Implementing the Pesticide Registration Improvement Act - Fiscal Year 2012

Ninth Annual Report

March 1, 2013

Table IV

Number of PRIA Decisions Pending at the End of Fiscal Year (FY 2009 through FY 2012)

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**			
		2009	**2010**	**2011**	**2012**
R01	New Active Ingredient, Food Use	5	1	1	1
R010	New Active Ingredient, Food Use	29	78	74	30
R020	New Active Ingredient, Food use; reduced risk	4	4	24	17
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	
R06	New Active Ingredient, Non-food use, outdoor	3			
R060	New Active Ingredient, Non-food use, outdoor	45	2		
R10	New Active Ingredient, Non-food use, outdoor, submitted after EUP	3			
R110	New Active Ingredient, Non-food use; indoor	3	3	7	5
R120	New Active Ingredient, Non-food use; indoor; reduced risk	2			
R123	New Active Ingredient, Seed treatment only; includes non-food and food uses; limited uptake into Raw Agricultural Commodities	2		2	4
R124	Conditional Ruling on Preapplication Study Waivers; applicant-initiated	2	2		4
R13	New Use, First food use, indoor food/food handling	2	2	2	
R140	Additional food use; Indoor; food/food handling		6	10	6
R15	New Use, First Food Use	2	2		
R150	New Use, First food use		11	25	14
R17	New Use, Each Additional New Food Use	31	11	7	5
R170	New Use, Additional Food Use	135	131	179	209
R180	New Use, Additional food use; reduced risk	17	13	7	28

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PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**			
		2009	**2010**	**2011**	**2012**
R19	New Use, Additional New Food Uses, Bundled, 6 or more	20	3	3	
R190	New Use, Additional food uses; 6 or more submitted in one application	60	58	75	62
R200	New Use, Additional food uses; 6 or more submitted in one application; reduced risk	19	9	14	21
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	3	1	1	1
R230	New Use, Additional use; non-food; outdoor	23	25	22	20
R240	New Use, Additional use; non-food; outdoor; reduced risk			2	
R250	New Use, Additional use; non-food; outdoor; EUP; no credit toward new use registration	5			
R260	New use; non-food; indoor	6	7	6	7
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	9	3	5	9
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	10	11	6	3
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	2	5		
R28	Import tolerance, New Active Ingredient or first food use	1			
R280	Establish import tolerance; new active ingredient or first food use	3	5	5	4
R29	Import tolerance, Additional new food use	3	3	1	1
R290	Establish import tolerance; additional food use	9	5	7	13
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	27	12	22	22
R293	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated		2		
R295	Establish tolerance(s) for residues in one rotational crop in response	4	5	5	5

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PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**			
		2009	**2010**	**2011**	**2012**
	to a specific rotational crop application; applicant-initiated				
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.	73	60	64	54
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.	15	11	11	31
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	112	140	122	118
R311	New product; requires approval of new food-use inert; applicant-initiated; excludes approval of safeners	2		3	2
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	1	2		
R32	New Product, Non Fast Track, new physical form (excludes selective citations)	1			
R320	New product; new physical form; requires data review in science divisions	15	25	18	15
R330	New manufacturing-use product; registered active ingredient; selective data citation	8	6	8	15
R340	Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient)	55	66	82	56
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)	76	55	45	57

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PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**			
		2009	**2010**	**2011**	**2012**
R37	Cancer Reassessment, applicant initiated	1			
R370	Cancer reassessment; applicant-initiated	1	3	1	2
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	1
A41	New Active Ingredient, Non-food use, outdoor, other uses	2	2	2	
A42	New Active Ingredient, Non-food use, indoor, FIFRA sec. 2(mm) uses	1	1	1	
A420	Non-food use; indoor; FIFRA section 2(mm) uses	4	7	10	8
A440	New Use, First food use; establish tolerance exemption	2	2	2	4
A460	New Food Use, Additional food use; establish tolerance exemption	7	6	6	6
A480	New use, Additional use; non-food; outdoor; FIFRA §2(mm) uses	4	2	1	3
A490	New use, Additional use; non-food; outdoor; uses other than FIFRA §2(mm)	1	1	2	3
A500	New use, Additional use; non-food; indoor; FIFRA §2(mm) uses	18	6	8	9
A510	Additional use; non-food; indoor; uses other than FIFRA section 2(mm)	2	1		
A520	Experimental Use Permit application	3	2	1	
A521	Review of public health efficacy study protocol within AD; per AD Internal Guidance for the Efficacy Protocol Review Process; applicant-initiated; Tier 1	2	3	4	10
A522	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; applicant-initiated; Tier 2	3	3	4	2
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.	18	21	24	28
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.	2	14	8	10
A532	New product; identical or substantially similar in composition and use	7	3	12	11

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		2009	**2010**	**2011**	**2012**
	to a registered product; registered active ingredient; unregistered source of active ingredient; cite-all data citation except for product chemistry; product chemistry data submitted				
A54	New Product, Non-Fast Track, FIFRA sec. 2 (mm) uses	1			
A540	New end use product; FIFRA §2(mm) uses only	48	41	48	45
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	6	7	7
A570	Label amendment requiring data submission	55	75	44	30
B59	New Active Ingredient, Food Use, Microbial/Biochemical, with exemption	8			
B590	New active ingredient; food use; establish tolerance exemption, Microbial/Biochemical,	31	63	60	40
B60	New Active Ingredient, Non-food use, Microbial/Biochemical	1			
B600	New active ingredient; non-food use, Microbial/Biochemical,	12	12	17	14
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	3		
B630	First food use; establish tolerance exemption, Microbial/Biochemical,	5	11	2	5
B631	Amend established tolerance exemption, Microbial/Biochemical	1	2	6	4
B641	Amend established tolerance (e.g., decrease or increase)			1	
B650	New use; Non-Food, Microbial/Biochemical	1	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	4	2	8	3
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	10	11	9	12

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		2009	**2010**	**2011**	**2012**
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	6			
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	11	10	18	12
B680	Label amendment requiring data submission, Microbial/Biochemical	12	4	2	6
B681	Label amendment; unregistered source of active ingredient; supporting data require scientific review, Microbial/Biochemical	5	2	4	1
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	
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	2	1	
B721	SCLP, New product; unregistered source of active ingredient	3	2	1	1
B730	SCLP, Label amendment requiring data submission	1	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	2		
B771	PIP, Experimental Use Permit application; new active ingredient; establish temporary tolerance or tolerance exemption; no SAP review required;	2		2	1
B773	PIP, Amend or extend existing Experimental Use Permit; minor changes to experimental design; extend established temporary		2		

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PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**			
		2009	**2010**	**2011**	**2012**
	tolerance or tolerance exemption				
B800	PIP, New active ingredient; establish permanent tolerance or tolerance exemption based on temporary tolerance or tolerance exemption; no SAP review required	5	4	8	
B820	PIP, New active ingredient, establish tolerance or exemption; no SAP				2
B84	PIP, Register New Active Ingredient, Set Tolerance or Exemption, SAP	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	19	2	3	3
B881	PIP, New product; SAP review required	1	5	3	
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
B901	PIP, Amendment (except #B890); SAP review required	1			
B902	PIP protocol review				1
B903	Inert ingredient tolerance exemption, e.g., a marker such as NPT II				1