

# Implementing the Pesticide Registration Improvement Act - Fiscal Year 2012

## Ninth Annual Report



*March 1, 2013*

**Table III**

**Number of PRIA Actions Completed in fiscal year 2009, 2010, 2011, and 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

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2009	FY 2010	FY 2011	FY 2012	FY 2009	FY 2010	FY 2011	FY 2012
R01	New active ingredient, food use	15	3			648	1106		
R010	New active ingredient, food use	6		11	51	570		703	910
R020	New active ingredient, food use, reduced risk				6				587
R06	New active ingredient, non-food use, outdoor	1	4			753	1433		
R060	New active ingredient, non-food use, outdoor	1	29	2		245	686	1069	
R10	New active ingredient, non-food use, outdoor, submitted after EUP		3				1199		
R110	New active ingredient, non-food use, indoor				3				630
R120	New active ingredient, non-food use; indoor; reduced risk		2				755		
R124	Conditional ruling on pre-application study waivers; applicant-initiated	15	2	3	1	153	179	164	164
R140	Additional food use; indoor; food/food handling			3	7			399	548
R150	New use, first food use	9		2	11	642		1224	673
R16	New use, first food use, reduced risk	3				555			
R17	New use, each additional new food use	21	4	4		714	1146	2098	
R170	New use, additional food use	71	105	59	108	440	453	508	467

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2009	FY 2010	FY 2011	FY 2012	FY 2009	FY 2010	FY 2011	FY 2012
R18	New use, each additional new food use, reduced risk	2				381			
R180	New use, additional food use; reduced risk	12	13	6		361	336	595	
R19	New use, additional new food uses, bundled, 6 or more	11	10		3	661	1829		1548
R190	New use, additional food uses; 6 or more submitted in one application	23	36	43	59	419	464	529	519
R20	New use, additional new food uses, bundled, 6 or more, reduced risk								
R200	New use, additional food uses; 6 or more submitted in one application; reduced risk	14	19	9	5	336	324	591	328
R210	Additional food use; experimental use permit application; establish temporary tolerance; no credit toward new use registration			2	3			368	341
R220	New use, additional food use; EUP; crop destruct basis; no credit toward new use registration	3	1			108	181		
R23	New use, non-food, outdoor	3				402			
R230	New use, additional use; non-food; outdoor	14	13	16	19	372	441	572	481
R240	New use, additional use; non-food; outdoor; reduced risk	5				331			
R250	New use, additional use; non-food; outdoor; EUP; no credit toward new use registration	1	4	2		182	158	82	
R260	New use; non-food; indoor	2	4	4	6	352	491	375	205
R270	New use; non-food; indoor; reduced risk		1	1			258	350	
R272	Review of study protocol; applicant-initiated; excludes DART, pre-registration conferences, rapid response review, DNT protocol review, protocols needing HSRB review	48	20	43	22	68	64	76	72
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		8	7	6		373	390	588
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	1	2	5		359	586	470	
R28	Import tolerance, new active ingredient or first food use		1				1155		

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2009	FY 2010	FY 2011	FY 2012	FY 2009	FY 2010	FY 2011	FY 2012
R280	Establish import tolerance; new active ingredient or first food use	1		3	2	637		572	694
R29	Import tolerance, additional new food use	1		1		1000		2485	
R290	Establish import tolerance; additional food use	1	5	4	4	432	480	496	431
R292	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated	16	22	7	6	329	399	311	385
R293	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated	3				317			
R295	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; applicant-initiated		1		5		506		448
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.	239	277	231	194	76	84	79	73
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.	43	36	40	24	122	123	138	131
R31	New product, non-fast track (includes review of product chemistry, acute toxicity, public health pest efficacy)	2				873			
R310	New end-use or manufacturing-use product; requires review of data package within RD; includes reviews and/or waivers of data for only: <ul style="list-style-type: none"> <li>• product chemistry and/or</li> <li>• acute toxicity and/or</li> <li>• public health pest efficacy</li> </ul>	236	167	250	225	194	204	198	190
R311	New product; requires approval of new food-use inert; applicant-initiated; excludes approval of safeners		2		3		406		353
R313	New product; requires amendment to existing inert tolerance	4	1	2		416	654	279	

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2009	FY 2010	FY 2011	FY 2012	FY 2009	FY 2010	FY 2011	FY 2012
	exemption (e.g., adding post-harvest use); applicant-initiated								
R32	New product, non-fast track, new physical form (excludes selective citations)	3	1			513	797		
R320	New product; new physical form; requires data review in science divisions	9	17	15	15	346	347	371	380
R33	New manufacturing-use product, old active ingredient, selective citation	1				551			
R330	New manufacturing-use product; registered active ingredient; selective data citation	3	8	6	6	386	360	320	354
R331	New product; repack of identical registered end-use product as a manufacturing-use product; same registrant uses only	1	4	6	2	77	72	65	22
R34	Amendment, non-fast track (includes changes to precautionary label statements, source changes to an unregistered source)	1				421			
R340	Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient)	200	162	218	228	111	113	116	116
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)	59	81	67	43	215	266	276	284
R37	Cancer reassessment, applicant initiated		1				1185		
R370	Cancer reassessment; applicant-initiated			2	1			534	535
A380	Food use; establish tolerance exemption			4				392	
A41	New active ingredient, non-food use, outdoor, other uses				2				1798
A42	New active ingredient, non-food use, indoor, FIFRA sec. 2(mm) uses	2			1	920			1864
A420	New active ingredient, non-food use, indoor FIFRA §2(mm) uses				3				736
A44	New use, first food use, with exemption	2				682			
A46	New food use, with exemption	2				492			
A460	Additional food use; establish tolerance exemption	6	5	2	4	199	620	432	740
A470	New food use, additional food use; establish tolerance	1				436			

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2009	FY 2010	FY 2011	FY 2012	FY 2009	FY 2010	FY 2011	FY 2012
A480	New use, additional use; non-food; outdoor; FIFRA §2(mm) uses	1	3	2		391	356	151	
A490	New use, additional use; non-food; outdoor; uses other than FIFRA §2(mm)	3	1			454	363		
A50	New use, non-food, indoor FIFRA sec. 2(mm) uses	1				1002			
A500	New use, additional use; non-food; indoor; FIFRA §2(mm) uses	22	19	1	6	263	309	273	244
A510	Additional use; non-food; indoor; uses other than FIFRA section 2(mm)		1	1			496	748	
A520	Experimental use permit application	2	1	4	1	181	321	403	274
A521	Review of public health efficacy study protocol within AD; per AD Internal Guidance for the Efficacy Protocol Review Process; applicant-initiated; Tier 1	1	4	11	8	342	208	143	177
A522	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; applicant-initiated; Tier 2	1	3		3	234	797		622
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.	49	57	55	89	95	97	95	91
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.	12	8	19	19	151	124	186	128
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	19	19	15	15	156	124	130	143
A54	New product, non-fast track, FIFRA sec. 2 (mm) uses	3	1			446	1261		

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2009	FY 2010	FY 2011	FY 2012	FY 2009	FY 2010	FY 2011	FY 2012
A540	New end use product; FIFRA §2(mm) uses only	70	65	66	69	139	190	159	193
A55	New product, non-fast track, other uses	1				615			
A550	New end-use product; uses other than FIFRA §2(mm); non-FQPA product	4	1	7	7	180	270	179	218
A560	New manufacturing-use product; registered active ingredient; selective data citation	3	2	8	7	349	530	262	385
A57	Amendments, non-fast track	1				454			
A570	Label amendment requiring data submission	136	120	151	99	123	145	136	180
B59	New active ingredient, food use, with exemption, microbial/biochemical		8				914		
B590	New active ingredient; food use; establish tolerance exemption, microbial/biochemical	3	18	10	38	487	634	734	692
B60	New active ingredient, non-food use, microbial/biochemical	6				732			
B600	New active ingredient; non-food use, microbial/biochemical	7	6	6	14	385	392	681	541
B610	Food use; EUP; establish temporary tolerance exemption, microbial/biochemical	6	2			286	222		
B620	Non-food use; experimental use permit application	4		2	3	127		103	143
B621	Extend or amend EUP, microbial/biochemical	3		4	8	101		69	37
B63	New use, first food use, with tolerance exemption microbial/biochemical,	4		3		541		1233	
B630	First food use; establish tolerance exemption, microbial/biochemical	2		12		313		614	
B631	Amend established tolerance exemption, microbial/biochemical	3	1	2	6	242	471	389	243
B641	Amend established tolerance				1				276
B650	New use; non-food, microbial/biochemical	2			2	239			209
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	6	11	12	22	73	106	61	85

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2009	FY 2010	FY 2011	FY 2012	FY 2009	FY 2010	FY 2011	FY 2012
	end-use or manufacturing-use product that requires no data submission nor data matrix. Microbial/biochemical								
B67	New product, non-fast track, microbial/biochemical	1				895			
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	9	11	16	13	282	188	262	189
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		7				529		
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	11	6	16	280	404	334	374
B680	Label amendment requiring data submission, microbial/biochemical	9	12	20	13	129	169	103	89
B681	Label amendment; unregistered source of active ingredient; supporting data require scientific review, microbial/biochemical	3	7	5	6	244	227	263	281
B682	Protocol review; applicant-initiated; excludes time for HSRB review (pre-application), microbial/biochemical	1	1	1	4	89	84	52	64
B690	SCLP, new active ingredient; food or non-food use	2	5	1	1	231	167	169	140
B700	SCLP, experimental use permit application; new active ingredient or new use	1				134			
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	5	1		1	94	92		67

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2009	FY 2010	FY 2011	FY 2012	FY 2009	FY 2010	FY 2011	FY 2012
	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								
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	7	3	3	2	143	107	130	141
B721	SCLP, new product; unregistered source of active ingredient		5	4	2		185	185	160
B730	SCLP, label amendment requiring data submission	3	2	3	1	72	129	158	122
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		135		208	
B771	PIP, experimental use permit application; new active ingredient; establish temporary tolerance or tolerance exemption; no SAP review required		2				370		
B772	PIP, amend or extend EUP; minor changes to experimental design; established temporary tolerance or tolerance exemption is unaffected	3		3	1	76		54	90
B773	PIP, amend or extend existing experimental use permit; minor changes to experimental design; extend established temporary tolerance or tolerance exemption			4				177	
B800	PIP, new active ingredient; establish permanent tolerance or tolerance exemption based on temporary tolerance or tolerance exemption; no SAP review required		1		8		357		773
B81	PIP, register new active ingredient, temporary tolerance or exemption exists, SAP	3				587			
B84	PIP, register new active ingredient, set tolerance or exemption, SAP		2				1052		
B851	New active ingredient, different genetic event of previously approved AI; same crop; no tolerance action required no SAP				1				394
B870	PIP, new use			1				269	
B880	PIP, new product; no SAP review required	2	20	5	6	382	395	274	259
B881	PIP, new product; SAP review required		1	3	3		697	458	456

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2009	FY 2010	FY 2011	FY 2012	FY 2009	FY 2010	FY 2011	FY 2012
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)	14	1	6	1	176	181	179	178
B904	PIP, import tolerance or tolerance exemption; processed commodities/food only	1				103			
	TOTAL	1570	1517	1554	1574				