

Implementing the Pesticide Registration Improvement Act - Fiscal Year 2013

Tenth Annual Report



March 1, 2014

Table III

Number of PRIA Actions Completed in fiscal year 2010, 2011, 2012, and 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

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2010	FY 2011	FY 2012	FY 2013	FY 2010	FY 2011	FY 2012	FY 2013
R01	New active ingredient, food use	3				1106			
R010	New active ingredient, food use		11	51	20		703	910	731
R020	New active ingredient, food use, reduced risk			6				587	
R06	New active ingredient, non-food use, outdoor	4				1433			
R060	New active ingredient, non-food use, outdoor	29	2			686	1069		
R10	New active ingredient, non-food use, outdoor, submitted after EUP	3				1199			
R110	New active ingredient, non-food use, indoor			3	3			630	1024
R120	New active ingredient, non-food use; indoor; reduced risk	2				755			
R123	New active ingredient, seed treatment only				2				718
R124	Conditional ruling on pre-application study waivers; applicant-initiated	2	3	1	5	179	164	164	175
R140	Additional food use; indoor; food/food handling		3	7	6		399	548	455
R150	New use, first food use		2	11			1224	673	
R17	New use, each additional new food use	4	4			1146	2098		
R170	New use, additional food use	105	59	108	138	453	508	467	524

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2010	FY 2011	FY 2012	FY 2013	FY 2010	FY 2011	FY 2012	FY 2013
R180	New use, additional food use; reduced risk	13	6		27	336	595		277
R19	New use, additional new food uses, bundled, 6 or more	10		3		1829		1548	
R190	New use, additional food uses; 6 or more submitted in one application	36	43	59	32	464	529	519	526
R200	New use, additional food uses; 6 or more submitted in one application; reduced risk	19	9	5	17	324	591	328	425
R210	Additional food use; experimental use permit application; establish temporary tolerance; no credit toward new use registration		2	3	2		368	341	389
R220	New use, additional food use; EUP; crop destruct basis; no credit toward new use registration	1				181			
R230	New use, additional use; non-food; outdoor	13	16	19	9	441	572	481	442
R250	New use, additional use; non-food; outdoor; EUP; no credit toward new use registration	4	2		4	158	82		122
R260	New use; non-food; indoor	4	4	6	5	491	375	205	606
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	20	43	22	21	64	76	72	99
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	3	373	390	588	300
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			586	470		
R28	Import tolerance, new active ingredient or first food use	1				1155			
R280	Establish import tolerance; new active ingredient or first food use		3	2	1		572	694	632
R29	Import tolerance, additional new food use		1				2485		
R290	Establish import tolerance; additional food use	5	4	4	7	480	496	431	357
R292	Amend an established tolerance (e.g., decrease or increase);	22	7	6	14	399	311	385	324

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2010	FY 2011	FY 2012	FY 2013	FY 2010	FY 2011	FY 2012	FY 2013
	domestic or import; applicant-initiated								
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.	277	231	194	157	84	79	73	92
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.	36	40	24	59	123	138	131	108
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"> • product chemistry and/or • acute toxicity and/or • public health pest efficacy 	167	250	225	178	204	198	190	186
R311	New product; requires approval of new food-use inert; applicant-initiated; excludes approval of safeners	2		3	1	406		353	365
R312	New Product; requires approval of new non-food use inert; applicant initiated				1				179
R313	New product; requires amendment to existing inert tolerance exemption (e.g., adding post-harvest use); applicant-initiated	1	2			654	279		
R314	New end use product, 2 or more registered active ingredients never before registered as this combination in a formulated product; new product label is substantially similar to labels of currently registered products which separately contain respective component active ingredients				10				236
R315	New end use, non-food animal product with 2 animal safety studies				2				63

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2010	FY 2011	FY 2012	FY 2013	FY 2010	FY 2011	FY 2012	FY 2013
R32	New product, non-fast track, new physical form (excludes selective citations)	1				797			
R320	New product; new physical form; requires data review in science divisions	17	15	15	14	347	371	380	382
R330	New manufacturing-use product; registered active ingredient; selective data citation	8	6	6	12	360	320	354	313
R331	New product; repack of identical registered end-use product as a manufacturing-use product; same registrant uses only	4	6	2	23	72	65	22	61
R333	New product with unregistered source of AI; cite-all or selective data citation where applicant owns all required data				1				220
R334	New product with unregistered source of AI; selective data citation				1				5
R340	Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient)	162	218	228	193	113	116	116	108
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)	81	67	43	54	266	276	284	279
R351	Amendment adding new unregistered source of AI				15				147
R37	Cancer reassessment, applicant initiated	1				1185			
R370	Cancer reassessment; applicant-initiated		2	1	2		534	535	349
A380	Food use; establish tolerance exemption		4				392		
A400	New active ingredient; non-food use; outdoor; FIFRA §2(mm)				1				1692
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			1				1864	
A420	New active ingredient, non-food use, indoor FIFRA §2(mm) uses			3	4			736	1204
A460	Additional food use; establish tolerance exemption	5	2	4	1	620	432	740	-5
A470	New food use, additional food use; establish tolerance								
A480	New use, additional use; non-food; outdoor; FIFRA §2(mm) uses	3	2		7	356	151		406
A490	New use, additional use; non-food; outdoor; uses other than FIFRA	1			1	363			1239

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2010	FY 2011	FY 2012	FY 2013	FY 2010	FY 2011	FY 2012	FY 2013
	§2(mm)								
A500	New use, additional use; non-food; indoor; FIFRA §2(mm) uses	19	1	6	9	309	273	244	365
A510	Additional use; non-food; indoor; uses other than FIFRA section 2(mm)	1	1			496	748		
A520	Experimental use permit application	1	4	1		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	4	11	8	12	208	143	177	204
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	1	797		622	829
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.	57	55	89	64	97	95	91	112
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.	8	19	19	14	124	186	128	119
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	15	15	17	124	130	143	139
A54	New product, non-fast track, FIFRA sec. 2 (mm) uses	1				1261			
A540	New end use product; FIFRA §2(mm) uses only	65	66	69	74	190	159	193	192
A550	New end-use product; uses other than FIFRA §2(mm); non-FQPA product	1	7	7	8	270	179	218	263

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2010	FY 2011	FY 2012	FY 2013	FY 2010	FY 2011	FY 2012	FY 2013
A560	New manufacturing-use product; registered active ingredient; selective data citation	2	8	7	7	530	262	385	368
A570	Label amendment requiring data submission	120	151	99	108	145	136	180	129
A572	New product or amendment (REI, PPE, use rate changes)				1				38
B59	New active ingredient, food use, with exemption, microbial/biochemical	8				914			
B590	New active ingredient; food use; establish tolerance exemption, microbial/biochemical	18	10	38	21	634	734	692	771
B60	New active ingredient, non-food use, microbial/biochemical								
B600	New active ingredient; non-food use, microbial/biochemical	6	6	14	9	392	681	541	469
B610	Food use; EUP; establish temporary tolerance exemption, microbial/biochemical	2				222			
B620	Non-food use; experimental use permit application		2	3	2		103	143	326
B621	Extend or amend EUP, microbial/biochemical		4	8	3		69	37	33
B63	New use, first food use, with tolerance exemption microbial/biochemical,		3				1233		
B630	First food use; establish tolerance exemption, microbial/biochemical		12				614		
B631	Amend established tolerance exemption, microbial/biochemical	1	2	6	4	471	389	243	393
B641	Amend established tolerance			1				276	
B650	New use; non-food, microbial/biochemical			2				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 end-use or manufacturing-use product that requires no data submission nor data matrix. Microbial/biochemical	11	12	22	6	106	61	85	85
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	11	16	13	17	188	262	189	211

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2010	FY 2011	FY 2012	FY 2013	FY 2010	FY 2011	FY 2012	FY 2013
	request for data waivers supported by scientific rationales, microbial/biochemical								
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	11	6	16	11	404	334	374	358
B673	New product; unregistered source; citation of TGA data previously reviewed				1				192
B680	Label amendment requiring data submission, microbial/biochemical	12	20	13	12	169	103	89	115
B681	Label amendment; unregistered source of active ingredient; supporting data require scientific review, microbial/biochemical	7	5	6	3	227	263	281	183
B682	Protocol review; applicant-initiated; excludes time for HSRB review (pre-application), microbial/biochemical	1	1	4	2	84	52	64	79
B690	SCLP, new active ingredient; food or non-food use	5	1	1		167	169	140	
B700	SCLP, experimental use permit application; new active ingredient or new use				1				120
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		92		67	
B720	SCLP, new product; registered source of active ingredient; all Tier I	3	3	2		107	130	141	

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2010	FY 2011	FY 2012	FY 2013	FY 2010	FY 2011	FY 2012	FY 2013
	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								
B721	SCLP, new product; unregistered source of active ingredient	5	4	2	2	185	185	160	176
B730	SCLP, label amendment requiring data submission	2	3	1	1	129	158	122	111
B740	Plant-incorporated protectants (PIP), EUP; registered active ingredient; non-food/feed or crop destruct basis; no Scientific Advisory Panel (SAP) review required		2				208		
B771	PIP, experimental use permit application; new active ingredient; establish temporary tolerance or tolerance exemption; no SAP review required	2			1	370			280
B772	PIP, amend or extend EUP; minor changes to experimental design; established temporary tolerance or tolerance exemption is unaffected		3	1	2		54	90	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	
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	20	5	6	7	395	274	259	270
B881	PIP, new product; SAP review required	1	3	3		697	458	456	
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)	1	6	1	4	181	179	178	142
B902	PIP protocol review				1				84

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2010	FY 2011	FY 2012	FY 2013	FY 2010	FY 2011	FY 2012	FY 2013
B903	Inert ingredient tolerance exemption; reviewed in BPPD				1				184
I002	Amend currently approved inert tolerance; new data				2				254
I003	Amend currently approved inert tolerance; no new data				1				273
I008	Approval of new polymer inert; food use				4				124
M006	Gold Seal letter				561				-13
M007	Extend exclusive use of data 3(c)(1)(F)(ii)				1				226
	TOTAL	1517	1554	1574	2048				