Implementing the Pesticide Registration Improvement Act - Fiscal Year 2015

Twelfth Annual Report

March 1, 2016

Table IV

Number of PRIA Decisions Pending at the End of The Fiscal Year (FY 2011 through FY 2015)

Key to the table

- R - Conventional Pesticides
- A - Antimicrobial Pesticides
- B - Biopesticides
- EUP - Experimental Use Permit
- PIP - Plant-Incorporated Protectants
- SAP - FIFRA Scientific Advisory Panel
- SCLP - Straight Chain Lepidopteran Pheromones

Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year					
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**			
		2012	**2013**	**2014**	**2015**
R01	New Active Ingredient, Food Use	1	1	1	
R010	New Active Ingredient, Food Use	30	38	40	20
R020	New Active Ingredient, Food use; reduced risk	17	20	10	26
R060	New Active Ingredient, Non-food use, outdoor		9	9	
R090	New Active Ingredient, Non-food use, outdoor, EUP		1		
R110	New Active Ingredient, Non-food use; indoor	5	3	2	3
R123	New Active Ingredient, Seed treatment only; includes non-food and food uses; limited uptake into Raw Agricultural Commodities	4	2		
R124	Conditional Ruling on Pre-application Study Waivers; applicant-initiated	4	2	7	2
R125	New Active Ingredient, Seed Treatment; EUP		1		
R140	Additional food use; Indoor; food/food handling	6	7	10	2
R150	New Use, First food use	14	14	10	10
R17	New Use, Each Additional New Food Use	5	5	5	5
R170	New Use, Additional Food Use	209	159	209	202
R175	Additional food uses covered within a crop grouping resulting from the conversion of an existing approved crop grouping		15	73	76
R180	New Use, Additional food use; reduced risk	28	22	12	16
R190	New Use, Additional food uses; 6 or more submitted in one application	62	52	54	73
R200	New Use, Additional food uses; 6 or more submitted in one application; reduced risk	21	4	8	10

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		2012	**2013**	**2014**	**2015**
R210	New Use, Additional food use; EUP; establish temporary tolerance; no credit toward new use registration	2		2	
R220	New Use, Additional food use; EUP; crop destruct basis; no credit toward new use registration	2			
R23	New use, Non-food, outdoor	1	1	1	
R230	New Use, Additional use; non-food; outdoor	20	17	20	19
R240	New Use, Additional use; non-food; outdoor; reduced risk				3
R250	EUP, new use; no credit toward new use registration				1
R251	EUP which requires no changes to tolerance; non-crop destruct		1	3	1
R260	New use; non-food; indoor	7	8	10	8
R270	New use; non-food; indoor; reduced risk		1		2
R272	Review of Study Protocol; applicant-initiated; excludes DART, pre-registration conferences, Rapid Response review, DNT protocol review, protocols needing HSRB review	9	3	4	3
R273	Additional use; seed treatment; limited uptake into Raw Agricultural Commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food or non-food uses	3	7	7	12
R280	Establish import tolerance; new active ingredient or first food use	4	4	3	2
R29	Import tolerance, Additional new food use	1	1	1	1
R290	Establish import tolerance; additional food use	13	12	10	7
B291	Establish import tolerances; additional food uses; 6 or more crops submitted in one petition			2	2
R292	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated	22	16	7	18
R293	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated		1		
R294	Establish tolerances for inadvertent residues; 6 or more				1
R295	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; applicant-initiated	5	5	1	1
R296	Establish tolerances for residues in rotational crops in response to specific petition; 6 or more crops submitted in one application		1	1	
R298	Amend established tolerance, submission of amended labels		18	39	28
R299	Amend 6 or more established tolerances; submission of amended labels.			4	
R300	New product; identical or substantially similar in composition and use	54	40	37	47

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	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.				
R301	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.	31	12	18	27
R310	New end-use or manufacturing-use product; requires review of data package within RD; includes reviews and/or waivers of data for only: • product chemistry and/or • acute toxicity and/or • public health pest efficacy	118	70	65	46
R311	New product; requires approval of new food-use inert; applicant-initiated; excludes approval of safeners	2	1	1	
R312	New product; requires approval of new non-food use inert, applicant initiated.	2			
R314	New product with 2 or more registered AIs never before registered as this combination		18	32	30
R315	New product, non-food, animal product with 2 animal safety studies		7	4	9
R320	New product; new physical form; requires data review in science divisions	15	15	23	25
R330	New manufacturing-use product; registered active ingredient; selective data citation	15			
R331	New product, repack of identical end-use product as a MUP				2
R333	New product with unregistered source of AI, cite-all		29	15	29
R334	New product with unregistered source of AI, selective citation		10	26	22
R340	Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient)	56	57	49	38
R35	Amendment, Non-fast track (changes to REI, PPE, PHI, rate and number of applications, add aerial application, modify GW/SW advisory statement)	2	2	2	2
R350	Amendment requiring data review in science divisions (e.g., changes	57	44	72	50

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	to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement)				
R351	Amendment adding new unregistered source of AI		33	45	51
R352	Amendment adding already approved uses,		2	5	5
R370	Cancer reassessment; applicant-initiated	2	2	3	1
R371	Amendment to EUP		1		
A380	New Active Ingredient, Food use; establish tolerance exemption		1		
A400	New Active Ingredient, Non-food use; outdoor; FIFRA section (2mm) uses	1			
A420	Non-food use; indoor; FIFRA section 2(mm) uses	8	6	7	17
A440	New Use, First food use; establish tolerance exemption	4	2	2	4
A460	New Food Use, Additional food use; establish tolerance exemption	6	6	4	5
A470	Additional food use, establish tolerance		1		
A480	New use, Additional use; non-food; outdoor; FIFRA §2(mm) uses	3	2	2	
A490	New use, Additional use; non-food; outdoor; uses other than FIFRA §2(mm)	3	2		1
A500	New use, Additional use; non-food; indoor; FIFRA §2(mm) uses	9	8	5	2
A510	Additional use; non-food; indoor; uses other than FIFRA section 2(mm)		3	3	4
A521	Review of public health efficacy study protocol within AD; per AD Internal Guidance for the Efficacy Protocol Review Process; applicant-initiated; Tier 1	10	6	3	1
A522	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; applicant-initiated; Tier 2	2	4	1	3
A523	Review of protocol other than public health efficacy study			1	1
A530	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.	28	9	11	11
A531	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	10	5	8	11

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	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.				
A532	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	11	9	13	5
A540	New end use product; FIFRA §2(mm) uses only	45	35	45	41
A550	New end-use product; uses other than FIFRA §2(mm); non-FQPA product	7		4	1
A560	New manufacturing-use product; registered active ingredient; selective data citation	7	1	5	16
A570	Label amendment requiring data submission	30	35	44	62
A572	New product or amendment requiring data review		1	1	3
B590	New active ingredient; food use; establish tolerance exemption, Microbial/Biochemical,	40	44	47	29
B600	New active ingredient; non-food use, Microbial/Biochemical,	14	7	4	5
B610	Food use; EUP; establish temporary tolerance exemption, Microbial/Biochemical			3	2
B612	New active ingredient; no change to permanent tolerance exemption.			2	10
B614	Conditional ruling preapplication study waiver				1
B620	Non-food use; Experimental Use Permit application, Microbial/Biochemical	1			1
B621	Extend or amend Experimental Use Permit, Microbial/Biochemical				2
B630	First food use; establish tolerance exemption, Microbial/Biochemical,	5	12	14	9
B631	Amend established tolerance exemption, Microbial/Biochemical	4			
B641	Amend established tolerance (e.g., decrease or increase)				1
B643	New food use; petition to amend tolerance exemption			3	5
B644	New use, no change to existing tolerance or tolerance exemption		1	1	1
B660	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. Microbial/biochemical	3	7	10	3

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B670	New product; registered source of active ingredient; all Tier I data for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product specific data or with request for data waivers supported by scientific rationales, Microbial/Biochemical	12	23	15	9
B671	New product; food use; unregistered source of active ingredient; requires amendment of established tolerance or tolerance exemption; all Tier I data requirements for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product-specific data or with request for data waivers supported by scientific rationales, Microbial/Biochemical		3	2	
B672	New product; non-food use or food use having established tolerance or tolerance exemption; unregistered source of active ingredient; no data compensation issues; all Tier I data requirements for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product-specific data or with request for data waivers supported by scientific rationales, Microbial/Biochemical	12	12	13	8
B673	New product, unregistered source of AI; citation of TGAI previously approved		5	4	7
B674	New product; MUP; repack of identical end-use product as MUP				1
B676	New product, more than 1 active ingredient where one is an unregistered source			1	
B680	Label amendment requiring data submission, Microbial/Biochemical	6	2	5	6
B681	Label amendment; unregistered source of active ingredient; supporting data require scientific review, Microbial/Biochemical	1	4	5	3
B690	SCLP, New active ingredient; food or non-food use		1	1	
B700	EUP, new AI or new use		1		
B710	SCLP, 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.		1		
B720	SCLP, New product; registered source of active ingredient; all Tier I data for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product specific data or with request for data waivers supported by scientific rationales		1	4	5

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B721	SCLP, New product; unregistered source of active ingredient	1			
B730	SCLP, Label amendment requiring data submission			1	1
B740	Plant-Incorporated Protectants (PIP), EUP; registered active ingredient; non-food/feed or crop destruct basis; no Scientific Advisory Panel (SAP) review required			1	
B771	PIP, Experimental Use Permit application; new active ingredient; establish temporary tolerance or tolerance exemption; no SAP review required;	1		5	
B772	Amend or extend EUP				1
B773	Amend or extend EUP with temporary tol exemption extension				2
B780	New PIP; non-food/feed				1
B790	New PIP; non-food/feed; SAP review				1
B820	PIP, New active ingredient, establish tolerance or exemption; no SAP	2	2		
B851	PIP, New active ingredient; different genetic event of a previously approved active ingredient; same crop; no tolerance action required; no SAP review required				1
B880	PIP, New product; no SAP review required	3	6	1	2
B884	New PIP, seed increase with negotiated acreage cap and time-limited registration with petition to establish permanent tolerance/tolerance exemption			3	
B885	PIP, seed increase, breeding stack of previously approved PIPs, same crop		1		2
B890	Amendment to seed increase registration; converts to commercial registration		2		
B900	PIP, Amendment (except #B890); No SAP review required; (e.g., new IRM requirements that are applicant initiated; or amending a conditional registration to extend the registration expiration date with additional data submitted)	3			
B902	PIP protocol review	1			
B903	Inert ingredient tolerance exemption, e.g., a marker such as NPT II	1			
I001	New food-use inert		10	23	26
I002	Amend existing inert tolerance or exemption, new data		2	1	2
I003	Amend existing inert tolerance or exemption, no new data		2	1	1
I004	New non-food use inert		1	13	3
I006	Amend existing non-food use inert with new use pattern, no new data		1		1

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		2012	**2013**	**2014**	**2015**
I007	Substantially similar non-food use inert		1	1	
I008	New polymer inert, food use		3	5	8
I009	New polymer inert, non-food use		1	6	3
I010	Amend a tolerance exemption descriptor to add CASRNs, no new data		1	1	
M001	Protocol review by HSRB				1
M002	Completed study requiring HSRB review			2	1
M005	New product, combination of AIs from AD, BPPD, RD		2	1	3
M006	Gold seal letters		10	1	36
M007	Extension of Exclusive use of data 3(c)(1)(F)(ii)		3	6	2
M008	Exclusive use of data for a minor use 3(c)(1)(F)(vi)			3	4