

## PRIA 4 Interpretations

**TABLE 3. REGISTRATION DIVISION - IMPORT AND OTHER TOLERANCES**

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
R280	34	Establish Import tolerance; new active ingredient or first food use (2) [This footnote modified for an import tolerance]	<p>A petition for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product or a petition for the first food use. The petition proposes the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The food or feed commodities are imported into the U.S. The applicant is not seeking a domestic registration for the new active ingredient and no tolerances exist in the U.S. for the active ingredient. For the first food use, there is a currently U.S. registered non-food use product and the applicant is not seeking a domestic registration for the proposed food use. All food tolerances included in the original petition for a new active ingredient or a first food use are covered by the base fee for that application in this category if submitted simultaneously. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags.</p> <p>Each application for a new inert ingredient approval that is submitted within this new</p>	21	335,026

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			<p>active ingredient package is subject to the registration service fee for a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time.</p> <p>Until the import tolerance(s) for an unregistered active ingredient or a registered non-food active ingredient is approved, any subsequent application for an additional import tolerance will be charged the R280 service fee and decision review timeframe.</p> <p>If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the import tolerance application.</p>		
R290	35	Establish Import tolerance; Additional new food use	<p>A petition application that proposes the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA for an active ingredient that has a currently approved U.S. food tolerance. The food or feed commodities are imported into the US. If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been established, then requesting the crop group will count as one additional use. The applicant is not seeking a domestic registration for the additional food use. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags.</p>	15	67,007

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R291	36	Establish import tolerances; additional food uses; 6 or more crops submitted in one petition	A petition application that proposes the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA for an active ingredient that has a currently approved U.S. food tolerance. The food or feed commodities will be imported into the US. The applicant is not seeking a domestic registration for the additional food use. The petition must propose at least (6) specific food or feed crops or 6 or more representative commodities for crop subgroups or crop groups. If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been established, then requesting the crop group will count as one additional use.	15	402,031
R292	37	Amend an established tolerance (e.g., decrease or increase) and/or harmonize established tolerances with Codex MRLs; domestic or import;	A petition to amend an existing tolerance on domestic or imported crops and for which there is not a related label amendment request necessitating the proposed tolerance amendment. This may be a request to increase or decrease an existing tolerance currently established under section 408 of the FFDCA. The fee for this category applies to each additional food use to which the requested tolerance amendments apply, up to 5 uses (i.e. the fee for this category is multiplied by 4 if 4 uses are proposed). If tolerance amendments are being requested for six or more uses, the fee category R297 applies. For purposes of counting, all tolerance amendments within a commodity (e.g., tomato) are counted as one use. If amendment to a crop group or subgroup tolerance is requested, the fee is based on the number of representative crops in that group or subgroup. This category is applicable when a tolerance amendment is being requested but no related label amendment is necessary or being requested.	11	47,609

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		applicant-initiated Domestic or import; applicant-initiated	<p>Additionally, this category includes an applicant's request to amend established tolerances to harmonize with existing Codex Maximum Residue Limits (MRLs) for an active ingredient. The base fee for the category covers all proposed tolerance amendments related to harmonization with Codex MRLs, provided no related label amendments or residue data are provided in conjunction with the harmonization request. A Codex MRL-related tolerance amendment request will count as one use in the multiplier framework described in the previous paragraph.</p> <p>Examples of situations to which this category might apply include but are not limited to requests to amend an existing tolerance (decrease level), requests to increase an existing tolerance to reflect residue data demonstrating higher observed residues than the existing tolerance, or requests to move an existing tolerance from one paragraph to another within the citation in 40 CFR Part 180. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags.</p> <p>If a tolerance amendment petition also requests the establishment of a tolerance in association with the raw agricultural commodity (RAC) (e.g., a processed form of the RAC for which a tolerance was not previously established), this tolerance establishment activity falls under R170.</p>		
R293	38	Establish tolerance(s) for	A petition that proposes to establish tolerances for each non-target crop resulting in inadvertent residues. The active ingredient is currently contained in a pesticide product registered in the U.S. The fee to establish tolerances for each crop will be multiplied by	12	56,158

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		inadvertent residues in one crop; applicant-initiated	the number of crops in the petition (i.e. 5 crops, the fee will be multiplied 5 times the fee for this category). If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been registered, then requesting the crop group will count as one additional use.		
R294	39	Establish tolerances for inadvertent residues; 6 or more crops submitted in one application; applicant-initiated	A petition that proposes to establish tolerances for 6 or more non-target crops resulting in inadvertent residues. The active ingredient is currently contained in a pesticide product registered in the U.S. If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been registered, then requesting the crop group will count as one additional use.	12	336,939
R295	40	Establish tolerances(s) for residues in one rotational crop in response to a specific rotational crop application; submission of corresponding	A petition that proposes to establish tolerances for each crop that is rotated and results in rotational crop residues. The active ingredient is currently contained in a pesticide product registered in the U.S. The fee to establish tolerances for each crop will be multiplied by the number of crops in the petition (i.e. 5 crops, the fee will be multiplied 5 times the fee for this category). If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been registered, then requesting the crop group will count as one additional use. The establishment of rotational crop tolerances usually also involves label amendments which specify the	15	69,431

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		label amendments which specify the necessary plant-back restrictions; applicant-initiated	<p>necessary plant-back restrictions. This category covers the establishment of the rotational crop tolerance as well as the corresponding label amendments which specify the necessary plant-back restrictions. Additional amendment requests not related to the proposed tolerance amendment would not be covered under this category.</p> <p>Amendment applications to add the revised use pattern(s) to registered product labels are covered by the base fee for the category. All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the amendment application package is subject to the registration service fee for a new product or a new inert approval. However, if an amendment application only proposes to register the amendment for a new product and there are no amendments in the application, then review of one new product application is covered by the base fee. All such associated applications that are submitted together will be subject to the category decision review time.</p> <p>The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested amendment 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</p>		

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			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.		
R296	41	Establish tolerances for residues in rotational crops in response to a specific rotational crop petition; 6 or more crops submitted in one application; submission of corresponding label amendments which specify the necessary plant-back restrictions;	<p>A petition that proposes to establish tolerances for 6 or more crops that are rotated and results in rotational crop residues. The active ingredient is currently contained in a pesticide product registered in the U.S. If a crop group or subgroup is requested, the fee is based on the number of representative crops in that group or subgroup that are not currently registered. If all of the representative crops have been registered, then requesting the crop group will count as one additional use. The establishment of rotational crop tolerances usually also involves label amendments which specify the necessary plant-back restrictions. This category covers the establishment of the rotational crop tolerances as well as the corresponding label amendments which specify the necessary plant-back restrictions.</p> <p>Additional amendment requests not related to the proposed tolerance amendment would not be covered under this category.</p> <p>Amendment applications to add the revised use pattern(s) to registered product labels are covered by the base fee for the category. All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the amendment application package is subject to the registration service fee for a new product or a new inert approval. However, if an amendment application only proposes to register the</p>	15	416,580

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		applicant initiated;	<p>amendment for a new product and there are no amendments in the application, then review of one new product application is covered by the base fee. All such associated applications that are submitted together will be subject to the category decision review time.</p> <p>The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.</p>		
R297	42	Amend 6 or more established tolerances (e.g. decrease or increase) in one petition; domestic or	A petition to amend six or more existing tolerances on domestic or imported crops and for which there is not a related label amendment request necessitating the proposed tolerance amendments. This may be a request to increase or decrease existing tolerances currently established under section 408 of the FFDCA. This category is applicable when tolerance amendments are being requested but no related label amendment is necessary or being requested. For purposes of counting, all tolerance amendments within a commodity (e.g., tomato) are counted as one use. If amendment to a crop group or subgroup tolerance is requested, the fee is based on the number of	11	285,639



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		import; applicant initiated	<p>representative crops in that group or subgroup. Examples of situations to which this category might apply include but are not limited to requests to increase 6 or more existing tolerances to reflect residue data demonstrating higher observed residues than the existing tolerances or requests to move 6 or more existing tolerances from one paragraph to another within the citation in 40 CFR Part180. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags.</p> <p>If a tolerance amendment petition also requests the establishment of a tolerance in association with the raw agricultural commodity (RAC) (e.g., a processed form of the RAC for which a tolerance was not previously established), this tolerance establishment activity falls under R170.</p>		
R298	43	Amend an established tolerance (e.g., decrease or increase); domestic or import; submission of corresponding	<p>An application and/or a petition request to amend an existing tolerance on domestic or imported crops in which an associated label amendment is also submitted. This may be a request to increase or decrease an existing tolerance(s) currently established under section 408 of the FFDCA. The fee for this category applies to tolerance amendments for each food use requested up to 5 uses (i.e. the fee for this category is multiplied by 4 if tolerance amendments for 4 uses are proposed) to which the label amendments apply. If tolerance and label amendments are being requested for six or more uses, the fee category <a href="#">R299</a> applies.</p>	13	61,494

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		amended labels (requiring science review) in addition to those associated with the amended tolerance; applicant-initiated	<p>This category (R298) applies to requests to a change in the labeled use pattern in a way which results in the need for the tolerance to be amended; often residue data supporting the tolerance amendment is included in the request. Examples of label changes that can require changes in tolerances include but are not limited to: changes in application rates, application frequency, application timing, application method or a change in PHIs); Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. Additional PRIA amendment requests not related to the proposed tolerance amendment would not be covered under this category.</p> <p>If a tolerance amendment petition also requests the establishment of a tolerance in association with the raw agricultural commodity (RAC) (e.g., a processed form of the RAC for which a tolerance was not previously established), this tolerance establishment activity falls under R170.</p> <p>All of the inerts used in this product must be either approved or pending with the Agency for the applicable uses.</p>		

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			<p>The Agency will provide the applicant with a pre-decisional determination 4 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested tolerance amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.</p>		
R299	44	Amend 6 or more established tolerances (e.g., decrease or increase); domestic or import; submission of corresponding amended labels	<p>An application and/or a petition request to amend six or more existing tolerances on domestic or imported crops in which an associated label amendment is also submitted. This may be a request to increase or decrease existing tolerances currently established under section 408 of the FFDCA. This category applies to requests to a change to the labeled use pattern in a way which results in the need for existing tolerances to be amended; often residue data supporting the tolerance amendments is included in the request. Examples of label changes that can require changes in tolerances include but</p>	13	299,525

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		(requiring science review) (3)(4)	<p>are not limited to: changes in application rates, application frequency, application timing, application method or a change in PHIs). Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. Additional PRIA amendment requests not related to the proposed tolerance amendments would not be covered under this category.</p> <p>If a tolerance amendment petition also requests the establishment of a tolerance in association with the raw agricultural commodity (RAC) (e.g., a processed form of the RAC for which a tolerance was not previously established), this tolerance establishment activity falls under R170.</p> <p>All of the inerts used in this product must be either approved or pending with the Agency for the applicable uses.</p> <p>The Agency will provide the applicant with a pre-decisional determination 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 tolerance amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a</p>		

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			<p>PRIA due date time extension has not been agreed upon, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.</p>		