TABLE 4. REGISTRATION DIVISION (RD) - NEW PRODUCTS

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
R300	50	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 child-resistant packaging -- only product chemistry data; cite-all data 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	An application for registration of an end-use or a manufacturing use pesticide product that is substantially similar or identical in its uses and formulation to a single product that is currently registered and differs only in ways that would not significantly increase the risk of unreasonable adverse effects. The applicant must identify the substantially similar (me-too) product for the proposed product on the EPA application form (8570-1, box 6). To fit this category, all applications require the following but are not limited to: • Certification with Respect to Citation of Data and a Data Matrix (except for 100% repacks). • Companies/registrants cannot claim formulator's exemption for a product they own, 40 CFR 152.85(b) and FIFRA 3 (c)(2)(D), and therefore, the formulation must be listed on the CSF. A data matrix using selective data citation for the generic data to a registered technical is only applicable in this category where the applicant owns all the required data which has been previously reviewed/accepted or the applicant submits a specific authorization letter from the data owner. • Product chemistry data (Group A and B) unless the product is identical (e.g., 100% repackaged product) and supporting CSF. In some cases, product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. If submitting self-certification for Group B data, an MRID must be assigned. • All inert ingredients must already be approved for the applicable uses in the product. • The active ingredient listed on the CSF must be an EPA registered product. • In all cases, the applicant must identify the currently registered similar product for this category. • 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. If using selective data citation for acute toxicity data, list only one set of data (6-pack that belongs to a single substantially similar product) to support the proposed product on the data matrix. If review of new data is needed, the application does not fall within this category. The application is not in this category if efficacy, acute toxicity, companion animal safety,	4	2,384

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		use or manufacturing-use product that requires no data submission nor data matrix (2)(3)	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 or bridge 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% identical in composition and uses to a currently registered product to be considered in this category. 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 cited me-too 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. Identical: Same composition and use patterns as a currently registered end use product. For 100% repack applications, only one Confidential Statement of Formula (listing a single 100% repack) will be accepted under an R300 fee. Additional alternate 100% repack CSFs under the same submission needs to be identical and a multiplier applies for each individual repack being added under one package. Alternatively, separate R300 applications can be submitted for each new repack product. 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. 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 active EPA registration numbers 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. 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		

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			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.		
R301	51	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; selective data citation only for data on product chemistry 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 authorization letter from data owner	An application for registration of an end-use or a manufacturing use pesticide product that is substantially similar or identical in its uses and formulation to a single product that is currently registered and differ only in ways that would not significantly increase the risk of unreasonable adverse effects. The applicant must identify the substantially similar product for the proposed product on EPA's application form (8570-1, box 6). To fit this category, all applications require the following but are not limited to: • Certification with Respect to Citation of Data and a Data Matrix. • Companies/registrants cannot claim formulator's exemption for a product they own, 40 CFR 152.85(b) and FIFRA 3 (c)(2)(D), and therefore, the formulation must be listed on the CSF. A data matrix using selective data citation for generic data is not applicable in this category. • Product chemistry data (Group A and B) unless the product is identical and supporting CSF. In some cases, product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. If submitting self-certification for Group B data, an MRID must be assigned. • All inert ingredients must already be approved for the applicable uses in the product. • The active ingredient listed on the CSF must be an EPA registered product. • In all cases, the applicant must identify the currently registered similar product for this category. • 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 using selective data citation for acute toxicity data, list only one set of data (6-pack that belongs to a single substantially similar product) to support the proposed product on the data matrix. If review of new data is needed, this application does not fall within this category.	4	2,856

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		(2)(3)	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 or bridge 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% identical in composition and use to a currently registered product to be considered in this category. Otherwise, the R315 category is applicable. An application proposed as a 100% re-packaged product does not fall within this category (see category R300). 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 cited me-too 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. Identical: Same composition and use patterns as a currently registered end-use product. 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. 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		

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			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.		
R310	52	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 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: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or	An application for registration of an end-use or manufacturing use pesticide product that is not substantially similar or identical in its uses and/or formulation to a single product that is currently registered, and for which efficacy data for up to 3 target pests or pest groups are submitted or cited selectively. This category also includes new product applications containing a single registered active ingredient. Applicants should identify in the cover letter and/or EPA application form (8570-1, in the comment field) the registered product(s) that is being referenced for formulation and uses, which contains the same uses and formulation type as the proposed product label. To fit this category, all applications require the following but are not limited to: • Certification with Respect to Citation of Data and a Data Matrix. • Companies/registrants cannot claim formulator's exemption for a product they own, 40 CFR 152.85(b) and FIFRA 3 (c)(2)(D), and therefore, the formulation must be listed on the CSF. • 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. If submitting self-certification for Group B data, an MRID must be assigned. • 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). • 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. If using selective data citation for acute toxicity data, list only one set of data (i.e., 6-pack, single MRID per guideline) to support the proposed product on the data matrix. A rationale for a waiver or bridging of these data falls within this category. If a bridging rationale or waiver request is submitted for any guideline, it must be assigned an MRID and listed on the data matrix. Any other MRIDs referenced within this MRID should also be listed on the data matrix.	7	10,990

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		4. pest(s) requiring efficacy – for up to 3 target pests (2)(3)(4)	New uses for the active ingredient are not covered under this category (See Table 2). 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). 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 requires animal safety data for support does not fit in this category (see R315). 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. If 4 to 7 target pests are submitted, then the action belongs in R316. For more than 7 target pests, the action belongs in R317. For the purposes of classifying proposed registration actions into PRIA categories, "pest(s) requiring efficacy" (hereafter referred to as PRE) are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, 40 CFR (Code of Federal Regulations) part 158, subpart R (87 FR 22464, https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-R). This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in PRN 2023-1 (https://www.regulations.gov/document/EPA-HQ-OPP-2020-0260-0014). To determine the number of PREs, which determines the appropriate PRIA category, pest groups, sub-groups and pest-specific claims as listed in 40 CFR Part 158, subpart R should		

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			be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, flies, etc.), each group will count as 1 PRE. If seeking a claim against a pest sub-group (e.g., small biting flies, filth flies, large biting flies, subterranean termites, fire and harvester ants, fire ants, etc.), or specific species (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each sub-group or specific pest count as 1 PRE. In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim *and* a speed-of-kill claim against the singular PRE Group "Cockroaches", then this will count as a *singular* PRE as long as the submitted or cited data adequately addresses each claim against the PRE. <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 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. The proposed label example may 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 the general pest group and American and German cockroaches are the representative test species for the group; therefore, the studies supporting "cockroaches" count as 1 PRE for purposes of determining the PRIA category. Oriental cockroaches are not part of the general cockroaches pest group, they are a specific pest species. However, all studies supporting cockroach claims, including oriental cockroaches, count as 1 PRE, because there is already a general pest claim for cockroaches. If a prospective registrant wishes to support a claim against "ticks", another general pest group, they 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 1 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, data were submitted or cited to support claims against 3 pests requiring efficacy (i.e., cockroach (pest group), including Oriental cockroach specific claim; tick (pest group); and chiggers).		

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			If the prospective registrant wishes to add a claim against the "gulf coast tick, which may transmit *Rickettsia parkeri*" an additional study will be required. Gulf coast ticks are not part of the general tick pest group, and not only is additional data required for this pest, but they also count as an additional PRE. This pest is one of the exceptions that is not covered by a general pest group or sub-group claim. The application would then contain product performance data supporting 4 pests requiring efficacy (i.e., cockroach (pest group), including Oriental cockroach specific claim; tick (pest group); chiggers; and gulf coast tick, which may transmit *Rickettsia parkeri*). 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. 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.		
R314	53	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	An application for registration of a new end-use product that contains up to three registered conventional 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 (only one registered label per active ingredient). 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. The application package should include a complimentary use table in the cover letter, listing the currently registered identical or substantially similar products from which the most restrictive directions for use/parameters such as use rates, PHI, REI, etc. were used to generate the proposed label.	8	12,983

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		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 of data package within RD only; includes data and/or waivers of data for only: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and or 4. pest(s) requiring efficacy – for up to 3 target pests (2)(3)(4)	To fit this category, all applications require the following but are not limited to: • Certification with Respect to Citation of Data and a Data Matrix. • Companies/registrants cannot claim formulator's exemption for a product they own, 40 CFR 152.85(b) and FIFRA 3 (c)(2)(D), and therefore, the formulation must be listed on the CSF. • 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. If submitting self-certification for Group B data, an MRID must be assigned. • 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). • Acute toxicity, efficacy, and/ or child resistant packaging data requirements must be addressed by using; (1) the cite-all method; (2) selective data citation which includes submitting required data. A rationale for a waiver or bridging of these data can be submitted. If a bridging rationale or waiver request is submitted for any guideline, it must be assigned an MRID and listed on the data matrix. Any other MRIDs referenced within this MRID should also be listed on the data matrix. 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 the application contains up to three active ingredients never registered before in combination that span regulatory divisions (antimicrobial, biopesticide, conventional) and require coordination among 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. If 4 to 7 target pests are submitted, then the action belongs in R319. For more than 7 target pests, the action belongs in R361.		

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			For the purposes of classifying proposed registration actions into PRIA categories, "pest(s) requiring efficacy" (hereafter referred to as PRE) are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, 40 CFR (Code of Federal Regulations) part 158, subpart R (87 FR 22464, https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-R). This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in PRN 2023-1 (https://www.regulations.gov/document/EPA-HQ-OPP-2020-0260-0014). To determine the number of PREs, which determines the appropriate PRIA category, pest groups, sub-groups and pest-specific claims as listed in 40 CFR Part 158, subpart R should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, flies, etc.), each group will count as 1 PRE. If seeking a claim against a pest sub-group (e.g., small biting flies, filth flies, large biting flies, subterranean termites, fire and harvester ants, fire ants, etc.), or specific species (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each sub-group or specific pest count as 1 PRE. In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim *and* a speed-of-kill claim against the singular PRE Group "Cockroaches", then this will count as a *singular* PRE as long as the submitted or cited data adequately addresses each claim against the PRE. Refer to the interpretation in R310 for examples on how to calculate the total number of PRE. 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		

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			of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R319	54	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 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: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant	An application for registration of a new end-use product that contains up to three registered conventional 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 (only one registered label per active ingredient). 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 use a registered source of active ingredient. Any science review must be within RD only. The application package should include a complimentary use table listing the currently registered identical or substantially similar products from which the most restrictive directions for use/parameters such as use rates, PHI, REI, etc. were used to generate the proposed label. To fit this category, all applications require the following but are not limited to: • Certification with Respect to Citation of Data and a data matrix. • Companies/registrants cannot claim formulator's exemption for a product they own, 40 CFR 152.85(b) and FIFRA 3 (c)(2)(D), and therefore, the formulation must be listed on the CSF. • 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. If submitting self-certification for Group B data, an MRID must be assigned. • 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). • Acute toxicity, efficacy, and or child resistant packaging data requirements must be addressed by using; (1) the cite-all method; (2) selective data citation which includes submitting required data. A rationale for a waiver or bridging of these data can be submitted. If a bridging rationale or waiver request is submitted for any guideline, it must be assigned an MRID and listed on the data matrix. Any other MRIDs referenced within this MRID should also be listed on the data matrix. 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).	10	19,002

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		packaging and/or 4. pest(s) requiring efficacy - for 4 to 7 target pests (2)(3)(4)	If the application contains up to three active ingredients never registered before in combination that span regulatory divisions (antimicrobial, biopesticide, conventional) and require coordination among 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. If 3 or less target pests are submitted, then the action belongs in R314. For more than 7 target pests, the action belongs in R361. For the purposes of classifying proposed registration actions into PRIA categories, "pest(s) requiring efficacy" (hereafter referred to as PRE) are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, 40 CFR (Code of Federal Regulations) part 158, subpart R (87 FR 22464, https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-R). This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in PRN 2023-1 (https://www.regulations.gov/document/EPA-HQ-OPP-2020-0260-0014). To determine the number of PREs, which determines the appropriate PRIA category, pest groups, sub-groups and pest-specific claims as listed in 40 CFR Part 158, subpart R should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, flies, etc.), each group will count as 1 PRE. If seeking a claim against a pest sub-group (e.g., small biting flies, filth flies, large biting flies, subterranean termites, fire and harvester ants, fire ants, etc.), or specific species (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each sub-group or specific pest count as 1 PRE. In addition, one individual PRE may encompass multiple claims. For example, if a		

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			registrant seeks both a general efficacy claim *and* a speed-of-kill claim against the singular PRE Group "Cockroaches", then this will count as a *singular* PRE as long as the submitted or cited data adequately addresses each claim against the PRE. Refer to the interpretation in R310 for examples on how to calculate the total number of PRE. 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.		
R318	55	New end-use 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	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 (only one registered label per active ingredient). Each source of active ingredient in the formulation must use a registered source of active ingredient. 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. The application package should include a complimentary use table listing the currently registered identical or substantially similar products from which the most restrictive directions for use/parameters such as use rates, PHI, REI, etc. were used to generate the proposed label. To fit this category, all applications require the following but are not limited to: • Certification with Respect to Citation of Data and a Data Matrix. • Companies/registrants cannot claim formulator's exemption for a product they own, 40 CFR 152.85(b) and FIFRA 3 (c)(2)(D), and therefore, the formulation must be listed on the CSF.	9	19,944

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		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: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. pest(s) requiring efficacy – for up to 3 target pests (2)(3)(4)	• 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. If submitting self-certification for Group B data, an MRID must be assigned. • 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). • Acute toxicity, efficacy, and or child resistant packaging data requirements must be addressed by using; (1) the cite-all method; (2) selective data citation which includes submitting required data. A rationale for a waiver or bridging of these data can be submitted. If a bridging rationale or waiver request is submitted for any guideline, it must be assigned an MRID and listed on the data matrix. Any other MRIDs referenced within this MRID should also be listed on the data matrix. 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 the application contains four or more active ingredients never registered before in combination that span regulatory divisions (antimicrobial, biopesticide, conventional) and require coordination among 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. If 4 to 7 target pests are submitted, then the action belongs in R321. For more than 7 target pests, the action belongs in R362. For the purposes of classifying proposed registration actions into PRIA categories, “pest(s) requiring efficacy” (hereafter referred to as PRE) are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive		

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			invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, 40 CFR (Code of Federal Regulations) part 158, subpart R (87 FR 22464, https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-R). This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in PRN 2023-1 (https://www.regulations.gov/document/EPA-HQ-OPP-2020-0260-0014). To determine the number of PREs, which determines the appropriate PRIA category, pest groups, sub-groups and pest-specific claims as listed in 40 CFR Part 158, subpart R should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, flies, etc.), each group will count as 1 PRE. If seeking a claim against a pest sub-group (e.g., small biting flies, filth flies, large biting flies, subterranean termites, fire and harvester ants, fire ants, etc.), or specific species (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each sub-group or specific pest count as 1 PRE. In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim *and* a speed-of-kill claim against the singular PRE Group "Cockroaches", then this will count as a *singular* PRE as long as the submitted or cited data adequately addresses each claim against the PRE. Refer to the interpretation in R310 for examples on how to calculate the total number of PRE. 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.		
R321	56	New end use product	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	11	25,964

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		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 requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. pest(s) requiring efficacy - for 4 to 7 target pests (2)(3)(4)	as a formulated product. The proposed label has the same uses as those found on the registered product labels for the single active ingredients (only one registered label per active ingredient). Each source of active ingredient in the formulation must use a registered source of active ingredient. Any science 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. The application package should include a complimentary use table listing the currently registered identical or substantially similar products from which the most restrictive directions for use/parameters such as use rates, PHI, REI, etc. were used to generate the proposed label. To fit this category, all applications require the following but are not limited to: • Certification with Respect to Citation of Data and a Data Matrix. • Companies/registrants cannot claim formulator's exemption for a product they own, 40 CFR 152.85(b) and FIFRA 3 (c)(2)(D), and therefore, the formulation must be listed on the CSF. • 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. If submitting self-certification for Group B data, an MRID must be assigned. • 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). • Acute toxicity, efficacy, and or child resistant packaging data requirements must be addressed by using; (1) the cite-all method; (2) selective data citation which includes submitting required data. A rationale for a waiver or bridging of these data can be submitted. If a bridging rationale or waiver request is submitted for any guideline, it must be assigned an MRID and listed on the data matrix. Any other MRIDs referenced within this MRID should also be listed on the data matrix. 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 the application contains four or more active ingredients never registered before in combination that span regulatory divisions (antimicrobial, biopesticide, conventional) and require coordination among those divisions, the application does not belong in this category (see category M005).		

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			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. If 3 or less target pests are submitted, then the action belongs in R318. For more than 7 target pests, the action belongs in R362. For the purposes of classifying proposed registration actions into PRIA categories, "pest(s) requiring efficacy" (hereafter referred to as PRE) are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, 40 CFR (Code of Federal Regulations) part 158, subpart R (87 FR 22464, https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-R). This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in PRN 2023-1 (https://www.regulations.gov/document/EPA-HQ-OPP-2020-0260-0014). To determine the number of PREs, which determines the appropriate PRIA category, pest groups, sub-groups and pest-specific claims as listed in 40 CFR Part 158, subpart R should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, flies, etc.), each group will count as 1 PRE. If seeking a claim against a pest sub-group (e.g., small biting flies, filth flies, large biting flies, subterranean termites, fire and harvester ants, fire ants, etc.), or specific species (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each sub-group or specific pest count as 1 PRE. In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim *and* a speed-of-kill claim against the singular PRE Group "Cockroaches", then this will count as a *singular* PRE as long as the submitted or cited data adequately addresses each claim against the PRE. Refer to the interpretation in R310 for examples on how to calculate the total number of		

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			PRE. 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.		
R315	57	New end-use on-animal product, registered source of active ingredient(s) with submission of data and/or waivers for only: 1. animal safety and 2. pest(s) requiring efficacy and/or 3. product chemistry and/or 4. acute toxicity and/or 5. child resistant packaging (2)(3)(4)	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 products that require animal safety studies include, but are not limited to, spot-ons, flea collars, shampoos and sprays. Each source of active ingredient in the formulation must use a registered source of active ingredient. Applicants should identify in the cover letter and/or EPA application form (8570-1, in the comment field) the registered product that is being referenced for formulation and uses which contains the same use(s) and formulation type as the proposed product label. To fit this category, all applications require the following but are not limited to: • Certification with Respect to Citation of Data and a Data Matrix. • Companies/registrants cannot claim formulator's exemption for a product they own, 40 CFR 152.85(b) and FIFRA 3 (c)(2)(D), and therefore, the formulation must be listed on the CSF. • 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. If submitting self-certification for Group B data, an MRID must be assigned. • 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). In those cases where the product relies upon a pending inert clearance or a new inert petition, 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.	9	14,779

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
			• 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. If using selective data citation for acute toxicity data, list only one set of data (i.e., 6-pack, single MRID per guideline) to support the proposed product on the data matrix. A rationale for a waiver or bridging of these data falls within this category. If a bridging rationale or waiver request is submitted for any guideline, it must be assigned an MRID and listed on the data matrix. Any other MRIDs referenced within this MRID should also be listed on the data matrix. • 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 ≥ 3 lbs and on breeding cats, then two companion animal studies are required: the first using kittens ≥ 12 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. 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. (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.) 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 both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, 40 CFR (Code of Federal Regulations) part 158, subpart R (87 FR 22464, https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-R). This list may be updated/refined as invasive pest needs arise. All other pests (e.g.,		

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			vertebrates) are listed in PRN 2023-1 (https://www.regulations.gov/document/EPA-HQ-OPP-2020-0260-0014). To determine the number of PREs, which determines the appropriate PRIA category, pest groups, sub-groups and pest-specific claims as listed in 40 CFR Part 158, subpart R should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, flies, etc.), each group will count as 1 PRE. If seeking a claim against a pest sub-group (e.g., small biting flies, filth flies, large biting flies, subterranean termites, fire and harvester ants, fire ants, etc.), or specific species (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each sub-group or specific pest count as 1 PRE. In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim *and* a speed-of-kill claim against the singular PRE Group "Cockroaches", then this will count as a *singular* PRE as long as the submitted or cited data adequately addresses each claim against the PRE. 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.		
R316	58	New end-use or manufacturing product with registered source(s) of active ingredient(s) including products containing two or more registered	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 a single product that is currently registered, and for which efficacy data for 4 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. Applicants should identify in the cover letter and/or EPA application form (8570-1, in the comment field) the registered products that are being referenced for formulation and uses which contains the same use(s) and formulation type as the proposed product label.	9	17,009

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		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: 1. product chemistry and/or 2. acute toxicity and/or 3.child resistant packaging and/or 4. pest(s) requiring efficacy – for 4 to 7 target pests (2)(3)(4)	To fit this category, all applications require the following but are not limited to: • Certification with Respect to Citation of Data and a Data Matrix. • Companies/registrants cannot claim formulator's exemption for a product they own, 40 CFR 152.85(b) and FIFRA 3 (c)(2)(D), and therefore, the formulation must be listed on the CSF. • 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. If submitting self-certification for Group B data, an MRID must be assigned. • 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). • 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. If using selective data citation for acute toxicity data, list only one set of data (i.e., 6-pack, single MRID per guideline) to support the proposed product on the data matrix. A rationale for a waiver or bridging of these data falls within this category. If a bridging rationale or waiver request is submitted for any guideline, it must be assigned an MRID and listed on the data matrix. Any other MRIDs referenced within this MRID should also be listed on the data matrix. 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). 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). 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		

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			product chemistry data previously for that source of the active ingredient for another end use product, the active ingredient is considered unregistered. If 3 or less target pests are submitted, then the action belongs in R310. For more than 7 target pests, the action belongs in R317. For the purposes of classifying proposed registration actions into PRIA categories, "pest(s) requiring efficacy" (hereafter referred to as PRE) are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, 40 CFR (Code of Federal Regulations) part 158, subpart R (87 FR 22464, https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-R). This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in PRN 2023-1 (https://www.regulations.gov/document/EPA-HQ-OPP-2020-0260-0014). To determine the number of PREs, which determines the appropriate PRIA category, pest groups, sub-groups and pest-specific claims as listed in 40 CFR Part 158, subpart R should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, flies, etc.), each group will count as 1 PRE. If seeking a claim against a pest sub-group (e.g., small biting flies, filth flies, large biting flies, subterranean termites, fire and harvester ants, fire ants, etc.), or specific species (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each sub-group or specific pest count as 1 PRE. In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim *and* a speed-of-kill claim against the singular PRE Group "Cockroaches", then this will count as a *singular* PRE as long as the submitted or cited data adequately addresses each claim against the PRE. Refer to the interpretation in R310 for examples on how to calculate the total number of PRE. 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		

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			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.		
R317	59	New end-use or 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: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. pest(s) requiring efficacy – for greater than 7 target pests	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 a single product that is 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. Applicants should identify in the cover letter and/or EPA application form (8570-1, in the comment field) the registered products that are being referenced for formulation and uses which contains the same use(s) and formulation type as the proposed product label. To fit this category, all applications require the following but are not limited to: • Certification with Respect to Citation of Data and a Data Matrix. • Companies/registrants cannot claim formulator's exemption for a product they own, 40 CFR 152.85(b) and FIFRA 3 (c)(2)(D), and therefore, the formulation must be listed on the CSF. A data matrix is required with the application. • 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. If submitting self-certification for Group B data, an MRID must be assigned. • 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). • 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. If using selective data citation for acute toxicity data, list only one set of data (i.e., 6-pack, single MRID per guideline) to support the proposed product on the data matrix. A rationale for a waiver or bridging of these data falls within this category. If a bridging rationale or waiver request is submitted for any guideline, it must be assigned an MRID and listed on the data matrix. Any other MRIDs referenced within this MRID should also be listed on the data matrix.	10	23,029

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		(2)(3)(4)	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). 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). 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. If 3 or less target pests are submitted, then the action belongs in R310. For 4 to 7 target pests, the action belongs in R316. For the purposes of classifying proposed registration actions into PRIA categories, "pest(s) requiring efficacy" (hereafter referred to as PRE) are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, 40 CFR (Code of Federal Regulations) part 158, subpart R (87 FR 22464, https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-R). This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in PRN 2023-1 (https://www.regulations.gov/document/EPA-HQ-OPP-2020-0260-0014). To determine the number of PREs, which determines the appropriate PRIA category, pest groups, sub-groups and pest-specific claims as listed in 40 CFR Part 158, subpart R should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, flies, etc.), each group will count as 1 PRE. If seeking a claim against a pest sub-group (e.g., small biting flies, filth flies, large biting flies,		

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			subterranean termites, fire and harvester ants, fire ants, etc.), or specific species (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each sub-group or specific pest count as 1 PRE. In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim *and* a speed-of-kill claim against the singular PRE Group "Cockroaches", then this will count as a *singular* PRE as long as the submitted or cited data adequately addresses each claim against the PRE. Refer to the interpretation in R310 for examples on how to calculate the total number of PRE. 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.		
R320	60	New product; new physical form; requires data review in science divisions (2)(3)(5)	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. New uses for the active ingredient are not covered under this category (See Table 2). Applications for new end use products that are submitted using an unregistered source of an	12	19,906

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			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 unregistered source of the active ingredient for another end use product, the active ingredient is considered unregistered. 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). 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. 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.		
R331	61	New product; repack of identical registered end-use product as a manufacturing-use product; same registered uses only (2)(3)	An application for registration of a manufacturing use pesticide product that is identical in its formulation and uses to an end use product that is currently registered. The registrant must identify in the Application Form (EPA Form 8570-1) the currently registered end use product to be repacked. To fit this category, all applications require the following but are not limited to: • A Formulator's Exemption statement. • Companies/registrants cannot claim formulator's exemption for a product they own, 40 CFR 152.85(b) and FIFRA 3 (c)(2)(D).	3	3,809

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			• Only one CSF per registration (listing a single registered end use product to be repackaged). • The active ingredient listed on the CSF must be an EPA registered product in order to satisfy the data requirements for the active ingredient. This category does not include data review or submission of a data matrix. The proposed MUP label can only have use sites identical to (or a subset of) the single repacked end use product (of the same formulation type). If the use sites for the proposed product differs from the currently registered repacked end use product, then additional data are required, and the application does not qualify for a repack or fall within this category. If the formulator's exemption statement is not available to the applicant, the application falls under another category (e.g., R300); in such cases the full formula of the end use product will need to be listed on the CSF, and generic and product-specific data citations will need to be provided on the data matrix. 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.		
R332	62	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of completely new	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: • Certification with Respect to Citation of Data and a Data Matrix.	24	426,215

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
		generic data package; registered uses only; requires review in RD and science divisions (2)(3)	• Product chemistry data (Group A and B) and CSF. • 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. If a bridging rationale or waiver request is submitted for any guideline, it must be assigned an MRID and listed on the data matrix. Any other MRIDs referenced within this MRID should also be listed on the data matrix. • The source of the active ingredient is unregistered. • The proposed uses must already be on currently registered products. • The applicant must cite the similar product with the proposed uses. • The application contains generic data such as toxicity, environmental fate and/or eco-toxicity. 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 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	63	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	An application for registration of a new product (MUP or end use product) where the active ingredient used in the formulation is derived from an unregistered source (i.e., does not have an EPA registration number) and is supported by cite-all or selective data citation where the applicant owns all data. 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) 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; cite-all or selective data citation where the applicant owns all required data. Applicants should identify in the cover letter and/or EPA application form (8570-1, in the comment field) the registered product that is being referenced for formulation and uses which contains the same use(s) and formulation type as the proposed product label. If the	11	29,856

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
		(2)(3)	submission includes addition of multiple unregistered sources/production sites, Group A data for each unregistered source should be submitted in separate MRIDs. Also, an additional fee will be charged for each additional unregistered source of active ingredient that is included in the application. To fit this category, all applications require the following but are not limited to: • Certification with Respect to Citation of Data and a Data Matrix. • If registering an MUP that is a technical product, one set of product specific product chemistry data and CSF is required (under #1 below). • If registering an end-use product, two sets of product chemistry data and CSFs are required ((under #1 and #2 below). 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 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. If submitting self-certification for Group B data, an MRID must be assigned. • 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). • 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. If using selective data citation for acute toxicity data, list only one set of data (i.e., 6-pack, single MRID per guideline) to support the proposed product on the data matrix. A rationale for a waiver or bridging of these data falls within this category. If a bridging rationale or waiver request is submitted for any guideline, it must be assigned an MRID and listed on the data matrix. Any other MRIDs referenced within this MRID should also be listed on the data matrix. • Proposed label for the MUP and/or end use product.		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
			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.		
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)	An application for registration of a new product (MUP or end use product) where the active ingredient used in the formulation is derived from an unregistered source (i.e., does not have an EPA registration number) and is supported by selective data citation. 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. Applicants should identify in the cover letter and/or EPA application form (8570-1, in the comment field) the registered product that is being referenced for formulation and uses which contains the same use(s) and formulation type as the proposed product label. If the submission includes addition of multiple unregistered sources/production sites, Group A data for each unregistered source should be submitted in separate MRIDs. Also, an additional fee will be charged for each additional unregistered source of active ingredient that is included in the application. To fit this category, all applications require the following but are not limited to: • Certification with Respect to Citation of Data and a Data Matrix. • If registering an MUP that is a technical product, one set of product specific product chemistry data and CSF is required (under #1 below). • If registering an end-use product, two sets of product chemistry data and CSFs are required ((under #1 and #2 below).	12	34,764

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
			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 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. If submitting self-certification for Group B data, an MRID must be assigned. • 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). • 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. When using selective data citation for acute toxicity data, list only one set of data (i.e., 6-pack, single MRID per guideline) to support the proposed product on the data matrix. A rationale for a waiver or bridging of these data falls within this category. If a bridging rationale or waiver request is submitted for any guideline, it must be assigned an MRID and listed on the data matrix. Any other MRIDs referenced within this MRID should also be listed on the data matrix. • Proposed label for the MUP and/or end use product The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product 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.		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
R361	65 (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 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: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. pest(s) requiring efficacy	An application for registration of a new end-use product that contains up to three registered conventional 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 (only one registered label per active ingredient). If the new combination product in this category requires efficacy data, more than 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 use a registered source of active ingredient. Any science review must be within RD only. The application package should include a complimentary use table listing the currently registered identical or substantially similar products from which the most restrictive directions for use/parameters such as use rates, PHI, REI, etc. were used to generate the proposed label. To fit this category, all applications require the following but are not limited to: • Certification with Respect to Citation of Data and a Data Matrix. • Companies/registrants cannot claim formulator's exemption for a product they own, 40 CFR 152.85(b) and FIFRA 3 (c)(2)(D), and therefore, the formulation must be listed on the CSF. • 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. If submitting self-certification for Group B data, an MRID must be assigned. • 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). • 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. If a bridging rationale or waiver request is submitted for any guideline, it must be assigned an MRID and listed on the data matrix. Any other MRIDs referenced within this MRID should also be listed on the data matrix. 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 the application contains up to three active ingredients never registered before in combination that span regulatory divisions (antimicrobial, biopesticide, conventional) and require coordination among those divisions, the application does not belong in this category	12	24,570

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
		– for more than 7 target pests (2)(3)(4)	(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. If 3 or less target pests are submitted, then the action belongs in R314. For 4 to 7 target pests, the action belongs in R319. For the purposes of classifying proposed registration actions into PRIA categories, "pest(s) requiring efficacy" (hereafter referred to as PRE) are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, 40 CFR (Code of Federal Regulations) part 158, subpart R (87 FR 22464, https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-R). This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in PRN 2023-1 (https://www.regulations.gov/document/EPA-HQ-OPP-2020-0260-0014). To determine the number of PREs, which determines the appropriate PRIA category, pest groups, sub-groups and pest-specific claims as listed in 40 CFR Part 158, subpart R should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, flies, etc.), each group will count as 1 PRE. If seeking a claim against a pest sub-group (e.g., small biting flies, filth flies, large biting flies, subterranean termites, fire and harvester ants, fire ants, etc.), or specific species (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each sub-group or specific pest count as 1 PRE. In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim *and* a speed-of-kill claim against the singular PRE Group "Cockroaches", then this will count as a *singular* PRE as long as the submitted or cited data adequately addresses each claim against the PRE.		

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			Refer to the interpretation in R310 for examples on how to calculate the total number of PRE. 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.		
R362	66 (new)	New end-use 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	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 (only one registered label per active ingredient). If the new combination product in this category requires efficacy review, data for greater than 7 target pests can be submitted or cited. 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. The application package should include a complimentary use table listing the currently registered identical or substantially similar products from which the most restrictive directions for use/parameters such as use rates, PHI, REI, etc. were used to generate the proposed label. To fit this category, all applications require the following but are not limited to: • Certification with Respect to Citation of Data and a Data Matrix. • Companies/registrants cannot claim formulator's exemption for a product they own, 40 CFR 152.85(b) and FIFRA 3 (c)(2)(D), and therefore, the formulation must be listed on the CSF. • 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. If submitting self-certification for Group B data, an MRID must be assigned.	13	26,618

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
		requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only: 1. product chemistry and/or 2. acute toxicity and/or 3. child resistant packaging and/or 4. pest(s) requiring efficacy – for more than 7 target pests (2)(3)(4)	• 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). • 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. If a bridging rationale or waiver request is submitted for any guideline, it must be assigned an MRID and listed on the data matrix. Any other MRIDs referenced within this MRID should also be listed on the data matrix. 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 the application contains four or more active ingredients never registered before in combination that span regulatory divisions (antimicrobial, biopesticide, conventional) and require coordination among 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. If 3 or less target pests are submitted, then the action belongs in R318. For 4 to 7 target pests, the action belongs in R321. For the purposes of classifying proposed registration actions into PRIA categories, “pest(s) requiring efficacy” (hereafter referred to as PRE) are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, 40 CFR (Code of Federal Regulations) part 158, subpart R (87 FR 22464, https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-		

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			R). This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in PRN 2023-1 (https://www.regulations.gov/document/EPA-HQ-OPP-2020-0260-0014). To determine the number of PREs, which determines the appropriate PRIA category, pest groups, sub-groups and pest-specific claims as listed in 40 CFR Part 158, subpart R should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, flies, etc.), each group will count as 1 PRE. If seeking a claim against a pest sub-group (e.g., small biting flies, filth flies, large biting flies, subterranean termites, fire and harvester ants, fire ants, etc.), or specific species (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each sub-group or specific pest count as 1 PRE. In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim *and* a speed-of-kill claim against the singular PRE Group "Cockroaches", then this will count as a *singular* PRE as long as the submitted or cited data adequately addresses each claim against the PRE. Refer to the interpretation in R310 for examples on how to calculate the total number of PRE. 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.		
R363	67 (new)	New product; repack of identical registered manufacturing-use product as an end-	An application for registration of an end use pesticide product that is identical in its formulation and use sites to a manufacturing use product (MUP) that is currently registered. The registrant must identify in the Application Form (EPA Form 8570-1) the currently registered MUP to be repacked, as well as a single currently registered end use product (of the same formulation type as the MUP). This cited end use product must have identical uses	6	8,190

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		use product; same registered uses only, with no additional data (2)(3)	(or a subset) as the MUP, that will be listed on the proposed end use product label. To fit this category, all applications require the following: • A Formulator's Exemption statement • Companies/registrants cannot claim formulator's exemption for a product they own, 40 CFR 152.85(b) and FIFRA 3 (c)(2)(D). • Only one CSF per registration (listing a single registered MUP to be repackaged). • The active ingredient listed on the CSF must be an EPA registered product in order to satisfy the data requirements for the active ingredient. This category does not include submission of data matrix or data review. If the use sites for the proposed product differs from the currently registered repacked MUP, then additional data are required, and the application does not qualify for a repack or fall within this category. If the formulator's exemption statement is not available to the applicant, the application falls under another category (e.g., R310); in such cases the full formula of the end use product will need to be listed on the CSF, and generic and product-specific data citations will need to be provided on the data matrix. This category does not apply to proposed end use labels containing structural pest claims, public health pest claims, quarantine pest claims; companion animal products or products that have child-resistant packaging. 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 the 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.		

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

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) For the purposes of classifying proposed registration actions into PRIA categories, ''pest(s) requiring efficacy'' are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, subpart R of part 158 of title 40, Code of Federal Regulations. This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in the Pesticide Registration Notice 2002-1. To determine the number of pests for the PRIA categories, pest groups, subgroups, and pest specific claims as listed in part 158 of title 40, Code of Federal Regulations, should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, etc.), each group will count as 1. If seeking a claim against a pest subgroup (e.g., small biting flies, filth flies, etc.) or specific pests (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each subgroup or specific pest will count as 1.

(5) 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.