

PRIA 5 Interpretations

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

EPA No.	New CR No.	Action	Interpretation	Decision Review Time (Months)⁽¹⁾	FY'23 – FY'24 Registration Service Fee (\$)
B690	147	SCLP; new active ingredient; food or non-food use (2) (6) (7)	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 satisfies the conditions for the category are covered by the base fee. All of the inerts used in the product must be either: (1) EPA approved for the proposed uses; (2) pending approval with the Agency; or (3) have been submitted as a new inert petition application (concurrent with an application for new a.i SCLP).	7	3,662
B700	148	SCLP; Experimental Use Permit application; new active ingredient or new use (6) (7)	An application for an experimental use permit (EUP) 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: (1) EPA approved for the proposed uses; (2) pending approval with the Agency; or (3) have been submitted as a new inert petition application	7	1,833

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			(concurrent with an application for an EUP new a.i./new use SCLP).		
B701	149	SCLP; Extend or amend Experimental Use Permit (6) (7)	An application to amend an existing Experimental Use Permit (EUP) for an 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.	4	1,833
B710	150	SCLP; 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 submission or data matrix (or only product chemistry data); (Includes 100% re-pack; repack of registered end-use product as a manufacturing-use product) (3) (6)	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, or if new data, scientific literature, and/or waivers are submitted, another category is applicable (B720 or B721). Identical products are identical to another registered product and bear identical use patterns. For a 100% repackaging or repack of a registered SCLP product, the data requirements are satisfied by the registered product that is being repackaged. The Confidential Statement of Formula (CSF) of the proposed product must indicate that the	4	1,833

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			<p>product is a 100% repack of the previously registered product.</p> <p>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. All of the inerts used in the product must be EPA approved for the proposed uses. The proposed product must have the same use patterns.</p> <p>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.</p> <p>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.</p>		
B720	151	SCLP; new product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption (including non-food); Must address Product-Specific Data Requirements (3) (6)	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 an EPA-registered product. If the proposed new product contains an unregistered source of active ingredient, then see category B721.	5	1,833

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			<p>All of the inerts used in the product must be either: (1) EPA approved for the proposed uses; (2) pending approval with the Agency; or (3) have been submitted as a new inert petition application (concurrent with the application). The application package must address product-specific data requirements on the formulated end-use product. Product-specific data requirements can be addressed with 1) submission of product-specific data; 2) citation of previously reviewed and accepted data; 3) submission or citation of data generated at government expense; 4) submission or citation of 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.</p>		
B721	152	<p>SCLP: new product; unregistered source of active ingredient; no change in an established tolerance or tolerance exemption (including non-food); must address Product-Specific and Generic Data Requirements (3) (6)</p>	<p>An application for a new product with an unregistered source of SCLP active ingredient. All of the inerts used in the product must be either: (1) EPA approved for the proposed uses; (2) pending approval with the Agency; or (3) have been submitted as a new inert petition application (concurrent with the application). The application must address product-specific data requirements on the formulated end-use product and generic data requirements on the active ingredient.</p>	7	3,836

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			Product-specific data requirements can be addressed with 1) submission of product-specific data; 2) citation of previously reviewed and accepted data; 3) submission or citation of data generated at government expense; 4) submission or citation of 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.		
B722	153	SCLP; new use and/or amendment; petition to establish a tolerance or tolerance exemption (4) (5) (6) (7)	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 FFDCSA 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: (1) EPA approved for the proposed uses; (2) pending approval with the Agency; or (3) have been submitted as a new inert petition application (concurrent with the application for the new use/amendment).	7	3,552
B730	154	SCLP; amendment requiring data submission (4) (6)	An application to amend an existing registration containing an SCLP active ingredient. The	5	1,833

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			application contains 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.).		

(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) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that 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 deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use.

Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(4) (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 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.

(5) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

(6) 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 draft accepted label, including any changes made 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.

(7) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to [section 33(c)(3)(G)] 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.