

## PRIA 4 Interpretations

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

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
B740	153	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; 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) (12)	<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. No issues that warrant an SAP.</p> <p style="padding-left: 40px;">1. 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 <u>2</u> 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 <i>agreed upon</i>, 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>	6	100,511
B741	154 new	Experimental Use Permit application; no petition for	<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. Issues that warrant an SAP.</p>	12	167,515

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
		<p>tolerance/tolerance exemption. Includes: 1. Non-food/feed use(s) for a new<sup>(2)</sup> or registered<sup>(3)</sup> PIP<sup>(12)</sup>; 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); SAP Review <sup>(12)</sup></p>	<p>The Agency will provide the applicant with a pre-decisional determination <u>2</u> 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 Experimental Use Permit. 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 <i>agreed upon</i>, 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>		
B750	155	<p>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<sup>(3)</sup> PIP. (4) (12)</p>	<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. No issues that warrant an SAP.</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 <u>2</u> 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 <i>agreed upon</i>, then the Agency will issue to the applicant its regulatory decision with the</p>	9	134,012

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
			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.		
B770	156	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; SAP review. (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 to support a federal registration can be developed to evaluate its efficacy and 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. Issues that warrant an SAP.</p> <p>The Agency will provide the applicant with a pre-decisional determination <u>4</u> 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 <i>agreed upon</i>, 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>	15	201,017
B771	157	Experimental Use Permit application; new (2) PIP; with petition to establish a temporary tolerance/tolerance	<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. No issues that warrant an SAP.</p>	10	134,012

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
		e exemption for the active ingredient; credit 75% of B771 fee toward registration application for a new active ingredient that follows. (12)	The Agency will provide the applicant with a pre-decisional determination <u>2</u> 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 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 <i>agreed upon</i> , 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.		
B772	158	Application to amend or extend an Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active ingredient is unaffected. (12)	An amendment making minor changes to or to extend the test period of an existing PIP EUP.  The Agency will provide the applicant with a pre-decisional determination <u>2</u> 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 <i>agreed upon</i> , 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.	3	13,403
B773	159	Application to amend or extend an Experimental Use Permit; with	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.	5	33,506

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
		petition to extend a temporary tolerance/tolerance exemption for the active ingredient. (12)	The Agency will provide the applicant with a pre-decisional determination <u>2</u> 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 <i>agreed upon</i> , 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.		
B780	160	Registration application; new (2) PIP; non-food/feed. (12)	An application for a new PIP active ingredient for a non-food/feed use. No issues that warrant an SAP. This category is used for full commercial registration; a seed increase registration can be obtained under B882, B883, B884, B885, or B886.  The Agency will provide the applicant with a pre-decisional determination <u>2</u> 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 <i>agreed upon</i> , 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.	12	167,514
B790	161	Registration application; new (2) PIP; non-	An application for a new PIP active ingredient for a non-food/feed use. Issues that warrant an SAP.	18	234,519

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
		food/feed; SAP review (5) (12)	<p>This category is used for full commercial registration; a seed increase registration can be obtained under B882, B883, B884, B885, or B886.</p> <p>The Agency will provide the applicant with a pre-decisional determination <u>4</u> 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 <i>agreed upon</i>, 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>		
B800	162	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.	<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. No issues that warrant an SAP.</p> <p>This category is used for full commercial registration; a seed increase registration can be obtained under B882, B883, B884, B885, or B886.</p> <p>The Agency will provide the applicant with a pre-decisional determination <u>4</u> 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 <i>agreed upon</i>, 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</p>	13	180,915

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			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.		
B810	163	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. SAP review. (5) (12)	<p>An application for a new PIP active ingredient for a food/feed use. A temporary tolerance or a 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. Issues that warrant an SAP.</p> <p>This category is used for full commercial registration; a seed increase registration can be obtained under B882, B883, B884, B885, or B886.</p> <p>The Agency will provide the applicant with a pre-decisional determination <u>4</u> 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 <i>agreed upon</i>, 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>	19	247,920
B820	164	Registration application; new (2) PIP; with petition to establish or amend a permanent	<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. No issues that warrant an SAP.</p>	15	214,419

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
		tolerance/tolerance exemption of an active ingredient. (12)	<p>This category is used for full commercial registration; a seed increase registration can be obtained under B882, B883, B884, B885, or B886.</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 <i>agreed upon</i>, 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>		
B840	165	Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient. SAP review. (5) (12)	<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 temporary 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. Issues that warrant an SAP.</p> <p>This category is used for full commercial registration; a seed increase registration can be obtained under B882, B883, B884, B885, or B886.</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 <i>agreed upon</i>, 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</p>	21	281,424



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			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.		
B851	166	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 are already covered under an existing tolerance or tolerance exemption. No issues that warrant an SAP.</p> <p>The Agency will provide the applicant with a pre-decisional determination <u>2</u> 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 event 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 <i>agreed upon</i>, 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	134,012
B870	167	Registration application; registered (3) PIP; new product; new use; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (4)	<p>An application for a new product containing a previously registered PIP active ingredient to add a new use.</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 <u>2</u> 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 <i>agreed</i></p>	9	40,205

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
		(12)	<p><i>upon</i>, 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	168	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 ingredient(s). (6) (7)	<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. No issues that warrant an SAP.</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 <u>2</u> 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 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 <i>agreed upon</i>, 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	33,506
B881	169	Registration application; registered (3) PIP; new product or new terms of registration; additional data	<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. Issues that warrant an SAP.</p> <p>Example: Stacking PIP traits within a crop using traditional breeding techniques.</p>	15	100,511

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		submitted; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). SAP review. (5) (6) (7) (12)	The Agency will provide the applicant with a pre-decisional determination <u>4</u> 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 <i>agreed upon</i> , 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.		
B882	170 new	Registration application; new <sup>(2)</sup> 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; SAP Review <sup>(8)(12)</sup>	<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). Issues that warrant an SAP. If a seed increase registration is granted under this PRIA category, full commercial registration can subsequently be obtained using B890.</p> <p>Registrants are encouraged to consult with the Agency prior to submission of an application in this category.</p> <p>The Agency will provide the applicant with a pre-decisional determination <u>4</u> 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 <i>agreed upon</i>, 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</p>	15	201,017

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			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	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 based on an existing temporary tolerance/tolerance exemption. (8) (12)	<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). No issues that warrant an SAP. If a seed increase registration is granted under this PRIA category, full commercial registration can subsequently be obtained using B890.</p> <p>Registrants are encouraged to consult with the Agency prior to submission of an application in this category.</p> <p>The Agency will provide the applicant with a pre-decisional determination <u>2</u> 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 <i>agreed upon</i>, 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	134,012
B884	172	Registration application; new (2) PIP, seed increase with negotiated acreage cap	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.	12	167,514

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
		and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient. (8) (12)	<p>Registrants are encouraged to consult with the Agency prior to submission of an application in this category.</p> <p>The Agency will provide the applicant with a pre-decisional determination <u>2</u> 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 <i>agreed upon</i>, 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>		
B885	173	Registration application; registered (3) 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 <u>2</u> 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 <i>agreed upon</i>, 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</p>	6	33,506

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
			of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
B886	174 new	Registration application; new <sup>(2)</sup> PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the a.i. SAP Review (8)(12)	<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). Issues that warrant an SAP. If a seed increase registration is granted under this PRIA category, full commercial registration can subsequently be obtained using B890.</p> <p>Registrants are encouraged to consult with the Agency prior to submission of an application in this category.</p> <p>The Agency will provide the applicant with a pre-decisional determination <u>4</u> 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 <i>agreed upon</i>, 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>	18	234,519
B890	175	Application to amend a seed increase registration; converts registration to commercial registration;	<p>An application to amend a registered PIP product that only allows the expansion of use from seed production to commercial registration. No issues that warrant an SAP.</p> <p>The Agency will provide the applicant with a pre-decisional determination <u>2</u> 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 <i>agreed upon</i>, then the Agency will</p>	9	67,007

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
		no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s). (12)	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.		
B891	176	Application to amend a seed increase registration; converts registration to a commercial registration; no petition since a permanent tolerance/tolerance exemption already established for the active ingredient(s); SAP review. (5) (12)	<p>An application to amend a registered PIP product that only allows the expansion of use from seed production to commercial registration. Issues that warrant an SAP.</p> <p>The Agency will provide the applicant with a pre-decisional determination <u>4</u> 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 <i>agreed upon</i>, 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>	15	134,012
B900	177	Application to amend a registration, including actions such as extending an expiration date, modifying	<p>An application to amend a registered PIP product – except as described in B870, B890 and B891. No issues that warrant an SAP.</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>	6	13,403

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
		an IRM plan, or adding an insect to be controlled. (10) (11) (12)	The Agency will provide the applicant with a pre-decisional determination <u>2</u> 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 <i>agreed upon</i> , 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.		
B901	178	Application to amend a registration, including actions such as extending an expiration date, modifying an IRM plan, or adding an insect to be controlled. SAP review. (10) (11) (12)	<p>An application to amend a registered PIP product, except as defined in B870, B890 and B891. Issues that warrant an SAP.</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 <u>2</u> 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 <i>agreed upon</i>, 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>	12	80,407



<b>EPA No.</b>	<b>CR No.</b>	<b>Action</b>	<b>Interpretation</b>	<b>Decision Review Time (Months)</b>	<b>FY'20-FY'21 Registration Service Fee (\$)</b>
B902	179	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	6,703
B903	180	Inert ingredient tolerance exemption; e.g. a marker such as NPT II, reviewed in BPPD	A petition to establish a tolerance or an exemption from tolerance for a PIP inert ingredient (for example, a marker protein).	6	67,007
B904	181	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.	9	134,012
B905	182 new	SAP 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 a SAP.	6	67,007
B906	183 new	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 PIP active ingredients. 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.	3	33,503
B907	184 new	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 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.	3	13,403

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
		tolerance/tolerance exemption			
B908	185 new	Petition to establish a temporary tolerance/tolerance exemption for one or more active ingredients or inert ingredients	A petition to establish a temporary tolerance or a temporary tolerance exemption for one or more PIP active or inert ingredients. PIP inert ingredients include marker proteins (e.g., NPT II). 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 for PIP active and/or inert ingredients.	3	46,905