PRIA 4 Interpretations

TABLE 18. INERT INGREDIENTS

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
I001	186	Approval of new food use inert ingredient (2) (3)	An application that proposes a food use approval for an inert ingredient that is not contained in any pesticide product registered for use in or on food. The use may require the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application must contain a petition to establish tolerances or exemptions from the requirement of a tolerance for all food/feed commodities for which food use approval is sought as well as the submission of data supporting the petition. 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; uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags and food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment). Prior to a submission under this category, OPP highly recommends the applicant request a meeting with the Agency to go over data needs. Additional information regarding applications for approval of new food use inert ingredients can be found at http://www.epa.gov/opprd001/inerts/inertpetition.pdf (4 pp 28.51 k PDF). If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients. This category does not include safeners [see category I011]. If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval	13	28,350

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due date for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If EPA data rules are amended to newly require clearance under section 408 of the FFDCA for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.		
I002	187	Amend currently approved inert ingredient tolerance or exemption from tolerance; new data (2)	An application that proposes a change in food use approval for an inert ingredient. The use requires an amendment to a tolerance or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application must contain a petition to amend existing tolerances or exemptions from the requirement of a tolerance for all food/feed commodities for which food use approval is sought as well as the submission of data supporting the amendment (e.g., toxicity data, residue chemistry data). This category also applies to inert ingredients for which an EPA risk assessment has not been conducted since 2006 even when no	11	7,875

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			new data are submitted. This category fits for changes in food use that require a change to the existing tolerance or tolerance exemption such as an increase in the limitation of the percentage of the inert ingredient under an existing tolerance exemption or the expansion of use limitations under an existing tolerance exemption such as the removal of a pre-emergent only 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; uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags and food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment). This category does not include safeners [see category I013]. Prior to a submission under this category, OPP highly recommends the applicant request a meeting with the Agency to discuss data needs. Additional information regarding applications for approval of new food use inert ingredients can be found at http://www.epa.gov/opprd001/inerts/inertpetition.pdf (4 pp 28.51 k PDF). If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action,		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			unless the decision review time due date for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I003	188	Amend currently approved inert ingredient tolerance or exemption from tolerance; no new data (2)	An application that proposes a change in food use for an inert ingredient. The use requires an amendment to a tolerance (or the exemption from the requirement of a tolerance) under section 408 of the FFDCA. The application submission must contain a petition to amend existing tolerances or exemptions from the requirement for all food/feed commodities for which food use approval is sought, but does not include the submission of data. This category does not include submissions for which an EPA risk assessment has not been conducted since 2006. Such submissions fall into category I002 even when no new data are submitted. This category fits for changes in food use that require a change to the existing tolerance or tolerance exemption that do not require the submission of data such as a change in the limitation of the percentage of the inert ingredient under an existing tolerance exemption or change in use limitations under an existing tolerance. 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; uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags and food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment). This category does not include safeners [see category I013]. Prior to a submission under this category OPP highly recommends the applicant request a meeting with the Agency to discuss data needs. Additional information regarding applications for approval of new food use inert ingredients can be found at http://www.epa.gov/opprd001/inerts/inertpetition.pdf (4 pp 28.51 k PDF).	9	3,474

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due date for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I004	189	Approval of new non-food use inert ingredient (2)	An application that proposes a new non-food use for an inert ingredient that is not currently approved for non-food use and is accompanied by the submission of supporting data (e.g., toxicity data, environmental fate data, ecotoxicity data). A non-food use includes a proposed use that is not a food use as described in the food use categories. Non-food uses could include treatment of ornamentals, turf uses, structural protection, residential use, cooling tower treatments, aquatic area application (e.g., wastewater treatment), oil fields (marine and terrestrial), sewage treatment plants (water is treated prior to discharge into the environment), wood preservatives, antifoulants, ballast water, residential use (e.g., carpet sanitizer, hard surface disinfectant), commercial, institutional, industrial premise and	6	11,577

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			equipment (e.g. offices, hotels, industrial buildings, nursing homes), agricultural premise treatment (e.g., farm structures, buildings and equipment, animal drinking water), materials preservatives (e.g., adhesives, coatings, plastic, fabric), industrial processes and water systems treatment (e.g., reverse osmosis water systems, recirculating cooling tower systems, evaporative condensers), medical premises and equipment (e.g., dental equipment, dental unit water lines, hospitals), HVAC, swimming pools, and spas. This category does not include safeners [see category I012]. Prior to a submission under this category, OPP highly recommends the applicant request a meeting with the Agency to discuss data needs. Additional information regarding applications for approval of new non-food use inert ingredients can be found at http://www.epa.gov/opprd001/inerts/nonfood_inert.pdf (3 pp 24.27 k PDF). If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due date for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time.		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I005	190	Amend currently approved non-food use inert ingredient with new use pattern; new data (2)	An application that proposes to amend a non-food use inert ingredient approval to include a new use pattern and is accompanied by the submission of supporting data (e.g., toxicity data, environmental fate data, ecotoxicity data). A non-food use includes a proposed use that is not a food use as described in the food use categories. Non-food uses could include treatment of ornamentals, turf uses, structural protection, residential use, cooling tower treatments, aquatic area application (e.g., wastewater treatment), oil fields (marine and terrestrial), sewage treatment plants (water is treated prior to discharge into the environment), wood preservatives, antifoulants, ballast water, residential use (e.g., carpet sanitizer, hard surface disinfectant), commercial, institutional, industrial premise and equipment (e.g. offices, hotels, industrial buildings, nursing homes), agricultural premise treatment (e.g., farm structures, buildings and equipment, animal drinking water), materials preservatives (e.g., adhesives, coatings, plastic, fabric), industrial processes and water systems treatment (e.g., reverse osmosis water systems, recirculating cooling tower systems, evaporative condensers), medical premises and equipment (e.g., dental equipment, dental unit water lines, hospitals), HVAC, swimming pools, and spas. This category does not include safeners [see category I014]. Prior to submission under this category, OPP highly recommends the applicant request a meeting with the Agency to discuss data needs. Additional information regarding applications for approval of new non-food use inert ingredients can be found at http://www.epa.gov/opprd001/inerts/nonfood_inert.pdf (3 pp 24.27 k PDF) If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's	6	5,789

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due date for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I006	191	Amend currently approved non-food use inert ingredient with new use pattern; no new data (2)	An application that proposes to amend a non-food use inert ingredient approval to include a new use and does not require the submission of supporting data. A non-food use includes a proposed use that is not a food use as described in the food use categories. Non-food uses could include treatment of ornamentals, turf uses, structural protection, residential use, cooling tower treatments, aquatic area application (e.g., wastewater treatment), oil fields (marine and terrestrial), sewage treatment plants (water is treated prior to discharge into the environment), wood preservatives, antifoulants, ballast water, residential use (e.g., carpet sanitizer, hard surface disinfectant), commercial, institutional, industrial premise and equipment (e.g. offices, hotels, industrial buildings, nursing homes), agricultural premise treatment (e.g., farm structures, buildings and equipment, animal drinking water), materials preservatives (e.g., adhesives, coatings, plastic, fabric), industrial processes and water systems treatment (e.g., reverse osmosis water systems, recirculating cooling tower systems, evaporative condensers), medical premises and equipment (e.g., dental equipment,	3	3,474

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			dental unit water lines, hospitals), HVAC, swimming pools, and spas. This category does not include safeners [see category I014]. Prior to a submission under this category OPP highly recommends the applicant request a meeting with the Agency to ensure that no additional data are required. Additional information regarding applications for approval of new non-food use inert ingredients can be found at http://www.epa.gov/opprd001/inerts/nonfood_inert.pdf (3 pp 24.27 k PDF). If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due date for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I007	192	Approval of substantially	An application that proposes a new non-food use for an inert ingredient which is proposed to be compositionally similar with a similar use pattern to an approved non-food use inert	4	1,737

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
		similar non-food use inert ingredients when original inert is compositionally similar with similar use pattern (2)	ingredient. The compositionally similar non-food use inert ingredient must be cited by the applicant and have been previously assessed by OPP and approved for use. Additionally, the applicant must demonstrate that the substantially similar inert ingredient does not differ in ways that would increase the risk of unreasonable adverse effects. A non-food use includes a proposed use that is not a food use as described in the food use categories. Non-food uses could include treatment of ornamentals, turf uses, structural protection, residential use, cooling tower treatments, aquatic area application (e.g., wastewater treatment), oil fields (marine and terrestrial), sewage treatment plants (water is treated prior to discharge into the environment), wood preservatives, antifoulants, ballast water, residential use (e.g., carpet sanitizer, hard surface disinfectant), commercial, institutional, industrial premise and equipment (e.g. offices, hotels, industrial buildings, nursing homes), agricultural premise treatment (e.g., farm structures, buildings and equipment, animal drinking water), materials preservatives (e.g., adhesives, coatings, plastic, fabric), industrial processes and water systems treatment (e.g., reverse osmosis water systems, recirculating cooling tower systems, evaporative condensers), medical premises and equipment (e.g., dental equipment, dental unit water lines, hospitals), HVAC, swimming pools, and spas. This category does not include safeners [see categories I011 or I012]. Prior to a submission under this category OPP highly recommends the applicant request a meeting with the Agency to ensure that no additional data are required. Additional information regarding applications for approval of new non-food use inert ingredients can be found at http://www.epa.gov/opprd001/inerts/nonfood_inert.pdf (3 pp 24.27 k PDF). If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the		

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			applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due date for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I008	193	Approval of new or amended polymer inert ingredient, food use (2)	An application that proposes a food use for a new or amended inert ingredient that meets the definition of a low risk polymer and all eligibility criteria as given under 40 CFR 723.250. The use requires the establishment of (or the exemption from the requirement of) a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemptions from the requirement for all food/feed commodities covered by the pending application. 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; uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags and food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment). Information demonstrating conformance with 40 CFR 723.250 must accompany the application. Prior to a submission under this category, OPP highly recommends the applicant request a meeting with the Agency to verify conformance with the 40 CFR 723.250 criteria. Additional information regarding applications for approval of new food use polymer	5	3,937

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			inert ingredients can be found at http://www.epa.gov/opprd001/inerts/lowriskpolymer.pdf (5 pp 30.73 k PDF). If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due date for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I009	194	Approval of new or amended polymer inert ingredient, non food use (2)	An application that proposes a non-food use for a new or amended inert ingredient which meets the definition of a low risk polymer and all eligibility criteria as given under 40 CFR 723.250. A non-food use includes a proposed use that is not a food use as described in the food use categories. Non- food uses could include treatment of ornamentals, turf uses, structural protection, residential use, cooling tower treatments, aquatic area application (e.g., wastewater treatment), oil fields (marine and terrestrial), sewage treatment plants (water is	4	3,242

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			treated prior to discharge into the environment), wood preservatives, antifoulants, ballast water, residential use (e.g., carpet sanitizer, hard surface disinfectant), commercial, institutional, industrial premise and equipment (e.g. offices, hotels, industrial buildings, nursing homes), agricultural premise treatment (e.g., farm structures, buildings and equipment, animal drinking water), materials preservatives (e.g., adhesives, coatings, plastic, fabric), industrial processes and water systems treatment (e.g., reverse osmosis water systems, recirculating cooling tower systems, evaporative condensers), medical premises and equipment (e.g., dental equipment, dental unit water lines, hospitals), HVAC, swimming pools, and spas. Information demonstrating conformance with 40 CFR 723.250 must accompany the application. Prior to a submission under this category, OPP highly recommends the applicant request a meeting with the Agency to verify conformance with the 40 CFR 723.250 criteria. Additional information regarding applications for approval of new non-food use polymer inert ingredients can be found at http://www.epa.gov/opprd001/inerts/lowriskpolymer.pdf (5 pp 30.73 k PDF). If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due date for the dependent covered application is further		

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			out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I010	195	Petition to amend a single tolerance exemption descriptor, or single non-food use descriptor, to add ≤10 CASRNs; no new data (2)	An application that proposes to amend a single tolerance exemption descriptor or single non-food use descriptor by adding ≤ 10 CAS Registry Numbers (CASRNs) to an existing tolerance exemption expression in which the tolerance exemption descriptor is for grouping of closely related substances with associated CASRNs rather than a single chemical entity. (An example of such a descriptor is "Dimethylaminopropylamine, isopropylamine, ethanolamine, and triethanolamine salts of alkyl (C8-C24) benzenesulfonic acid "). An application under this category must demonstrate that the additional CASRNs to be added to the tolerance exemption expression are part of the grouping and are supported by the safety finding that was made to establish the group tolerance exemption. The application submission must contain a petition to amend existing tolerances or exemptions from the requirement but does not include the submission of data. Prior to a submission under this category OPP highly recommends the applicant request a meeting with the Agency to ensure that no additional data are required. Additional information regarding applications for approval of new food use inert ingredients can be found at http://www.epa.gov/opprd001/inerts/inertpetition.pdf (4 pp 28.51 k PDF). If another covered application intends to associate with and depend upon an already pending application for an inert ingredient approval in this category, the dependent application must identify the pending inert ingredient action with its inert approval tracking number assigned by the Agency, name of the inert ingredient(s) that is pending and the inert ingredient's applicant's name. Due to CBI concerns, the Agency will not provide information to the	6	1,737

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			applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the inert ingredient's approval action MUST come from the inert ingredient applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending inert ingredient approval action, unless the decision review time due date for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.		
I011	196 new	Approval of new food use safener with tolerance or exemption from tolerance (2)(8)	An application that proposes a food use approval for a safener (a chemical that selectively protects crop plants against herbicide injury) that is not contained in any pesticide product registered for use in or on food. The use may require the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application must contain a petition to establish tolerances or exemptions from the requirement of a tolerance for all food/feed commodities for which food use approval is sought as well as the submission of data supporting the petition. 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; uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags and food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment).	24	627,568

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			If another covered application intends to associate with and depend upon an already pending application for an approval in this category, the dependent application must identify the pending action with its inert approval tracking number assigned by the Agency, name of the safener that is pending and the safener's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending safener action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the safener's approval action MUST come from the inert ingredient applicant. If a new safener is submitted in the same package as a new active ingredient, and that new active ingredient is determined to be reduced risk, then the safener would get the same reduced timeframe as the new active ingredient. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending safener approval action, unless the decision review time due date for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time.		
I012	197 new	Approval of new non-food use safener (2)(8)	An application that proposes a new non-food use for a safener (a chemical that selectively protects crop plants against herbicide injury) inert ingredient that is not currently approved for non-food use and is accompanied by the submission of supporting data (e.g., toxicity data, environmental fate data, ecotoxicity data). A non-food use includes a proposed use that is not a food use as described in the food use categories. Non-food uses could include treatment of ornamentals, turf uses, structural	21	436,004

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			protection, residential use, cooling tower treatments, aquatic area application (e.g., wastewater treatment), oil fields (marine and terrestrial), sewage treatment plants (water is treated prior to discharge into the environment), wood preservatives, antifoulants, ballast water, residential use (e.g., carpet sanitizer, hard surface disinfectant), commercial, institutional, industrial premise and equipment (e.g. offices, hotels, industrial buildings, nursing homes), agricultural premise treatment (e.g., farm structures, buildings and equipment, animal drinking water), materials preservatives (e.g., adhesives, coatings, plastic, fabric), industrial processes and water systems treatment (e.g., reverse osmosis water systems, recirculating cooling tower systems, evaporative condensers), medical premises and equipment (e.g., dental equipment, dental unit water lines, hospitals), HVAC, swimming pools, and spas. Prior to a submission under this category, OPP highly recommends the applicant request a meeting with the Agency to discuss data needs. Additional information regarding applications for approval of new non-food use inert ingredients can be found at http://www.epa.gov/opprd001/inerts/nonfood_inert.pdf. If another covered application intends to associate with and depend upon an already pending application for a safener approval in this category, the dependent application must identify the pending safener approval action with its inert approval tracking number assigned by the Agency, name of the safener that is pending and the safener's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending safener approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the safener's approval action MUST come from the safener applicant.		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			If a new safener is submitted in the same package as a new active ingredient, and that new active ingredient is determined to be reduced risk, then the safener would get the same reduced timeframe as the new active ingredient. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending safener approval action, unless the decision review time due date for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time.		
I013	198 new	Approval of additional food use for previously approved safener with tolerance or exemption from tolerance (2)	An application that proposes a change in food use approval for a safener (a chemical that selectively protects crop plants against herbicide injury). The use requires an amendment to a tolerance or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application must contain a petition to amend existing tolerances or exemptions from the requirement of a tolerance for all food/feed commodities for which food use approval is sought as well as the submission of data supporting the amendment (e.g., toxicity data, residue chemistry data). This category fits for changes in food use that require a change to the existing tolerance or tolerance exemption. 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; uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags and food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment). If another covered application intends to associate with and depend upon an already pending application for a safener approval in this category, the dependent application	15	66,124

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			must identify the pending safener action with its inert approval tracking number assigned by the Agency, name of the safener that is pending and the safener's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending safener approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the safener's approval action MUST come from the safener applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending safener approval action, unless the decision review time due date for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time.		
I014	199 new	Approval of additional non-food use for previously approved safener (2)	An application that proposes an additional non-food use for a safener (a chemical that selectively protects crop plants against herbicide injury) inert ingredient and may be accompanied by the submission of supporting data if necessary. A non-food use includes a proposed use that is not a food use as described in the food use categories. Non-food uses could include treatment of ornamentals, turf uses, structural protection, residential use, cooling tower treatments, aquatic area application (e.g., wastewater treatment), oil fields (marine and terrestrial), sewage treatment plants (water is treated prior to discharge into the environment), wood preservatives, antifoulants, ballast water, residential use (e.g., carpet sanitizer, hard surface disinfectant), commercial, institutional, industrial premise and equipment (e.g. offices, hotels, industrial buildings, nursing homes), agricultural premise treatment (e.g., farm structures, buildings and equipment, animal drinking water), materials preservatives (e.g., adhesives, coatings, plastic, fabric), industrial processes and water systems	15	26,427

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			treatment (e.g., reverse osmosis water systems, recirculating cooling tower systems, evaporative condensers), medical premises and equipment (e.g., dental equipment, dental unit water lines, hospitals), HVAC, swimming pools, and spas. Prior to a submission under this category, OPP highly recommends the applicant request a meeting with the Agency to discuss data needs. Additional information regarding applications for approval of new non-food use inert ingredients can be found at http://www.epa.gov/opprd001/inerts/nonfood_inert.pdf. If another covered application intends to associate with and depend upon an already pending application for a safener approval in this category, the dependent application must identify the pending safener action with its inert approval tracking number assigned by the Agency, name of the safener that is pending and the safener's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending safener approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the safener's approval action MUST come from the safener applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending safener approval action, unless the decision review time due date for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time.		
I015	200 new	Approval of new generic data for previously	An application that proposes a food use approval for a new source of a safener (a chemical that selectively protects crop plants against herbicide injury) that has been previously approved for use in a pesticide product registered for use in or on food and	24	283,215

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		approved food use safener (2)	for which there is an existing tolerance or exemption from the requirement of a tolerance under section 408 of the FFDCA. The application does not cite previously submitted generic data but rather seeks to satisfy generic data requirements by submitting new generic data. The proposed uses must already be on a currently registered products. 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; uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags and food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment). If another covered application intends to associate with and depend upon an already pending application for a safener approval in this category, the dependent application must identify the pending safener action with its inert approval tracking number assigned by the Agency, name of the safener that is pending and the safener's applicant's name. Due to CBI concerns, the Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending safener approval action beyond information that must be shared to adjust decision review times for the dependent application as discussed below. All other information on the safener's approval action MUST come from the safener applicant. The decision review time due date for the dependent covered application will be extended to match the decision review time due date of the pending safener approval action, unless the decision review time due date for the dependent covered application is further out, in which case the dependent covered application will initially be subject to its own decision review time.		

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I016	201 new	Approval of amendment(s) to tolerance and label for previously approved safener(2)	An application and/or a petition request to amend an existing tolerance or exemption from the requirement of a tolerance related to an approved safener ingredient. 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 (i.e. the fee for this category is multiplied by 4 if tolerance amendments for 4 uses are proposed). If there is a related label amendment application submitted in conjunction with the tolerance amendment request for the safener, review of the label(s) is included under the base fee. If the label amendment request related to the amendment of the safener ingredient also dictates that amendment to an established tolerance(s) for active ingredient(s) are needed, additional PRIA categories may apply (e.g. R292). 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.	13	58,565