TABLE 15. BIOPESTICIDES AND POLLUTION PREVENTION DIVISION - STRAIGHT CHAIN LEPIDOPTERAN PHEROMONES (SCLPS)

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
B690	142	New active ingredient; food or non-food use (2) (6)	An application for a product containing a new active ingredient SCLP which either has no food uses or if there is a food use, is anticipated to meet the existing tolerance exemption for SCLPs. All uses (food and/or non-food) included in any original application or petition for a first food use that otherwise satisfy the conditions for the category are covered by the base fee. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe. Any additional information that was neither requested nor required by the Agency, submitted at the applicant's initiative after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, shall be assessed an additional 25% of the full service fee. The Agency will provide the applicant with a pre-decisional determination 2	7	2,682

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested amendment. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been *agreed upon*, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA review time due date. 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.		
B700	143	Experimental Use Permit application; new active ingredient or new use (6)	An application for an experimental use permit where the SCLP fits within the existing tolerance exemption for SCLPs, or with an agreement to destroy, or use only for experimental purposes, any crops treated during the experimental program. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 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 review time due date.	7	1,342

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			At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
B701	144	Extend or amend Experimental Use Permit (6)	An application to amend an existing Experimental Use Permit for a SCLP product, which could include (but is not limited to): changing the uses, use sites, and/or acreage tested, and/or extending the length of time for completion of the experimental program. 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 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 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.	4	1,342

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
B710	145	New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption. No data review, or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data or authorization from	An application for registration of a SCLP product that is substantially similar or identical in its uses and formulation to products that are currently registered, or differ from a currently registered product only in ways that would not significantly increase the risk of unreasonable adverse effects to humans or the environment. In all cases, the product must contain a registered source of active ingredient, and the applicant must identify the similar registered product. If the proposed new product contains an unregistered source of active ingredient, then see category B721. Identical products are identical to another registered product and bear identical use patterns. For an identical (100% repackaging or repack) of a registered SCLP product, the data requirements are satisfied by the registered identical product. The Confidential Statement of Formula (CSF) of the proposed product must indicate the product is a 100% repack of the previously registered product. Substantially similar products must contain the same active ingredient, in substantially the same proportion. They must have the same physical state (solid, liquid, granular), and contain substantially similar other (inert) ingredients. The proposed product must have the same use patterns. Identical/substantially similar products may have fewer uses, but all of its uses must have been approved for the claimed similar product. Adding or changing the use patterns (other than removal of uses) excludes the product from treatment as a substantially similar product. If the new product is a simple dilution of, or differs only by a minor change in inert ingredients from the registered product, some minor product chemistry may be required. Any cited data must have been previously reviewed and accepted by the Agency. A new product is not substantially similar to a registered product if an unregistered source of	4	1,342

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		data owner is demonstrated. Category includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission or data matrix. (3) (6)	TGAI material is used to formulate the new product, or if new data, scientific literature, and/or waivers are submitted to satisfy the data requirements for the new product. 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. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been *agreed upon*, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
B720	146	New product; registered source of active ingredient(s); requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data	An application for a new product for an existing SCLP active ingredient that includes data to support the registration. The source of the active ingredient must be registered. If the proposed new product contains an unregistered source of active ingredient, then see category B721. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any	5	1,342

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
		generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. (3) (6)	label changes that have to be made in order to grant the requested new product. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been *agreed upon*, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
B721	147	New product; unregistered source of active ingredient (3) (6)	An application for a new product for a registered SCLP active ingredient; the source of the active ingredient used in the product is not registered. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 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. If the label issues cannot be resolved prior to the PRIA decision	7	2,810

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			review time due date and if a PRIA due date time extension has not been *agreed upon*, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
B722	148	New use and/or amendment; petition to establish a tolerance or tolerance exemption (4) (5) (6)	An application for a new use for a registered SCLP active ingredient that is not covered by the SCLP tolerance exemption. A petition to amend the established tolerance exemption for SCLPs, with supporting data to demonstrate that dietary exposures to residues of the active ingredient meet the FFDCA safety standard, i.e., there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, must accompany the application. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d)	7	2,601

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new use or amendment. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been *agreed upon*, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA review time due date. 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.		
B730	149	Label amendment requiring data submission (4) (6)	An application to amend an existing registration containing an SCLP active ingredient. The application contains for Agency review data that is submitted to support a change to the formulation and/or data that is necessary to support a product labeling change (e.g., use pattern, use sites, etc.) 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.	5	1,342

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			(a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new use or amendment. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been *agreed upon*, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA review time due date. 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.		