
B800	165	<p>Registration application; new (2) PIP; with petition to establish permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption (5) (12) (14)</p>	<p>An application for a new PIP active ingredient for a food/feed use. A temporary tolerance or temporary exemption from a tolerance already exists to support a EUP for the active ingredient. A permanent tolerance or tolerance exemption is needed for registration. A petition to establish a tolerance or exemption from the requirement of a tolerance with supporting data must accompany the application.</p> <p>This category is used for full commercial registration; a seed increase registration can be obtained under B883, B884, or B885.</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 new PIP 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</p>	17	246,949

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			<p>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.</p>		
B820	166	<p>Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient (5) (12) (14)</p>	<p>An application for a new PIP active ingredient for a food/feed use. A tolerance or an exemption from a tolerance must be established. No previous temporary tolerance or tolerance exemption has been established. A petition to establish a tolerance or exemption from the requirement of a tolerance with supporting data must accompany the application.</p> <p>This category is used for full commercial registration; a seed increase registration can be obtained under B883, B884, or B885.</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 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</p>	19	292,682

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			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.		
B851	167	Registration application; new event of a previously registered PIP active ingredient(s); no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s). (12)	<p>An application for a new event of a previously registered PIP active ingredient(s). The new event and the proposed use is already covered under an existing tolerance or tolerance exemption.</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 EUP 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 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.</p>	9	182,927
B870	168	Registration application; registered (3) PIP; new product; new use; no	An application for a new product containing a previously registered PIP active ingredient to add a new use.	9	54,881

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		petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (4) (12) (14)	<p>Example: transfer existing PIP trait by traditional breeding, such as from field corn to sweet corn.</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 EUP 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 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.</p>		
B880	169	Registration application; registered (3) PIP; new product or new terms of registration; additional data submitted; no petition since a permanent tolerance/ tolerance exemption is already established for the active	<p>An application for a new product, intended for commercial use, containing a previously registered PIP active ingredient that is in an existing registered product.</p> <p>Example: Stacking PIP traits within a crop using traditional breeding techniques.</p> <p>The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due</p>	9	45,737

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		ingredient(s). (5) (6) (7) (12) (14)	date which specifies any label changes that have to be made in order to grant the requested EUP 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 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.		
B883	170	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. (5) (8) (12) (14)	<p>An application for a new PIP active ingredient for seed increase/breeding purposes only. The application must propose a time limitation (expiration date) and a per-season acreage cap. A petition for a permanent tolerance/tolerance exemption is needed and must be based on a previously-established temporary tolerance or exemption (e.g., a tolerance or exemption established with an experimental use permit). If a seed increase registration is granted under this PRIA category, full commercial registration can subsequently be obtained using B890.</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 EUP amendment. If the label issues</p>	13	182,927

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			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.		
B884	171	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient. (5) (8) (12) (14)	<p>An application for a new PIP active ingredient for seed increase/breeding purposes only. The application must propose a time limitation (expiration date) and a per-season acreage cap. A petition for a permanent tolerance/tolerance exemption is needed (not based on a previously-established temporary tolerance or exemption). If a seed increase registration is granted under this PRIA category, full commercial registration can subsequently be obtained using B890.</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 EUP 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</p>	19	228,657

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			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.		
B885	172	Registration application; registered (2) PIP, seed increase; breeding stack of previously approved PIPs, same crop; no petition since a permanent tolerance/ tolerance exemption is already established for the active ingredient(s). (9) (12)	<p>An application for a new PIP product for seed increase/breeding purposes only that contains a previously-registered active ingredient that is in an existing product. A new tolerance or exemption is not needed since a permanent tolerance/exemption is already in place for the previously-registered active ingredient. If a seed increase registration is granted under this PRIA category, full commercial registration can subsequently be obtained using B890.</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 EUP 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 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;</p>	6	45,737

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			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.		
B890	173	Application to amend a seed increase registration; converts registration to commercial registration; no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s). (5) (12) (14)	<p>An application to amend a registered PIP product that only allows the expansion of use from seed production to commercial registration.</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 EUP 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 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.</p>	9	91,465
B900	174	Application to amend a registration, including actions such as modifying	An application to amend a registered PIP product – except as described in B870, B890 and B891. This category includes amendments involving data review, including (but not limited to)	6	18,296

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		<p>an IRM plan, or adding an insect to be controlled (5) (10) (11) (12)</p>	<p>changes to Insect Resistance Management plans, new information related to the molecular characterization of the PIP, revised bioinformatics analysis, and adding a target pest to the label.</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 PR Notice timelines and are not subject to PRIA 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 amended 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.</p>		
B902	175	PIP Protocol review.	An applicant-initiated request for Agency review of the proposed description of the study(ies) that will be performed to support the registration of a PIP.	3	9,151

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B903	176	Inert ingredient permanent tolerance exemption; e.g., a marker such as NPT II; reviewed in BPPD.	A petition to establish a permanent tolerance or an exemption from tolerance for a PIP inert ingredient (for example, a marker protein).	12	91,465
B904	177	Import tolerance or tolerance exemption; processed commodities/food only (inert or active ingredient).	A petition to establish a tolerance or tolerance exemption for foods imported into the United States that contain PIP active ingredients.	12	182,927
B905	178	FIFRA Scientific Advisory Panel Review	A Scientific Advisory Panel (SAP) meeting to address Issue(s) identified during review of a regulatory action (EUP, registration, amendment). This category can be used with other PRIA actions that do not include an SAP in the PRIA category or for non-PRIA actions that warrant an SAP. When this category is used with other PRIA actions, the provisions of footnote 5 apply.	6	91,465
B906	179	Petition to establish a temporary tolerance/tolerance exemption for one or more active ingredients	A petition to establish a temporary tolerance or temporary tolerance exemption for one or more active ingredients covered under Table 17 (e.g., PIPs, GE animals, exogenous RNA). This category can be used in association with non-PRIA actions (e.g., small scale testing on less than 10 acres) or with other PRIA actions that do not include an associated temporary tolerance/tolerance exemption.	9	45,733
B907	180	Petition to establish a permanent tolerance/tolerance exemption for one or more active ingredients based on an existing temporary	A petition to establish a permanent tolerance or a permanent tolerance exemption based on a temporary tolerance or tolerance exemption for one or more PIP active ingredients. The petition must be based on a previously issued temporary tolerance/tolerance exemption for the same ingredient(s), though the previous tolerance/tolerance exemption does not need to be active at the time	9	18,296

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		tolerance/tolerance exemption.	of the new petition. This category can be used for non-PRIA actions (e.g., small scale testing on less than 10 acres) or with other PRIA actions that do not include an associated temporary tolerance/tolerance exemption.		
B909	181 (new)	PIP tolerance exemption determination; applicant-initiated; request to determine if an existing tolerance exemption applies to a PIP.	An application requesting EPA determination as to whether a PIP active or inert ingredient is covered by an existing PIP tolerance exemption.	6	18,296
B910	182 (new)	Biotechnology Notification for small-scale field testing of genetically engineered microbes.	An application to submit a Biotechnology Notification, as required under 40 CFR 172 Subpart C for small-scale testing (i.e., <10 acres) of a genetically engineered microbial pesticide. EPA will review the notification and issue a determination as to whether an Experimental Use Permit will be needed to conduct the small-scale testing. This category also covers requests for EPA to confirm if a genetically modified microbe is exempt from 40 CFR 172 Subpart C requirements (e.g., an inactivated microbe).	3	9,151
B921	183 (new)	Experimental Use Permit application; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); non-food/feed. This category would cover substances produced and used in animals that are intended	An application for an EUP to allow a new genetic modification in an animal intended for pesticidal use to be tested under controlled, field or actual use conditions so that data required for a federal registration can be developed to evaluate its efficacy and/or potential for adverse effects on humans and the environment. A temporary tolerance or exemption is not needed because all uses are non-food/feed. The limitations specified in footnote 13 apply to this category.	12	182,927

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		for use as a pesticide, such as for pest population control, including the genetic material in such animals. Credit 75% of B921 fee toward registration application for the new active ingredient that follows (B922) (5) (12) (13)	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 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.		
B922	184 (new)	Registration application; new active ingredient; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); non-food/feed. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest	An application for a new active ingredient registration consisting of a genetic modification in an animal intended for pesticidal use. No tolerance or tolerance exemption because all uses are non-food/feed. The limitations specified in footnote 13 apply to this category. 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	16	228,657

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) ⁽¹⁾	FY'23 - FY'24 Registration Service Fee (\$)
		population control, including the genetic material in such animals (5) (12) (13) (14)	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.		
B923	185 (new)	Experimental Use Permit application; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); with petition to establish a temporary or permanent tolerance/tolerance exemption of an active ingredient. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such	An application for an EUP to allow a new genetic modification in an animal intended for pesticidal use to be tested under controlled, field or actual use conditions so that data required for a federal registration can be developed to evaluate its efficacy and/or potential for adverse effects on humans and the environment. A petition to establish a temporary tolerance or tolerance exemption is needed to support food/feed uses. The limitations specified in footnote 13 apply to this category. 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 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	15	228,658

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) ⁽¹⁾	FY'23 - FY'24 Registration Service Fee (\$)
		animals. Credit 75% of B923 fee toward registration application for the new active ingredient that follows (B924) (5) (12) (13) (14)	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.		
B924	186 (new)	Registration application; new active ingredient; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); with petition to establish a permanent tolerance/tolerance exemption of an active ingredient. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals (5) (12) (13) (14)	<p>An application for a new active ingredient registration consisting of a genetic modification in an animal intended for pesticidal use. A petition to establish a permanent tolerance or tolerance exemption is needed to support food/feed uses. The tolerance or exemption petition can (but is not required to) be based on a temporary exemption previously established for an EUP. The limitations specified in footnote 13 apply to this category.</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</p>	19	292,682

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) ⁽¹⁾	FY'23 - FY'24 Registration Service Fee (\$)
			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.		
B925	187 (new)	Experimental Use Permit application; exogenous applications of RNA to elicit the RNA interference pathway in pests; non-food/feed; credit 75% of B925 fee toward registration application for the new active ingredient that follows (B926) (5) (12)	<p>An application for an EUP to allow a new exogenous RNA active ingredient to be used under controlled, field or actual use conditions so that data required for a federal registration can be developed to evaluate its efficacy and/or potential for adverse effects on humans and the environment. Exogenous RNA is defined as formulations of gene silencing/interfering RNAs applied by spraying, injection, spreading, bait formulations, mechanical inoculation, root/seek soaking, or other non-transgenic methods. A temporary tolerance or exemption is not needed because all uses are non-food/feed.</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 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</p>	11	27,452

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) ⁽¹⁾	FY'23 - FY'24 Registration Service Fee (\$)
			changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
B926	188 (new)	Registration application; new active ingredient; exogenous applications of RNA to elicit the RNA interference pathway in pests; non-food/feed (5) (12) (14)	<p>An application for registration of a new exogenous RNA active ingredient. Exogenous RNA is defined as formulations of gene silencing/interfering RNAs applied by spraying, injection, spreading, bait formulations, mechanical inoculation, root/seek soaking, or other non-transgenic methods. No tolerance or tolerance exemption because all uses are non-food/feed.</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 (c) withdraw the application without prejudice.</p>	17	82,329
B927	189 (new)	Experimental Use Permit application; exogenous applications of RNA to	An application for an EUP to allow a new exogenous RNA active ingredient to be used under controlled, field or actual use conditions so that data required for a federal registration can be developed to	14	54,889

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) ⁽¹⁾	FY'23 - FY'24 Registration Service Fee (\$)
		<p>elicit the RNA interference pathway in pests; with petition to establish a temporary or permanent tolerance/tolerance exemption of an active ingredient; credit 75% of B927 fee toward registration application for the new active ingredient that follows (B928) (5) (12)</p>	<p>evaluate its efficacy and/or potential for adverse effects on humans and the environment. Exogenous RNA is defined as formulations of gene silencing/interfering RNAs applied by spraying, injection, spreading, bait formulations, mechanical inoculation, root/seek soaking, or other non-transgenic methods. A petition to establish a temporary tolerance or tolerance exemption is needed to support food/feed 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 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.</p>		
B928	190 (new)	<p>Registration application; new active ingredient; exogenous applications of RNA to elicit the RNA</p>	<p>An application for registration of a new exogenous RNA active ingredient. Exogenous RNA is defined as formulations of gene silencing/interfering RNAs applied by spraying, injection, spreading, bait formulations, mechanical inoculation, root/seek</p>	22	137,210

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) ⁽¹⁾	FY'23 - FY'24 Registration Service Fee (\$)
		interference pathway in pests; with petition to establish a permanent tolerance/tolerance exemption of an active ingredient (5) (12) (14)	<p>soaking, or other non-transgenic methods. A petition to establish a permanent tolerance or tolerance exemption is needed to support food/feed uses. The tolerance or exemption petition can (but is not required to) be based on a temporary exemption previously established for an EUP.</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 (c) withdraw the application without prejudice.</p>		
B929	191 (new)	Registration application; new product, registered active ingredient; exogenous applications of RNA to elicit the RNA interference pathway in	An application for a new product, intended for commercial use, containing a previously registered exogenous RNA active ingredient that is in an existing registered product. Exogenous RNA is defined as formulations of gene silencing/interfering RNAs applied by spraying, injection, spreading, bait formulations, mechanical inoculation, root/seek soaking, or other non-transgenic	10	7,322

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) ⁽¹⁾	FY'23 - FY'24 Registration Service Fee (\$)
		pests; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s) (5) (12)	<p>methods. The product must be either (a) for non-food/feed uses only; or (b) covered under an existing tolerance or tolerance exemption to support food/feed 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 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 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.</p>		
B930	192 (new)	Application to amend or extend a non-PIP Emerging Technologies Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active	An amendment making minor changes to or to extend the test period of an existing Emerging Technologies EUP. This category applies to EUPs that are either (a) non-food/feed uses only; or (b) covered under an existing temporary or permanent tolerance exemption that will be unaffected by the requested amendment. Emerging Technologies EUPs are defined as those issued under categories B921, B923, B925, or B927 (i.e., non-PIP EUPs) in Table 17.	3	18,296

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) ⁽¹⁾	FY'23 - FY'24 Registration Service Fee (\$)
		ingredient is unaffected (12)	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 EUP 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 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.		
B931	193 (new)	Application to amend or extend a non-PIP Emerging Technologies Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient (12)	An amendment making minor changes to or to extend the test period of an existing Emerging Technologies EUP. A petition to extend an existing temporary tolerance/tolerance exemption is needed to support food/feed uses. Emerging Technologies EUPs are defined as those issued under categories B921, B923, B925, or B927 (i.e., non-PIP EUPs) in Table 17. 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 EUP amendment. If the label issues	9	45,737

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) ⁽¹⁾	FY'23 - FY'24 Registration Service Fee (\$)
			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.		
B932	194 (new)	Amendment; application to amend a non-PIP Emerging Technologies registration (4) (5) (12)	<p>An application to amend a registered Emerging Technologies product. This category includes amendments involving data review, including changes 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, 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. Emerging Technologies products are defined as registered non-PIP products issued under categories B922, B924, B926, B928, and B929 in Table 17.</p> <p>EPA-initiated amendments shall not be charged fees. Label amendments submitted by notification under PR Notices such as</p>	6	18,296

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) ⁽¹⁾	FY'23 - FY'24 Registration Service Fee (\$)
			<p>PR Notice 95-2 and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA 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 amended 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.</p>		

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) 'New PIP' means a PIP with an active ingredient that has not been registered.

(3) 'Registered PIP' means a PIP with an active ingredient that is currently registered.

- (4) Transfer registered PIP through conventional breeding for new food/feed use, such as from field corn to sweet corn.
- (5) If, during review of the application, it is determined that review by the FIFRA Scientific Advisory Panel (SAP) is needed, the applicant will submit an application for category B905, which will be processed concurrently, and the decision review time for both applications will be the longer of the two associated applications. The scientific data involved in this category are complex. EPA often seeks technical advice from the SAP on risks that pesticides pose to wildlife, farm workers, pesticide applicators, non-target species, insect resistance, and novel scientific issues surrounding new technologies. The scientists of the SAP neither make nor recommend policy decisions. They provide advice on the science used to make these decisions. Their advice is invaluable to the EPA as it strives to protect humans and the environment from risks posed by pesticides. Due to the time it takes to schedule and prepare for meetings with the SAP, additional time and costs are needed.
- (6) Registered PIPs stacked through conventional breeding.
- (7) Deployment of a registered PIP with a different Insecticide Resistance Management (IRM) plan (e.g., seed blend).
- (8) The negotiated acreage cap will depend upon EPA's determination of the potential environmental exposure, risk(s) to non-target organisms, and the risk of targeted pest developing resistance to the pesticidal substance. The uncertainty of these risks may reduce the allowable acreage, based upon the quantity and type of non-target organism data submitted and the lack of insect resistance management data, which is usually not required for seed-increase registrations. Registrants are encouraged to consult with EPA prior to submission of a registration application in this category.
- (9) Application can be submitted prior to or concurrently with an application for commercial registration.
- (10) For example, IRM plan modifications that are applicant-initiated.
- (11) (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 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 section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (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.

(12) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a pre-decisional letter including any changes requested by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(13) This category does not include genetic modifications in animals not intended for use as a pesticide, e.g., genetic modifications in animals intended for food use or animals used as intended for use as companion animals.

(14) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.