



US Environmental Protection Agency Office of Pesticide Programs

**Pesticide Registration Improvement Renewal Act (PRIA 2)
Fee Category Interpretations - Fiscal Year 2011/ 2012**

September 15, 2010

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Under the Pesticide Registration Improvement Renewal Act of 2007, there are 140 fee categories. Interpretations of these categories are provided in the tables below, are the same as those on the [Fee Determination Decision Tree](#) and the [PRIA 2 Fee Table](#) and describe the Agency's current thinking at this time. To the extent feasible, the Agency has provided examples of actions that fall within each of the 140 categories. If an applicant has a question regarding the category in which a potential submission may fall, the applicant may contact one of the [Registration Fee Ombudspersons](#). These interpretations will be revised based on experience and feedback from applicants.

The 140 fee categories have been separated into three (3) tables for the **R** (Registration Division), **A** (Antimicrobial) and **B** (Biopesticides and Pollution Prevention Division) fee categories and further separated into application types. The tables provide a crosswalk of the fee code numbers listed in the Congressional Record and the Federal Register (Published August 11, 2010 (Volume 75, Number 154) Page 48672-48683), the timeframes in which the Agency is to make a decision on the application and the fee for Fiscal Years (FY) 2011 and 2012.

New Active Ingredient

An active ingredient that is not currently contained as an active ingredient in any registered pesticide product.

New Use (As Defined in 40 CFR 152.3)

New use, when used with respect to a product containing a particular active ingredient, means:

1. Any proposed use pattern that would require the establishment of, the increase in, or the exemption from the requirement of, a tolerance or food additive regulation under section 408 or 409 of the Federal Food, Drug and Cosmetic Act;
2. Any aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern; or
3. Any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms.

Experimental Use Permit as Define in 40 CFR 172.2

Any person wishing to accumulate information necessary to register under section 3 of the Act and the regulations thereunder

1. a pesticide not registered with this Agency or
2. a registered pesticide for a use not previously approved in the registration of the pesticide may apply to the Administrator at any time for an experimental use permit. (b) Pesticides under experimental use permits may not be sold or distributed other than through participants and, if sold or distributed through participants, may be used only at an application site of a cooperator and in accordance with the terms and conditions of the experimental use permit.

Definitions for additional terms used in these interpretations are available in the [Fee Determination Decision Tree glossary](#).

Registration Division

EPA No.	CR No.	Action	Interpretation	Decision time (months)	FY 11/12 Registration Service Fee (\$)
				FY 11/12	
			Table 1. New Active Ingredients		
R010	1	New Active Ingredient, Food use	An application that proposes a food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The use may require the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCa. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted simultaneously. Some examples of food uses include corn, apples, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, pasture, rangeland, home garden, beehive, livestock, livestock housing, livestock dips, and livestock ear tags.	24	569,221
R020	2	New Active Ingredient, Food use; reduced risk	An application that proposes a food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The use may require the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCa. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted simultaneously. Some examples of food uses include corn, apples, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, pasture, rangeland, home garden, beehive, livestock, livestock housing, livestock dips, and livestock ear tags. A "reduced risk"(http://www.epa.gov/opprd001/workplan/reducedrisk.html) submission must accompany the application for registration. The Agency's Reduced Risk Committee will evaluate the submission and make the determination, based on criteria listed in PR Notice 97-3 and FIFRA 3(c)(10) (B) (-iv), whether the requested use(s) qualify as "reduced risk" when compared to currently registered pesticides for the same use(s). The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as "reduced risk" by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the non-reduced risk category and the action will receive the longer timeframes (e.g. from an R020 New Active Ingredient, Food Use, "reduced risk" to an R010 New Active Ingredient, Food Use).	18	569,221
R030	3	New Active Ingredient, Food use; Experimental Use Permit	An Experimental Use Permit (EUP) application and the first application for the same active ingredient submitted simultaneously for the same food use(s) that is not contained as an active ingredient in any currently U.S. registered pesticide product. The submission contains both a EUP request and an application for registration of a pesticide product. The applications propose a food	24	629,197

		application submitted simultaneously with application for registration; decision time for Experimental Use Permit and temporary tolerance same as #4 (R040)	use. The use may require the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted simultaneously. Some examples of food uses include corn, apples, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, pasture, rangeland, home garden, beehive, livestock, livestock housing, livestock dips, and livestock ear tags. The Agency will not accept a certification for crop destruct once the review clock has started. A change to a crop destruct application would require the applicant to withdraw their application and start the process application again.		
R040	4	New Active Ingredient, Food use; Experimental Use Permit application; establish temporary tolerance; submitted before application for registration; credit \$326, 025 toward new active ingredient application that follows	An Experimental Use Permit (EUP) application for food use(s) of an active ingredient that is not contained as an active ingredient in any currently U.S. registered pesticide product. The application proposes a food use. The use may require the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted simultaneously. Some examples of food uses include corn, apples, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, pasture, rangeland, home garden, beehive, livestock, livestock housing, livestock dips, and livestock ear tags. The Agency will not accept a certification for crop destruct once the review clock has started. A change to a crop destruct application would require the applicant to withdraw their application and start the process application again.	18	419,502
R050	5	New Active Ingredient, Food use; application submitted after Experimental Use Permit application; decision time begins after Experimental Use Permit and temporary tolerance are granted	An application that proposes a food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The use may require the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). Data required to support the first application for registration has been previously reviewed in association with the earlier EUP for the same use(s). All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted simultaneously. Some examples of food uses include corn, apples, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, pasture, rangeland, home garden, beehive, livestock, livestock housing, livestock dips, and livestock ear tags.	14	209,806
R060	6	New Active Ingredient, Non-food use; outdoor	An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Outdoor use means any use that is not indoor as described in the indoor category. All non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Non-food outdoor uses could include treatment of ornamentals in a shade house and turf uses.	21	395,467

R070	7	New Active Ingredient, Non-food use; outdoor; reduced risk	<p>An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Outdoor use means any use that is not indoor as described in the indoor category. All non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Non-food outdoor uses could include treatment of ornamentals in a shade house and turf uses.</p> <p>A “reduced risk” (http://www.epa.gov/opprd001/workplan/reducedrisk.html) submission must accompany the application for registration. The Agency’s Reduced Risk Committee will evaluate the submission and make the determination, based on criteria listed in PR Notice 97-3 and FIFRA 3(c)(10) (B) (-iv) , whether the requested use(s) qualify as “reduced risk” when compared to currently registered pesticides for the same use(s). The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as “reduced risk” by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the non-reduced risk category and the action will receive the longer timeframes (e.g. from an R070 New Active Ingredient, Non- Food Use, “reduced risk” to an R060 New Active Ingredient, Non-Food Use).</p>	16	395,467
R080	8	New Active Ingredient, Non-food use; outdoor; Experimental Use Permit application submitted simultaneously with application for registration; decision time for Experimental Use Permit same as #9 (R090)	<p>An Experimental Use Permit (EUP) application and the first application for the same active ingredient submitted simultaneously for the same non-food use(s) that is not contained as an active ingredient in any currently U.S. registered pesticide product. The submission contains both a EUP request and an application for registration of a pesticide product. The applications propose a non-food use. A non-food use includes a proposed use that is not a food use as described in the food use categories. Outdoor use means any use that is not indoor as described in the indoor category. All non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Non-food outdoor uses could include treatment of ornamentals in a shade house and turf uses.</p>	21	437,472
R090	9	New Active Ingredient, Non-food use; outdoor; Experimental Use Permit application submitted before application for registration; credit \$228,225 toward new active ingredient application that	<p>An Experimental Use Permit (EUP) application for non-food use(s) of an active ingredient that is not contained as an active ingredient in any currently U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Outdoor use means any use that is not indoor as described in the indoor category. All non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Non-food outdoor uses could include treatment of ornamentals in a shade house and turf uses.</p>	16	293,596

		follows			
R100	10	New Active Ingredient, Non-food use; outdoor; submitted after Experimental Use Permit application; decision time begins after Experimental Use Permit is granted	An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Outdoor use means any use that is not indoor as described in the indoor category. Data required to support the first application for registration has been previously reviewed in association with the earlier EUP for the same use(s). All non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Nonfood outdoor uses could include treatment of ornamentals in a shade house and turf uses.	12	143,877
R110	11	New Active Ingredient, Non-food use; indoor	An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Indoor means that the proposed use is for use inside of manmade structures. All indoor non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Some examples of indoor uses are termiticide structural protection, and indoor residential treatments (i.e. cockroach treatments). Treatment of ornamentals in a shade house is classified as outdoor uses and is not covered in this category.	20	219,949
R120	12	New Active Ingredient, Non-food use; indoor reduced risk	<p>An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Indoor means that the proposed use is for use inside of manmade structures. All indoor non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Some examples of indoor uses are termiticide structural protection and indoor residential treatments (i.e. cockroach treatments). Treatment of ornamentals in a shade house is classified as outdoor uses and is not covered in this category.</p> <p>A “reduced risk” (http://www.epa.gov/opprd001/workplan/reducedrisk.html) submission must accompany the application for registration. The Agency’s Reduced Risk Committee will evaluate the submission and make the determination, based on criteria listed in PR Notice 97-3 and FIFRA 3(c)(10)(B)(-iv), whether the requested use(s) qualify as “reduced risk” when compared to currently registered pesticides for the same use(s). The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as “reduced risk” by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the non-reduced risk category and the action will receive the longer timeframes (e.g. from an R120 New Active Ingredient, Food Use, “reduced risk” to an R110 New Active Ingredient, Food Use).</p>	14	219,949
R121	13	New Active Ingredient, Non-food use; indoor; Experimental Use	An Experimental Use Permit (EUP) application for non-food use(s) of an active ingredient that is not contained as an active ingredient in any currently U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Indoor means that the proposed use is for use inside of manmade structures. All indoor non-food	18	165,375

		Permit application submitted before application for registration; credit \$100,000 toward new active ingredient application that follows	uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Some examples of indoor uses are termiticide structural protection, and indoor residential treatments (i.e. cockroach treatments). Treatment of ornamentals in a shade house is classified as outdoor uses and is not covered in this category.		
R122	14	Enriched isomer(s) of registered mixed-isomer active ingredient	An application that proposes using an enriched isomer of an active ingredient, where such enriched isomer is not currently contained as an active ingredient in any U.S. registered pesticide product. This category consists of active ingredients that are a variation on the molecular structure or composition of a registered product and which will cite at least some of the generic data conducted with a registered product. All uses (food and non-food) included in the original application or petition for each new active ingredient are covered by the base fee for the application in this category if submitted simultaneously.	18	287,643
R123	15	New Active Ingredient, Seed treatment only; includes non-food and food uses; limited uptake into Raw Agricultural Commodities	An application for seed treatment only that proposes a food use or non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. All uses (food and non-food) included in the original application or petition for each new active ingredient are covered by the base fee for the application in this category if submitted simultaneously. In order for a food crop seed treatment to be considered a nonfood use, data from a radiotracer study must be available showing no uptake of residues (radioactivity) from treated seed into the aerial portion of the growing crop and guidance (http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/) is available. If residues occur in the aerial portion of the plant, or if there is no data available to make this determination, seed treatments are considered to be food uses requiring tolerances and fall into a different category.	18	427,991
R124	16	Conditional Ruling on Preapplication Study Waivers; applicant initiated	A pre-application request for an active ingredient, new use, or new product. The request is for review of each study waiver associated with any of the above pre-applications. The fee for this category is multiplied by each additional waiver request submitted for review. The study waiver request must include a written rationale for the study waiver and the identity of the new active ingredient (chemical structure). The application follows after the Agency has made a ruling on the study waiver(s). If a study waiver is denied, the application for the new active ingredient, new use or new product can only be submitted once the study has been conducted and the applicant has a complete application for registration. The decision on the waiver is conditional upon the review of the formal registration application and the data accompanying the application. Formal decisions or formal feedback on study waivers will not be made in meetings such as pre-registration conferences, Dose Adequacy Response Team meetings (DART), or any other pre-registration meeting with the Agency.	6	2,294
			Table 2. New Uses		
R130	17	First Food Use; Indoor; Food/Food Handling	An application that proposes the first indoor food use. First food use includes a proposed use of any U. S. registered active ingredient for which there is no registered "food use". The use may require the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). Indoor means that the proposed use is for use inside of manmade structures. All	21	173,644

			indoor food uses included in any original application or petition for the first food use are covered by the base fee for the application in this category if submitted simultaneously. Some examples of food uses include use in a food handling and/or processing establishment, use on food crops in a greenhouse, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, home garden, livestock, livestock housing, and livestock dips.		
R140	18	Additional food use; Indoor, Food/Food Handling	An application that proposes an additional indoor food use. Additional food use includes a proposed food use of any U. S. registered active ingredient for which there currently is a registered food use. The use may require the establishment of the exemption from the requirement of a tolerance under section 408 of the FFDCa. If residues are reasonably foreseeable or likely to occur in food or feed or around food, the application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). Increases in exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. Indoor means that the proposed use is for use inside of manmade structures. Some examples of food uses include use in a food handling and/or processing establishment, use on food crops in a greenhouse, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, home garden, livestock, livestock housing, and livestock dips. The fee applies to each additional food use requested (i.e. the fee for this category is multiplied by 4 if 4 uses are proposed). 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.	15	40,518
R150	19	First Food Use	An application that proposes the first food use. First food use includes a proposed use for any U. S. registered active ingredient for which there is no registered food use. The use may require the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCa. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses included in any original application or petition for the first food use are covered by the base fee for the application in this category if submitted simultaneously. Some examples of food uses include corn, apples, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, pasture, rangeland, home garden, beehive, livestock, livestock housing, livestock dips, and livestock ear tags. Some examples of unusual outdoor uses are livestock uses, (i.e. ear tags), livestock dips, and feed through treatments of livestock.	21	239,684
R160	20	First Food Use; Reduced Risk	An application that proposes the first food use. First food use includes a proposed use for any U. S. registered active ingredient for which there is no registered food use. The use may require the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCa. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All food uses included in any original application or petition for the first food use are covered by the base fee for the application in this category if submitted simultaneously. Some examples of food uses include corn, apples, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, pasture, rangeland, home garden, beehive, livestock, livestock housing, livestock dips, and livestock ear tags. A "reduced risk" (http://www.epa.gov/opprd001/workplan/reducedrisk.html) submission must accompany the application for registration. The Agency's Reduced Risk Committee will evaluate	16	239,684

			the submission and make the determination, based on criteria listed in PR Notice 97-3 and FIFRA 3(10) (B) (-iv), whether the requested use(s) qualify as “reduced risk” when compared to currently registered pesticides for the same use(s). The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as “reduced risk” by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the non-reduced risk category and the action will receive the longer timeframes (e.g. from an R160 New Use, First Food Use, “reduced risk” to an R150 New Use, First Food Use).		
R170	21	Additional Food Use	An application that proposes an additional food use. Additional food use includes a proposed food use for any U. S. registered active ingredient for which there currently is an approved food use. The use may require the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCa. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. Some examples of food uses include corn, apples, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, pasture, rangeland, home garden, beehive, livestock, livestock housing, livestock dips, and livestock ear tags. The fee applies to each additional food use requested up to 5 uses (i.e. the fee for this category is multiplied by 4 if 4 uses are proposed). If six or more additional food uses are requested in the application, fee category R190 applies. 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. Some unusual examples of outdoor uses are livestock uses, (i.e. ear tags), livestock dips, and feed through treatments of livestock.	15	59.976
R180	22	Additional Food Use; Reduced Risk	An application that proposes an additional food use. Additional food use includes a proposed food use for any U. S. registered active ingredient for which there currently is a registered food use. The use may require the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCa. If residues are reasonably foreseeable or likely to occur in food or feed or around food, the application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. Some examples of food uses include corn, apples, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, pasture, rangeland, home garden, beehive, livestock, livestock housing, livestock dips, and livestock ear tags. The fee applies to each additional food use requested up to 5 uses (i.e. the fee for this category is multiplied by 4 if 4 uses are proposed). If six or more additional food uses are requested in the application, fee category R200 applies. 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. Some unusual examples of outdoor uses are livestock uses, (i.e. ear tags), livestock dips, and feed through treatments of livestock.	10	59,976

			<p>A “reduced risk” (http://www.epa.gov/opprd001/workplan/reducedrisk.html) submission must accompany the application for registration. The Agency’s Reduced Risk Committee will evaluate the submission and make the determination, based on criteria listed in PR Notice 97-3 and FIFRA 3(c)(10) (B) (-iv), whether the requested use(s) qualify as “reduced risk” when compared to currently registered pesticides for the same use(s). In the event that any uses do not qualify as reduced risk, the application will not receive the reduced risk decision timeframes. The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as “reduced risk” by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the non-reduced risk category and the action will receive the longer timeframes (e.g. from an R180 New Use, Additional New Food Use, “reduced risk” to an R170 New Use, Additional New Food Use).</p>		
R190	23	Additional Food Uses, 6 or more submitted in one application	<p>An application that proposes additional food uses. Additional food use includes a proposed food use for any U. S. registered active ingredient for which there currently is a registered food use. The use may require the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCa. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. Some examples of food uses include corn, apples, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, pasture, rangeland, home garden, beehive, livestock, livestock housing, livestock dips, and livestock ear tags. The application must propose at least (6) specific additional food or feed crops or 6 or more additional 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 registered, then requesting the crop group will count as one additional use.</p>	15	359,856
R200	24	Additional Food Use; 6 or more submitted in one application; Reduced Risk	<p>An application that proposes additional food uses. Additional food use includes a proposed food use for any U. S. registered active ingredient for which there currently is a registered food use. The use may require the establishment of, or the exemption from the requirement of a tolerance under section 408 of the FFDCa. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. Some examples of food uses include corn, apples, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, pasture, rangeland, home garden, beehive, livestock, livestock housing, livestock dips, and livestock ear tags. The application must propose at least (6) specific additional food or feed crops or 6 or more additional 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 registered, then requesting the crop group will count as one additional use.</p>	10	359,856

			<p>A “reduced risk” (http://www.epa.gov/opprd001/workplan/reducedrisk.html) submission must accompany the application for registration. The Agency’s Reduced Risk Committee will evaluate the submission and make the determination, based on criteria listed in PR Notice 97-3 and FIFRA 3(c)(10) (B) (-iv), whether the requested use(s) qualify as “reduced risk” when compared to currently registered pesticides for the same use(s). In the event that any uses do not qualify as reduced risk, the application will not receive the reduced risk decision timeframes. The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as “reduced risk” by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the non-reduced risk category and the action will receive the longer timeframes (e.g. from an R200 New Use, Additional Food Uses “reduced risk” to an R190 New Use, Additional Food Use).</p>		
R210	25	Additional food use; Experimental Use Permit application; establish temporary tolerance; no credit toward new use registration	<p>An Experimental Use Permit (EUP) application for a new food use(s) that includes a proposed additional food use for any U. S. registered active ingredient that is currently not registered for the proposed use. The use may require the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCa. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). Increases in exposure such as a dosage rate increase or different method of application that will result in a temporary tolerance increase belong to this category. Some examples of food uses include corn, apples, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, pasture, rangeland, home garden, beehive, livestock, livestock housing, livestock dips, and livestock ear tags. The Agency will not accept a certification for crop destruct once the review clock has started (the “clock” or decision review timeframe starts 21 days after the Agency receives the application and the required fees or approves a fee waiver or fee exemption). A change to a crop destruct application would require the applicant to withdraw-their application and start the process application again.</p>	12	44,431
R220	26	Additional food use; Experimental Use Permit application; Crop Destruct Basis; no credit toward new use registration	<p>An Experimental Use Permit (EUP) application for a new food use(s) includes a proposed food for any U. S. registered active ingredient that is currently not registered for the proposed use. Food/feed commodities covered by the pending application(s) must have a certification that all food/feed treated under the EUP will be destroyed or fed to experimental animals for testing purposes only. Some examples of food uses include corn, apples, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, pasture, rangeland, home garden, beehive, livestock, livestock housing, livestock dips, and livestock ear tags.</p>	6	17,993
R230	27	Additional use; Non-food; Outdoor	<p>An application that proposes a new non-food use. A non-food use includes a proposed use that is not a food use as described in the food use categories. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. Outdoor use means any use that is not indoor as described in the indoor category. Non-food outdoor uses could include treatment of ornamentals in a shade house, termiticide use around the perimeter of a house and turf uses.</p>	15	23,969
R240	28	Additional use; Non-food, Outdoor, Reduced Risk	<p>An application that proposes a new non-food use. A non-food use includes a proposed use that is not a food use as described in the food use categories. A different pattern in a non-food outdoor use that significantly changes or increases exposure such as a dosage rate increase or</p>	10	23,969

			<p>different method of application will result in the application that belongs in this category. Outdoor use means any use that is not indoor as described in the indoor category. Examples of non-food outdoor uses are treatment of ornamentals in a shade house, termiticide use around the perimeter of a house, and turf uses.</p> <p>A “reduced risk” (http://www.epa.gov/opprd001/workplan/reducedrisk.html) submission must accompany the application for registration. The Agency’s Reduced Risk Committee will evaluate the submission and make the determination, based on criteria listed in PR Notice 97-3 and FIFRA 3(c)(10) (B) (-iv), whether the requested use(s) qualify as “reduced risk” when compared to currently registered pesticides for the same use(s). In the event that any uses do not qualify as reduced risk, the application will not receive the reduced risk decision timeframes. The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as “reduced risk” by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the non-reduced risk category and the action will receive the longer timeframes (e.g. from an R240 New Use, Non-Food Use, “reduced risk” to an R230 New Use, Food Use).</p>		
R250	29	Additional Use; Non-food; Outdoor; Experimental Use Permit Application; no credit toward new use registration	An Experimental Use Permit (EUP) application that proposes a new non-food use for any U.S. registered active ingredient that is currently not registered for the proposed use. A non-food use includes a proposed use that is not a food use as described in the food use categories. A different pattern in a non-food outdoor use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application that belongs in this category. Outdoor use means any use that is not indoor as described in the indoor category. Fees will not cover any subsequent application for registration of the new use. Non-food outdoor uses could include treatment of ornamentals in a shade house, and turf uses.	6	17,993
R260	30	New Use, Non-food, Indoor	An application that proposes a new non-food use. A non-food use includes a proposed use that is not a food use as described in the food use categories. A different pattern in a non-food indoor use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application that belongs in this category. The proposed use is for use inside of manmade structures and is not a food use. Some examples of indoor uses are termiticides and indoor residential treatments (i.e. cockroach treatments). Treatment of ornamentals in a shade house is classified as outdoor uses and is not covered in this category.	12	11,577
R270	31	New Use, Non-food, Indoor, Reduced Risk	<p>An application that proposes a new non-food use. A non-food use includes a proposed use that is not a food use as described in the food use categories. A different pattern in a non-food indoor use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application that belongs in this category. The proposed use is for use inside of manmade structures and is not a food use. Some examples of indoor uses are termiticides and indoor residential treatments (i.e. cockroach treatments). Treatment of ornamentals in a shade house is classified as outdoor uses and is not covered in this category.</p> <p>A “reduced risk” (http://www.epa.gov/opprd001/workplan/reducedrisk.html) submission must accompany the application for registration. The Agency’s Reduced Risk Committee will evaluate the submission and make the determination, based on criteria listed in PR Notice 97-3 and FIFRA 3 (c (10) (B) (-iv), whether the requested use(s) qualify as “reduced risk” when compared to</p>	9	11,577

			currently registered pesticides for the same use(s). In the event that any uses do not qualify as reduced risk, the application will not receive the reduced risk decision timeframes. The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as "reduced risk" by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the non-reduced risk category and the action will receive the longer timeframes (e.g. from an R270 New Use, Non-Food Use "reduced risk" to an R260 New Use, Non-Food Use).		
R271	32	New use; non-food; indoor; Experimental Use Permit application; no credit toward new use registration	An Experimental Use Permit (EUP) application for a new non-food use(s) includes a proposed non-food use for any U. S. registered active ingredient that is currently not registered for the proposed use. A non-food use includes a proposed use that is not a food use as described in the food use categories. Increases in exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The proposed use is for use inside of manmade structures and is not a food use. Some examples of indoor uses are termiticide structural protection and indoor residential treatments (i.e. cockroach treatments). Treatment of ornamentals in a shade house is classified as outdoor uses and is not covered in this category.	6	8,820
R272	33	Review of Study Protocol; applicant-initiated; excludes DART, pre-registration conferences, Rapid Response review, DNT protocol review, protocols needing HSRB review	An application for approval of each study protocol. Applicant provides a written copy of the protocol along with any specific questions about the protocol. The fee for this category is multiplied by each additional protocol submitted for review. PRIA-2 fees are not applicable for pre-submission or pre-registration conferences or discussions with the EPA such as Dose Adequacy Response Team (DART), EFED Rapid Response review, ChemSac review, DNT protocol reviews and HSRB review.	3	2,294
R273	34	Additional use; seed treatment; limited uptake into Raw Agricultural Commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food and/or non-food uses	An application that proposes an additional seed treatment use for any U.S. registered active ingredient for food use or non-food use seed treatment. In order for a seed treatment to be considered in this category when proposed for seed treatment use on a food crop, data from a radiotracer study must be available showing no uptake of residues (radioactivity) from treated seed into the aerial portion of the growing crop and guidance (http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/) is available. If residues occur in the aerial portion of the plant, or if there is no data available to make this determination, seed treatments are considered to be food uses requiring tolerances and fall into a different category. Examples of food uses are corn, soybean, and wheat. If a seed treatment use is proposed on ornamental seed or other non-food use seed treatment then the application would be in this category because it is known, without consideration of any data, that a tolerance is not required. The fee applies to each seed treatment use requested up to 5 uses (i.e. the fee for this category is multiplied by 4 if 4 seed uses are proposed). 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	12	45,754

			additional use. If a numerical tolerance needs to be established, the application does not belong in this category. If six or more seed treatment uses are being proposed, this is not the correct category (see R274).		
R274	35	Additional uses; seed treatment only; 6 or more submitted in one application; limited uptake into Raw Agricultural Commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food and/or non food uses	An application that proposes an additional seed treatment use for any U.S. registered active food use or non-food use for an active ingredient that is currently contained as an active ingredient in any U.S. registered pesticide product. The application must propose at least (6) specific seed treatment uses or 6 or more representative seeds for crop subgroups or crop groups. In order for a seed treatment to be considered in this category when proposed for seed treatment use on a food crop, data from a radiotracer study must be available showing no uptake of residues (radioactivity) from treated seed into the aerial portion of the growing crop and guidance (http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/) is available. If residues occur in the aerial portion of the plant, or if there is no data available to make this determination, seed treatments are considered to be food uses requiring tolerances and fall into a different category. Examples of food uses are corn, soybean, and wheat. If a seed treatment use is proposed on ornamental seed or other non-food use seed treatment use, then the application would be in this category because it is known, without consideration of any data, that a tolerance is not required. 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. If a numerical tolerance needs to be established, the application does not belong in this category.	12	274,523
			Table 3. Import and Other Tolerances		
R280	36	Establish Import tolerance New active ingredient or first food use	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. Some examples of food uses include corn, apples, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, pasture, rangeland, home garden, beehive, livestock, livestock housing, livestock dips, and livestock ear tags.	21	289,407
R290	37	Establish Import tolerance Additional new food use	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. Some examples of food uses include corn, apples, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, pasture, rangeland, home garden, beehive, livestock, livestock housing, livestock dips, and livestock ear tags.	15	57,882
R291	38	Establish import tolerances;	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	15	347,288

		additional food uses; 6 or more crops submitted in one petition	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		
R292	39	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated	An application and/or a petition request to amend an existing tolerance on domestic or imported crops. This may be a request to increase or decrease an existing tolerance currently established under section 408 of the FFDCa. This may be a request to add a representative commodity to an existing tolerance currently established in order to complete a group or subgroup. The fee for this category is multiplied by each additional request to amend an existing tolerance. 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. Some examples of food uses include corn, apples, and aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish, pasture, rangeland, home garden, beehive, livestock, livestock housing, livestock dips, and livestock ear tags.	10	41,124
R293	40	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated	An application and 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 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.	12	48,510
R294	41	Establish tolerances for inadvertent residues; 6 or more crops submitted in one application; applicant-initiated	An application and 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	291,060
R295	42	Establish tolerances(s) for residues in one rotational crop in response to a specific rotational crop application; applicant-initiated	An application and 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.	15	59,976
R296	43	Establish tolerances for residues in rotational crops in response to a	An application and 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	15	359,856

		specific rotational crop petition; 6 or more crops submitted in one application; applicant-initiated	as one additional use.		
			Table 4. New Products		
R300	44	New product; identical or substantially similar in composition and use to a registered product; no data review or 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 use or manufacturing-use product that requires no data submission nor data matrix	<p>An application for registration of an end-use or a manufacturing use pesticide product that is substantially similar or identical in its uses and/or formulation to products that are currently registered or differ only in ways that would not significantly increase the risk of unreasonable adverse effects. The applicant must identify the similar products for all active ingredients in the proposed product. All applications require the following:</p> <ul style="list-style-type: none"> • A data matrix is required with the application. • Product chemistry data (Group A and B) unless the product is identical (e.g. 100% repackaged product). In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • 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. <p>The application is not in this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted and must be reviewed to support the application. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category.</p> <p>Substantially similar: Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular), and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the proposed product bears the same use patterns. Adding to or changing existing use patterns exclude the proposed product from treatment as a substantially similar product. Deleting use patterns is acceptable.</p> <p>Identical: Same composition and use patterns as a currently registered end use product.</p> <p>Manufacturing Use Product: A 100% re-package of a manufacturing use product that requires no data submission or data matrix is covered by this category.</p>	3	1,434
R301	45	New product; identical or substantially similar in composition and use to a registered	An application for registration of an end-use pesticide product that is substantially similar or identical in its uses and/or formulation to products that are currently registered or differ only in ways that would not significantly increase the risk of unreasonable adverse effects. The applicant must identify the similar products for all active ingredients in the proposed product. All applications require the following:	4	1,720

		<p>product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner</p>	<ul style="list-style-type: none"> • A data matrix is required with the application. • Product chemistry data (Group A and B) unless the product is identical. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • 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, public health pest efficacy, companion animal safety data and/or child resistant packaging data requirements must be addressed by using: 1) the cite-all method, or 2) selective data citation where the applicant does not own all required data and does not have a specific authorization letter from the data owner. If review of data is needed, this application does not fall within this category. <p>The application is not in this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted and must be reviewed to support the application. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category.</p> <p>An application proposed as a 100% re-packaged product does not fall within this category (see category R300).</p> <p>Substantially similar: Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular), and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the proposed product bears the same use patterns. Adding to or changing existing use patterns exclude the proposed product from treatment as a substantially similar product. Deleting use patterns is acceptable.</p> <p>Identical: Same composition and use patterns as a currently registered end use product.</p>		
R310	46	<p>New end-use or manufacturing-use product; requires review of data package within RD; includes reviews and/or waivers of data for only: - product chemistry and/or - acute toxicity and/or -public health pest efficacy</p>	<p>An application for registration of an end-use or manufacturing use pesticide product that is not substantially similar or identical in its uses and formulation to products that are currently registered. All applications require the following:</p> <ul style="list-style-type: none"> • A data matrix is required with the application. • Product chemistry data (Group A and B). In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • All inert ingredients must already be approved for the applicable uses in the product. • Acute toxicity, efficacy, public health pest efficacy, companion animal safety data 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. <p>An application proposed as a 100% re-packaged product does not fall within this category (see category R300).</p> <p>If an applicant owns the generic data and does not qualify for the formulator's exemption, the</p>	6	4,807

			new product application belongs in this category. 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.		
R311	49	New product; requires approval of a new food-use inert; applicant-initiated; excludes approval of safeners	<p>An application for registration for a new end-use pesticide product containing an active ingredient that is currently registered for the proposed food uses in the US. The proposed formulation contains an inert ingredient that has <u>not</u> been approved for use on food use sites (refer to definition of food use). The applicant requests the inert ingredient be granted a tolerance exemption or a tolerance.</p> <p>The request for the new inert ingredient's tolerance or tolerance exemption on food sites must include an application for registration of a new pesticide product. All data (inert ingredient and end use product) and the petition and Notice of Filing (NOF) for the inert ingredient tolerance or tolerance exemption must be submitted with the application. If a new product registration is not sought, then the request for food use inert ingredient tolerance falls outside of the scope of PRIA.</p> <p>Approval of a safener does not fall within this category, but falls within the applicable new active ingredient category.</p> <p>Data on the new food use inert ingredient: OPP highly recommends the applicant request a meeting with the Inert Ingredients Assessment Branch (IIAB) staff prior to submission under PRIA to go over data needs. Data to support the inert ingredient approval must accompany the application.</p> <p>Inert ingredients are found in section 180.910 – 960 (http://www.epa.gov/opprd001/inerts/decisiondoc_a2k.html) [Note: A number of exemptions have expiration dates.]</p> <p>All applications require the following:</p> <ul style="list-style-type: none"> • A data matrix is required with the application. • Product chemistry data (Group A and B) unless the product is identical. In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • All other inert ingredients must already be approved for the applicable uses in the product. • Acute toxicity, efficacy, public health pest efficacy, companion animal safety data 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 the required data. A rationale for a waiver or bridging of these data falls within this category. <p>Since this category requires both an application for the product and a petition to approve the inert ingredient, the entire package must be processed together. If one part of the package fails (i.e., inert ingredient approval) then the application for the product also fails. A change to the application would require the applicant to withdraw their application and petition and start the process application again.</p>	12	17,133
R312	50	New product; requires approval of new non-food use inert; applicant	An application for registration of a new an end-use or manufacturing use pesticide product containing an active ingredient that is currently registered in the US for the proposed non-food uses. The proposed formulation contains an inert ingredient that has <u>not</u> been approved for non-food uses and the applicant requests that the inert ingredient be approved for a non-food uses.	6	9,151

		initiated	<p>The request for the new inert ingredient's use on non-food sites must include an application for registration of a new pesticide product. All data (inert ingredient and end use product) and a request for approval of the non-food use inert ingredient must be submitted with the application. If a new product registration is not sought, then the request for non-food use falls outside of the scope of PRIA.</p> <p>Approval of a safener does not fall within this category, but falls within the applicable new active ingredient category.</p> <p>Data on the new non food inert ingredient: OPP highly recommends the applicant request a meeting with IIAB staff (inertsbranch@epa.gov) prior to product submission under PRIA to go over data needs. Data to support the inert ingredient approval must accompany the application.</p> <p>All applications require the following:</p> <ul style="list-style-type: none"> • A data matrix is required with the application. • Product chemistry data (Group A and B). In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • All other inert ingredients must already be approved for the applicable uses in the product. • Acute toxicity, efficacy, public health pest efficacy, companion animal safety data and/or child resistant packaging data requirements must be addressed by using: 1) the cite-all method, or 2) selective data citation. A rationale for a waiver or bridging of these data falls within this category. <p>Since this category requires both an application for the product and inert ingredient information, the entire package must be processed together. If one part of the package fails (i.e., inert ingredient or product specific data) then the whole category fails. Any change to the application would require the applicant to withdraw their application and start the process application again.</p>		
R313	51	New product; requires amendment to existing inert tolerance exemption (e.g., adding post-harvest use); applicant initiated	<p>An application for registration of a new end-use or manufacturing use pesticide product containing an active ingredient that is currently registered in the US for the proposed uses. The proposed formulation contains an inert ingredient that has an exemption from a tolerance and the product's use will require amending the tolerance exemption of the inert ingredient only. In addition to the request for a pesticide product registration, the application contains a petition to amend the existing exemption(s) from a tolerance for all uses covered by the pending registration application. Appropriate tolerances exist for the active ingredient for the uses proposed in the application.</p> <p>The request to amend an inert ingredient's tolerance exemption must include an application for registration of a new pesticide product. All data (inert ingredient and end use product) and the petition and Notice of Filing (NOF) for the inert ingredient or tolerance exemption must be submitted with the application. If a new product registration is not sought, then the request for food use inert ingredient tolerance falls outside of the scope of PRIA.</p> <p>Approval of a safener does not fall within this category, but falls within the applicable new active ingredient category.</p>	10	12,591

			<p>Inert ingredients are found in section 180.910 – 960 (http://www.epa.gov/opprd001/inerts/decisiondoc_a2k.html) [Note: A number of exemptions have expiration dates.]</p> <p>All applications require the following:</p> <ul style="list-style-type: none"> • A data matrix is required with the application. • Product chemistry data (Group A and B). In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • All other inert ingredients must already be approved for the applicable uses in the product. • Acute toxicity, efficacy, public health pest efficacy, companion animal safety data 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 the required data. A rationale for a waiver or bridging of these data falls within this category. <p>Since this category requires both an application for the product and a petition to approve the inert ingredient, the entire package must be processed together. If one part of the package fails (i.e., inert ingredient approval) then the application for the product also fails. A change to the application would require the applicant to withdraw their application and petition and start the process application again.</p>		
R320	47	New product; new physical form; requires data review in science divisions	<p>An application for registration of a pesticide product that is not substantially similar or identical in its uses or formulation to products that are currently registered. A change in the formulation type or timing of application for the registered physical form that would require residue data (http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/), environmental fate data (http://www.epa.gov/oppefed1/ecorisk_ders/terrestrial_field_dissipation.htm#IC), and/or ecotoxicity, exposure data, etc., to support the change. For example this includes a change in the formulation that would change the way a product is applied (i.e. spot-on treatments, controlled release formulation), a change in the toxicity and/or exposure profile of the product, a pre-mix product that is not currently registered that requires science review per current guidelines, a change in the application rates or PHI, animal products with rate depletion data, change in the formulation, e.g. going from a liquid to a solid, etc.</p>	12	11,996
R330	48	New manufacturing-use product; registered active ingredient; selective data citation	<p>An application for registration of a manufacturing use pesticide product that is not substantially similar or identical in its formulation to products that are currently registered for which the selective data citation is used. 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.</p> <p>All applications require the following:</p> <ul style="list-style-type: none"> • A data matrix is required with the application. • Product chemistry data (Group A and B). In some cases product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • All inert ingredients must already be approved for the applicable uses in the product. • Acute toxicity, efficacy, public health pest efficacy, companion animal safety data and/or 	12	17,993

			<p>child resistant packaging data requirements must be addressed by using: 1) selective data citation. A rationale for a waiver or bridging of these data falls within this category.</p> <p>An application proposed as a 100% re-packaged product does not fall within this category (see category R300).</p> <p>An application for registration of a new product that is a new salt form of an already registered active ingredient and there are not any currently registered products for this salt form falls into this category. The Agency will decide on a case-by-case basis if the active ingredient is a new active ingredient.</p>		
R331	52	New product; repack of identical registered end-use product as a manufacturing-use product; same registered uses only	<p>An application for registration of a manufacturing use pesticide product that is identical in its formulation and uses to end use products that are currently registered. All applications require the following:</p> <ul style="list-style-type: none"> • A formulator's Exemption statement • The applicant must identify the registered identical product for this category • The active ingredient listed on the CSF must be an EPA registered product in order to satisfy the data requirements for the active ingredient. <p>If the use pattern for the proposed product differs from the currently registered product, then additional data are required and the application does not fall within this category (see applicable new use categories).</p>	3	2,294
R332	53	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of completely new generic data package; registered uses only	<p>An application for registration of a manufacturing use pesticide product that is not substantially similar or identical in its formulation to products that are currently registered. New manufacturing use product is any product intended (labeled) for formulation or repackaging into an end use formulated pesticide product. This product does not contain directions for use of the product as distributed or sold, or after combination by the user with other substances. All applications require the following:</p> <ul style="list-style-type: none"> • A data matrix is required with the application. • Product chemistry data (Group A and B). • 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. • 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 ecotoxicity. 	24	256,883
Table 5. Amendments to Registration					
R340	54	Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient)	<p>Modification in the label, formula, or packaging of a registered product which is substantially similar or is not substantially similar to a currently registered product and which requires the submission of data or the citation of data by the registrant which requires an analysis by the Registration Division (RD) only. In all cases the inert ingredients must be already be approved for the applicable uses in the product. Examples of actions in this category include: formulation changes to use an unregistered source of active ingredient using the cite-all method of support for the generic requirements, alternate formulations with data including, 5-batch analysis data, label changes to Precautionary Statements based on product chemistry and/or acute product toxicity data; efficacy data; companion animal safety data; child resistant packaging data. Registered source of active ingredient means that the active ingredient has been issued an EPA Registration</p>	4	3,617

			Number (license). EPA-initiated amendment shall not be charged fees. Label amendments submitted by notification under PR Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees.		
R350	55	Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement)	Modification in the label of a registered product that is not substantially similar to a currently registered product and that requires risk analysis by the Agency (i.e. by the Health Effects Division (HED), the Environmental Fate and Effects Division (EFED), the Biological and Economic Analysis Division (BEAD), Alternate Risk Integration Assessment Team (ARIA) etc.) to support the change. Examples of actions in this category include: label changes to Directions for Use (including REI, PPE, PHI, application rate, application frequency, application timing, addition of aerial or chemigation application methods consistent with PR Notice 87-1 and 93-2, ground water or surface water advisory statements, etc. that require risk analysis by EPA. In some cases, the applicant might not submit new data to support the label amendment, but the Agency would need a determination of whether the existing database would support a change or modification to the amended label. EPA-initiated amendment shall not be charged fees. Label amendments submitted by notification under PR Notices, such as and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA 2 fees.	8	11,996
R370	56	Cancer reassessment, applicant-initiated	An application which requests to change the cancer classification.	18	179,818
R371	57	Amendment to Experimental Use Permit; requires data review/risk assessment	An application to amend an Experimental Use Permit (EUP) application for the currently registered uses. The application requires review of the amendment, including data review and/or new risk assessments for the currently registered uses. If new uses are being proposed, then the application would not fall within this category.	6	9,151
R372	58	Refined ecological and/or endangered species assessment; applicant-initiated	To be determined and will be published when available.	12	171,219

Antimicrobials Division

			Table 6. New Active Ingredients		
A380	59	New Active Ingredient Food use, establish tolerance exemption	An application that proposes a food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The use may require the establishment of an exemption from the requirement of a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), or an increase in or a food additive regulation or other clearance under section 409 of the FFDCA. The application may need to include a petition to establish an exemption from tolerance for all food commodities covered by the pending registration application(s) or, if residues would not be subject to FFDCA section 408, documentation of an applicable food additive regulation or other clearance under section 409 of the FFDCA. Refer to the definition of a "food use" for the uses subject to this category. All uses (food and non-food) included in any original application or 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 include:	24	104,187

			<ul style="list-style-type: none"> ▪ Pre- and post-harvest use on crops (other than agricultural fungicides and aquatic herbicides, which are handled as conventional pesticides) ▪ Animal drinking water treatment (meat, meat by-products and/or milk tolerance exemption) ▪ Process water treatment for post harvest use (field washing of raw agricultural commodities) ▪ Treatment of permanent or semi-permanent food contact surfaces (sanitizers and disinfectants) ▪ Use of the product in food contact articles, other than food packaging with an intended ongoing effect in the finished article, including the articles surface or in food that may contact the article (e.g., conveyor belt-claims to kill bacteria on articles that come in contact with belt; or a lubricant with claims that the lubricant kills bacteria) ▪ Treatment of raw agricultural commodities in a food processing facility (FDA food additive regulation) ▪ Process water treatment in a food handling facility to control a pest in the water (FDA food additive regulation) ▪ Slimicides (FDA food additive regulation) (e.g., pulp and paper board) ▪ Production of food packaging (FDA food additive regulation)(e.g., adhesives, coatings) ▪ Production of food contact articles other than food packaging (FDA food additive regulation) (cutting board that contains an antimicrobial as a preservative) ▪ Food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment) ▪ Aseptic packaging (FDA food additive regulation) ▪ Ethanol production (treatment of empty fermentation tank) (check with the Agency prior to submission of an application) ▪ Aquatic area application (e.g., lakes, ponds, reservoirs, irrigation systems)(other than aquatic herbicides which are handled as conventional pesticides) ▪ Home produce washes (dietary risk assessment required) ▪ Human drinking water systems (e.g., water purifier units, emergency water systems, municipal water treatment) 		
A390	60	New Active Ingredient Food use, establish tolerance	<p>An application that proposes a food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The use may require the establishment of or the increase in a tolerance under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA). If residues are reasonably foreseeable or likely to occur in or around food, either directly or indirectly, the application may need to include a petition to establish a tolerance for all food commodities covered by the pending registration application(s). However, some uses may not require a petition but still be considered under this category. Refer to the definition of a "food use" for the uses subject to this category. All uses (food and non-food) included in any original application or 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.</p> <p>Examples include:</p> <ul style="list-style-type: none"> ▪ Pre- and post-harvest use on crops (other than agricultural fungicides and aquatic herbicides, which are handled as conventional pesticides) ▪ Animal drinking water treatment (meat, meat by-products, and/or milk tolerance) ▪ Process water treatment for post harvest use (field washing of raw agricultural 	24	173,644

			<ul style="list-style-type: none"> commodities) ▪ Treatment of permanent or semi-permanent food contact surfaces (sanitizers and disinfectants) ▪ Use in the production of food contact articles, other than food packaging, with an intended ongoing effect in the finished article including the article's surface or in food that may contact the article (e.g. conveyor belt with claims to kill bacteria on articles that come in contact with belt) ▪ Food handling storage establishments premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment) ▪ Ethanol production (treatment of empty fermentation tank)) (check with the Agency prior to submission of an application) ▪ Aquatic area application (e.g., lakes, ponds, reservoirs, irrigation systems)(other than aquatic herbicides which are handled as conventional pesticides) 		
A400	61	New Active Ingredient, Non-food use, outdoor, FIFRA sec. 2(mm) uses	<p>An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a "food use" as described in the food use categories. Outdoor use means any use that is not indoor as described in the "indoor category" and that fits the definition of an antimicrobial found in FIFRA section 2(mm). All non-food, section 2(mm) uses included in the original application or petition are covered by the base fee for that application in this category if submitted simultaneously.</p> <p>Examples include:</p> <ul style="list-style-type: none"> ▪ Once through cooling tower treatments ▪ Aquatic area application (e.g., wastewater treatment)(other than aquatic herbicides which are handled as conventional pesticides) ▪ Oil fields (marine) ▪ Sewage treatment plants (water is treated prior to discharge into the environment) 	18	86,823
A410	62	New Active Ingredient Non-food use, outdoor, uses other than FIFRA 2(mm)	<p>An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a "food use" as described in the food use categories. Outdoor means any use that is not indoor as described in the "indoor category". Other uses are those uses not covered by the definition of an antimicrobial found in FIFRA section 2(mm). All non-food uses included in the original application or petition are covered by the base fee for that application in this category if submitted simultaneously.</p> <p>Examples include:</p> <ul style="list-style-type: none"> ▪ Wood preservatives ▪ Antifoulants ▪ Ballast water 	21	173,644
A420	63	New Active Ingredient Non-food use, indoor, FIFRA sec. 2(mm) uses	<p>An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a "food use" as described in the food use categories. The product is for use inside a manmade structure and fits the definition of an antimicrobial found in FIFRA section 2(mm). All indoor, non-food, section (2mm) uses included in the original application or petition are covered by the base fee for that application in this category if submitted</p>	18	57,882

			<p>simultaneously. Examples include:</p> <ul style="list-style-type: none"> ▪ Residential use (i.e., 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, spas ▪ Oil fields (terrestrial) 		
A430	64	New Active Ingredient, Non-Food Use Indoor, uses other than FIFRA 2(mm) uses	<p>An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a “food use” as described in the food use categories. The product is for use inside a man made structure. Other uses are those not covered by the definition of an antimicrobial found in FIFRA 2(mm). All indoor non-food uses included in the original application are covered by the base fee for that application if submitted simultaneously. Examples include:</p> <ul style="list-style-type: none"> ▪ Wood preservative (pressure and non-pressure treatments, e.g., joinery and mill work for door, window frames) 	20	86,823
A431	65	New Active Ingredient, Non-food use; indoor; low-risk and low-toxicity food-grade active ingredient(s), efficacy testing for public health claims required under GLP and following DIS/TSS or AD-approved study protocol	<p>An application that proposes an indoor non-food use for a low risk/low toxicity food grade active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a “food use” as described in the food use categories. The product is for use inside a manmade structure. Low risk/low toxicity food grade active ingredients are those described in PR Notice 2000-6 (www.epa.gov/PR_Notices/pr2000-6.pdf). Other active ingredients proposed as low risk/low toxicity will be considered on a case-by-case basis. A product making public health claims require efficacy data be submitted using AOAC, ASTM or OECD protocol. Other approved protocols are DSS/TSS and those listed on the Antimicrobial Policy & Guidance Documents Web page. All studies must be completed under GLP.</p>	12	60,638
			Table 7. New Uses		
A440	66	New Use, First Food Use, establish tolerance exemption	<p>An application that proposes the first food use. First food use includes a proposed use for any U.S. registered active ingredient for which there is no registered “food use”. The use may require an exemption from the requirement of a tolerance under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) or a food additive regulation or other clearance under section 409 of the FFDCA. If residues are reasonably foreseeable or likely to occur in or around food, either directly or indirectly, and the risks from all foreseeable residues are minimal, the application submission may need to include a petition to establish an exemption for tolerance for all food</p>	21	28,942

			<p>commodities covered by the pending registration application or if residues would not be subject to FFDCa section 408, documentation of an applicable food additive regulation or other clearance under section 409 of the FFDCa. Refer to the definition of a “food use” for the uses subject to this category. All uses (food and non-food) included in any original application or petition for a first food use and to establish tolerance exemptions are covered by the base fee for that application in this category if submitted simultaneously.</p> <p>Examples include:</p> <ul style="list-style-type: none"> ▪ Pre- and post-harvest use on crops (other than agricultural fungicides and aquatic herbicides, which are handled as conventional pesticides) ▪ Animal drinking water treatment (meat, meat by-products and/or milk tolerance exemption) ▪ Process water treatment for post harvest use (field washing of raw agricultural commodities) ▪ Treatment of permanent or semi-permanent food contact surfaces (sanitizers and disinfectants). ▪ Use of the product in food contact articles, other than food packaging with an intended ongoing effect in the finished article, including the articles surface or in ood that may contact the article (e.g., conveyor belt - claims to kill bacteria on articles that come in contact with belt) ▪ Treatment of raw agricultural commodities in a food processing facility (FDA food additive regulation) ▪ Process water treatment in a food handling facility to control a pest in the water (FDA food additive regulation) ▪ Production of food packaging (FDA food additive regulation) (e.g. adhesives, coatings) ▪ Production of food contact articles other than food packaging (FDA food additive regulation) (conveyor belt, cutting board that contains an antimicrobial as a preservative) ▪ Slimicides (FDA food additive regulation) (e.g., pulp and paper board) ▪ Production of food packaging (FDA food additive regulation) (e.g. adhesives, coatings) ▪ Food handling storage establishments premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment) ▪ Aseptic packaging (FDA food additive regulation) ▪ Ethanol production (treatment of empty fermentation tank) (check with the Agency prior to submission of an application) ▪ Aquatic area application (e.g., lakes, ponds, reservoirs, irrigation systems)(other than aquatic herbicides which are handled as conventional pesticides) ▪ Home produce washes (dietary risk assessment required) ▪ Human drinking water systems (e.g., water purifier units, emergency water systems, municipal water treatment) 		
A450	67	New use First food use, establish tolerance	An application that proposes the first food use. First food use includes a proposed use of any U.S. registered active ingredient for which there is no registered “food use”. The use may require the establishment of an exemption from the requirement of a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCa), or an increase in or a food additive regulation or other clearance under section 409 of the FFDCa. The application may need to include a petition to establish an exemption from tolerance for all food commodities covered by the pending	21	86,823

			<p>registration application(s) or, if residues would not be subject to FFDCA section 408, documentation of an applicable food additive regulation or other clearance under section 409 of the FFDCA. Refer to the definition of a “food use” for the uses subject to this category. All uses (food and non-food) included in any original application or petition for a first food use are covered by the base fee for that application in this category if submitted simultaneously.</p> <p>Examples include:</p> <ul style="list-style-type: none"> ▪ Pre- and post-harvest use on crops (other than agricultural fungicides and aquatic herbicides, which are handled as conventional pesticides). ▪ Animal drinking water treatment ▪ Process water treatment for post harvest use (field washing of raw agricultural commodities) ▪ Treatment of permanent or semi-permanent food contact surfaces (sanitizers). In some cases this will include a disinfectant use ▪ Use in the product of food contact articles, other than food packaging with an intended ongoing effect in the finished article, including the articles surface or in food that may contact the article (e.g., conveyor belt: claims to kill bacteria on articles that come in contact with belt) ▪ Food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment) ▪ Ethanol production (treatment of empty fermentation tank)(check with the Agency prior to the submission of an application) ▪ Aquatic area application (e.g., lakes, ponds, reservoirs, irrigation systems)(other than aquatic herbicides which are handled as conventional pesticides) 		
A460	68	New use, additional food use; establish tolerance exemption	<p>An application that proposes an additional food use. Additional food use includes a proposed food use of any U. S. registered active ingredient for which there currently is an approved food use. The use may require the establishment of an exemption from the requirement of a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), or an increase in or a food additive regulation or other clearance under section 409 of the FFDCA. The application may need to include a petition to establish an exemption from tolerance for all food commodities covered by the pending registration application(s) or, if residues would not be subject to FFDCA section 408, documentation of an applicable food additive regulation or other clearance under section 409 of the FFDCA. Refer to the definition of a “food use” for the uses subject to this category. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use.</p> <p>The fee applies to each additional food use requested in the application.</p> <p>Examples of the uses in this category include:</p> <ul style="list-style-type: none"> ▪ Pre- and post-harvest use on crops (other than agricultural fungicides and aquatic herbicides, which are handled as conventional pesticides). ▪ Animal drinking water treatment (meat, meat by-products and/or milk tolerance exemption) ▪ Process water treatment for post harvest use (field washing of raw agricultural commodities) ▪ Treatment of permanent or semi-permanent food contact surfaces (sanitizers and disinfectants) 	15	11,577

			<ul style="list-style-type: none"> ▪ Use in the product of food contact articles, other than food packaging with an intended ongoing effect in the finished article, including the articles surface or in food that may contact the article (conveyor belt - claims to kill bacteria that are on articles that come in contact with belt) ▪ Treatment of raw agricultural commodities in a food processing facility (FDA food additive regulation) ▪ Process water treatment in a food handling facility to control a pest in the water (FDA food additive regulation-EPA dietary risk assessment) ▪ Production of food contact articles other than food packaging (FDA food additive regulation) (conveyor belt, cutting board that contains an antimicrobial as a preservative) ▪ Slimicides (FDA food additive regulation) (e.g., pulp and paper board) ▪ Production of food packaging (FDA food additive regulation)(e.g. adhesives, coatings) ▪ Food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment) ▪ Aseptic packaging (FDA food additive regulation) ▪ Ethanol production (treatment of empty fermentation tank) (check with the Agency prior to submission of any application) ▪ Aquatic area application (e.g., lakes, ponds, reservoirs, irrigation systems)(other than aquatic herbicides which are handled as conventional pesticides) ▪ Home produce washes (dietary risk assessment required) ▪ Human drinking water systems (e.g., water purifier units, emergency water systems, municipal water treatment) 		
A470	69	New use, additional food use, establish tolerance	<p>An application that proposes a food use. Additional food use includes a proposed food use of any U. S. registered active ingredient for which there currently is an approved food use. The use may require the establishment of a tolerance, the increase in, or modification of a tolerance under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA). The application may need to include a petition to establish a tolerance for all food commodities covered by the pending application(s). Refer to the definition of a “food use” for the uses subject to this category. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use.</p> <p>The fee applies to each additional new food use requested in the application.</p> <p>Examples include:</p> <ul style="list-style-type: none"> ▪ Pre and post harvest use on crops (other than agricultural fungicides and aquatic herbicides, which are handled as conventional pesticides) ▪ Animal drinking water treatment ▪ Process water treatment for post harvest use (field washing of raw agricultural commodities) ▪ Treatment of permanent or semi-permanent food contact surfaces (sanitizers and disinfectants). ▪ Use in the product of food contact articles, other than food packaging with an intended ongoing effect in the finished article, including the articles surface or in food that may contact the article) ▪ Food handling storage establishment premises and equipment (e.g. eating establishments, meat processing equipment, food handling equipment) 	15	28,942

			<ul style="list-style-type: none"> ▪ Ethanol production (treatment of empty fermentation tank) (check with the Agency prior to submission of an application) ▪ Aquatic area application (e.g., lakes, ponds, reservoirs, irrigation systems)(other than aquatic herbicides which are handled as conventional pesticides) 		
A480	70	New use, Additional use, non-food, outdoor FIFRA sec. 2(mm) uses	<p>An application that proposes a non-food use for an active ingredient with a current EPA registration. A non-food use includes a proposed use that is not a “food use” as described in the food use categories. Outdoor use means any use that is not indoor as described in the “indoor category” and that fits the definition of an antimicrobial found in FIFRA section 2(mm). The fee applies to each new non-food use requested. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use.</p> <p>Examples include:</p> <ul style="list-style-type: none"> ▪ Once through cooling tower ▪ Aquatic area application (other than aquatic herbicides which are handled as conventional pesticides) ▪ Oil fields (marine) ▪ Sewage/wastewater treatment plants (water is treated prior to discharge into the environment) ▪ Any of the above use patterns that would result in a significant increase in the level of exposure (increase in dosage rate, or a change in the route of exposure fog vs. spray), to the active ingredient of man or other organisms. 	9	17,365
A490	71	New use, additional use, non-food, outdoor, other uses	<p>An application that proposes a non-food use for an active ingredient with a current EPA registration. The fee applies to each non-food use in this category requested in the application. A non-food use includes a proposed use that is not a “food use” as described in the food use categories. Outdoor means any use that is not indoor as described in the “indoor category”. Other uses are those uses not covered by the definition of an antimicrobial found in FIFRA section 2(mm). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use.</p> <p>Examples include:</p> <ul style="list-style-type: none"> ▪ Wood preservatives ▪ Antifoulants ▪ Ballast water ▪ Any of the above use patterns that would result in a significant increase in the level of exposure (increase in dosage rate, or a change in the route of exposure (fog vs. spray), to the active ingredient of man or other organisms. 	15	28,942
A500	72	New use, additional use, non-food, indoor FIFRA sec. 2(mm) uses	<p>An application that proposes a non-food use for an active ingredient with a current EPA registration. The fee applies to each non-food use in this category requested in the application. A non-food use includes a proposed use that is not a “food use” as described in the food use categories. The product is for use inside a manmade structure or is a low exposure use pattern that requires minimal ecological and/or environmental fate data (see examples below) and that fits the definition of an antimicrobial found in FIFRA section 2(mm). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use.</p>	9	11,577

			<p>Examples include:</p> <ul style="list-style-type: none"> ▪ Residential use (i.e., 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 equipment) ▪ Materials Preservatives (e.g., adhesives, coatings, plastic, fabric) ▪ Swimming pool, spa ▪ Industrial processes and water systems treatment (e.g., reverse osmosis water systems, re-circulating cooling tower systems, evaporative condensers) ▪ Medical premises and equipment (e.g., dental equipment, dental unit water lines, hospitals) ▪ HVAC ▪ Oil field (terrestrial) ▪ Any of the above use patterns that would result in a significant increase in the level of exposure (increase in dosage rate, or a change in the route of exposure (fog vs. spray), to the active ingredient of man or other organisms. 		
A510	73	New use, additional use, non-food, indoor, other than FIFRA 2(mm) uses	<p>An application that proposes a non-food use for an active ingredient with a current EPA registration. The fee applies to each non-food use in this category requested in the application. A non-food use includes a proposed use that is not a “food use” as described in the food use categories. The product is for use inside a manmade structure. Other uses are those uses not covered by the definition of an antimicrobial found in FIFRA 2(mm). A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use.</p> <p>Examples include:</p> <ul style="list-style-type: none"> ▪ Wood preservative, pressure and non-pressure treatments (e.g., joinery and mill work for door, window frames) ▪ Any significant increase in exposure requiring science review (increase in dosage rate, different method of application (fog vs. spray) will be treated as a new use 	12	11,577
A520	74	Experimental Use Permit application	<p>An experimental use permit is a tool that allows an unregistered pesticide to be used, or a registered pesticide to be used for an off-label use, under controlled, field or actual use conditions so that data required to support a FIFRA section 3 registration can be developed (e.g., data necessary to evaluate efficacy and potential for safe use or adverse effects on humans and the environment such as a swimming pool use). If residues are reasonably foreseeable or likely to occur, the application submission must contain one of the following: (i) evidence of applicable FFDCAs tolerances, exemptions, or clearances; (ii) a petition to establish a tolerance(s) or exemption(s) for all food commodities; (iii) certification that all food or feed derived from the experimental use will be destroyed, fed only to experimental animals for testing purposes, or disposed of in a manner that precludes its consumption as food or feed and presents no unreasonable adverse effects on the environment.</p>	9	5,789
A521	75	Review of public	<p>An application that requires the review of a modified protocol where only minor changes are made</p>	3	2,205

		health efficacy study protocol within AD; per AD Internal Guidance for the Efficacy Protocol Review Process; Applicant initiated; Tier 1	to an existing efficacy method (e.g. AOAC International, ASTM, AATCC, or an AD approved method described in A431). The study design for a Tier 1 protocol will be reviewed and approved within AD. A draft label with proposed directions for use and use claims must accompany the application. Examples of minor changes include: varied test conditions (e.g., contact time, use of different hard surface carrier types [porcelain penicylinders vs. stainless steel penicylinders], modification of standard method to support additional microorganisms [e.g., Germicidal Spray Products test for spore-formers], and changes to support alternate application types [e.g., foams]. A pre-registration meeting is recommended prior to submission of the protocol. The Agency will make every effort during this meeting to determine if the protocol is Tier 1. If during further review, the Agency determines that a Tier I protocol should be elevated to Tier 2 status, the applicant will receive notification prior to this change. Protocol review and approval must be completed before efficacy data is generated using the approved protocol and an application for registration is submitted to AD.		
A522	76	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; Applicant initiated; Tier 2	An application that requires the review of a new public health efficacy protocol, or a major change to an existing efficacy method (e.g. AOAC International, ASTM, AATCC, or an AD approved method described in A431). Applies to study design that requires review by external members of an AD Efficacy Protocol Review Expert Panel. A draft label with proposed directions for use and use claims must accompany the application, along with proposed performance measures. Examples of major protocol changes would include surrogate consideration, field test component, air sanitizers, simulated or in-use testing, changes in growth conditions [e.g., shaking vs. static for TB testing] and novel protocols for products with label claims that don't meet the conventional sterilant/disinfectant/sanitizer standards (e.g., treated materials). A pre-registration meeting is recommended prior to submission of the protocol. The Agency will make every effort during this meeting to determine if the protocol is Tier 2. Protocol review and approval must be completed before efficacy data is generated using the approved protocol and an application for registration is submitted to AD.	12	11,025
Table 8. New Products and Amendments					
A530	77	New product, identical or substantially similar in composition and use to a registered product; no data review or 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-	<p>An application for registration of an end-use or a manufacturing use pesticide product that is substantially similar, identical in its uses and formulation or that differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment to products that are currently registered. The applicant must identify the similar products for all active ingredients in the proposed product. All applications require the following:</p> <ul style="list-style-type: none"> ▪ A data matrix is required with the application if it is not a 100% re-packaged product. ▪ Product chemistry data (Group A and B) unless the product is identical (e.g. 100% repackaged product). ▪ The active ingredient listed on the CSF must be an EPA registered product. ▪ In all cases, the registrant must identify the registered similar product for this category. ▪ Acute toxicity requirements must be addressed by using: <ol style="list-style-type: none"> 1) the cite-all method 2) selective data citation where the applicant owns all required data, or 3) applicant submits specific authorization letter from the data owner. <p>The application is not in this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted and must be reviewed to support the application. The application does not fall into this category if it contains a request to waive any of these data.</p>	3	1,159

		<p>package of registered end-use or manufacturing use product that requires no data submission nor data matrix.</p>	<p>An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category. If the use pattern on the TGA1 differs from the proposed products, then additional data are required and the application does not fall within this category.</p> <p>Substantially similar: Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular), and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the product bears the same use patterns or fewer. Adding to or changing existing use patterns excludes the product from treatment as a substantially similar product. Substantially similar use patterns for public health products are limited to identical organisms on both products. For non-public health products substantially similar use patterns-are limited to identical organisms on both products.</p> <p>Deleting use patterns is acceptable</p> <p>Identical products: Same composition and use patterns as an already registered end-use product.</p> <p>Manufacturing Use Product: A 100% re-package of a manufacturing use product that requires no data submission nor data matrix is covered by this category.</p> <p>Unregistered: The Agency has not issued an EPA Registration Number (license) for the source material.</p>		
A531	78	<p>New product; 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 acute toxicity and/or public health pest efficacy, where the applicant does not own all required data and does not have a specific authorization letter from data owner.</p>	<p>An application for registration of an end-use pesticide product that is substantially similar or identical in its uses and/or formulation to products that are currently registered or differ only in ways that would not significantly increase the risk of unreasonable adverse effects. The applicant must identify the similar products for all active ingredients in the proposed product. All applications require the following:</p> <ul style="list-style-type: none"> ▪ A data matrix is required with the application. ▪ Product chemistry data (Group A and B) unless the product is identical. In some cases product chemistry data can be satisfied as outlined in PR Notice 98-1. ▪ All inert ingredients must be already approved for the applicable uses in the product. ▪ The source of the active ingredient must be currently registered (licensed) with the Agency. ▪ In all cases, the applicant must identify the currently registered similar product for this category. ▪ Acute toxicity, efficacy, public health pest efficacy, and/or child resistant packaging data requirement 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 a review of data other than product chemistry is needed, the application does not fall into this category. <p>The application does not fall into this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted and must be reviewed to support the application. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category.</p>	4	1,654

			<p>If the use pattern on the TGAI differs from the proposed products, then additional data are required and the application does not fall within this category.</p> <p>Substantially similar: Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular) and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the proposed product bears the same use patterns. Adding to or changing existing use patterns excludes the proposed product from treatment as a substantially similar product. Deleting use patterns is acceptable.</p> <p>Identical: Same composition and use patterns as a currently registered end use product.</p>		
A532	85	<p>New product; identical or substantially similar in composition and use to a registered product; registered active ingredient; unregistered source of active ingredient; cite-all data citation except for product chemistry; product chemistry data submitted.</p>	<p>An application for registration of an end-use pesticide or manufacturing use product that uses an unregistered source of the active ingredient and that is substantially similar or identical in its uses and/or formulation to products that are currently registered or differ only in ways that would not significantly increase the risk of unreasonable adverse effects. All applications require the following:</p> <ul style="list-style-type: none"> ▪ Product chemistry data (Group A and B) on the end-use product as well as the unregistered source of active ingredient. ▪ The cite-all method must be used to satisfy the generic data requirements. ▪ Acute toxicity requirements must be addressed by using the cite-all method. ▪ In all cases, the applicant must identify the currently registered similar product for this category. <p>The application is not this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted and must be reviewed to support the application. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category. If the use pattern on the TGAI differs from the proposed product, then additional data are required and the application does not fall within this category.</p> <p>Substantially similar: Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular) and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the proposed product bears the same use patterns. Adding to or changing existing use patterns excludes the proposed product from treatment as a substantially similar product. Deleting use patterns is acceptable.</p> <p>Identical: Same composition and use patterns as a currently registered end use product.</p>	4	4,631
A540	79	<p>New end use product; FIFRA § 2(mm) uses only</p>	<p>An application for registration of a pesticide product that is not substantially similar or identical in its uses or formulation to products that are currently registered. All applications require the following:</p> <ul style="list-style-type: none"> ▪ A data matrix is required with the application. ▪ Product chemistry data (Group A and B) unless the product is identical. In some cases product chemistry data can be satisfied as outlined in PR Notice 98-1. 	4	4,631

			<ul style="list-style-type: none"> ▪ All inert ingredients must be already approved for the applicable uses in the product. ▪ Acute toxicity, efficacy, public health pest efficacy, companion animal safety data 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 the required data. A rationale for a waiver of these data falls within this category. <p>A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use.</p>		
A550	80	New end use product, uses other than FIFRA sec. 2(mm); non-FQPA product	<p>An application for registration of a pesticide product that is not substantially similar or identical in its uses or formulation to products that are currently registered. These applications require product chemistry data (Group A and Group B), acute toxicity data (addressing all 6 endpoints), and possibly leaching data. Examples include:</p> <ul style="list-style-type: none"> ▪ Wood preservatives ▪ Antifoulants ▪ Ballast water ▪ Any of the above use patterns that would result in a significant increase in the level of exposure (increase in dosage rate, or a change in the route of exposure (fog vs. spray), to the active ingredient of man or other organisms. 	6	4,631
A560	81	New manufacturing use product, registered active ingredient, selective data citation	<p>An application for registration of a manufacturing use pesticide product that is 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.</p> <p>All applications require the following:</p> <ul style="list-style-type: none"> ▪ A data matrix is required with the application. ▪ Product chemistry data (Group A and B) are required. In some cases, product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. ▪ All inert ingredients must be approved for the applicable uses in the product. <p>An application proposed as a 100% re-packaged product does not fall within this category.</p> <p>An application for registration of a new product that is a salt of an already registered active ingredient and there are not any currently registered products for this salt. The Agency will decide on a case-by-case basis whether an ingredient should be classified as a new active ingredient.</p>	12	17,365
A570	82	Label Amendment requiring data submission	<p>An application for amended registration which requires review of data. This includes chemistry, toxicology, efficacy or other science review. Examples include:</p> <ul style="list-style-type: none"> ▪ Any submission that includes efficacy data or that requires an efficacy review. ▪ Signal word changes/review of acute toxicity data ▪ New active ingredient (ai) sources - change from one unregistered source to another or change from a registered source to an unregistered source ▪ Any submission requesting a CRP exemption 	4	3,474

			<ul style="list-style-type: none"> ▪ Any formula change that requires efficacy data, including confirmatory data. Routine formula changes are not PRIA actions. Routine formula changes are those which do not require data to support the change such as a new fragrance, dye or other addition or modification to the inert ingredients in the formula. ▪ Antifoulant product formula changes which require a release rate study to be submitted ▪ Any application that is significantly inconsistent with an applicable RED. For example, disagreement with a batching designation. <p>NOTE: Any significant increase in exposure requiring science review (increase in dosage rate, different method of application (fog vs. spray) will be treated as a new use.</p>		
A571	83	Cancer reassessment; applicant initiated	An application in which a request is made to change the cancer classification.	18	86,823
A572	84	Refined ecological risk and/or endangered species assessment; applicant initiated.	To be determined. Will be posted when available.	12	82,688

Biopesticides and Pollution Prevention Division

Table 9. Microbial and Biochemical Pesticides; New Products and Amendments					
B580	86	New active ingredient; food use; establish tolerance	<p>A new microbial or biochemical pesticide active ingredient. The use requires the applicant submit a petition to establish a tolerance under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA). A tolerance is the maximum residue level permitted for a pesticide active ingredient in or on food or animal feed, in accordance with FFDCA.</p> <p>All uses (food and/or non-food) included in any original application or petition for a new active ingredient or a first food uses that otherwise satisfy the conditions for the category are covered by the base fee for that application.</p>	18	46,305
B590	87	New active ingredient; food use; establish tolerance exemption	<p>An application for a product containing a new microbial or biochemical pesticide active ingredient. The proposed use meets the definition of a food use, requires that the applicant submit data to enable the Agency to conduct a dietary exposure assessment and may require that the applicant submit a petition for an exemption from the requirement of a tolerance for the active ingredient. All uses (food and non-food) included in any original application or tolerance exemption petition for a new active ingredient are covered by the base fee for the application in this category if submitted simultaneously.</p>	16	28,942
B600	88	New active ingredient; non-food use	<p>An application for a product containing a new microbial or biochemical pesticide active ingredient, with uses that do not fall under the definition of a food use.</p> <p>All non-food uses included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted simultaneously.</p>	12	17,365
B610	89	Food Use; Experimental Use Permit application; establish temporary tolerance	<p>An application for an Experimental Use Permit for a microbial or biochemical pesticide, where the proposed use meets the definition of a food use and requires that the applicant submit data to enable the Agency to conduct a dietary exposure assessment. The proposed use may require that the applicant submit a petition for an exemption from the requirement of a tolerance for the active ingredient. If required, the temporary tolerance exemption is established for an appropriate</p>	9	11,577

		exemption	period of time to allow the harvested commodity to enter the food or feed supply during the experimental period.		
B620	90	Non-Food Use; Experimental Use Permit application	An application for an Experimental Use Permit for a microbial or biochemical pesticide, with uses that do not fall under the definition of a food use, or with an agreement to destroy or use only for experimental purposes any crops treated during the experimental program.	6	5,789
B621	91	Extend or amend Experimental Use Permit	An application to amend an existing Experimental Use Permit for a microbial or biochemical pesticide. Amendments could include but are not limited to changing the uses, use sites, and/or acreage tested, and/or extending the length of time for completion of the experimental program. If a tolerance or tolerance exemption needs to be amended in connection with this action, you must add the cost of a petition (see B631 or B641, below, as appropriate).	6	4,631
B630	92	First food use; establish tolerance exemption	An application for registration of a new use for a microbial or biochemical pesticide, where the proposed first food use meets the definition of a food use, requires that the applicant submit data to enable the Agency to conduct a dietary exposure assessment and may require that the applicant submit a petition for an exemption from the requirement of a tolerance for the active ingredient.	12	11,577
B631	93	Amend established tolerance exemption	A petition to amend an existing tolerance exemption for a microbial or biochemical pesticide active ingredient where the proposed use meets the definition of a food use and requires that the applicant submit data to enable the Agency to conduct a dietary exposure assessment and that the applicant submit a petition for an exemption from the requirement of a tolerance for the active ingredient. This category includes amendments to temporary tolerance exemptions and other time-limited tolerance exemptions. In addition to the petition, there may be an application to amend an existing registered product or experimental use permit.	9	11,577
B640	94	First food use; establish tolerance	An application for registration of a new use for a microbial or biochemical pesticide where there is a reasonable expectation or certainty that residues of the active ingredient could occur in human food, animal feed, or in livestock from the proposed use. The first food use requires the applicant submit a petition to establish a tolerance for the active ingredient for the proposed use, and to submit data to demonstrate that dietary exposures to residues of the active ingredient at the tolerance level meet the FFDCA standard of reasonable certainty of no harm. All uses included in any original application or petition for a first food use that otherwise satisfy the conditions for the category are covered by the base fee for that application.	18	17,365
B641	95	Amend established tolerance (e.g., decrease or increase)	A petition to amend an established tolerance for a microbial or biochemical pesticide, with supporting data to demonstrate that dietary exposures to residues of the active ingredient at the tolerance level meet the FFDCA standard of reasonable certainty of no harm. This category includes amendments to temporary tolerances, such as those established in connection with an experimental use permit. In addition to the petition, there may be an application to register a product, or to amend an existing registered product or experimental use permit.	12	11,577
B650	96	New use; non-food	An application for registration of a new use for a microbial or biochemical pesticide, with uses that do not fall under the definition of a food use. This category also includes a change in use pattern such that the exposure to humans and the environment could be significantly increased (e.g., additional routes of exposure) and therefore must be evaluated for increased risks.	6	5,789
B660	97	New product; identical or substantially similar in composition and	An application for registration of an end-use or a manufacturing use microbial or biochemical pesticide product that is substantially similar, identical in its uses and formulation, or that differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment to products that are currently registered. The applicant must identify the similar	3	1,159

		<p>use to a registered product; no data review or 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-use or manufacturing-use product that requires no data submission or data matrix.</p>	<p>registered products for all active ingredients in the proposed product. All applications require the following:</p> <ul style="list-style-type: none"> • A data matrix is required with the application if it is not a 100% re-packaged product. • Product chemistry data (Group A and B) unless the product is identical (e.g., 100% repackaged product). In some cases, product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • The active ingredient(s) must be currently registered and the CSF must include its EPA Registration Number(s). • In all cases, the registrant must identify the registered similar product for this category. • Acute toxicity requirements must be addressed by using: <ol style="list-style-type: none"> 1) The cite-all method 2) Selective data citation where the applicant owns all required data, or 3) Applicant submits specific authorization letter from the data owner <p>The application is not in this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted and must be reviewed to support the application. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category. If the use pattern on the TGAI differs from the proposed products, then additional data are required and the application does not fall within this category.</p> <p>Substantially similar: Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular), and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the proposed product bears the same use pattern. Adding to or changing existing use patterns excludes the proposed product from treatment as a substantially similar product. Deleting use patterns is acceptable.</p> <p>Identical: Same composition and use patterns as a currently registered end-use product.</p> <p>Manufacturing Use Product: A 100% re-package of a manufacturing use product that requires no data submission or data matrix is covered by this category.</p>		
B670	98	<p>New product; registered source of active ingredient; all Tier I data for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product specific data or with request for data</p>	<p>An application for registration of a microbial or biochemical pesticide product that is not substantially similar or identical in its uses and/or formulation to products that are currently registered. These applications require product specific chemistry data, acute toxicity data and other Tier I mammalian and non-target toxicity data as determined by the general use patterns for the product. When public health pests are claimed, efficacy (product performance) data for the product must be submitted. Formulator's exemption for the data requirements can be claimed when the source of the TGAI is registered by another pesticide registrant. If the registered source of the active ingredient is owned by the current applicant, Formulator's exemption is not applicable. The data used to support the registered source is instead referenced on the applicant's data matrix. This category is not for a new use.</p>	6	4,631

		waivers supported by scientific rationales.			
B671	99	New product; food use; unregistered source of active ingredient; requires amendment of established tolerance or tolerance exemption; all Tier I data requirements for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product-specific data or with requests for data waivers supported by scientific rationales.	An application for registration of a microbial or biochemical pesticide product that is not substantially similar or identical in its uses and/or formulation to products that are currently registered. These applications require product specific chemistry data, acute toxicity data and other Tier I mammalian and non-target toxicity data as determined by the general use patterns for the product. When public health pests are claimed, efficacy (product performance) data for the product must be submitted. This category includes products containing an active ingredient(s) that requires a change in, or establishment of, a tolerance or tolerance exemption, and in those situations there must be a petition to establish or amend an existing tolerance or tolerance exemption for the active ingredient.	16	11,577
B672	100	New product; non-food use or food use having established tolerance or tolerance exemption; unregistered source of active ingredient; no data compensation issues; all Tier I data requirements for product chemistry, toxicology, non-target organisms, and product performance must be addressed with	An application for registration of a microbial or biochemical pesticide product that is not substantially similar or identical in its uses and/or formulation to products that are currently registered. These applications require product specific chemistry data, acute toxicity data and other Tier I mammalian and non-target toxicity data as determined by the general use patterns for the product. When public health pests are claimed, efficacy (product performance) data for the product must be submitted. This category does not include products containing an active ingredient(s) that requires a change in, or establishment of, a tolerance or tolerance exemption or require the Agency to conduct a dietary risk assessment.	12	8,269

		product-specific data or with request for data waivers supported by scientific rationales.			
B680	101	Label amendment requiring data submission	An application to amend a registration is in this category when it contains data to support a change in the label (such as use patterns, use site changes) or to add an alternate formulation, or change the basic formulation of a currently registered product. These data include but are not limited to: toxicity data, product chemistry data, manufacturing process, non-target toxicity data, efficacy/product performance, child-resistant packaging data, and data to support a new pattern of use (e.g., increased application rate, different application methods) that changes the potential for human and/or environmental risks or exposure. EPA-initiated amendments shall not be charged fees. Label amendments submitted by notification under PR Notices., such as PR Notice 95-2 and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees.	4	4,631
B681	102	Label amendment; unregistered source of active ingredient; supporting data require scientific review	An application to amend a registration is in this category when it contains data to support a change in the label (such as use patterns, use site changes) or to add an alternate formulation or change the basic formulation of a currently registered product. These data include but are not limited to: toxicity data, non-target toxicity data, efficacy/product performance, child-resistant packaging data, additional (unregistered) sources of the active ingredient with supporting chemistry data, manufacturing process, efficacy (if public health pests are claimed), and data to support a pattern of use (e.g., increased application rate, different application methods) that changes the potential for human and/or environmental risks or exposure.	6	5,513
B682	103	Protocol review; applicant-initiated; excludes time for HSRB review (pre-application)	An applicant-initiated request to review a study protocol to address a data requirement prior to submission of an application to register a product (or amend a currently registered product). If the study protocol is for a product performance study involving human test subjects (such as mosquito repellents and other products designed to protect humans from public health pests), it must be reviewed by the Human Studies Review Board (HSRB) before the registrant conducts the study. Protocols reviewed by the HSRB are not included in this fee category.	3	2,205
			Table 10. Straight Chain Lepidopteran Pheromones (SCLPS)		
B690	104	New active ingredient; food or non-food use	An application for a product containing a new active ingredient SCLP which either has no food uses or if there is a food use, is anticipated to meet the existing tolerance exemption for SCLPs. All uses (food and/or non-food) included in any original application or petition for a first food use that otherwise satisfy the conditions for the category are covered by the base fee.	6	2,316
B700	105	Experimental Use Permit application; new active ingredient or new use	An application for an experimental use permit where the SCLP fits within the existing tolerance exemption for SCLPs, or with an agreement to destroy, or use only for experimental purposes, any crops treated during the experimental program.	6	1,159
B701	106	Extend or amend Experimental Use Permit	An application to amend an existing Experimental Use Permit for a SCLP product, which could include (but is not limited to): changing the uses, use sites, and/or acreage tested, and/or extending the length of time for completion of the experimental program.	3	1,159
B710	107	New product;	An application for registration of a SCLP product that is substantially similar or identical in its uses	3	1,159

		<p>identical or substantially similar in composition and use to a registered product; no data review or 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% repackage of registered end-use or manufacturing-use product that requires no data submission or data matrix.</p>	<p>and formulation to products that are currently registered, or differ from a currently registered product only in ways that would not significantly increase the risk of unreasonable adverse effects to humans or the environment. In all cases, the applicant must identify the similar registered product.</p> <p>Identical products are identical to another registered product and bear identical use patterns. For an identical (100% repackaging or repack) of a registered SCLP product, the data requirements are satisfied by the registered identical product. The Confidential Statement of Formula (CSF) of the proposed product must indicate the product is a 100% repack of the previously registered product.</p> <p>Substantially similar products must contain the same active ingredient, in substantially the same proportion. They must have the same physical state (solid, liquid, granular), and contain substantially similar other (inert) ingredients. The proposed product must have the same use patterns.</p> <p>Identical/substantially similar products may have fewer uses, but all of its uses must have been approved for the claimed similar product. Adding or changing the use patterns (other than removal of uses) excludes the product from treatment as a substantially similar product.</p> <p>If the new product is a simple dilution of, or differs only by a minor change in inert ingredients from the registered product, some minor product chemistry may be required. Any cited data must have been previously reviewed and accepted by the Agency.</p> <p>A new product is not substantially similar to a registered product if an unregistered source of TGA material is used to formulate the new product, or if new data, scientific literature, and/or waivers are submitted to satisfy the data requirements for the new product.</p>		
B720	108	<p>New product; registered source of active ingredient; all Tier 1 data for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product specific data or with request for data waivers supported by scientific rationales</p>	<p>An application for a new product for an existing SCLP active ingredient that includes data to support the registration.</p>	4	1,159
B721	109	<p>New product; unregistered source of active</p>	<p>An application for a new product for a registered SCLP active ingredient; the source of the active ingredient used in the product is not registered.</p>	6	2,426

		ingredient			
B722	110	New use and/or amendment to tolerance or tolerance exemption	An application for a new use for a registered SCLP active ingredient that is not covered by the SCLP tolerance exemption. A petition to amend the established tolerance exemption for SCLPs, with supporting data to demonstrate that dietary exposures to residues of the active ingredient meet the FFDCA safety standard, i.e., there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, must accompany the application.	6	2,426
B730	111	Label amendment requiring data submission	An application to amend an existing registration containing an SCLP active ingredient. The application contains for Agency review data that is submitted to support a change to the formulation and/or data that is necessary to support a product labeling change (e.g., use pattern, use sites, etc.) EPA-initiated amendments shall not be charged fees. Label amendments submitted by notification under PR Notices, such as PR Notice 95-2 and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees.	4	1,159
Table 11. Plant Incorporated Protectants (PIPS)					
B740	112	Experimental Use Permit application; registered active ingredient; non-food/feed or crop destruct basis; no SAP review required	An application for an EUP using a registered PIP active ingredient, without food or feed uses, or with an agreement to destroy, or use only for experimental purposes, any crops treated during the experimental program. No issue(s) raised that would require a SAP. Example: transfer existing PIP trait by traditional breeding, such as from field corn to sweet corn.	6	86,823
B750	113	Experimental Use Permit application; registered active ingredient; establish temporary tolerance or tolerance exemption; no SAP review required	An application for an EUP to allow a registered PIP active ingredient to be used under controlled, field or actual use conditions so that the data required to support a federal registration can be developed to evaluate the PIP's efficacy and potential for adverse effects on human health and the environment. A temporary tolerance or exemption is set for an appropriate period of time to allow the harvest of any treated food or feed commodities during the experimental period. No issue(s) raised that would require a SAP. Example: transfer existing PIP trait by traditional breeding, such as from field corn to sweet corn.	9	115,763
B760	114	Experimental Use Permit application; new active ingredient; non-food/feed or crop destruct basis; SAP review required; credit \$78,750 toward new active ingredient application that follows	An application for an EUP using a new PIP active ingredient without food or feed uses, or with an agreement to destroy, or use only for experimental purposes, any crops treated during the experimental program. The new PIP active ingredient raises issue(s) which require a SAP.	12	144,704
B761	115	Experimental Use	An application for an EUP using a new PIP active ingredient with no food or feed uses, or with an	7	86,823

		Permit application; new active ingredient; non-food/feed or crop destruct; no SAP review required; credit \$78,750 toward new active ingredient application that follows	agreement to destroy, or use only for experimental purposes, any crops treated during the experimental program. No issue(s) raised that would require a SAP.		
B770	116	Experimental Use Permit application; new active ingredient; establish temporary tolerance or tolerance exemption; SAP review required; credit \$105,000 toward new active ingredient application that follows	An application for an EUP to allow a new PIP active ingredient to be used under controlled, field or actual use conditions so that data required to support a federal registration can be developed to evaluate its efficacy and potential for adverse effects on humans and the environment. A temporary tolerance or exemption will be established for an appropriate period of time to allow the harvest of any treated food or feed commodities during the experimental period. The new PIP raises issue(s) that require a SAP review.	15	173,644
B771	117	Experimental Use Permit application; new active ingredient; establish temporary tolerance or tolerance exemption; no SAP review required; credit \$105,000 toward new active ingredient application that follows	An application for an EUP to allow a new PIP active ingredient to be used under controlled, field or actual use conditions so that data required for a federal registration can be developed to evaluate its efficacy and potential for adverse effects on humans and the environment. A temporary tolerance or exemption will be established for an appropriate period of time to allow the harvest of any treated food or feed commodities during the experimental period. The new PIP raises no issue(s) that require a SAP review.	10	115,763
B772	118	Amend or extend existing Experimental Use Permit; minor changes to experimental	An amendment making minor changes to or extend the test period of an existing PIP EUP registration.	3	11,577

		design; established temporary tolerance or tolerance exemption is unaffected			
B773	119	Amend or extend Experimental Use Permit; minor changes to experimental design; extend established temporary tolerance or tolerance exemption	An amendment making minor changes to or to extend the test period of an existing PIP EUP; an extension of an existing temporary tolerance/tolerance exemption is needed.	5	28,942
B860	120	Amend Experimental Use Permit; first food use or major revision of experimental design.	An amendment to expand, extend or modify a PIP EUP. A tolerance or tolerance exemption must be established for the first food use of the active ingredient in the product. A petition to establish a tolerance or exemption from the requirement of a tolerance with supporting data must accompany an application for the first food use.	6	11,577
B780	121	New active ingredient; non-food/feed; no SAP review required	An application for a new PIP active ingredient for a non-food/feed use. No issue(s) identified that warrant a SAP. May be either a registration for seed increase or a full commercial registration. If a seed increase registration is granted first, full commercial registration is obtained using B890.	12	144,704
B790	122	New active ingredient; non-food/feed; SAP review required	An application for a new PIP active ingredient for a non-food/feed use with issue(s) identified that warrant a SAP. May be either a registration for seed increase or a full commercial registration. If a seed increase registration is granted first, full commercial registration is obtained using B890.	18	202,585
B800	123	New active ingredient; establish permanent tolerance or tolerance exemption based on temporary tolerance or tolerance exemption; no SAP review required	An application for a new PIP active ingredient for a food/feed use. A temporary tolerance or temporary exemption from a tolerance already exists to support an EUP for the active ingredient. A permanent tolerance or tolerance exemption is needed for registration. A petition to establish a tolerance or exemption from the requirement of a tolerance with supporting data must accompany the application. No issue(s) identified that warrant a SAP. May be either a registration for seed increase or a full commercial registration. If a seed increase registration is granted first, full commercial registration is obtained using B890.	12	231,525
B810	124	New active	An application for a new PIP active ingredient for a food/feed use. A temporary tolerance or a	18	289,407

		ingredient; establish permanent tolerance or tolerance exemption based on temporary tolerance or tolerance exemption; SAP review required	temporary exemption from a tolerance already exists to support an EUP for the active ingredient. A permanent tolerance or tolerance exemption is needed for registration. A petition to establish a tolerance or exemption from the requirement of a tolerance with supporting data must accompany the application. Issue(s) identified that warrant a SAP. May be either a registration for seed increase or a full commercial registration. If a seed increase registration is granted first, full commercial registration is obtained using B890.		
B820	125	New active ingredient; establish tolerance or tolerance exemption; no SAP review required.	An application for a new PIP active ingredient for a food/feed use. A tolerance or an exemption from a tolerance must be established. No previous temporary tolerance or tolerance exemption has been established. A petition to establish a tolerance or exemption from the requirement of a tolerance with supporting data must accompany the application. No issue(s) identified that warrant a SAP. May be either a registration for seed increase or a full commercial registration. If a seed increase registration is granted first, full commercial registration is obtained using B890.	15	289,407
B840	126	New active ingredient; establish tolerance or tolerance exemption; SAP review required.	An application for a new PIP active ingredient for a food/feed use. A tolerance or an exemption from a tolerance must be established. No previous temporary tolerance or temporary tolerance exemption has been established. A petition to establish a tolerance or exemption from the requirement of a tolerance with supporting data must accompany the application. Issue(s) identified that warrant a SAP. May be either a registration for seed increase or a full commercial registration. If a seed increase registration is granted first, full commercial registration is obtained using B890.	21	347,288
B830	127	New active ingredient; Experimental use Permit application submitted simultaneously; establish tolerance or tolerance exemption; no SAP review required	An application for a new PIP active ingredient for a food/feed use. An EUP application accompanies the registration application. A tolerance or an exemption from a tolerance must be established. A petition to establish a tolerance or exemption from the requirement of a tolerance with supporting data must accompany the application. No issue(s) identified that warrant a SAP. May be either a registration for seed increase or a full commercial registration. If a seed increase registration is granted first, full commercial registration is obtained using B890.	15	347,288
B850	128	New active ingredient; Experimental Use Permit requested simultaneously; establish tolerance or tolerance exemption; SAP review required.	An application for a new PIP active ingredient for a food/feed use. An EUP application accompanies the registration application. A tolerance or an exemption from a tolerance must be established. A petition to establish a tolerance or exemption from the requirement of a tolerance with supporting data must accompany the application. Issue(s) identified that warrant a SAP. May be either a registration for seed increase or a full commercial registration. If a seed increase registration is granted first, full commercial registration is obtained using B890.	21	405,169
B851	129	New active	An application for a new PIP active ingredient for a food/feed use that differs from a similar active	9	115,763

		ingredient; different genetic event of a previously approved active ingredient; same crop; no tolerance action required; no SAP review required.	ingredient that is registered due to its origination from a different genetic event. The new PIP active ingredient and the proposed use is already covered under an existing tolerance or tolerance exemption. No issue(s) identified that warrant a SAP.		
B852	130	New active ingredient; different genetic event of a previously approved active ingredient; same crop; no tolerance action required; SAP review required.	An application for a new PIP active ingredient for a food/feed use that differs from a similar active ingredient that is registered due to its origination from a different genetic event. The new PIP active ingredient and the proposed use is already covered under an existing tolerance or tolerance exemption. Issue(s) identified that warrant a SAP.	9	173,644
B870	131	New Use	An application to amend a registered PIP product to add a new use site. Example: transfer existing PIP trait by traditional breeding, such as from field corn to sweet corn.	9	34,729
B880	132	New Product; no SAP review required.	An application for a new PIP product containing a previously registered active ingredient that is in an existing registered product. No issue(s) identified that require a SAP review. Example: Stacking PIP traits within a crop using traditional breeding techniques.	9	28,942
B881	133	New product; SAP review required.	An application for a new PIP product containing a previously registered active ingredient that is in an existing registered product. Issue(s) identified that requires a SAP review. Example: Stacking PIP traits within a crop using traditional breeding techniques.	15	86,823
B890	134	Amendment; seed production to commercial registration; no SAP review required	An application to amend a registered PIP product that only allows for seed production to allow for commercial registration. No issue(s) identified that require a SAP review.	9	57,882
B891	135	Amendment; seed production to commercial registration; SAP review required	An application to amend a registered PIP product that only allows for seed production to allow for commercial registration. Issue(s) identified that require a SAP review.	15	115,763
B900	136	Amendment (except #B890); No SAP review required; (e.g., new IRM requirements that are applicant initiated; or	An application to amend a registered PIP product – except as described in B870, B890 and B891. No issue(s) identified that require a SAP review. EPA-initiated amendments shall not be charged fees. Label amendments submitted by notification under PR Notices such as PR Notice 95-2 and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees.	6	11,577

		amending a conditional registration to extend the registration expiration date with additional data submitted)			
B901	137	Amendment (except #B890); SAP review required	An application to amend a registered PIP product, except as defined in B870, B890 and B891. Issue(s) identified that require an SAP review. EPA-initiated amendments shall not be charged fees. Label amendments submitted by notification under PR Notices such as PR Notice 95-2 and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees.	12	69,458
B902	138	PIP Protocol Review	An applicant-initiated request for Agency review of the proposed description of the study(ies) that will be performed to support the registration of a PIP	3	5,789
B903	139	Inert ingredient tolerance exemption; e.g. a marker such as NPT II, reviewed in BPPD	A petition to establish a tolerance or an exemption from tolerance for a PIP inert ingredient (for example, a marker protein).	6	57,882
B904	140	Import tolerance or tolerance exemption; processed commodities/food only	A petition to establish a tolerance or tolerance exemption for foods imported into the United States that contain PIP active ingredients.	9	115,763