Implementing the Pesticide Registration Improvement Act - Fiscal Year 2013

Tenth Annual Report

March 1, 2014

Table IV

Number of PRIA Decisions Pending at the End of Fiscal Year (FY 2010 through FY 2013)

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**			
		2010	**2011**	**2012**	**2013**
R01	New Active Ingredient, Food Use	1	1	1	1
R010	New Active Ingredient, Food Use	78	74	30	38
R020	New Active Ingredient, Food use; reduced risk	4	24	17	20
R040	Food use; Experimental Use Permit application; establish temporary tolerance; submitted before application for registration; credit $326,025 toward new active ingredient application that follows	2	1		
R060	New Active Ingredient, Non-food use, outdoor	2			9
R090	New Active Ingredient, Non-food use, outdoor, EUP				1
R110	New Active Ingredient, Non-food use; indoor	3	7	5	3
R123	New Active Ingredient, Seed treatment only; includes non-food and food uses; limited uptake into Raw Agricultural Commodities		2	4	2
R124	Conditional Ruling on Pre-application Study Waivers; applicant-initiated	2		4	2
R125	New Active Ingredient, Seed Treatment; EUP				1
R13	New Use, First food use, indoor food/food handling	2	2		
R140	Additional food use; Indoor; food/food handling	6	10	6	7
R15	New Use, First Food Use	2			
R150	New Use, First food use	11	25	14	14
R17	New Use, Each Additional New Food Use	11	7	5	5
R170	New Use, Additional Food Use	131	179	209	159
R175	Additional food uses covered within a crop grouping resulting from the conversion of an existing approved crop grouping				15

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		2010	**2011**	**2012**	**2013**
R180	New Use, Additional food use; reduced risk	13	7	28	22
R19	New Use, Additional New Food Uses, Bundled, 6 or more	3	3		
R190	New Use, Additional food uses; 6 or more submitted in one application	58	75	62	52
R200	New Use, Additional food uses; 6 or more submitted in one application; reduced risk	9	14	21	4
R210	New Use, Additional food use; EUP; establish temporary tolerance; no credit toward new use registration	2	3	2	
R220	New Use, Additional food use; EUP; crop destruct basis; no credit toward new use registration		2	2	
R23	New use, Non-food, outdoor	1	1	1	1
R230	New Use, Additional use; non-food; outdoor	25	22	20	17
R240	New Use, Additional use; non-food; outdoor; reduced risk		2		
R251	EUP which requires no changes to tolerance; non-crop destruct				1
R260	New use; non-food; indoor	7	6	7	8
R270	New use; non-food; indoor; reduced risk	1			1
R272	Review of Study Protocol; applicant-initiated; excludes DART, pre-registration conferences, Rapid Response review, DNT protocol review, protocols needing HSRB review	3	5	9	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	11	6	3	7
R274	New Uses, Additional uses; seed treatment only; 6 or more submitted in one application; limited uptake into Raw Agricultural Commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food and/or non-food uses	5			
R280	Establish import tolerance; new active ingredient or first food use	5	5	4	4
R29	Import tolerance, Additional new food use	3	1	1	1
R290	Establish import tolerance; additional food use	5	7	13	12
B291	Establish import tolerances; additional food uses; 6 or more crops submitted in one petition	1	1		
R292	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated	12	22	22	16
R293	Establish tolerance(s) for inadvertent residues in one crop; applicant-	2			1

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		2010	**2011**	**2012**	**2013**
	initiated				
R295	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; applicant-initiated	5	5	5	5
R296	Establish tolerances for residues in rotational crops in response to specific petition; 6 or more crops submitted in one application				1
R298	Amend established tolerance, submission of amended labels				18
R300	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.	60	64	54	40
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.	11	11	31	12
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	140	122	118	70
R311	New product; requires approval of new food-use inert; applicant-initiated; excludes approval of safeners		3	2	1
R312	New product; requires approval of new non-food use inert, applicant initiated.			2	
R313	New product; requires amendment to existing inert tolerance exemption (e.g., adding post-harvest use); applicant-initiated	2			
R314	New product with 2 or more registered AIs never before registered as this combination				18
R315	New product, non-food, animal product with 2 animal safety studies				7
R32	New Product, Non Fast Track, new physical form (excludes selective citations)				
R320	New product; new physical form; requires data review in science divisions	25	18	15	15
R330	New manufacturing-use product; registered active ingredient;	6	8	15	

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PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**			
		2010	**2011**	**2012**	**2013**
	selective data citation				
R333	New product with unregistered source of AI, cite-all				29
R334	New product with unregistered source of AI, selective citation				10
R340	Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient)	66	82	56	57
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 to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement)	55	45	57	44
R351	Amendment adding new unregistered source of AI				33
R352	Amendment adding already approved uses,				2
R370	Cancer reassessment; applicant-initiated	3	1	2	2
R371	Amendment to EUP				1
A380	New Active Ingredient, Food use; establish tolerance exemption	1			1
A400	New Active Ingredient, Non-food use; outdoor; FIFRA section (2mm) uses	1	1	1	
A41	New Active Ingredient, Non-food use, outdoor, other uses	2	2		
A42	New Active Ingredient, Non-food use, indoor, FIFRA sec. 2(mm) uses	1	1		
A420	Non-food use; indoor; FIFRA section 2(mm) uses	7	10	8	6
A440	New Use, First food use; establish tolerance exemption	2	2	4	2
A460	New Food Use, Additional food use; establish tolerance exemption	6	6	6	6
A470	Additional food use, establish tolerance				1
A480	New use, Additional use; non-food; outdoor; FIFRA §2(mm) uses	2	1	3	2
A490	New use, Additional use; non-food; outdoor; uses other than FIFRA §2(mm)	1	2	3	2
A500	New use, Additional use; non-food; indoor; FIFRA §2(mm) uses	6	8	9	8
A510	Additional use; non-food; indoor; uses other than FIFRA section 2(mm)	1			3
A520	Experimental Use Permit application	2	1		
A521	Review of public health efficacy study protocol within AD; per AD Internal Guidance for the Efficacy Protocol Review Process;	3	4	10	6

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		2010	**2011**	**2012**	**2013**
	applicant-initiated; Tier 1				
A522	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; applicant-initiated; Tier 2	3	4	2	4
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.	21	24	28	9
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 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.	14	8	10	5
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	3	12	11	9
A540	New end use product; FIFRA §2(mm) uses only	41	48	45	35
A550	New end-use product; uses other than FIFRA §2(mm); non-FQPA product	3	6	7	
A560	New manufacturing-use product; registered active ingredient; selective data citation	6	7	7	1
A570	Label amendment requiring data submission	75	44	30	35
A572	New product or amendment requiring data review				1
B590	New active ingredient; food use; establish tolerance exemption, Microbial/Biochemical,	63	60	40	44
B600	New active ingredient; non-food use, Microbial/Biochemical,	12	17	14	7
B610	Food use; EUP; establish temporary tolerance exemption, Microbial/Biochemical	2			
B620	Non-food use; Experimental Use Permit application, Microbial/Biochemical	1	1	1	
B621	Extend or amend Experimental Use Permit, Microbial/Biochemical	1	1		
B63	New Use, First Food Use, Microbial/Biochemical, with exemption	3			

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		2010	**2011**	**2012**	**2013**
B630	First food use; establish tolerance exemption, Microbial/Biochemical,	11	2	5	12
B631	Amend established tolerance exemption, Microbial/Biochemical	2	6	4	
B641	Amend established tolerance (e.g., decrease or increase)		1		
B644	New use, no change to existing tolerance or tolerance exemption				1
B650	New use; Non-Food, Microbial/Biochemical	3			
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	2	8	3	7
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	11	9	12	23
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
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	10	18	12	12
B673	New product, unregistered source of AI; citation of TGAI previously approved				5
B680	Label amendment requiring data submission, Microbial/Biochemical	4	2	6	2
B681	Label amendment; unregistered source of active ingredient; supporting data require scientific review, Microbial/Biochemical	2	4	1	4
B682	Protocol review; applicant-initiated; excludes time for HSRB review (pre application), Microbial/Biochemical		1		
B690	SCLP, New active ingredient; food or non-food use		1		1

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		2010	**2011**	**2012**	**2013**
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		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	2	1		1
B721	SCLP, New product; unregistered source of active ingredient	2	1	1	
B730	SCLP, Label amendment requiring data submission	2			
B740	Plant-Incorporated Protectants (PIP), EUP; registered active ingredient; non-food/feed or crop destruct basis; no Scientific Advisory Panel (SAP) review required	2			
B771	PIP, Experimental Use Permit application; new active ingredient; establish temporary tolerance or tolerance exemption; no SAP review required;		2	1	
B773	PIP, Amend or extend existing Experimental Use Permit; minor changes to experimental design; extend established temporary tolerance or tolerance exemption	2			
B800	PIP, New active ingredient; establish permanent tolerance or tolerance exemption based on temporary tolerance or tolerance exemption; no SAP review required	4	8		
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		
B870	PIP, New use	1			
B880	PIP, New product; no SAP review required	2	3	3	6
B881	PIP, New product; SAP review required	5	3		
B885	PIP, seed increase, breeding stack of previously approved PIPs, same crop				1
B890	Amendment to seed increase registration; converts to commercial registration				2

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PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**			
		2010	**2011**	**2012**	**2013**
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)	5		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
I002	Amend existing inert tolerance or exemption, new data				2
I003	Amend existing inert tolerance or exemption, no new data				2
I004	New non-food use inert				1
I006	Amend existing non-food use inert with new use pattern, no new data				1
I007	Substantially similar non-food use inert				1
I008	New polymer inert, food use				3
I009	New polymer inert, non-food use				1
I010	Amend a tolerance exemption descriptor to add CASRNs, no new data				1
M005	New product, combination of AIs from AD, BPPD, RD				2
M006	Gold seal letters				10
M007	Extension of Exclusive use of data 3©(1)(F)(ii)				3