

**PRIA 5 Interpretations**

**TABLE 1. REGISTRATION DIVISION (RD) - NEW ACTIVE INGREDIENTS**

<b>EPA No.</b>	<b>CR No.</b>	<b>Action</b>	<b>Interpretation</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>FY'23-FY'24 Registration Service Fee (\$)</b>
R010	1	New Active Ingredient, Food use (2)(3)	<p>An application that proposes a food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The use requires the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application for a new active ingredient are covered by the base fee for the application in this category if submitted in the same package. Examples of food uses include use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags.</p> <p>A maximum of five new products (e.g., any combination of technical product, manufacturing-use product, and end use product) are covered by the base fee. After the first five new products, each application for an additional new product approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product approval. Any inert ingredient petition submitted concurrently with a new active ingredient package will receive its own PRIA category and will not be counted among the five products covered under the base fee for the new active ingredient category. All such associated applications that are submitted together will be subject to the new active ingredient decision review time.</p> <p>Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe.</p> <p>If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application.</p>	36	1,079,356

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			<p>All of the inerts used in the product must be either approved, pending with the Agency, or a new inert petition submitted within the package for the applicable uses (food or nonfood).</p> <p>Footnote 4 does not apply to this category as consideration of ESA has already been included in the review timeline.</p> <p>The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that must be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.</p>		
R020	2	New Active Ingredient, Food use; reduced risk (2)(3)	<p>An application that proposes a food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The use requires the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCFA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application for a new active ingredient are covered by the base fee for the application in this category if submitted simultaneously. Examples of food uses include use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags.</p> <p>A “reduced risk” (<a href="https://www.epa.gov/pesticide-registration/conventional-reduced-risk-pesticide-program">https://www.epa.gov/pesticide-registration/conventional-reduced-risk-pesticide-program</a>) submission must accompany the application for registration. The Agency’s Reduced Risk Committee will evaluate the submission and make the determination, based on criteria and guidance listed in PR Notice 97-3 and in</p>	27	899,464

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			<p>FIFRA §3(c)(10) (B) (i-iv), whether the requested use(s) qualify as “reduced risk” when compared to currently registered pesticides for the same use(s). The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that the uses do not qualify as “reduced risk” by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframe or fees. The fee category will be changed to category R010, and the action will receive the R010 decision review timeframe or fees. The decision review time of the R010 action shall be based on the submission date of the application originally submitted under R020 category.</p> <p>A maximum of five new products (e.g., any combination of technical product, manufacturing-use product, and end use product) are covered by the base fee. After the first five new products, each application for an additional new product approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product approval. Any inert ingredient petition submitted concurrently with a new active ingredient package will receive its own PRIA category and will not be counted among the five products covered under the base fee for the new active ingredient category. All such associated applications that are submitted together will be subject to the new active ingredient decision review time.</p> <p>Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe.</p> <p>If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application.</p> <p>All of the inerts used in the product must be either approved, pending with the Agency, or a new inert petition submitted within the package for the applicable uses (food or nonfood).</p>		

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			<p>Footnote 4 does not apply to this category as consideration of ESA has already been included in the review timeline.</p> <p>The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that must be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.</p>		
R040	3	<p>New Active Ingredient, Food use; Experimental Use Permit application; establish temporary tolerance; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows (3)(4)</p>	<p>An Experimental Use Permit (EUP) application for food use(s) of an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The application proposes a food use. The use requires the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted simultaneously. Examples of food uses include use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags.</p> <p>The Agency will not accept a certification for crop destruct once the review clock has started. A change to a crop destruct application would require the applicant to withdraw their application and start the process application again.</p> <p>45% of this category's fee will be credited against the new active ingredient's application fee whose submission follows that of this EUP application.</p>	18	662,883

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			<p>All of the inerts used in the product must be either approved, pending with the Agency, or a new inert petition submitted within the package for the applicable uses (food or nonfood).</p> <p>If the Agency determines that endangered species analysis is required according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended to conduct the endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. This extension is contingent on Agency issuing the ESA guidance applicable to this PRIA category.</p> <p>The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that must be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been 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>		

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R060	4	New Active Ingredient, Non-food use; outdoor (2)(3)	<p>An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Outdoor use means any use that is not indoor as described in the indoor category. All non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Non-food outdoor uses could include, for example, treatment of ornamentals in a shade house or turf uses.</p> <p>A maximum of five new products (e.g., any combination of technical product, manufacturing-use product, and end use product) are covered by the base fee. After the first five new products, each application for an additional new product approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product approval. Any inert ingredient petition submitted concurrently with a new active ingredient package will receive its own PRIA category and will not be counted among the five products covered under the base fee for the new active ingredient category. All such associated applications that are submitted together will be subject to the new active ingredient decision review time.</p> <p>Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe.</p> <p>If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application.</p> <p>All of the inerts used in the product must be either approved, pending with the Agency, or a new inert clearance petition submitted within the package for the applicable uses (food or nonfood).</p> <p>Footnote 4 does not apply to this category as consideration of ESA has already been included in the review timeline.</p>	30	749,886

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			<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 must be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.</p>		
R070	5	New Active Ingredient, Non-food use; outdoor; reduced risk (2)(3)	<p>An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Outdoor use means any use that is not indoor as described in the indoor category. All non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Non-food outdoor uses could include, for example, treatment of ornamentals in a shade house or turf uses.</p> <p>A “reduced risk” (<a href="https://www.epa.gov/pesticide-registration/conventional-reduced-risk-pesticide-program">https://www.epa.gov/pesticide-registration/conventional-reduced-risk-pesticide-program</a>) submission must accompany the application for registration. The Agency’s Reduced Risk Committee will evaluate the submission and make the determination, based on criteria and guidance listed in PR Notice 97-3 and in FIFRA §3(c)(10) (B) (i-iv), whether the requested use(s) qualify as “reduced risk” when compared to currently registered pesticides for the same use(s). The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that the uses do not qualify as “reduced risk” by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframe or fees. The fee category will be changed to the category R060, and the action will receive R060 decision review timeframe or fees. The decision review time of the R060 action shall be</p>	24	624,905

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			<p>based on the submission date of the application originally submitted under R070 category.</p> <p>A maximum of five new products (e.g., any combination of technical product, manufacturing-use product, and end use product) are covered by the base fee. After the first five new products, each application for an additional new product approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product approval. Any inert ingredient petition submitted concurrently with a new active ingredient package will receive its own PRIA category and will not be counted among the five products covered under the base fee for the new active ingredient category. All such associated applications that are submitted together will be subject to the new active ingredient decision review time.</p> <p>Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe.</p> <p>If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application.</p> <p>All of the inerts used in the product must be either approved, pending with the Agency, or a new inert petition submitted within the package for the applicable uses (food or nonfood).</p> <p>Footnote 4 does not apply to this category as consideration of ESA has already been included in the review timeline.</p> <p>The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that must be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that</p>		



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			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.		
R090	6	New Active Ingredient, Non-food use; outdoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows (3)(4)	<p>An Experimental Use Permit (EUP) application for non-food use(s) of an active ingredient that is not contained as an active ingredient in any currently U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Outdoor use means any use that is not indoor as described in the indoor category. All non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Non-food outdoor uses could include, for example, treatment of ornamentals in a shade house or turf uses. 45% of this category's fee will be credited against the new active ingredient's application fee whose submission follows that of this EUP application.</p> <p>All of the inerts used in the product must be either approved, pending with the Agency, or a new inert petition submitted within the package for the applicable uses (food or nonfood).</p> <p>If the Agency determines that endangered species analysis is required according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended to conduct the endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. This extension is contingent on Agency issuing the ESA guidance applicable to this PRIA category.</p> <p>The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that must be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been 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>	16	463,930

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R110	7	New Active Ingredient, Non-food use; indoor (2)(3)(4)	<p>An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Indoor means that the proposed use is for use inside of manmade structures. All indoor non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Some examples of indoor uses are termiticide structural protection, and indoor residential treatments (i.e. cockroach treatments).</p> <p>Treatment of ornamentals in a shade house is classified as outdoor uses and is not covered in this category.</p> <p>A maximum of five new products (e.g., any combination of technical product, manufacturing-use product and end use product) are covered by the base fee. After the first five new products, each application for an additional new product approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product approval. Any inert ingredient petition submitted concurrently with a new active ingredient package will receive its own PRIA category and will not be counted among the five products covered under the base fee for the new active ingredient category. All such associated applications that are submitted together will be subject to the new active ingredient decision review time.</p> <p>Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe.</p> <p>If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application.</p> <p>All of the inerts used in the product must be either approved, pending with the Agency, or a new inert petition submitted within the package for the applicable uses (food or nonfood).</p> <p>If the Agency determines that endangered species analysis is required according to section 33(c)(3)(B) for this specific type of action, the decision review time can be</p>	20	417,069

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			<p>extended to conduct the endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. This extension is contingent on Agency issuing the ESA guidance applicable to this PRIA category.</p> <p>The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that must be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.</p>		
R120	8	New Active Ingredient, Non-food use; indoor reduced risk (2)(3)(4)	<p>An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Indoor means that the proposed use is for use inside of manmade structures. All indoor non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Some examples of indoor uses are termiticide structural protection and indoor residential treatments (i.e., cockroach treatments).</p> <p>Treatment of ornamentals in a shade house is classified as outdoor uses and is not covered in this category.</p> <p>A “reduced risk” (<a href="https://www.epa.gov/pesticide-registration/conventional-reduced-risk-pesticide-program">https://www.epa.gov/pesticide-registration/conventional-reduced-risk-pesticide-program</a>) submission must accompany the application for registration. The Agency’s Reduced Risk Committee will evaluate the submission and make the determination, based on criteria and guidance listed in PR Notice 97-3 and in FIFRA §3(c)(10) (B) (i-iv), whether the requested use(s) qualify as “reduced risk” when compared to currently registered pesticides for the same use(s). The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or</p>	14	347,556

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			<p>upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that the uses do not qualify as “reduced risk” by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframe or fees. The fee category will be changed to the category R110 and the action will receive the R110 decision review timeframe or fees. The decision review time of the R110 action shall be based on the submission date of the application originally submitted under R120 category.</p> <p>A maximum of five new products (e.g., any combination of technical product, manufacturing-use product, and end use product) are covered by the base fee. After the first five new products, each application for an additional new product approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product approval. Any inert ingredient petition submitted concurrently with a new active ingredient package will receive its own PRIA category and will not be counted among the five products covered under the base fee for the new active ingredient category. All such associated applications that are submitted together will be subject to the new active ingredient decision review time.</p> <p>Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe.</p> <p>If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application.</p> <p>All of the inerts used in the product must be either approved, pending with the Agency, or a new inert petition submitted within the package for the applicable uses (food or nonfood).</p> <p>If the Agency determines that endangered species analysis is required according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended to conduct the endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening.</p>		

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			<p>This extension is contingent on Agency issuing the ESA guidance applicable to this PRIA category.</p> <p>The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that must be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.</p>		
R121	9	<p>New Active Ingredient, Non-food use; indoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows (3)(4)</p>	<p>An Experimental Use Permit (EUP) application for non-food use(s) of an active ingredient that is not contained as an active ingredient in any currently U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Indoor means that the proposed use is for use inside of manmade structures. All indoor non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Some examples of indoor uses are termiticide structural protection, and indoor residential treatments (i.e., cockroach treatments).</p> <p>Treatment of ornamentals in a shade house is classified as an outdoor use and is not covered in this category. 45% of this category's fee will be credited against the new active ingredient's application fee whose submission follows that of this EUP application.</p> <p>All of the inerts used in the product must be either approved, pending with the Agency, or a new inert clearance petition submitted within the package for the applicable uses (food or nonfood).</p> <p>If the Agency determines that endangered species analysis is required according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended to conduct the endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening.</p>	18	261,322

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			<p>This extension is contingent on Agency issuing the ESA guidance applicable to this PRIA category.</p> <p>The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that must be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been 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 this 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>		
R122	10	Enriched isomer(s) of registered mixed-isomer active ingredient (2)(3)	<p>An application that proposes using an enriched isomer of an active ingredient, where such enriched isomer is not currently contained as an active ingredient in any U.S. registered pesticide product. This category consists of active ingredients that are a variation on the molecular structure or composition of a registered product, and which will cite at least some of the generic data conducted with a registered product. If a food use is included in this new active ingredient package, the use may require the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. If a tolerance or exemption from the requirement of a tolerance is required, the application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application. All uses (food and non-food) included in the original application or petition for each new active ingredient are covered by the base fee for the application in this category if submitted in this package.</p> <p>A maximum of five new products (e.g., any combination of technical product, manufacturing-use product, and end use product) are covered by the base fee. After the first five new products, each application for an additional new product approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product approval. Any inert ingredient petition submitted concurrently with a new active ingredient package will receive its own PRIA category and will not be counted among the five products covered under the base fee for the new active ingredient category.</p>	27	454,526

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			<p>All such associated applications that are submitted together will be subject to the new active ingredient decision review time.</p> <p>Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe.</p> <p>If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application.</p> <p>All of the inerts used in the product must be either approved, pending with the Agency, or a new inert petition submitted within the package for the applicable uses (food or nonfood).</p> <p>Footnote 4 does not apply to this category as consideration of ESA has already been included in the review timeline.</p> <p>The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that must be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.</p>		
R123	11	New Active Ingredient, Seed treatment only; includes agricultural and	An application for seed treatment only that proposes a use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product and is not expected to result in residues in raw agricultural commodities. All uses included in the original application for each new active ingredient are covered by the base fee for the application in this category if submitted in this package. In order for a	27	676,296

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		non-agricultural seeds; non-food use, not requiring a tolerance (2)(3)	<p>food crop seed treatment to be considered in this category (i.e., considered a non-food use), data must be available showing all raw agricultural commodity residues of concern in a radiotracer study are &lt;5 ppb, OR the calculated theoretical maximum residue of concern is ≤5 ppb, OR other non-food uses described in the guidance. Guidance is available at (<a href="https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-860-residue-chemistry-test-guidelines">https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-860-residue-chemistry-test-guidelines</a>). Seed treatments that are considered to be food uses requiring tolerances fall into a different category.</p> <p>A maximum of five new products (e.g., any combination of technical product, manufacturing-use product, and end use product) are covered by the base fee. After the first five new products, each application for an additional new product approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product approval. Any inert ingredient petition submitted concurrently with a new active ingredient package will receive its own PRIA category and will not be counted among the five products covered under the base fee for the new active ingredient category. All such associated applications that are submitted together will be subject to the new active ingredient decision review time.</p> <p>Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe.</p> <p>If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application.</p> <p>All of the inerts used in the product must be either approved, pending with the Agency, or a new inert petition submitted within the package for the applicable uses (food or nonfood).</p> <p>Footnote 4 does not apply to this category as consideration of ESA has already been included in the review timeline.</p> <p>The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that must be made in order to grant the requested new active ingredient registration. If the label</p>		



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			<p>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>		
R126	12 (new)	<p>New Active Ingredient, Seed treatment only; limited uptake into raw agricultural commodities; use requiring a tolerance (2)(3)</p>	<p>An application for seed treatment only that proposes a use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product that has limited uptake into raw agricultural commodities. All uses included in the original application for each new active ingredient are covered by the base fee for the application in this category if submitted in this package. In order for a food crop seed treatment to be considered in this category, residues in all raw agricultural commodities must be less than the level of quantitation (LOQ) of the enforcement method, requiring a tolerance at the LOQ. If residues are above the LOQ, the use falls into a different category (i.e. R010).</p> <p>A maximum of five new products (e.g., any combination of technical product, manufacturing-use product and end use product) are covered by the base fee. After the first five new products, each application for an additional new product approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product approval. Any inert ingredient petition submitted concurrently with a new active ingredient package will receive its own PRIA category and will not be counted among the five products covered under the base fee for the new active ingredient category. All such associated applications that are submitted together will be subject to the new active ingredient decision review time.</p> <p>Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe.</p> <p>If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the</p>	31	743,925

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			<p>applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application.</p> <p>All of the inerts used in the product must be either approved, pending with the Agency, or a new inert petition submitted within the package for the applicable uses (food or nonfood).</p> <p>Footnote 4 does not apply to this category as consideration of ESA has already been included in the review timeline.</p> <p>The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that must be made in order to grant the requested new active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.</p>		
R125	13	New Active Ingredient, Seed treatment; Experimental Use Permit application, submitted before application for registration; credit 45% of fee toward new active ingredient application that follows (3)(4)	<p>An Experimental Use Permit (EUP) application for seed treatment only that proposes a use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product, that and is not expected to result in residues in raw agricultural commodities. All uses included in the original application for a new active ingredient are covered by the base fee for the application in this category. In order for a food crop seed treatment to be considered in this category, (i.e., considered a non-food use), data must be available showing all raw agricultural commodity residues of concern in a radiotracer study are &lt;5 ppb, OR the calculated theoretical maximum residue of concern is ≤5 ppb, OR other non-food uses described in the guidance. Guidance is available at <a href="https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-860-residue-chemistry-test-guidelines">https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-860-residue-chemistry-test-guidelines</a>.</p> <p>If residues occur in raw agricultural commodities, or if there are no data available to make this determination, seed treatments are considered to be food uses requiring tolerances and fall into a different category. 45% of this category's fee will be credited</p>	16	463,930

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) <sup>(1)</sup>	FY'23-FY'24 Registration Service Fee (\$)
			<p>against the new active ingredient's application fee whose submission follows that of this EUP application.</p> <p>All of the inerts used in the product must be either approved, pending with the Agency, or a new inert clearance petition submitted within the package for the applicable uses (food or nonfood).</p> <p>If the Agency determines that endangered species analysis is required according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended to conduct the endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. This extension is contingent on Agency issuing the ESA guidance applicable to this PRIA category.</p> <p>The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.</p>		

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

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

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

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

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