

Primary and Secondary New Product Applications, Submitted at the Same Time
(PC = Product Chemistry Data)

FY'20-FY'21 Fees

Description	Primary Application ¹		Secondary Application ²			
	PRIA Code	Application Fee (\$)	Where the only data submitted with a secondary application is product chemistry data or where the secondary application is a 100% repack of the primary		Where the secondary application contains more data than just PC such as efficacy and/or acute toxicity data	
			Agency Code ³	Expected Fee ⁴ (\$)	Agency Code ³	Expected Fee ⁴ (\$)
Registration Division						
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: <ul style="list-style-type: none"> • product chemistry and/or • acute toxicity and/or • child resistant packaging and/or • pest(s) requiring efficacy – for up to 3 target pests 	R310	7,667	R310.1	1,917	R310.2	7,667
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: <ul style="list-style-type: none"> • product chemistry and/or • acute toxicity and/or 	R314	9,058	R314.1	2,265	R314.2	7,667

¹ Each new product application is subject to a PRIA fee. Where one set of data or data waivers apply to two or more new product applications that are submitted at the same time, the Agency refers to the first product application containing the data or data waivers as the primary application.

² Additional new product applications that rely on data or data waivers that were submitted with the primary product application are referred to as secondary applications.

³ EPA will assign a tracking code to alert reviewers to the relationship between primary and secondary applications. These codes are internal EPA tracking codes only.

⁴ Based on previous years of experience, EPA expects that it can grant a discretionary refund that will likely result in a reduced fee equal to the amount indicated in this column. This expected fee is based on either the fee for an identical/substantially similar product with no data review for the type of product (i.e. conventional, antimicrobial, or biopesticide) or 25% of the fee for the primary, whichever is greater and rounded up to the nearest whole dollar. In accordance with FIFRA 33(b)(2)(C), payment of at least 25% of the fee for the applicable PRIA category accompanied by a request for a refund of all or part of the remaining fee would allow this application to go forward into review. **Where this chart indicates the expected fee is more than 25%, EPA recommends submitting the amount of the expected fee as listed in this column along with a request for a refund to avoid delays in processing applications for which a complete fee has not been received.**

Description	Primary Application ¹		Secondary Application ²			
	PRIA Code	Application Fee (\$)	Where the only data submitted with a secondary application is product chemistry data or where the secondary application is a 100% repack of the primary		Where the secondary application contains more data than just PC such as efficacy and/or acute toxicity data	
			Agency Code ³	Expected Fee ⁴ (\$)	Agency Code ³	Expected Fee ⁴ (\$)
<ul style="list-style-type: none"> • child resistant packaging and/or • pest(s) requiring efficacy – for up to 3 target pests 						
<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> <ul style="list-style-type: none"> . product chemistry and/or . acute toxicity and/or . child resistant packaging and/or . pest(s) requiring efficacy – for 4 to 7 target pests 	R319	13,258	R319.1	3,315	R319.2	7,667
<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> <p>Only:</p> <ul style="list-style-type: none"> . product chemistry and/or . acute toxicity and/or . child resistant packaging and/or . pest(s) requiring efficacy – for up to 3 target pests 	R318	13,915	R318.1	3,479	R318.2	7,667

<p>New end-use product containing four or more registered active ingredient(s) 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; and requires review of data and/or waivers for only:</p> <ul style="list-style-type: none"> . product chemistry and/or . acute toxicity and/or . child resistant packaging and/or . pest(s) requiring efficacy – for 4 to 7 target pests 	R321	18,115	R321.1	4,529	R321.2	7,667
<p>New end-use on animal product with submission of two or more target animal safety studies; includes data and/or waivers of data for only:</p> <ul style="list-style-type: none"> • animal safety and • pest(s) requiring efficacy and/or • product chemistry and/or • acute toxicity and/or <p>child resistant packaging</p>	R315	10,311	R315.1	2,578	R315.2	7,667
<p>New end-use or manufacturing product with registered source(s) of active ingredient(s) including products containing two or more registered active ingredient 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:</p> <ul style="list-style-type: none"> . product chemistry and/or . acute toxicity and/or . child resistant packaging and/or . pest(s) requiring efficacy – for greater than 3 and up to 7 target pests 	R316	11,867	R316.1	2,967	R316.2	7,667
<p>New end-use or manufacturing product with registered source(s) of active ingredient(s) including products containing two or more registered active ingredient 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:</p> <ul style="list-style-type: none"> . product chemistry and/or . acute toxicity and/or . child resistant packaging and/or . pest(s) requiring efficacy – for greater than 7 target pests 	R317	16,067	R317.1	4,017	R317.2	7,667
<p>New product; new physical form; requires data review in science divisions</p>	R320	13,888	R320.1	3,472	R320.2	7,667

New product; repack of identical registered end-use product as a manufacturing-use product; same registered uses only	R331	2,657	R331	N/A	R331	N/A
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	R332	297,376	R332.1	74,344	R332.2	74,344
New product; MUP or end-use product with unregistered source of active ingredient; requires science data review; new physical form; etc. Cite-all or selective data citation where applicant owns all required data	R333	20,830	R333.1	5,208	R333.2	7,667
New product; MUP or end-use product with unregistered source of the active ingredient; requires science data review; new physical form; etc. Selective data citation.	R334	24,255	R334.1	6,064	R334.2	7,667

Description	Primary Application ¹		Secondary Application ²			
	PRIA Code	Application Fee (\$)	Where the only data submitted with a secondary application is product chemistry data or where the secondary application does not require confirmatory efficacy data		Where the secondary application contains more data than just PC such as efficacy and/or acute toxicity data	
			Agency Code ³	Expected Fee ⁴ (\$)	Agency Code ³	Expected Fee ⁴ (\$)
Antimicrobials Division						
New end use product; FIFRA §2(mm) uses only; up to 25 public health organisms	A540	5,363	A540.1	1,341	A540.2	5,363
New end use product; FIFRA §2(mm) uses only; 26 – 50 public health organisms	A541	8,925	A541.1	2,231	A541.2	5,363
New end use product; FIFRA §2(mm) uses only; ≥ 51 public health organisms	A542	15,750	A542.1	3,938	A542.2	5,363
New end-use product; uses other than FIFRA §2(mm); non-FQPA product	A550	13,888	A550.1	3,472	A550.2	5,363
New manufacturing-use product; registered active ingredient; selective data citation	A560	13,226	A560.1	3,307	A560.2	5,363
New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of new generic data package; registered uses only; requires science review	A565	19,146	A565.1	4,787	A565.2	5,363
Label amendment requiring data review	A570	4,023	A570.1	1,006	A570.2	5,363

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			Agency Code ³	Expected Fee ⁴ (\$)	Agency Code ³	Expected Fee ⁴ (\$)
Biopesticides and Pollution Prevention Division						
New product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption; requires: submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply.	B670	5,363	B670.1	1,341	B670.2	5,363

<p>New product; unregistered source of active ingredient(s); requires a petition to amend an established tolerance or tolerance exemption; requires:</p> <ol style="list-style-type: none"> 1) submission of product specific data; or 3) citation of previously reviewed and accepted data; or submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. 	B671	13,403	B671.1	3,351	B671.2	5,363
<p>New product; unregistered source of active ingredient(s); non-food use or food use with a tolerance or tolerance exemption previously established for the active ingredient(s); requires:</p> <ol style="list-style-type: none"> 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. 	B672	9,574	B672.1	2,394	B672.2	5,363

New product MUP/EP; 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 supports the new product.	B673	5,363	B673.1	1,341	B673.2	5,363
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			Agency Code ³	Expected Fee ⁴ (\$)	Agency Code ³	Expected Fee ⁴ (\$)
New Product MUP; registered source of active ingredient; submission of completely new generic data package; registered uses only.	B675	9,574	B675.1	2,394	B675.2	5,363
New product; more than one active ingredient where one active ingredient is an unregistered source; product chemistry data must be submitted; requires: 1) submission of product specific data, and 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply.	B676	9,574	B676.1	2,394	B676.2	5,363
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: - product chemistry and/or - acute toxicity and/or - public health pest efficacy and/or - animal safety studies and/or - child resistant packaging	B677	9,261	B677.1	2,315	B677.2	5,363

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New product; unregistered source of active ingredient (SCLP)	B721	2,810	B721.1	703	B721.2	2,810
Registration application; registered 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).	B880	33,506	B880.1	8,377	B880.2	8,377
Registration application; registered 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). SAP review.	B881	100,511	B881.1	25,128	B881.2	25,128
Registration application; registered (3) 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).	B885	33,506	B885.1	8,377	B885.2	8,377

Example

A company submits 3 new antimicrobial registration applications. The 3 applications are: one 20% concentrate, a 15% concentrate and a 10% concentrate. The package consists of chemistry data for each application, one set of acute toxicity studies using the 20% concentrate and one set of efficacy data generated at the use dilution (the use dilution is the same for all three products). All three products will rely on the same efficacy data because all three products will be diluted to the same concentration and the difference in the inert ingredients is water.

Description of action	Expected Fee (\$)	Tracking Code
New product conc 20%	5,363	A540
New product conc 15%	1,341	A540.1
New product conc 10%	1,341	A540.1
Total Fee	8,045	