

4045

“TABLE 1. — REGISTRATION DIVISION (RD) — NEW ACTIVE INGREDIENTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R010	1	New Active Ingredient, Food use. (2) (3)	36	1,079,356
R020	2	New Active Ingredient, Food use; reduced risk. (2) (3)	27	899,464
R040	3	New Active Ingredient, Food use; Experimental Use Permit application; establish temporary tolerance; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3) (4)	18	662,883
R060	4	New Active Ingredient, Non-food use; outdoor. (2) (3)	30	749,886
R070	5	New Active Ingredient, Non-food use; outdoor; reduced risk. (2) (3)	24	624,905

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“TABLE 1. — REGISTRATION DIVISION (RD) — NEW ACTIVE INGREDIENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R090	6	New Active Ingredient, Non-food use; outdoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3) (4)	16	463,930
R110	7	New Active Ingredient, Non-food use; indoor. (2) (3) (4)	20	417,069
R120	8	New Active Ingredient, Non-food use; indoor; reduced risk. (2) (3) (4)	14	347,556
R121	9	New Active Ingredient, Non-food use; indoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3) (4)	18	261,322

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“TABLE 1. — REGISTRATION DIVISION (RD) — NEW ACTIVE INGREDIENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R122	10	Enriched isomer(s) of registered mixed-isomer active ingredient. (2) (3)	27	454,526
R123	11	New Active Ingredient, Seed treatment only; includes agricultural and non-agricultural seeds; non-food use, not requiring a tolerance. (2) (3)	27	676,296
R126	12 (new)	New Active Ingredient, Seed treatment only; limited uptake into raw agricultural commodities; use requiring a tolerance. (2) (3)	31	743,925

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“TABLE 1. — REGISTRATION DIVISION (RD) — NEW ACTIVE INGREDIENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R125	13	New Active Ingredient, Seed treatment; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3) (4)	16	463,930

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

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant’s initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

## 4049

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

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

“TABLE 2. — REGISTRATION DIVISION (RD) — NEW USES

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R130	14	First food use; indoor; food/food handling. (2) (3) (5)	23	274,388
R140	15	Additional food use; Indoor; food/food handling. (3) (4) (5)	17	64,028
R150	16	First food use. (2) (3) (5)	23	454,490
R155	17	First food use, Experimental Use Permit application; active ingredient registered for non-food use. (3) (4) (5)	21	378,742

## 4050

“TABLE 2. — REGISTRATION DIVISION (RD) — NEW USES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R160	18	First food use; reduced risk. (2) (3) (5)	18	378,742
R170	19	Additional food use. (3) (4) (5)	17	113,728
R175	20	Additional food uses covered within a crop group resulting from the conversion of existing approved crop group(s) to one or more revised crop groups. (3) (4) (5)	14	94,774
R180	21	Additional food use; reduced risk. (3) (4) (5)	12	94,774
R190	22	Additional food uses; 6 or more submitted in one application. (3) (4) (5)	17	682,357
R200	23	Additional Food Use; 6 or more submitted in one application; Reduced Risk. (3) (4) (5)	12	568,632

## 4051

“TABLE 2. — REGISTRATION DIVISION (RD) — NEW USES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R210	24	Additional food use; Experimental Use Permit application; establish temporary tolerance; no credit toward new use registration. (3) (4) (5)	12	70,210
R220	25	Additional food use; Experimental Use Permit application; crop destruct basis; no credit toward new use registration. (3) (4) (5)	6	28,434
R230	26	Additional use; non-food; outdoor. (3) (4) (5)	16	45,453
R240	27	Additional use; non-food; outdoor; reduced risk. (3) (4) (5)	10	37,878
R250	28	Additional use; non-food; outdoor; Experimental Use Permit application; no credit toward new use registration. (3) (4) (5)	6	28,434

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“TABLE 2. — REGISTRATION DIVISION (RD) — NEW USES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R251	29	Experimental Use Permit application which requires no changes to the tolerance(s); non-crop destruct basis. (3) (5)	8	28,434
R260	30	New use; non-food; indoor. (3) (4) (5)	12	21,954
R270	31	New use; non-food; indoor; reduced risk. (3) (4) (5)	9	18,296
R271	32	New use; non-food; indoor; Experimental Use Permit application; no credit toward new use registration. (3) (4) (5)	6	13,940
R273	33	Additional use; seed treatment only; use not requiring a new tolerance; includes crops with established tolerances (e.g., for soil or foliar application). (3) (4) (5)	12	72,302



## 4053

“TABLE 2. — REGISTRATION DIVISION (RD) — NEW USES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R274	34	Additional use; seed treatment only; 6 or more submitted in one application; uses not requiring new tolerances; includes crops with established tolerances (e.g., for soil or foliar application). (3) (4) (5)	12	433,793
R276	35 (new)	Additional use, seed treatment only; limited uptake into raw agricultural commodities; use requiring a tolerance. (3) (4) (5)	14	79,560
R277	36 (new)	Additional use, seed treatment only; 6 or more submitted in one application; limited uptake into raw agricultural commodities; use requiring a tolerance. (3) (4) (5)	14	477,360

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

## 4054

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

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

(4) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

## 4055

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

“TABLE 3. — REGISTRATION DIVISION (RD) — IMPORT AND OTHER TOLERANCES

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R280	37	Establish tolerances for residues in imported commodities; new active ingredient or first food use. (2)	22	457,311
R290	38	Establish tolerances for residues in imported commodities; Additional new food use.	16	91,465
R291	39	Establish tolerances for residues in imported commodities; additional food uses; 6 or more crops submitted in one petition.	16	548,773

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“TABLE 3. — REGISTRATION DIVISION (RD) — IMPORT AND OTHER TOLERANCES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R292	40	Amend an established tolerance (e.g., decrease or increase) and/or harmonize established tolerances with Codex Maximum Residue Limits; domestic or import; applicant-initiated.	12	64,987
R293	41	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated.	13	76,656
R294	42	Establish tolerances for inadvertent residues; 6 or more crops submitted in one application; applicant-initiated.	13	459,922

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“TABLE 3. — REGISTRATION DIVISION (RD) — IMPORT AND OTHER TOLERANCES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R295	43	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; submission of corresponding label amendments which specify the necessary plant-back restrictions; applicant-initiated. (3) (4)	16	94,774
R296	44	Establish tolerances for residues in rotational crops in response to a specific rotational crop petition; 6 or more crops submitted in one application; submission of corresponding label amendments which specify the necessary plant-back restrictions; applicant-initiated. (3) (4)	16	568,632

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“TABLE 3. — REGISTRATION DIVISION (RD) — IMPORT AND OTHER TOLERANCES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R297	45	Amend 6 or more established tolerances (e.g., decrease or increase) in one petition; domestic or import; applicant-initiated.	12	389,897
R298	46	Amend an established tolerance (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3) (4)	14	83,940
R299	47	Amend 6 or more established tolerances (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3) (4)	14	408,853

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“TABLE 3. — REGISTRATION DIVISION (RD) — IMPORT AND OTHER TOLERANCES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R281	48 (new)	Establish tolerances for residues in imported commodities; additional new food use; submission of residue chemistry data review conducted by Codex or other competent national regulatory authority.	12	68,599
R282	49 (new)	Establish tolerances for residues in imported commodities; additional new food uses; 6 or more crops submitted in one petition; submission of residue chemistry data review conducted by Codex or other competent national regulatory authority.	12	411,580

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

## 4060

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

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

(4) Amendment applications to add the revised use pattern(s) to registered product labels are covered by the base fee for the category. All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the amendment application package is subject to the registration service fee for a new product or a new inert approval. However, if an amendment application only proposes to register the amendment for a new product and there are no amendments in the application, then review of one new product application is covered by the base fee. All such associated applications that are submitted together will be subject to the category decision review time.



## 4061

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R300	50	New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; no data review on acute toxicity, efficacy or child-resistant packaging — only product chemistry data; cite all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% repackage of registered end-use or manufacturing-use product that requires no data submission nor data matrix. (2) (3)	4	2,270

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“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R301	51	New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy (identical data citation and claims to cited product(s)), where applicant does not own all required data and does not have a specific authorization letter from data owner. (2) (3)	4	2,720

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“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R310	52	<p>New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>4. Child-resistant packaging and/or</li> <li>4. pest(s) requiring efficacy – for up to 3 target pests.</li> </ol> <p>(2) (3) (4)</p>	7	10,466

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“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R314	53	<p>New end-use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. child resistant packaging and/or</li> <li>4. pest(s) requiring efficacy (4) for up to 3 target pests. (2) (3)</li> </ol>	8	12,364

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“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R319	54	<p>New end-use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. child resistant packaging and/or</li> <li>4. pest(s) requiring efficacy (4) - for 4 to 7 target pests. (2) (3)</li> </ol>	10	18,097

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“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R318	55	<p>New end-use product containing four or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. child resistant packaging and/or</li> <li>4. pest(s) requiring efficacy – for up to 3 target pests.</li> </ol> <p>(2) (3) (4)</p>	9	18,994

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“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R321	56	<p>New end-use product containing four or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. child resistant packaging and/or</li> <li>4. pest(s) requiring efficacy (4) - for 4 to 7 target pests. (2) (3)</li> </ol>	11	24,727

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“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R315	57	New end-use on-animal product, registered source of active ingredient(s) with submission of data and/or waivers for only: <ol style="list-style-type: none"> <li>1. animal safety and</li> <li>2. pest(s) requiring efficacy and/or</li> <li>3. product chemistry and/or</li> <li>4. acute toxicity and/or</li> <li>5. child resistant packaging. (2) (3) (4)</li> </ol>	9	14,075



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“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R316	58	New end-use or manufacturing-use product with registered source(s) of active ingredient(s) including products containing two or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; and requires review of data and/or waivers for only: <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. child resistant packaging and/or</li> <li>4. pest(s) requiring efficacy - for 4 to 7 target pests.</li> </ol> (2) (3) (4)	9	16,199

4070

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R317	59	New end-use or manufacturing-use product with registered source(s) of active ingredient(s) including products containing two or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; and requires review of data and/or waivers for only: <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. child resistant packaging and/or</li> <li>4. Pest(s) requiring efficacy - for greater than 7 target pests, (2) (3) (4)</li> </ol>	10	21,932
R320	60	New product; new physical form; requires data review in science divisions. (2) (3) (5)	12	18,958

4071

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R331	61	New product; re-pack of identical registered end-use product as a manufacturing-use product; same registered uses only. (2) (3)	3	3,627
R332	62	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of completely new generic data package; registered uses only; requires review in RD and science divisions. (2) (3)	24	405,919
R333	63	New product; manufacturing-use product or end-use product with unregistered source of active ingredient; requires science data review; new physical form; etc. Cite-all or selective data citation where applicant owns all required data. (2) (3)	11	28,434

4072

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R334	64	New product; manufacturing-use product or end-use product with unregistered source of the active ingredient; requires science data review; new physical form; etc. Selective data citation. (2) (3)	12	33,108

4073

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R361	65 (new)	<p>New end-use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. Child resistant packaging and/or</li> <li>4. pest(s) requiring efficacy – for more than 7 target pests. (2) (3) (4)</li> </ol>	12	23,400

4074

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R362	66 (new)	<p>New end-use product containing four or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. Child resistant packaging and/or</li> <li>4. pest(s) requiring efficacy – for more than 7 target pests. (2) (3) (4)</li> </ol>	13	25,350

4075

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R363	67 (new)	New product; re-pack of identical registered manufacturing-use product as an end-use product; same registered uses only, with no additional data. (2) (3)	6	7,800

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

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

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

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

## 4076

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

“TABLE 5. — REGISTRATION DIVISION (RD) — AMENDMENTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R340	68	Amendment requiring data review within RD (e.g., changes to precautionary label statements); includes adding/modifying pest(s) claims for up to 2 target pests; excludes products requiring or citing an animal safety study. (2) (3)	4	7,150
R341	69	Amendment requiring data review within RD (e.g., changes to precautionary label statements), includes adding/modifying pest(s) claims for greater than 2 target pests; excludes products requiring or citing an animal safety study. (2) (3)	6	8,584



4077

“TABLE 5. — REGISTRATION DIVISION (RD) —  
AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R345	70	Amending on-animal products previously registered, with the submission of data and/or waivers for only: <ol style="list-style-type: none"> <li>1. animal safety and</li> <li>2. pest(s) requiring efficacy and/or</li> <li>3. product chemistry and/or</li> <li>4. acute toxicity and/or</li> <li>5. child resistant packaging. (2) (3) (4)</li> </ol>	7	12,643
R350	71	Amendment requiring data review in science divisions (e.g., changes to Restricted Entry Interval, or Personal Protective Equipment, or Preharvest Interval, or use rate, or number of applications; or add aerial application; or modify Ground Water/Surface Water advisory statement). (2) (3) (5)	9	18,958

4078

“TABLE 5. — REGISTRATION DIVISION (RD) —  
AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R351	72	Amendment adding a new unregistered source of active ingredient. (2) (3)	8	18,958
R352	73	Amendment adding already approved uses; selective method of support; does not apply if the applicant owns all cited data. (2) (3)	8	18,958
R371	74	Amendment to Experimental Use Permit; (does not include extending a permit's time period). (3)	6	14,463

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

(2) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

## 4079

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

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

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

“TABLE 6. — REGISTRATION DIVISION (RD) — OTHER ACTIONS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R124	75	Conditional Ruling on Pre-application Study Waivers; applicant-initiated.	6	3,627

4080

“TABLE 6. — REGISTRATION DIVISION (RD) — OTHER ACTIONS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R272	76	Review of Study Protocol applicant- initiated; excludes Data Analysis Reporting Tool, pre- registration conference, Rapid Response review, developmental neurotoxicity protocol review, protocol needing Human Studies Review Board review, companion animal safety protocol.	3	3,627
R275	77	Rebuttal of Agency reviewed protocol, applicant initiated.	3	3,627
R278	78 (new)	Review of Protocol for companion animal safety study.	5	4,927

4081

“TABLE 6. — REGISTRATION DIVISION (RD) — OTHER ACTIONS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R279	79 (new)	Comparative product determination for reduced risk submission, applicant initiated; submitted before application for reduced risk new active ingredient or reduced risk new use.	3	5,200

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

“TABLE 7. — ANTIMICROBIAL DIVISION (AD) — NEW ACTIVE INGREDIENTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A380	80	New Active Ingredient; Indirect Food use; establish tolerance or tolerance exemption if required. (2) (3) (4)	26	227,957
A390	81	New Active Ingredient; Direct Food use; establish tolerance or tolerance exemption if required. (2) (3) (4)	26	329,265

4082

“TABLE 7. — ANTIMICROBIAL DIVISION (AD) — NEW ACTIVE INGREDIENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A410	82	New Active Ingredient Non-food use. (2) (3) (4)	23	278,659
A431	83	New Active Ingredient, Non-food use; low-risk. (2) (3) (4)	14	114,984

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

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant’s initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

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

## 4083

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

“TABLE 8. — ANTIMICROBIAL DIVISION (AD) — NEW USES

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
A440	84	New Use, Indirect Food Use, establish tolerance or tolerance exemption. (2) (3) (4) (6)	23	45,737
A441	85	Additional Indirect food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application. (3) (4) (5) (6)	23	164,639
A450	86	New use, Direct food use, establish tolerance or tolerance exemption. (2) (3) (4) (6)	23	137,198
A451	87	Additional Direct food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application. (3) (4) (5) (6)	22	261,333

4084

“TABLE 8. — ANTIMICROBIAL DIVISION (AD) — NEW USES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A500	88	New use, non-food. (4) (5) (6)	15	45,737
A501	89	New use, non-food; 6 or more submitted in one application. (4) (5) (6)	17	109,764

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

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant’s initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) If EPA data rules are amended to newly require clearance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.



## 4085

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

(5) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

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

4086

“TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A530	90	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. (2) (3)	4	1,833

4087

“TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A531	91	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 applicant does not own all required data and does not have a specific authorization letter from data owner. (2) (3)	4	2,616

4088

“TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A532	92	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. (2) (3)	5	7,322
A550	93	New end-use product; uses other than FIFRA §2(mm); non-FQPA product. (2) (3) (5)	9	18,958
A560	94	New manufacturing-use product; registered active ingredient; selective data citation. (2) (3)	6	18,054

4089

“TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A565	95	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of new generic data package; registered uses only; requires science review. (2) (3)	18	26,135
A572	96	New Product or amendment requiring data review for risk assessment by Science Branch (e.g., changes to Restricted Entry Interval, or Personal Protective Equipment, or use rate). (2) (3) (4) (7)	9	18,958
A460	97 (new)	New end-use product; FIFRA §2(mm) uses only; 0 to 10 public health organisms. (2) (3) (5) (6)	5	7,322

## 4090

“TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A461	98 (new)	New end-use product; FIFRA §2(mm) uses only; 11 to 20 public health organisms. (2) (3) (5) (6)	6	10,158
A462	99 (new)	New end-use product; FIFRA §2(mm) uses only; 21 to 30 public health organisms. (2) (3) (5) (6)	7	12,995
A463	100 (new)	New end-use product; FIFRA §2(mm) uses only; 31 to 40 public health organisms. (2) (3) (5) (6)	9	15,831
A464	101 (new)	New end-use product; FIFRA §2(mm) uses only; 41 to 50 public health organisms. (2) (3) (5) (6)	10	18,668
A465	102 (new)	New end-use product; FIFRA §2(mm) uses only; 51 or more public health organisms. (2) (3) (5) (6)	11	21,505

## 4091

“TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A470	103 (new)	Label amendment requiring data review; 0 to 10 public health organisms. (3) (4) (5) (6)	4	5,493
A471	104 (new)	Label amendment requiring data review; 11 to 20 public health organisms. (3) (4) (5) (6)	5	8,506
A472	105 (new)	Label amendment requiring data review; 21 to 30 public health organisms. (3) (4) (5) (6)	6	10,219
A473	106 (new)	Label amendment requiring data review; 31 to 40 public health organisms. (3) (4) (5) (6)	7	11,933
A474	107 (new)	Label amendment requiring data review; 41 to 50 public health organisms. (3) (4) (5) (6)	8	13,646

4092

“TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A475	108 (new)	Label amendment requiring data review; 51 or more public health organisms. (3) (4) (5) (6)	9	15,766

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

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

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

(4) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

(5) The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements.

(6) Once an application for an amendment or a new product with public health organisms has been submitted and classified into any of categories A460 through A465 or A470 through A475, additional organisms submitted for the same product before the first application is granted will result in combination and reclassification of both the original and subsequent submissions into the appropriate new category based on the sum of the number of organisms in both submissions. Submission of additional organisms would result in a new PRIA start date and may require additional fees to meet the fee of a new category.



## 4093

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

“TABLE 10. — ANTIMICROBIAL DIVISION (AD) —  
EXPERIMENTAL USE PERMITS AND OTHER ACTIONS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A520	109	Experimental Use Permit application, non-food use. (2) (3)	9	9,151
A521	110	Review of public health efficacy study protocol within AD, per AD Internal Guidance for the Efficacy Protocol Review Process; Code will also include review of public health efficacy study protocol; applicant-initiated; Tier 1.	6	6,776
A522	111	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; Code will also include review of public health efficacy study protocol; applicant-initiated; Tier 2.	12	17,424

4094

“TABLE 10. — ANTIMICROBIAL DIVISION (AD) — EXPERIMENTAL USE PERMITS AND OTHER ACTIONS—  
Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A537	112	New Active Ingredient/New Use, Experimental Use Permit application; Direct food use; Establish tolerance or tolerance exemption if required. Credit 45% of fee toward new active ingredient/new use application that follows. (3)	18	219,512
A538	113	New Active Ingredient/New Use, Experimental Use Permit application; Indirect food use; Establish tolerance or tolerance exemption if required Credit 45% of fee toward new active ingredient/new use application that follows. (3)	18	137,198

4095

“TABLE 10. — ANTIMICROBIAL DIVISION (AD) — EXPERIMENTAL USE PERMITS AND OTHER ACTIONS—  
Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A539	114	New Active Ingredient/New Use, Experimental Use Permit application; Nonfood use. Credit 45% of fee toward new active ingredient/new use application that follows. (3)	15	132,094
A529	115	Amendment to Experimental Use Permit; requires data review or risk assessment. (2) (3)	9	16,383
A523	116	Review of protocol other than a public health efficacy study (i.e., Toxicology or Exposure Protocols).	9	17,424
A571	117	Science reassessment: refined ecological risk, and/or endangered species; applicant-initiated. (3)	18	137,198
A533	118	Exemption from the requirement of an Experimental Use Permit. (2)	4	3,559

## 4096

“TABLE 10. — ANTIMICROBIAL DIVISION (AD) — EXPERIMENTAL USE PERMITS AND OTHER ACTIONS—  
Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A534	119	Rebuttal of Agency reviewed protocol, applicant initiated.	4	6,776
A535	120	Conditional ruling on pre-application study waiver or data bridging argument; applicant-initiated.	6	3,454
A536	121	Conditional ruling on pre-application direct food, indirect food, nonfood use determination; applicant-initiated.	4	3,559
A575	122 (new)	Efficacy similarity determination; if two products can be bridged or if confirmatory efficacy data are needed.	4	3,389

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

## 4097

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

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

“TABLE 11. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW ACTIVE INGREDIENTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B580	123	New active ingredient; petition to establish a tolerance. (2) (3) (4)	22	73,173
B590	124	New active ingredient; petition to establish a tolerance exemption. (2) (3) (4)	20	45,737

4098

“TABLE 11. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW ACTIVE INGREDIENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B600	125	New active ingredient; no change to a permanent tolerance or tolerance exemption (includes non-food uses). (2) (3) (4)	15	27,443
B610	126	New active ingredient; Experimental Use Permit application; petition to establish a permanent or temporary tolerance or temporary tolerance exemption. (3) (4)	12	18,296
B620	127	New active ingredient; Experimental Use Permit application; non-food use (includes crop destruct). (3) (4)	9	9,151

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

## 4099

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

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

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

## 4100

“TABLE 12. — BIOPESTICIDES AND POLLUTION  
PREVENTION DIVISION (BPPD) — NEW USES

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
B630	128	First food use; petition to establish/amend a tolerance exemption. (2) (4) (5)	13	18,296
B640	129	First food use; petition to establish/amend a tolerance. (2) (4) (5)	19	27,443
B644	130	New use, no change to an established tolerance or tolerance exemption (includes non-food uses). (3) (4) (5)	8	18,296
B645	131	New use; Experimental Use Permit; petition to establish a permanent or temporary tolerance or tolerance exemption. (4) (5)	12	18,296
B646	132	New use; Experimental Use Permit; non-food use (includes crop destruct). (4) (5)	7	9,151

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



## 4101

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screen, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

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

## 4102

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

“TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW PRODUCTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
B660	133	New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption; no data submission or data matrix (or submission of product chemistry data only). (2) (3)	6	1,833
B670	134	New product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption; (including non-food); Must address Product-Specific Data Requirements. (2) (3)	9	7,322

4103

“TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B672	135	New product; unregistered source of at least one active ingredient (or registered source with new generic data package); no change in an established tolerance or tolerance exemption (including non-food); must address Product-Specific and Generic Data Requirements. (2) (3)	15	13,069
B673	136	New product; unregistered source of active ingredient(s); citation of Technical Grade Active Ingredient (TGAI) data previously reviewed and accepted by the Agency; requires an Agency determination that the cited data support the new product. (2) (3)	12	7,322

## 4104

“TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B674	137	New product; repack of identical registered end-use product or repack of an end-use product as a manufacturing-use product; same registered uses only. (2) (3)	4	1,833
B677	138	New end-use non-food animal product with submission of two or more target animal safety studies; includes data and/or waivers of data for only: <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. public health pest efficacy and/or</li> <li>4. animal safety studies and/or</li> <li>5. child resistant packaging. (2) (3)</li> </ol>	12	12,643

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

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

## 4105

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

“TABLE 14. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — AMENDMENTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B621	139	Amendment; Experimental Use Permit; no change to an established temporary or permanent tolerance or tolerance exemption. (3) (4)	7	7,322
B622	140	Amendment; Experimental Use Permit; petition to amend a permanent or temporary tolerance or tolerance exemption. (3) (4)	11	18,296
B641	141	Amendment; changes to an established tolerance or tolerance exemption. (4)	13	18,296

## 4106

“TABLE 14. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B680	142	Amendment; registered sources of active ingredient(s); no new use(s); no changes to an established tolerance or tolerance exemption; requires data submission. (2) (3)	5	7,322
B681	143	Amendment; unregistered source of active ingredient(s); no change to an established tolerance or tolerance exemption; requires data submission. (2) (3)	7	8,714

4107

“TABLE 14. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B683	144	Amendment; no change to an established tolerance or tolerance exemption; requires review/update of previous risk assessment(s) without data submission (e.g., labeling changes to Restricted Entry Interval, Personal Protective Equipment, Preharvest Interval). (2) (3)	6	7,322
B684	145	Amending non-food animal product that includes submission of target animal safety data; previously registered. (2) (3)	8	12,643

4108

“TABLE 14. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
B685	146	Amendment; add a new bio-chemical un-registered source of active ingredient or a new microbial production site; requires submission of analysis of samples data and source/production site-specific manufacturing process description. (3)	5	7,322

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

(2) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

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



## 4109

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

“TABLE 15. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — STRAIGHT-CHAIN LEPIDOPTERAN PHEROMONES (SCLP)

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B690	147	SCLP; new active ingredient; food or non-food use. (2) (6) (7)	7	3,662
B700	148	SCLP; Experimental Use Permit application; new active ingredient or new use. (6) (7)	7	1,833
B701	149	SCLP; Extend or amend Experimental Use Permit. (6) (7)	4	1,833

## 4110

“TABLE 15. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — STRAIGHT-CHAIN LEPIDOPTERAN PHEROMONES (SCLP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B710	150	SCLP; new product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption; no data submission or data matrix (or only product chemistry data); (Includes 100% re-pack; re-pack of registered end-use product as a manufacturing-use product). (3) (6)	4	1,833

4111

“TABLE 15. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — STRAIGHT-CHAIN LEPIDOPTERAN PHEROMONES (SCLP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B720	151	SCLP; new product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption (including non-food); Must address Product-Specific Data Requirements. (3) (6)	5	1,833
B721	152	SCLP: new product; unregistered source of active ingredient; no change in an established tolerance or tolerance exemption (including non-food); must address Product-Specific and Generic Data Requirements. (3) (6)	7	3,836
B722	153	SCLP; new use and/or amendment; petition to establish a tolerance or tolerance exemption. (4) (5) (6) (7)	7	3,552

4112

“TABLE 15. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — STRAIGHT-CHAIN LEPIDOPTERAN PHEROMONES (SCLP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B730	154	SCLP; amendment requiring data submission. (4) (6)	5	1,833

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

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant’s initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

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

(4) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

## 4113

(5) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

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

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

## 4114

“TABLE 16. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — OTHER ACTIONS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
B614	155	Pre-application; Conditional Ruling on rationales for addressing a data requirement in lieu of data; applicant-initiated; applies to one (1) rationale at a time.	3	3,627
B682	156	Protocol review; applicant initiated; excludes time for Human Studies Review Board review (Includes rebuttal of protocol review).	3	3,487
B616	157 (new)	Pre-application; Conditional Ruling on a non-food use determination.	5	4,715
B617	158 (new)	Pre-application; biochemical classification determination.	5	4,715

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

4115

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B740	159	Experimental Use Permit application; no petition for tolerance/tolerance exemption; includes: <ol style="list-style-type: none"> <li>1. non-food/feed use(s) for a new (2) or registered (3) PIP (12);</li> <li>2. food/feed use(s) for a new or registered PIP with crop destruct;</li> <li>3. food/feed use(s) for a new or registered PIP in which an established tolerance/tolerance exemption exists for the intended use(s). (4) (5) (12)</li> </ol>	9	137,198

## 4116

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B750	160	Experimental Use Permit application; with a petition to establish a temporary or permanent tolerance/tolerance exemption for the active ingredient. Includes new food/feed use for a registered (3) PIP. (4) (12)	12	182,927
B771	161	Experimental Use Permit application; new (2) PIP; with petition to establish a temporary tolerance/tolerance exemption for the active ingredient; credit 75% of B771 fee toward registration application for a new active ingredient that follows. (5) (12)	13	182,927



## 4117

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B772	162	Application to amend or extend a PIP Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active ingredient is unaffected. (12)	3	18,296
B773	163	Application to amend or extend a PIP Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient. (12)	9	45,737
B780	164	Registration application; new (2) PIP; non-food/feed or food/feed without tolerance petition based on an existing permanent tolerance exemption. (5) (12) (14)	16	228,657

4118

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B800	165	Registration application; new (2) PIP; with petition to establish permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. (5) (12) (14)	17	246,949
B820	166	Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient. (5) (12) (14)	19	292,682

4119

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B851	167	Registration application; new event of a previously registered PIP active ingredient(s); no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s). (12)	9	182,927
B870	168	Registration application; registered (3) PIP; new product; new use; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (4) (12) (14)	9	54,881

4120

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B880	169	Registration application; registered (3) PIP; new product or new terms of registration; additional data submitted; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (5) (6) (7) (12) (14)	9	45,737
B883	170	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. (5) (8) (12) (14)	13	182,927

4121

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B884	171	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient. (5) (8) (12) (14)	19	228,657
B885	172	Registration application; registered (2) PIP, seed increase; breeding stack of previously approved PIPs, same crop; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (9) (12)	6	45,737

4122

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B890	173	Application to amend a seed increase registration; converts registration to commercial registration; no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s). (5) (12) (14)	9	91,465
B900	174	Application to amend a registration, including actions such as modifying an IRM plan, or adding an insect to be controlled. (5) (10) (11) (12)	6	18,296
B902	175	PIP Protocol review.	3	9,151
B903	176	Inert ingredient permanent tolerance exemption; e.g., a marker such as NPT II; reviewed in BPPD.	12	91,465

4123

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B904	177	Import tolerance or tolerance exemption; processed commodities/food only (inert or active ingredient).	12	182,927
B905	178	FIFRA Scientific Advisory Panel Review.	6	91,465
B906	179	Petition to establish a temporary tolerance/tolerance exemption for one or more active ingredients.	9	45,733
B907	180	Petition to establish a permanent tolerance/tolerance exemption for one or more active ingredients based on an existing temporary tolerance/tolerance exemption.	9	18,296

4124

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B909	181 (new)	PIP tolerance exemption determination; applicant-initiated; request to determine if an existing tolerance exemption applies to a PIP.	6	18,296
B910	182 (new)	Biotechnology Notification for small-scale field testing of genetically engineered microbes.	3	9,151



4125

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B921	183 (new)	Experimental Use Permit application; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); non-food/feed. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. Credit 75% of B921 fee toward registration application for the new active ingredient that follows (B922). (5) (12) (13)	12	182,927

4126

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B922	184 (new)	Registration application; new active ingredient; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); non-food/feed. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. (5) (12) (13) (14)	16	228,657

4127

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B923	185 (new)	Experimental Use Permit application; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); with petition to establish a temporary or permanent tolerance/tolerance exemption of an active ingredient. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. Credit 75% of B923 fee toward registration application for the new active ingredient that follows (B924). (5) (12) (13) (14)	15	228,658

4128

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B924	186 (new)	Registration application; new active ingredient; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); with petition to establish a permanent tolerance/tolerance exemption of an active ingredient. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. (5) (12) (13) (14)	19	292,682

4129

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B925	187 (new)	Experimental Use Permit application; exogenous applications of RNA to elicit the RNA interference pathway in pests; non-food/feed; credit 75% of B925 fee toward registration application for the new active ingredient that follows (B926). (5) (12)	11	27,452
B926	188 (new)	Registration application; new active ingredient; exogenous applications of RNA to elicit the RNA interference pathway in pests; non-food/feed. (5) (12) (14)	17	82,329

4130

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B927	189 (new)	Experimental Use Permit application; exogenous applications of RNA to elicit the RNA interference pathway in pests; with petition to establish a temporary or permanent tolerance/tolerance exemption of an active ingredient; credit 75% of B927 fee toward registration application for the new active ingredient that follows (B928). (5) (12)	14	54,889

4131

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B928	190 (new)	Registration application; new active ingredient; exogenous applications of RNA to elicit the RNA interference pathway in pests; with petition to establish a permanent tolerance/tolerance exemption of an active ingredient. (5) (12) (14)	22	137,210
B929	191 (new)	Registration application; new product, registered active ingredient; exogenous applications of RNA to elicit the RNA interference pathway in pests; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (5) (12)	10	7,322

4132

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B930	192 (new)	Application to amend or extend a non-PIP Emerging Technologies Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active ingredient is unaffected. (12)	3	18,296
B931	193 (new)	Application to amend or extend a non-PIP Emerging Technologies Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient. (12)	9	45,737
B932	194 (new)	Amendment; application to amend a non-PIP Emerging Technologies registration. (4) (5) (12)	6	18,296

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

(2) ‘New PIP’ means a PIP with an active ingredient that has not been registered.

(3) ‘Registered PIP’ means a PIP with an active ingredient that is currently registered.

(4) Transfer registered PIP through conventional breeding for new food/feed use, such as from field corn to sweet corn.



## 4133

(5) If, during review of the application, it is determined that review by the FIFRA Scientific Advisory Panel (SAP) is needed, the applicant will submit an application for category B905, which will be processed concurrently, and the decision review time for both applications will be the longer of the two associated applications. The scientific data involved in this category are complex. EPA often seeks technical advice from the SAP on risks that pesticides pose to wild-life, farm workers, pesticide applicators, non-target species, insect resistance, and novel scientific issues surrounding new technologies. The scientists of the SAP neither make nor recommend policy decisions. They provide advice on the science used to make these decisions. Their advice is invaluable to the EPA as it strives to protect humans and the environment from risks posed by pesticides. Due to the time it takes to schedule and prepare for meetings with the SAP, additional time and costs are needed.

(6) Registered PIPs stacked through conventional breeding.

(7) Deployment of a registered PIP with a different Insecticide Resistance Management (IRM) plan (e.g., seed blend).

(8) The negotiated acreage cap will depend upon EPA's determination of the potential environmental exposure, risk(s) to non-target organisms, and the risk of targeted pest developing resistance to the pesticidal substance. The uncertainty of these risks may reduce the allowable acreage, based upon the quantity and type of non-target organism data submitted and the lack of insect resistance management data, which is usually not required for seed-increase registrations. Registrants are encouraged to consult with EPA prior to submission of a registration application in this category.

(9) Application can be submitted prior to or concurrently with an application for commercial registration.

(10) For example, IRM plan modifications that are applicant-initiated.

(11) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

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

(13) This category does not include genetic modifications in animals not intended for use as a pesticide, e.g., genetic modifications in animals intended for food use or animals intended for use as companion animals.

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

4134

“TABLE 18. — INERT INGREDIENTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
I001	195	Approval of new food use inert ingredient. (2) (3)	15	38,698
I002	196	Amend currently approved inert ingredient tolerance or exemption from tolerance; new data. (2)	13	10,750
I003	197	Amend currently approved inert ingredient tolerance or exemption from tolerance; no new data. (2)	11	4,742
I004	198	Approval of new non-food use inert ingredient. (2)	6	15,803
I005	199	Amend currently approved non-food use inert ingredient with new use pattern; new data. (2)	6	7,903
I006	200	Amend currently approved non-food use inert ingredient with new use pattern; no new data. (2)	4	4,742

4135

“TABLE 18. — INERT INGREDIENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
I007	201	Approval of substantially similar non-food use inert ingredients when original inert is compositionally similar with similar use pattern. (2)	5	2,371
I008	202	Approval of new or amended polymer inert ingredient, food use. (2)	7	5,374
I009	203	Approval of new or amended polymer inert ingredient, non-food use. (2)	4	4,427
I010	204	Petition to amend a single tolerance exemption descriptor, or single non-food use descriptor, to add ≤ 10 CASRNs; no new data. (2)	7	2,371
I011	205	Approval of new food use safener with tolerance or exemption from tolerance. (2)	26	856,631
I012	206	Approval of new non-food use safener. (2)	21	595,147

4136

“TABLE 18. — INERT INGREDIENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
I013	207	Approval of additional food use for previously approved safener with tolerance or exemption from tolerance. (2)	17	90,260
I014	208	Approval of additional non-food use for previously approved safener. (2)	15	36,074
I015	209	Approval of new generic data for previously approved food use safener. (2)	26	386,589
I016	210	Approval of amendment(s) to tolerance and label for previously approved safener. (2)	15	79,942
I017	211 (new)	Add new source of previously approved safener.	8	18,958

4137

“TABLE 18. — INERT INGREDIENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
I018	212 (new)	Petition to add one approved inert ingredient (CASRN) to the Commodity Inert Ingredient List; no data. (4)	3	2,371

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

(2) If another covered application is submitted that depends upon an application to approve an inert ingredient, each application will be subject to its respective registration service fee. The decision review time for both submissions will be the longest of the associated applications. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.

(3) If EPA data rules are amended to newly require clearance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.

(4) Due to low fee and short time frame this category is not eligible for small business waivers.

“TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
M001	213	Study protocol requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of a currently registered active ingredient.	14	11,378

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“TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
M002	214	Completed study requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of an active ingredient. (2)	14	11,378
M003	215	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of less than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA § 25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (3)	12	91,651

4139

“TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
M004	216	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of greater than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA § 25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (3)	18	91,651

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“TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
M005	217	New Product: Combination, Contains a combination of active ingredients from a registered and/or unregistered source; conventional, antimicrobial and/or biopesticide. Requires coordination with other regulatory divisions to conduct review of data, label and/or verify the validity of existing data as cited. Only existing uses for each active ingredient in the combination product. (4) (5) (6)	9	31,604
M006	218	Request for up to 5 letters of certification (Gold Seal) for one actively registered product (excludes distributor products). (7)	1	398



4141

“TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
M007	219	Request to extend Exclusive Use of data as provided by FIFRA Section 3(e)(1)(F)(ii).	12	7,903
M008	220	Request to grant Exclusive Use of data as provided by FIFRA Section 3(e)(1)(F)(vi) for a minor use, when a FIFRA Section 2(l)(2) determination is required.	15	2,371
M009	221	Non-FIFRA Regulated Determination; applicant-initiated, per product.	6	3,389
M010	222	Conditional ruling on pre-application, product substantial similarity.	4	3,389
M011	223	Label amendment to add the DfE logo; requires data review; no other label changes. (8)	4	5,230

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“TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
M012	224 (new)	Request for up to 5 letters of certification (Certificate of Establishment) for one actively registered product or one product produced for export (excludes distributor products). (7)	1	398
M013	225 (new)	Cancer reassessment; applicant-initiated.	18	284,144
M014	227 (new)	Pre-application nano-particle determination.	8	17,424

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

(2) Any other covered application that is associated with and dependent on the review by the Human Studies Review Board will be subject to its separate registration service fee. The decision review times for the associated actions run concurrently, but will end at the date of the latest review time.

(3) Any other covered application that is associated with and dependent on the FIFRA Scientific Advisory Panel review will be subject to its separate registration service fee. The decision review time for the associated action will be extended by the decision review time for the SAP review.

(4) If another covered application is submitted that depends upon an application to approve an inert ingredient, each application will be subject to its respective registration service fee. The decision review time for both submissions will be the longest of the associated applications. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.

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

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

(7) Due to low fee and short time frame this category is not eligible for small business waivers.

(8) This category includes amendments the sole purpose of which is to add 'Design for the Environment' (DfE) (or equivalent terms that do not use 'safe' or derivatives of 'safe') logos to a label. DfE is a voluntary program. A label bearing a DfE logo is not considered an Agency endorsement because the ingredients in the qualifying product must meet objective, scientific criteria established and widely publicized by EPA.”.

## 1 **SEC. 707. INFORMATION.**

2 Not later than 180 days after the date of enactment  
3 of this title, the Administrator of the Environmental Pro-  
4 tection Agency shall post on a single webpage of the  
5 website of the Environmental Protection Agency aggre-  
6 gated information on pesticide regulation under the Fed-  
7 eral Insecticide, Fungicide, and Rodenticide Act (7 U.S.C.  
8 136 et seq.), including—

9 (1) all guidance relating to risk assessment,  
10 risk mitigation, benefits assessments, and cost-ben-  
11 efit balancing;

12 (2) hyperlinks to resources, including the De-  
13 partment of Agriculture's “national list of allowed  
14 and prohibited substances” for organic crop and  
15 livestock production;