

## PRIA 4 Interpretations

**TABLE 4. REGISTRATION DIVISION - NEW PRODUCTS**

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
R300	45	New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; no data review on acute toxicity, efficacy or CRP -- only product chemistry data; cite-all data	<p>An application for registration of an end-use or a manufacturing use pesticide product that is substantially similar or identical in its uses and/or formulation to products that are currently registered or differ only in ways that would not significantly increase the risk of unreasonable adverse effects. The applicant must identify the similar products for all active ingredients in the proposed product. To fit this category, all applications require the following but are not limited to:</p> <ul style="list-style-type: none"> <li>• A data matrix is required with the application.</li> <li>• Product chemistry data (Group A and B) unless the product is identical (e.g. 100% repackaged product) and CSF. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1.</li> <li>• All inert ingredients must already be approved for the applicable uses in the product.</li> <li>• The active ingredient listed on the CSF must be an EPA registered product.</li> <li>• In all cases, the applicant must identify the currently registered similar product for this category.</li> <li>• Acute toxicity requirements must be addressed by using: 1) cite-all method or 2) selective data citation where the applicant owns all required data or; the applicant submits specific authorization letter from data owner.</li> </ul>	4	1,662

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		<p>citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end use or manufacturing-use product that requires no data submission nor data matrix (2) (3)</p>	<p>The application is not in this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted or cited and must be reviewed to support the application. Data that are selectively cited to support the application must have already been reviewed by the Agency for the same uses, formulation type, active ingredient and claims. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category. Companion animal end use products must be 100% compositionally identical to a currently registered product to be considered in this category.</p> <p>Substantially similar: Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular), and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the proposed product bears the same use patterns. Adding use patterns or changing existing use patterns (other than deleting them) would exclude the proposed product from treatment as a substantially similar product. Deleting use patterns is acceptable.</p> <p>Identical: Same composition and use patterns as a currently registered end use product.</p> <p>Manufacturing Use Product: A 100% re-package of a manufacturing use product that requires no data submission or data matrix is covered by this category.</p> <p>Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active</p>		

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			<p>ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that source of the active ingredient for another end use product, the active ingredient is considered unregistered.</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>		
R301	46	New product; or similar combination product (already registered) to an identical or substantially similar in	<p>An application for registration of an end-use pesticide product that is substantially similar or identical in its uses and/or formulation to products that are currently registered or differ only in ways that would not significantly increase the risk of unreasonable adverse effects. The applicant must identify the similar products for all active ingredients in the proposed product. To fit this category all applications require the following but are not limited to:</p> <ul style="list-style-type: none"> <li>• A data matrix is required with the application.</li> </ul>	4	1,992

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		composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy (identical data citation and claims to cited product(s)), where applicant does not own all required data and does not have a specific data and does not have a specific	<ul style="list-style-type: none"> <li>• Product chemistry data (Group A and B) unless the product is identical and CSF. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1.</li> <li>• All inert ingredients must already be approved for the applicable uses in the product.</li> <li>• The active ingredient listed on the CSF must be an EPA registered product.</li> <li>• In all cases, the applicant must identify the currently registered similar product for this category.</li> <li>• Acute toxicity, efficacy, and/or child resistant packaging data requirements must be addressed by using: 1) the cite-all method, or 2) selective data citation where the applicant does not own all required data and does not have a specific authorization letter from the data owner. If review of data is needed, this application does not fall within this category.</li> </ul> <p>The application is not in this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted or cited and must be reviewed to support the application. Data that are selectively cited to support the application must have already been reviewed by the Agency for the same uses, formulation type, active ingredient and claims. For selective citation of efficacy data, the R301 category applies only if studies cited are identical to those for the cited product, and efficacy claims made on the proposed label are identical in meaning to those of the cited product. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category. Companion animal end use products must be 100% compositionally identical to a currently registered product to be considered in this category.</p>		

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		authorization letter from data owner (2) (3)	<p>Companion on-animal end use products must be 100% compositionally identical to a currently registered product to be considered in this category. Otherwise the R315 category is applicable.</p> <p>An application proposed as a 100% re-packaged product does not fall within this category (see category R300).</p> <p>Substantially similar: Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular), and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the proposed product bears the same use patterns. Adding use patterns or changing existing use patterns (other than deleting them) would exclude the proposed product from treatment as a substantially similar product. Deleting use patterns is acceptable.</p> <p>Identical: Same composition and use patterns as a currently registered end-use product.</p> <p>Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that source of the active ingredient for another end use product, the active ingredient is considered unregistered.</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</p>		

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			<p>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>		
R310	47	<p>New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in</p>	<p>An application for registration of an end-use or manufacturing use pesticide product that is not substantially similar or identical in its uses and formulation to products that are currently registered. This category also includes new product applications containing a single registered active ingredient. To fit this category all applications require the following but are not limited to:</p> <ul style="list-style-type: none"> <li>• A data matrix is required with the application.</li> <li>• Product chemistry data (Group A and B) and CSF. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1.</li> <li>• All inert ingredients must already be approved or pending before the Agency for the applicable uses in the product.</li> <li>• Acute toxicity, efficacy, and/or child resistant packaging data requirements must be addressed by using: 1) the cite-all method, or 2) selective data</li> </ul>	7	7,667

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		<p>other registered products; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ul style="list-style-type: none"> <li>- product chemistry and/or</li> <li>- acute toxicity and/or</li> <li>- Child resistant packaging and/or</li> </ul>	<p>citation which includes submitting required data. A rationale for a waiver or bridging of these data falls within this category.</p> <p>An application proposed as a 100% re-packaged product does not fall within this category (see category R300).</p> <p>An end use on-animal product which requires animal safety data for support does not fit in this category (see R315). If more than 3 target pest groups are submitted, then the action belongs in either R316 or R317.</p> <p>Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that source of the active ingredient for another end use product, the active ingredient is considered unregistered.</p> <p>The application does not fall into this category if it contains a request to waive generic data or a request to review any generic data.</p> <p>For the purposes of classifying proposed registration actions into PRIA categories, “pest(s) requiring efficacy” (hereafter referred to as PRE) are: public health pests (e.g., disease transmitting, pathogen transferring, biting, stinging, allergen producing or pests otherwise injurious to humans or companion animals), livestock pests (e.g., horn flies, stable flies, cattle ticks, etc...), wood-destroying pests (i.e., termites, carpenter ants,</p>		

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		<p>- pest(s) requiring efficacy – for up to 3 target pests (2) (3)(4)</p>	<p>and wood-boring beetles) and certain invasive species (e.g., Asian longhorned beetle and emerald ash borer).</p> <p>The number of PREs, which determines the appropriate PRIA category, is the sum of: 1) the number of pest Groups (general; e.g., cockroaches, filth flies, mosquitoes, etc...) for which submitted or cited data require efficacy review, and 2) the number of individual pest Species not already covered as part of a Group for which submitted or cited data require efficacy review. If a registrant submits or cites data seeking a claim against an individual PRE species not already covered by a Group, then each pest species will count as 1 PRE. If a registrant submits or cites data seeking a label claim against a pest Group, then each Group will count as 1 PRE, even if data are required for more than one Species to support claims against that Group.</p> <p>To determine whether a claim will count toward a Group or a Species, the Agency maintains a publicly available document, “Technical Support Document – Scientific Issues Associated with Product Performance Data Needs for Pesticide Products Claiming efficacy against Invertebrate Pests of Significant Public Health or Economic Importance”, which outlines Groups and Species. In this document, Appendix 1 (entitled “Pest Tables”) lists Groups of pests and the Species contained within each Group, and will serve as the guiding reference to determine Groups or Species as PREs. Use of this document in determining a PRIA category is limited to determining the number of PREs in a registrant’s application.</p> <p><u>NOTE:</u> Appendix 5 of this document, entitled “Label Claims and Representative Test Species for Pesticide Products Claiming Efficacy against Invertebrate Pests of Significant Public Health or Economic Importance”,</p>		

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			<p>provides guidance on the tests a registrant must provide to obtain a Group claim.</p> <p>In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim <i>and</i> a speed-of-kill claim against the singular PRE Group “Cockroaches”, then this will count as a <i>singular</i> PRE as long as the submitted or cited data adequately addresses each claim against the PRE.</p> <p><u>Total Number of PRE Example:</u> A prospective registrant wishes to register a new end-use product with registered sources of active ingredients. The formula contains two active ingredients previously combined in other registered products. The application will not require any animal safety data. The application will include product chemistry data, acute toxicology data and submitted or cited product performance data to support claims against pests of public health significance.</p> <p>The proposed label will include a general cockroach claim, a claim to control Oriental cockroaches, a general tick claim, and a claim against chiggers. In this example, the data necessary to support the desired claims are not on file at the Agency, so the registrant must submit or cite data with their application. To support the general cockroach claim, the Agency requires testing on both American and German cockroaches, so the prospective registrant must develop and submit or cite data supporting the desired claim on both species. Cockroaches are pest Group 8 and American and German cockroaches are the representative test species for the group; therefore, the studies supporting “cockroaches” count as one PRE for purposes of determining the PRIA category. Oriental cockroaches are part of pest Group 8. No additional data are required to support a claim against oriental cockroaches. The</p>		

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			<p>prospective registrant wishes to support a claim against “ticks”, pest Group 2. The prospective registrant must submit studies for each- lone star ticks, deer (blacklegged) ticks, and American or brown dog ticks- to support the general tick claim. The data to support the three required species of ticks count as one PRE for purposes of determining the PRIA category. Finally, the prospective registrant submits or cites data to support claims against chiggers. Chiggers count as a single PRE. Thus, the PRIA category for this action is R310 since data were submitted or cited to support claims against 3 pests requiring efficacy (i.e., cockroach (pest group 8), including Oriental cockroach specific claim; tick (pest group 2); and chiggers).</p> <p>If the prospective registrant wishes to add a claim against the “gulf coast tick, which may transmit <i>Rickettsia parkeri</i>” an additional study will be required. The application would then contain product performance data supporting 4 pests requiring efficacy (i.e., cockroach (pest group 8), including Oriental cockroach specific claim; tick (pest group 2); chiggers; and gulf coast tick, which may transmit <i>Rickettsia parkeri</i>). The PRIA category would now be R316.</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 end-use 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</p>		

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			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.		
R314	48	New end use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective	<p>An application for registration of a new end-use product that contains up to three registered active ingredients. The active ingredients have never been registered as this combination before as a formulated product. The proposed label has the same uses as those found on the registered product labels for the single active ingredients. If the new combination product in this category requires efficacy data, up to 3 target pests can be proposed on the label. This category excludes on-animal products submitting or citing animal safety data for support. Each source of active ingredient in the formulation must use a registered source of active ingredient. Any science review must be within RD only; excludes products or citing an animal safety data. All of the inerts used in the product must be approved or pending with the Agency for the applicable uses. To fit this category all applications require the following but are not limited to:</p> <ul style="list-style-type: none"> <li>• Certification with Respect to Citation of Data and a data matrix</li> <li>• Product chemistry data (Group A and B) and CSF. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1.</li> <li>• If applicable, acute toxicity, efficacy, and or child resistant packaging data requirements must be addressed by using; (1) the cite-all method; (2) selective data citation. A rationale for a waiver or bridging of these data can be submitted.</li> </ul>	8	9,058

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		<p>component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ul style="list-style-type: none"> <li>- product chemistry and/or</li> <li>- acute toxicity and/or</li> <li>child resistant packaging and or pest(s) requiring efficacy (4) – for up to 3 target</li> </ul>	<p>This category does not include applications that require a determination on whether data can be bridged or translated to other formulation types (for the individual active ingredients).</p> <p>If the application contains up to three active ingredients never registered before in combination that span regulatory divisions (antimicrobial, biopesticide, conventional) and require coordination between those divisions, the application does not belong in this category (see category M005).</p> <p>The application does not fall into this category if it contains a request to waive generic data or a request to review any generic data.</p> <p>Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that source of the active ingredient for another end use product, the active ingredient is considered unregistered.</p> <p>For the purposes of classifying proposed registration actions into PRIA categories, “pest(s) requiring efficacy” (hereafter referred to as PRE) are: public health pests (e.g., disease transmitting, pathogen transferring, biting, stinging, allergen producing or pests otherwise injurious to humans or companion animals), livestock pests (e.g., horn flies, stable flies, cattle ticks, etc...), wood-destroying pests (i.e., termites, carpenter ants, and wood-boring beetles) and certain invasive species (e.g., Asian longhorned beetle and emerald ash borer).</p>		

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		pests (2)(3).	<p>The number of PREs, which determines the appropriate PRIA category, is the sum of: 1) the number of pest Groups (general; e.g., cockroaches, filth flies, mosquitoes, etc...) for which submitted or cited data require efficacy review, and 2) the number of individual pest Species not already covered as part of a Group for which submitted or cited data require efficacy review. If a registrant submits or cites data seeking a claim against an individual PRE species not already covered by a Group, then each pest species will count as 1 PRE. If a registrant submits or cites data seeking a label claim against a pest Group, then each Group will count as 1 PRE, even if data are required for more than one Species to support claims against that Group.</p> <p>To determine whether a claim will count toward a Group or a Species, the Agency maintains a publicly available document, “Technical Support Document – Scientific Issues Associated with Product Performance Data Needs for Pesticide Products Claiming efficacy against Invertebrate Pests of Significant Public Health or Economic Importance”, which outlines Groups and Species. In this document, Appendix 1 (entitled “Pest Tables”) lists Groups of pests and the Species contained within each Group, and will serve as the guiding reference to determine Groups or Species as PREs. Use of this document in determining a PRIA category is limited to determining the number of PREs in a registrant’s application.</p> <p><u>NOTE:</u> Appendix 5 of this document, entitled “Label Claims and Representative Test Species for Pesticide Products Claiming Efficacy against Invertebrate Pests of Significant Public Health or Economic Importance”, provides guidance on the tests a registrant must provide to obtain a Group claim.</p>		

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			<p>In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim <i>and</i> a speed-of-kill claim against the singular PRE Group “Cockroaches”, then this will count as a <i>singular</i> PRE as long as the submitted or cited data adequately addresses each claim against the PRE.</p> <p><u>Total Number of PRE Example:</u> A prospective registrant wishes to register a new end-use product with registered sources of active ingredients. The formula contains two active ingredients never before registered in this combination in other registered products. The application will not require any animal safety data. The application will include product chemistry data, acute toxicology data and submitted or cited product performance data to support claims against pests of public health significance.</p> <p>The proposed label will include a general cockroach claim, a claim to control Oriental cockroaches, a general tick claim, and a claim against chiggers. In this example, the data necessary to support the desired claims are not on file at the Agency, so the registrant must submit or cite data with their application. To support the general cockroach claim, the Agency requires testing on both American and German cockroaches, so the prospective registrant must develop and submit or cite data supporting the desired claim on both species. Cockroaches are pest Group 8 and American and German cockroaches are the representative test species for the group; therefore, the studies supporting “cockroaches” count as one PRE for purposes of determining the PRIA category. Oriental cockroaches are part of pest Group 8. No additional data are required to support a claim against oriental cockroaches. The prospective registrant wishes to support a claim against “ticks”, pest Group 2. The prospective registrant must submit studies for each- lone star ticks, deer (blacklegged)</p>		

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			<p>ticks, and American or brown dog ticks- to support the general tick claim. The data to support the three required species of ticks count as one PRE for purposes of determining the PRIA category. Finally, the prospective registrant submits or cites data to support claims against chiggers. Chiggers count as a single PRE. Thus, the PRIA category for this action is R310 since data were submitted or cited to support claims against 3 pests requiring efficacy (i.e., cockroach (pest group 8), including Oriental cockroach specific claim; tick (pest group 2); and chiggers).</p> <p>If the prospective registrant wishes to add a claim against the “gulf coast tick, which may transmit <i>Rickettsia parkeri</i>” an additional study will be required. The application would then contain product performance data supporting 4 pests requiring efficacy (i.e., cockroach (pest group 8), including Oriental cockroach specific claim; tick (pest group 2); chiggers; and gulf coast tick, which may transmit <i>Rickettsia parkeri</i>). The PRIA category would now be R316.</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 end-use 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</p>		

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			Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R319	49 new	New end use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active	<p>An application for registration of a new end-use product that contains up to three registered active ingredients. The active ingredients have never been registered as this combination before as a formulated product. The proposed label has the same uses as those found on the registered product labels for the active ingredients. If the new combination product in this category requires efficacy data, 4 to 7 target pests can be proposed on the label. This category excludes on-animal products submitting or citing animal safety data for support. Each source of active ingredient in the formulation must be an EPA-registered product. Any science review must be within RD only; excludes products or citing an animal safety data. All of the inerts used in the product must be approved or pending with the Agency for the applicable uses.</p> <p>To fit this category all applications require the following but are not limited to:</p> <ul style="list-style-type: none"> <li>• Certification with Respect to Citation of Data and a data matrix</li> <li>• Product chemistry data (Group A and B) and CSF. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1.</li> <li>• If applicable, acute toxicity, efficacy, and or child resistant packaging data requirements must be addressed by using; (1) the cite-all method; (2) selective data citation. A rationale for a waiver or bridging of these data can be submitted.</li> </ul> <p>This category does not include applications that require a determination on whether data can be bridged or translated to other formulation types (for the individual active</p>	10	13,258

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		ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: product chemistry and/or acute toxicity and/or child resistant packaging and/or pest(s) requiring efficacy <sup>(4)</sup> - for 4 to 7 target pests. <sup>(2) (3)</sup>	ingredients).  If the application contains up to three active ingredients never registered before in combination that span regulatory divisions (antimicrobial, biopesticide, conventional) and require coordination between those divisions, the application does not belong in this category (see category M005).  The application does not fall into this category if it contains a request to waive generic data or a request to review any generic data.  Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that source of the active ingredient for another end use product, the active ingredient is considered unregistered. For the purposes of classifying proposed registration actions into PRIA categories, “pest(s) requiring efficacy” (hereafter referred to as PRE) are: public health pests (e.g., disease transmitting, pathogen transferring, biting, stinging, allergen producing or pests otherwise injurious to humans or companion animals), livestock pests (e.g., horn flies, stable flies, cattle ticks, etc...), wood-destroying pests (i.e., termites, carpenter ants, and wood-boring beetles) and certain invasive species (e.g., Asian longhorned beetle and emerald ash borer).  The number of PREs, which determines the appropriate PRIA category, is the sum of: 1) the number of pest Groups (general; e.g., cockroaches, filth flies, mosquitoes, etc...)		

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			<p>for which submitted or cited data require efficacy review, and 2) the number of individual pest Species not already covered as part of a Group for which submitted or cited data require efficacy review. If a registrant submits or cites data seeking a claim against an individual PRE species not already covered by a Group, then each pest species will count as 1 PRE. If a registrant submits or cites data seeking a label claim against a pest Group, then each Group will count as 1 PRE, even if data are required for more than one Species to support claims against that Group.</p> <p>To determine whether a claim will count toward a Group or a Species, the Agency maintains a publicly available document, “Technical Support Document – Scientific Issues Associated with Product Performance Data Needs for Pesticide Products Claiming efficacy against Invertebrate Pests of Significant Public Health or Economic Importance”, which outlines Groups and Species. In this document, Appendix 1 (entitled “Pest Tables”) lists Groups of pests and the Species contained within each Group, and will serve as the guiding reference to determine Groups or Species as PREs. Use of this document in determining a PRIA category is limited to determining the number of PREs in a registrant’s application.</p> <p><u>NOTE:</u> Appendix 5 of this document, entitled “Label Claims and Representative Test Species for Pesticide Products Claiming Efficacy against Invertebrate Pests of Significant Public Health or Economic Importance”, provides guidance on the tests a registrant must provide to obtain a Group claim.</p> <p>In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim <i>and</i> a speed-of-kill claim against the</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
			<p>singular PRE Group “Cockroaches”, then this will count as a <i>singular</i> PRE as long as the submitted or cited data adequately addresses each claim against the PRE.</p> <p><u>Total Number of PRE Example:</u> A prospective registrant wishes to register a new end-use product with registered sources of active ingredients. The formula contains two active ingredients never before registered as this combination in other registered products. The application will not require any animal safety data. The application will include product chemistry data, acute toxicology data and submitted or cited product performance data to support claims against pests of public health significance.</p> <p>The proposed label will include a general cockroach claim, a claim to control Oriental cockroaches, a general tick claim, and a claim against chiggers. In this example, the data necessary to support the desired claims are not on file at the Agency, so the registrant must submit or cite data with their application. To support the general cockroach claim, the Agency requires testing on both American and German cockroaches, so the prospective registrant must develop and submit or cite data supporting the desired claim on both species. Cockroaches are pest Group 8 and American and German cockroaches are the representative test species for the group; therefore, the studies supporting “cockroaches” count as one PRE for purposes of determining the PRIA category. Oriental cockroaches are part of pest Group 8. No additional data are required to support a claim against oriental cockroaches. The prospective registrant wishes to support a claim against “ticks”, pest Group 2. The prospective registrant must submit studies for each- lone star ticks, deer (blacklegged) ticks, and American or brown dog ticks- to support the general tick claim. The data to support the three required species of ticks count as one PRE for purposes of determining the PRIA category. Finally, the prospective registrant submits or cites data</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
			<p>to support claims against chiggers. Chiggers count as a single PRE. Thus, the PRIA category for this action is R310 since data were submitted or cited to support claims against 3 pests requiring efficacy (i.e., cockroach (pest group 8), including Oriental cockroach specific claim; tick (pest group 2); and chiggers).</p> <p>If the prospective registrant wishes to add a claim against the “gulf coast tick, which may transmit <i>Rickettsia parkeri</i>” an additional study will be required. The application would then contain product performance data supporting 4 pests requiring efficacy (i.e., cockroach (pest group 8), including Oriental cockroach specific claim; tick (pest group 2); chiggers; and gulf coast tick, which may transmit <i>Rickettsia parkeri</i>). The PRIA category would now be R316.</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 end-use 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>		
R318	50	New end-use	An application for registration of a new end-use product that contains four or more	9	13,915

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
	new	product containing four or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products	<p>registered conventional active ingredients which have never been registered in combination as a formulated product. The proposed label has the same uses as those found on the registered product labels for the single active ingredients. Each source of active ingredient in the formulation must be an EPA-registered product. Any science review must be within RD only. If the new combination product in this category requires efficacy review, data for up to 3 target pests can be submitted or cited. This category excludes on-animal products submitting or citing animal safety data for support. All of the inerts used in the product must be approved or pending with the Agency for the applicable uses.</p> <p>To fit this category all applications require the following but are not limited to:</p> <ul style="list-style-type: none"> <li>• Certification with Respect to Citation of Data and a data matrix</li> <li>• Product chemistry data (Group A and B) and CSF. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1.</li> <li>• If applicable, acute toxicity, efficacy, and or child resistant packaging data requirements must be addressed by using; (1) the cite-all method; (2) selective data citation. A rationale for a waiver or bridging of these data can be submitted.</li> </ul> <p>This category does not include applications that require a determination on whether data can be bridged or translated to other formulation types (for the individual active ingredients) (If this is the case, see category R320).</p> <p>If the application contains four or more active ingredients never registered before in</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
		<p>requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ul style="list-style-type: none"> <li>-product chemistry and/or</li> <li>-acute toxicity and/or</li> <li>-child resistant packaging and/or</li> <li>-pest(s) requiring efficacy – for up to 3 target pests (2)(3)(4)</li> </ul>	<p>combination that span regulatory divisions (antimicrobial, biopesticide, conventional) and require coordination between those divisions, the application does not belong in this category (see category M005).</p> <p>The application does not fall into this category if it contains a request to waive generic data or a request to review any generic data.</p> <p>Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that source of the active ingredient for another end use product, the active ingredient is considered unregistered. For the purposes of classifying proposed registration actions into PRIA categories, “pest(s) requiring efficacy” (hereafter referred to as PRE) are: public health pests (e.g., disease transmitting, pathogen transferring, biting, stinging, allergen producing or pests otherwise injurious to humans or companion animals), livestock pests (e.g., horn flies, stable flies, cattle ticks, etc...), wood-destroying pests (i.e., termites, carpenter ants, and wood-boring beetles) and certain invasive species (e.g., Asian longhorned beetle and emerald ash borer).</p> <p>The number of PREs, which determines the appropriate PRIA category, is the sum of: 1) the number of pest Groups (general; e.g., cockroaches, filth flies, mosquitoes, etc...) for which submitted or cited data require efficacy review, and 2) the number of individual pest Species not already covered as part of a Group for which submitted or cited data require efficacy review. If a registrant submits or cites data seeking a claim</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
			<p>against an individual PRE species not already covered by a Group, then each pest species will count as 1 PRE. If a registrant submits or cites data seeking a label claim against a pest Group, then each Group will count as 1 PRE, even if data are required for more than one Species to support claims against that Group.</p> <p>To determine whether a claim will count toward a Group or a Species, the Agency maintains a publicly available document, “Technical Support Document – Scientific Issues Associated with Product Performance Data Needs for Pesticide Products Claiming efficacy against Invertebrate Pests of Significant Public Health or Economic Importance”, which outlines Groups and Species. In this document, Appendix 1 (entitled “Pest Tables”) lists Groups of pests and the Species contained within each Group, and will serve as the guiding reference to determine Groups or Species as PREs. Use of this document in determining a PRIA category is limited to determining the number of PREs in a registrant’s application.</p> <p><u>NOTE:</u> Appendix 5 of this document, entitled “Label Claims and Representative Test Species for Pesticide Products Claiming Efficacy against Invertebrate Pests of Significant Public Health or Economic Importance”, provides guidance on the tests a registrant must provide to obtain a Group claim.</p> <p>In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim <i>and</i> a speed-of-kill claim against the singular PRE Group “Cockroaches”, then this will count as a <i>singular</i> PRE as long as the submitted or cited data adequately addresses each claim against the PRE.</p> <p><u>Total Number of PRE Example:</u> A prospective registrant wishes to register a new end-</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
			<p>use product with registered sources of active ingredients. The formula contains four active ingredients never before registered as this combination in other registered products. The application will not require any animal safety data. The application will include product chemistry data, acute toxicology data and submitted or cited product performance data to support claims against pests of public health significance.</p> <p>The proposed label will include a general cockroach claim, a claim to control Oriental cockroaches, a general tick claim, and a claim against chiggers. In this example, the data necessary to support the desired claims are not on file at the Agency, so the registrant must submit or cite data with their application. To support the general cockroach claim, the Agency requires testing on both American and German cockroaches, so the prospective registrant must develop and submit or cite data supporting the desired claim on both species. Cockroaches are pest Group 8 and American and German cockroaches are the representative test species for the group; therefore, the studies supporting “cockroaches” count as one PRE for purposes of determining the PRIA category. Oriental cockroaches are part of pest Group 8. No additional data are required to support a claim against oriental cockroaches. The prospective registrant wishes to support a claim against “ticks”, pest Group 2. The prospective registrant must submit studies for each- lone star ticks, deer (blacklegged) ticks, and American or brown dog ticks- to support the general tick claim. The data to support the three required species of ticks count as one PRE for purposes of determining the PRIA category. Finally, the prospective registrant submits or cites data to support claims against chiggers. Chiggers count as a single PRE. Thus, the PRIA category for this action is R310 since data were submitted or cited to support claims against 3 pests requiring efficacy (i.e., cockroach (pest group 8), including Oriental cockroach specific claim; tick (pest group 2); and chiggers).</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
			<p>If the prospective registrant wishes to add a claim against the “gulf coast tick, which may transmit <i>Rickettsia parkeri</i>” an additional study will be required. The application would then contain product performance data supporting 4 pests requiring efficacy (i.e., cockroach (pest group 8), including Oriental cockroach specific claim; tick (pest group 2); chiggers; and gulf coast tick, which may transmit <i>Rickettsia parkeri</i>). The PRIA category would now be R316.</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 end-use 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>		
R321	51 (new)	New end use product containing four or more registered active	An application for registration of a new end-use product that contains four or more registered conventional active ingredients which have never been registered in combination as a formulated product. The proposed label has the same uses as those found on the registered product labels for the single active ingredients. Each source of active ingredient in the formulation must be an EPA-registered product. Any science	11	18,115

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
		<p>ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review</p>	<p>review must be within RD only. If the new combination product in this category requires efficacy review, data for 4 to 7 target pests can be submitted or cited. This category excludes on-animal products submitting or citing animal safety data for support. All of the inerts used in the product must be approved or pending with the Agency for the applicable uses.</p> <p>To fit this category all applications require the following but are not limited to:</p> <ul style="list-style-type: none"> <li>• Certification with Respect to Citation of Data and a data matrix</li> <li>• Product chemistry data (Group A and B) and CSF. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1.</li> <li>• If applicable, acute toxicity, efficacy, and or child resistant packaging data requirements must be addressed by using; (1) the cite-all method; (2) selective data citation. A rationale for a waiver or bridging of these data can be submitted.</li> </ul> <p>This category does not include applications that require a determination on whether data can be bridged or translated to other formulation types (for the individual active ingredients) (If this is the case, see category R320).</p> <p>If the application contains four or more active ingredients never registered before in combination that span regulatory divisions (antimicrobial, biopesticide, conventional) and require coordination between those divisions, the application does not belong in this category (see category M005).</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
		<p>of data package within RD only; includes data and/or waivers of data for only: product chemistry and/or acute toxicity and/or child resistant packaging and/or pest(s) requiring efficacy<sup>(4)</sup> - for 4 to 7 target pests. <sup>(2)</sup> <sup>(3)</sup></p>	<p>The application does not fall into this category if it contains a request to waive generic data or a request to review any generic data.</p> <p>Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that source of the active ingredient for another end use product, the active ingredient is considered unregistered. For the purposes of classifying proposed registration actions into PRIA categories, “pest(s) requiring efficacy” (hereafter referred to as PRE) are: public health pests (e.g., disease transmitting, pathogen transferring, biting, stinging, allergen producing or pests otherwise injurious to humans or companion animals), livestock pests (e.g., horn flies, stable flies, cattle ticks, etc...), wood-destroying pests (i.e., termites, carpenter ants, and wood-boring beetles) and certain invasive species (e.g., Asian longhorned beetle and emerald ash borer).</p> <p>The number of PREs, which determines the appropriate PRIA category, is the sum of: 1) the number of pest Groups (general; e.g., cockroaches, filth flies, mosquitoes, etc...) for which submitted or cited data require efficacy review, and 2) the number of individual pest Species not already covered as part of a Group for which submitted or cited data require efficacy review. If a registrant submits or cites data seeking a claim against an individual PRE species not already covered by a Group, then each pest species will count as 1 PRE. If a registrant submits or cites data seeking a label claim against a pest Group, then each Group will count as 1 PRE, even if data are required for more than one Species to support claims against that Group.</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
			<p>To determine whether a claim will count toward a Group or a Species, the Agency maintains a publicly available document, “Technical Support Document – Scientific Issues Associated with Product Performance Data Needs for Pesticide Products Claiming efficacy against Invertebrate Pests of Significant Public Health or Economic Importance”, which outlines Groups and Species. In this document, Appendix 1 (entitled “Pest Tables”) lists Groups of pests and the Species contained within each Group, and will serve as the guiding reference to determine Groups or Species as PREs. Use of this document in determining a PRIA category is limited to determining the number of PREs in a registrant’s application.</p> <p><u>NOTE:</u> Appendix 5 of this document, entitled “Label Claims and Representative Test Species for Pesticide Products Claiming Efficacy against Invertebrate Pests of Significant Public Health or Economic Importance”, provides guidance on the tests a registrant must provide to obtain a Group claim.</p> <p>In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim <i>and</i> a speed-of-kill claim against the singular PRE Group “Cockroaches”, then this will count as a <i>singular</i> PRE as long as the submitted or cited data adequately addresses each claim against the PRE.</p> <p>Total Number of PRE Example: A prospective registrant wishes to register a new end-use product with registered sources of active ingredients. The formula contains four active ingredients never before registered in this combination in other registered products. The application will not require any animal safety data. The application will</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
			<p>include product chemistry data, acute toxicology data and submitted or cited product performance data to support claims against pests of public health significance.</p> <p>The proposed label will include a general cockroach claim, a claim to control Oriental cockroaches, a general tick claim, and a claim against chiggers. In this example, the data necessary to support the desired claims are not on file at the Agency, so the registrant must submit or cite data with their application. To support the general cockroach claim, the Agency requires testing on both American and German cockroaches, so the prospective registrant must develop and submit or cite data supporting the desired claim on both species. Cockroaches are pest Group 8 and American and German cockroaches are the representative test species for the group; therefore, the studies supporting “cockroaches” count as one PRE for purposes of determining the PRIA category. Oriental cockroaches are part of pest Group 8. No additional data are required to support a claim against oriental cockroaches. The prospective registrant wishes to support a claim against “ticks”, pest Group 2. The prospective registrant must submit studies for each- lone star ticks, deer (blacklegged) ticks, and American or brown dog ticks- to support the general tick claim. The data to support the three required species of ticks count as one PRE for purposes of determining the PRIA category. Finally, the prospective registrant submits or cites data to support claims against chiggers. Chiggers count as a single PRE. Thus, the PRIA category for this action is R318 since data were submitted or cited to support claims against 3 pests requiring efficacy (i.e., cockroach (pest group 8), including Oriental cockroach specific claim; tick (pest group 2); and chiggers).</p> <p>If the prospective registrant wishes to add a claim against the “gulf coast tick, which may transmit <i>Rickettsia parkeri</i>” an additional study will be required. The application</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
			<p>would then contain product performance data supporting 4 pests requiring efficacy (i.e., cockroach (pest group 8), including Oriental cockroach specific claim; tick (pest group 2); chiggers; and gulf coast tick, which may transmit <i>Rickettsia parkeri</i>). The PRIA category would now be R316.</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 end-use 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>		
R315	52	New end-use on-animal product, registered source of active ingredient(s) with submission of data and/or waivers for	<p>This category applies to an application for registration of a new end-use on-animal product where animal safety studies are required to be submitted or cited. The types of product that require animal safety studies include, but are not limited to, spot-ons, flea collars, shampoos and sprays.</p> <p>To fit this category all applications require the following but are not limited to:</p> <ul style="list-style-type: none"> <li>• A data matrix is required with the application.</li> </ul>	9	10,311

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
		<p>only: -animal safety and -pest(s) requiring efficacy and/or -Product chemistry and/or -Acute toxicity and/or Child resistant packaging (2) (3) (4)</p>	<ul style="list-style-type: none"> <li>• Product chemistry data (Group A and B) and CSF. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1.</li> <li>• All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. In those cases where the product relies upon a pending inert clearance, the new animal safety studies must be conducted with the pending inert in the tested product in the same concentrations as is intended to be marketed and sold.</li> <li>• Acute toxicity, efficacy, child resistant packaging data, companion animal safety data and/or requirements must be addressed by using: 1) the cite-all method, or 2) selective data citation which includes submitting required data. A rationale for a waiver or bridging of these data falls within this category.</li> <li>• Appropriate animal safety studies based upon the specific label claims in the proposed label. For example, if the proposed end use product label claim is to use the product on 12-week old kittens weighing <math>\geq 3</math> lbs and on breeding cats, then two companion animal studies are required: the first using kittens <math>\geq 12</math> weeks of age and weighing at least 3 lbs. and a second study on pregnant and nursing adult cats. Each of these studies must demonstrate an adequate margin of safety.</li> </ul> <p>An application proposed as a 100% re-packaged product does not fall within this category (see category R300). The application does not fall into this category if it contains a request to waive generic data or a request to review any generic data. Even if the Agency may have reviewed the animal safety data previously, a product citing those data will need to be re-assessed for applicability of those data to the new product.</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
			<p>(If the new product is a 100% repack of a registered product, the R300 category applies. If selective citation is utilized and the formulation is identical to the cited product, the R301 category may apply.)</p> <p>Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that source of the active ingredient for another end use product, the active ingredient is considered unregistered.</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 end-use 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>		
	53	New end-use or	An application for registration of an end-use or manufacturing use pesticide product		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
R316	new	<p>manufacturing product with registered source(s) of active ingredient(s) including products containing two or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; and requires review of data and/or waivers for only: -product</p>	<p>that is not substantially similar or identical in its uses and formulation to products that are currently registered, and for which efficacy data for greater than 3 but up to 7 target pests or pest groups are submitted or cited selectively. This category also includes new product applications containing a single registered active ingredient. This category excludes on-animal products submitting or citing animal safety data for support. To fit this category all applications require the following but are not limited to:</p> <ul style="list-style-type: none"> <li>• A data matrix is required with the application.</li> <li>• Product chemistry data (Group A and B) and CSF. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1.</li> <li>• Acute toxicity, efficacy, and/or child resistant packaging data requirements must be addressed by using: 1) the cite-all method, or 2) selective data citation which includes submitting required data. A rationale for a waiver or bridging of these data falls within this category.</li> </ul> <p>All inert ingredients must already be approved or pending before the Agency for the applicable uses in the product.</p> <p>An application proposed as a 100% re-packaged product does not fall within this category (see category R300). An end use on-animal product which is submitting or citing animal safety data for support does not fit in this category (see category R315).</p> <p>The application does not fall into this category if it contains a request to waive generic data or a request to review any generic data.</p>	9	11,867

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
		chemistry and/or -acute toxicity and/or -child resistant packaging and/or -pest(s) requiring efficacy – for greater than 3 and up to 7 target pests (2)(3)(4)	<p>Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that source of the active ingredient for another end use product, the active ingredient is considered unregistered.</p> <p>For the purposes of classifying proposed registration actions into PRIA categories, “pest(s) requiring efficacy” (hereafter referred to as PRE) are: public health pests (e.g., disease transmitting, pathogen transferring, biting, stinging, allergen producing or pests otherwise injurious to humans or companion animals), livestock pests (e.g., horn flies, stable flies, cattle ticks, etc...), wood-destroying pests (i.e., termites, carpenter ants, and wood-boring beetles) and certain invasive species (e.g., Asian longhorned beetle and emerald ash borer).</p> <p>The number of PREs, which determines the appropriate PRIA category, is the sum of: 1) the number of pest Groups (general; e.g., cockroaches, filth flies, mosquitoes, etc...) for which submitted or cited data require efficacy review, and 2) the number of individual pest Species not already covered as part of a Group for which submitted or cited data require efficacy review. If a registrant submits or cites data seeking a claim against an individual PRE species not already covered by a Group, then each pest species will count as 1 PRE. If a registrant submits or cites data seeking a label claim against a pest Group, then each Group will count as 1 PRE, even if data are required for more than one Species to support claims against that Group.</p> <p>To determine whether a claim will count toward a Group or a Species, the Agency maintains a publicly available document, “Technical Support Document – Scientific Issues Associated with Product Performance Data Needs for Pesticide Products</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
			<p>Claiming efficacy against Invertebrate Pests of Significant Public Health or Economic Importance”, which outlines Groups and Species. In this document, Appendix 1 (entitled “Pest Tables”) lists Groups of pests and the Species contained within each Group, and will serve as the guiding reference to determine Groups or Species as PREs. Use of this document in determining a PRIA category is limited to determining the number of PREs in a registrant’s application.</p> <p><u>NOTE:</u> Appendix 5 of this document, entitled “Label Claims and Representative Test Species for Pesticide Products Claiming Efficacy against Invertebrate Pests of Significant Public Health or Economic Importance”, provides guidance on the tests a registrant must provide to obtain a Group claim.</p> <p>In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim <i>and</i> a speed-of-kill claim against the singular PRE Group “Cockroaches”, then this will count as a <i>singular</i> PRE as long as the submitted or cited data adequately addresses each claim against the PRE.</p> <p>Total Number of PRE Example: A prospective registrant wishes to register a new end-use product with registered sources of active ingredients. The formula contains two active ingredients previously combined in other registered products. The application will not require any animal safety data. The application will include product chemistry data, acute toxicology data and submitted or cited product performance data to support claims against pests of public health significance.</p> <p>The proposed label will include a general cockroach claim, a claim to control Oriental</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
			<p>cockroaches, a general tick claim, and a claim against chiggers. In this example, the data necessary to support the desired claims are not on file at the Agency, so the registrant must submit or cite data with their application. To support the general cockroach claim, the Agency requires testing on both American and German cockroaches, so the prospective registrant must develop and submit or cite data supporting the desired claim on both species. Cockroaches are pest Group 8 and American and German cockroaches are the representative test species for the group; therefore, the studies supporting “cockroaches” count as one PRE for purposes of determining the PRIA category. Oriental cockroaches are part of pest Group 8. No additional data are required to support a claim against oriental cockroaches. The prospective registrant wishes to support a claim against “ticks”, pest Group 2. The prospective registrant must submit studies for each- lone star ticks, deer (blacklegged) ticks, and American or brown dog ticks- to support the general tick claim. The data to support the three required species of ticks count as one PRE for purposes of determining the PRIA category. Finally, the prospective registrant submits or cites data to support claims against chiggers. Chiggers count as a single PRE. Thus, the PRIA category for this action is R310 since data were submitted or cited to support claims against 3 pests requiring efficacy (i.e., cockroach (pest group 8), including Oriental cockroach specific claim; tick (pest group 2); and chiggers).</p> <p>If the prospective registrant wishes to add a claim against the “gulf coast tick, which may transmit <i>Rickettsia parkeri</i>” an additional study will be required. The application would then contain product performance data supporting 4 pests requiring efficacy (i.e., cockroach (pest group 8), including Oriental cockroach specific claim; tick (pest group 2); chiggers; and gulf coast tick, which may transmit <i>Rickettsia parkeri</i>). The PRIA category would now be R316.</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 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 new end-use 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>		
R317	54 new	New end-use or manufacturing product with registered source(s) of active ingredient(s) including products containing two or more registered active	<p>An application for registration of an end-use or manufacturing use pesticide product that is not substantially similar or identical in its uses and formulation to products that are currently registered, and for which efficacy data for greater than 7 target pests or pest groups are submitted or cited selectively. This category also includes new product applications containing a single registered active ingredient. This category excludes on- animal products submitting or citing animal safety data for support.</p> <p>To fit this category all applications require the following but are not limited to:</p> <ul style="list-style-type: none"> <li>• A data matrix is required with the application.</li> </ul>	10	16,067

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
		ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; and requires review of data and/or waivers for only: -product chemistry and/or -acute toxicity and/or -Child resistant packaging and/or -pest(s) requiring efficacy – for	<ul style="list-style-type: none"> <li>• Product chemistry data (Group A and B) and CSF. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1.</li> <li>• All inert ingredients must already be approved or pending before the Agency for the applicable uses in the product.</li> <li>• Acute toxicity, efficacy, and/or child resistant packaging data requirements must be addressed by using: 1) the cite-all method, or 2) selective data citation which includes submitting required data. A rationale for a waiver or bridging of these data falls within this category.</li> </ul> <p>An application proposed as a 100% re-packaged product does not fall within this category (see category R300). An end use on-animal product which is submitting or citing animal safety data for support does not fit in this category (see category R315).</p> <p>The application does not fall into this category if it contains a request to waive generic data or a request to review any generic data.</p> <p>Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that source of the active ingredient for another end use product, the active ingredient is considered unregistered.</p> <p>For the purposes of classifying proposed registration actions into PRIA categories, “pest(s) requiring efficacy” (hereafter referred to as PRE) are: public health pests (e.g.,</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
		greater than 7 target pests (2)(3)(4)	<p>disease transmitting, pathogen transferring, biting, stinging, allergen producing or pests otherwise injurious to humans or companion animals), livestock pests (e.g., horn flies, stable flies, cattle ticks, etc...), wood-destroying pests (i.e., termites, carpenter ants, and wood-boring beetles) and certain invasive species (e.g., Asian longhorned beetle and emerald ash borer).</p> <p>The number of PREs, which determines the appropriate PRIA category, is the sum of: 1) the number of pest Groups (general; e.g., cockroaches, filth flies, mosquitoes, etc...) for which submitted or cited data require efficacy review, and 2) the number of individual pest Species not already covered as part of a Group for which submitted or cited data require efficacy review. If a registrant submits or cites data seeking a claim against an individual PRE species not already covered by a Group, then each pest species will count as 1 PRE. If a registrant submits or cites data seeking a label claim against a pest Group, then each Group will count as 1 PRE, even if data are required for more than one Species to support claims against that Group.</p> <p>To determine whether a claim will count toward a Group or a Species, the Agency maintains a publicly available document, “Technical Support Document – Scientific Issues Associated with Product Performance Data Needs for Pesticide Products Claiming efficacy against Invertebrate Pests of Significant Public Health or Economic Importance”, which outlines Groups and Species. In this document, Appendix 1 (entitled “Pest Tables”) lists Groups of pests and the Species contained within each Group, and will serve as the guiding reference to determine Groups or Species as PREs. Use of this document in determining a PRIA category is limited to determining the number of PREs in a registrant’s application.</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
			<p>NOTE: Appendix 5 of this document, entitled “Label Claims and Representative Test Species for Pesticide Products Claiming Efficacy against Invertebrate Pests of Significant Public Health or Economic Importance”, provides guidance on the tests a registrant must provide to obtain a Group claim.</p> <p>In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim <i>and</i> a speed-of-kill claim against the singular PRE Group “Cockroaches”, then this will count as a <i>singular</i> PRE as long as the submitted or cited data adequately addresses each claim against the PRE.</p> <p>Total Number of PRE Example: A prospective registrant wishes to register a new end-use product with registered sources of active ingredients. The formula contains two active ingredients previously combined in other registered products. The application will not require any animal safety data. The application will include product chemistry data, acute toxicology data and submitted or cited product performance data to support claims against pests of public health significance.</p> <p>The proposed label will include a general cockroach claim, a claim to control Oriental cockroaches, a general tick claim, and a claim against chiggers. In this example, the data necessary to support the desired claims are not on file at the Agency, so the registrant must submit or cite data with their application. To support the general cockroach claim, the Agency requires testing on both American and German cockroaches, so the prospective registrant must develop and submit or cite data supporting the desired claim on both species. Cockroaches are pest Group 8 and American and German cockroaches are the representative test species for the group;</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
			<p>therefore, the studies supporting “cockroaches” count as one PRE for purposes of determining the PRIA category. Oriental cockroaches are part of pest Group 8. No additional data are required to support a claim against oriental cockroaches. The prospective registrant wishes to support a claim against “ticks”, pest Group 2. The prospective registrant must submit studies for each- lone star ticks, deer (blacklegged) ticks, and American or brown dog ticks- to support the general tick claim. The data to support the three required species of ticks count as one PRE for purposes of determining the PRIA category. Finally, the prospective registrant submits or cites data to support claims against chiggers. Chiggers count as a single PRE. Thus, the PRIA category for this action is R310 since data were submitted or cited to support claims against 3 pests requiring efficacy (i.e., cockroach (pest group 8), including Oriental cockroach specific claim; tick (pest group 2); and chiggers).</p> <p>If the prospective registrant wishes to add a claim against the “gulf coast tick, which may transmit <i>Rickettsia parkeri</i>” an additional study will be required. The application would then contain product performance data supporting 4 pests requiring efficacy (i.e., cockroach (pest group 8), including Oriental cockroach specific claim; tick (pest group 2); chiggers; and gulf coast tick, which may transmit <i>Rickettsia parkeri</i>). The PRIA category would now be R316.</p> <p>If the prospective registrant decides to include 4 additional claims to control pests requiring efficacy, then the application would contain product performance data supporting in total 8 pests requiring efficacy, and the PRIA category would be R317.</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 end-use product registration. If the</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
			<p>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>		
R320	55	<p>New product; new physical form; requires data review in science divisions (2) (3)</p>	<p>An application for registration of an end use product that is not substantially similar or identical in its uses or formulation to products that are currently registered and requires data review and/or risk evaluation in the science divisions. A change in the formulation type or timing of application for the registered physical form that would require residue chemistry data, environmental fate data, and/or ecotoxicity, exposure data, etc., to support the change. For example this includes a change in the formulation that would change the way a product is applied (i.e. spot-on treatments, controlled release formulation), a change in the toxicity and/or exposure profile of the product, a pre-mix product that is not currently registered that requires science review per current guidelines, a change in the application rates or PHI, animal products with rate depletion data, change in the formulation, e.g. going from a liquid to a solid, etc.</p> <p>Applications for new end use products that are submitted using an unregistered source of an existing active ingredient will be recoded to either category R333 or R334. All active ingredients derived from a manufacturing source which does not hold an active EPA</p>	12	13,888

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
			<p>registration number are considered unregistered. Even if the Agency may have reviewed the product chemistry data previously for that unregistered source of the active ingredient for another end use product, the active ingredient is considered unregistered.</p> <p>All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.</p> <p>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>		
R331	56	New product; repack of identical registered end-use product as a manufacturing-	<p>An application for registration of a manufacturing use pesticide product that is identical in its formulation and uses to end use products that are currently registered or an application for registration of an end use product that is identical in formulation and use sites to a registered manufacturing-use product.</p> <p>To fit this category all applications require the following but are not limited to:</p>	3	2,657

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
		<p>use product, or identical registered manufacturing-use product as an end-use product; same registered uses only (2) (3)</p>	<ul style="list-style-type: none"> <li>• A Formulator’s Exemption statement and/or data matrix</li> <li>• CSF</li> <li>• The applicant must identify the EPA-registered identical product for this category</li> <li>• The active ingredient listed on the CSF must be an EPA registered product in order to satisfy the data requirements for the active ingredient.</li> </ul> <p>If the use pattern for the proposed product differs from the currently registered product, then additional data are required and the application does not fall within this category (see applicable new use categories).</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>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
R332	57	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of completely new generic data package; registered uses only; requires review in RD and science divisions (2) (3)	<p>An application for registration of a manufacturing use pesticide product that is not substantially similar or identical in its formulation to products that are currently registered. New manufacturing use product is any product intended (labeled) for formulation or repackaging into an end use formulated pesticide product. This product does not contain directions for use of the product as distributed or sold, or after combination by the user with other substances. To fit this category all applications require the following but are not limited to:</p> <ul style="list-style-type: none"> <li>• A data matrix is required with the application.</li> <li>• Product chemistry data (Group A and B) and CSF.</li> <li>• Acute toxicity data must be addressed by submitting data or using: selective data citation. A rationale for a waiver or bridging of these data falls within this category.</li> <li>• The source of the active ingredient is unregistered</li> <li>• The proposed uses must already be on currently registered products.</li> <li>• The applicant must cite the similar product with the proposed uses.</li> <li>• The application contains generic data such as toxicity, environmental fate and/or eco-toxicity.</li> </ul> <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 manufacturing-use 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</p>	24	297,376

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
			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.		
R333	58	New product; MUP or end use product with unregistered source of active ingredient; requires science data review; new physical form; etc. Cite-all or selective data citation where applicant owns all required data (2) (3)	<p>An application for registration of a new product (MUP or end use product). New manufacturing use product is any product intended (labeled) for formulation or repackaging into an end use formulated pesticide product. The active ingredient is not a new active ingredient, but either (1) one that claims to be substantially similar or identical to another active ingredient which is currently registered (as referenced by EPA registration number) and has the selective data citation used, or (2) an end use product which claims to be substantially similar or identical in its formulation to another end use product that is currently registered for which the selective data citation was used, but the active ingredient used in the formulation is derived from an unregistered source (i.e., does not have a EPA registration number).</p> <p>To fit this category all applications require the following but are not limited to:</p> <ul style="list-style-type: none"> <li>• A data matrix is required with the application.</li> <li>• Two sets of product specific product chemistry data and 2 CSF's are required:               <ol style="list-style-type: none"> <li>1) Product chemistry (Group A and B) on the unregistered source of the active ingredient and CSF. The applicant must identify to the Agency the toxicity of the impurities associated with the active ingredient; particularly impurities of toxicological significance (at any level). The impurity profile of the</li> </ol> </li> </ul>	10	20,830

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
			<p>unregistered source of the active ingredient will be compared to the registered source and if new impurities of toxicological concern are found, then the application is routed to HED for review. If the data on the unregistered source was previously reviewed by the Agency, please cite the MRID and/or Reg number in the cover letter to the application and the date of Agency review; 2) Product chemistry data (Group A and B) for the end use product and CSF. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1.</p> <ul style="list-style-type: none"> <li>• All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.</li> <li>• Acute toxicity, public health pest efficacy, companion animal safety data and/or child resistant packaging data requirements must be addressed by using: 1) cite- all, 2) selective data citation. A rationale for a waiver or bridging of these data falls within this category.</li> <li>• Proposed label for the MUP and/or end use product</li> </ul> <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</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
			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.		
R334	59	New product; MUP or end use product with unregistered source of the active ingredient; requires science data review; new physical form; etc. Selective data citation (2) (3)	<p>An application for registration of a new product (MUP or end use product). New manufacturing use product is any product intended (labeled) for formulation or repackaging into an end use formulated pesticide product. The active ingredient is not a new active ingredient, but either (1) one that claims to be substantially similar or identical to another active ingredient which is currently registered (as referenced by EPA registration number) and will use selective data citation, or (2) an end use product which claims to be substantially similar or identical in its formulation to another end use product that is currently registered for which the selective data citation was used, but the active ingredient used in the formulation is derived from an unregistered source (i.e., does not have a EPA registration number).</p> <p>To fit this category all applications require the following but are not limited to:</p> <ul style="list-style-type: none"> <li>• A data matrix is required with the application.</li> <li>• Two sets of product specific product chemistry data and 2 CSF's are required: 1) product chemistry (Group A and B) on the unregistered source of the active ingredient and CSF. The applicant must identify to the Agency the toxicity of the impurities associated with the active ingredient; particularly impurities of toxicological significance (at any level). The impurity profile of the unregistered source of the active ingredient will be compared to registered source. The impurity profile of the unregistered source of the active ingredient</li> </ul>	11	24,255

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
			<p>either results in new impurities; or impurities of toxicological significance, or if the toxicity of new impurities is unknown to the applicant, then the application is submitted to HED for review. 2) Product chemistry data (Group A and B) for the end use product and CSF. In some cases, product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1.</p> <ul style="list-style-type: none"> <li>• All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.</li> <li>• Acute toxicity, public health pest efficacy, companion animal safety data and/or child resistant packaging data requirements must be addressed by using: 1) selective data citation. A rationale for a waiver or bridging of these data falls within this category.</li> <li>• Proposed label for the MUP and/or end use product</li> </ul> <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</p>		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
			prejudice.		