

Implementing the Pesticide Registration Improvement Act - Fiscal Year 2014

Eleventh Annual Report



March 1, 2015

Table III

Number of PRIA Actions Completed in fiscal year 2011, 2012, 2013, and 2014

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 2011	FY 2012	FY 2013	FY 2014	FY 2011	FY 2012	FY 2013	FY 2014
R010	New active ingredient, food use	11	51	20	10	703	910	731	1087
R020	New active ingredient, food use, reduced risk		6		16		587		940
R060	New active ingredient, non-food use, outdoor	2				1069			
R090	New active ingredient, non-food use, outdoor, EUP				1				606
R110	New active ingredient, non-food use, indoor		3	3	1		630	1024	478
R123	New active ingredient, seed treatment only			2	2			718	861
R124	Conditional ruling on pre-application study waivers; applicant-initiated	3	1	5	5	164	164	175	159
R125	New active ingredient, seed treatment, EUP				1				491
R140	Additional food use; indoor; food/food handling	3	7	6	1	399	548	455	456
R150	New use, first food use	2	11		4	1224	673		1161
R17	New use, each additional new food use	4				2098			
R170	New use, additional food use	59	108	138	82	508	467	524	515
R175	Additional food uses covered within a crop grouping/conversion				14				325
R180	New use, additional food use; reduced risk	6		27	13	595		277	306

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2011	FY 2012	FY 2013	FY 2014	FY 2011	FY 2012	FY 2013	FY 2014
R19	New use, additional new food uses, bundled, 6 or more		3				1548		
R190	New use, additional food uses; 6 or more submitted in one application	43	59	32	40	529	519	526	488
R200	New use, additional food uses; 6 or more submitted in one application; reduced risk	9	5	17	4	591	328	425	743
R210	Additional food use; experimental use permit application; establish temporary tolerance; no credit toward new use registration	2	3	2		368	341	389	
R230	New use, additional use; non-food; outdoor	16	19	9	4	572	481	442	511
R250	New use, additional use; non-food; outdoor; EUP; no credit toward new use registration	2		4		82		122	
R251	EUP, non-crop destruct, no change to tolerance				1				358
R260	New use; non-food; indoor	4	6	5	2	375	205	606	390
R270	New use; non-food; indoor; reduced risk	1			1	350			272
R272	Review of study protocol; applicant-initiated; excludes DART, pre-registration conferences, rapid response review, DNT protocol review, protocols needing HSRB review	43	22	21	25	76	72	99	89
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	7	6	3	9	390	588	300	354
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				470			
R280	Establish import tolerance; new active ingredient or first food use	3	2	1	3	572	694	632	716
R29	Import tolerance, additional new food use	1				2485			
R290	Establish import tolerance; additional food use	4	4	7	10	496	431	357	643
R292	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated	7	6	14	10	311	385	324	561
R293	Establish tolerance(s) for inadvertent residues in one crop, applicant initiated				1				497

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2011	FY 2012	FY 2013	FY 2014	FY 2011	FY 2012	FY 2013	FY 2014
R295	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; applicant-initiated		5		5		448		560
R298	Amend established tolerance and amended labels				14				380
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.	231	194	157	118	79	73	92	115
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.	40	24	59	33	138	131	108	130
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 	250	225	178	96	198	190	186	248
R311	New product; requires approval of new food-use inert; applicant-initiated; excludes approval of safeners		3	1			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	2				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	32			236	235
R315	New end use, non-food animal product with 2 animal safety studies			2	9			63	345

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2011	FY 2012	FY 2013	FY 2014	FY 2011	FY 2012	FY 2013	FY 2014
R320	New product; new physical form; requires data review in science divisions	15	15	14	10	371	380	382	390
R330	New manufacturing-use product; registered active ingredient; selective data citation	6	6	12		320	354	313	
R331	New product; repack of identical registered end-use product as a manufacturing-use product; same registrant uses only	6	2	23	2	65	22	61	94
R333	New product with unregistered source of AI; cite-all or selective data citation where applicant owns all required data			1	29			220	305
R334	New product with unregistered source of AI; selective data citation			1	13			5	302
R340	Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient)	218	228	193	142	116	116	108	126
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)	67	43	54	42	276	284	279	372
R351	Amendment adding new unregistered source of AI			15	83			147	215
R352	Amendment adding already approved uses;				6				193
R371	Amendment to EUP				1				184
R370	Cancer reassessment; applicant-initiated	2	1	2		534	535	349	
A380	Food use; establish tolerance exemption	4			1	392			332
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	2	4	1	2	432	740	-5	454
A470	New food use, additional food use; establish tolerance								
A480	New use, additional use; non-food; outdoor; FIFRA §2(mm) uses	2		7	1	151		406	274
A490	New use, additional use; non-food; outdoor; uses other than FIFRA §2(mm)			1	2			1239	835

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2011	FY 2012	FY 2013	FY 2014	FY 2011	FY 2012	FY 2013	FY 2014
A500	New use, additional use; non-food; indoor; FIFRA §2(mm) uses	1	6	9	6	273	244	365	389
A510	Additional use; non-food; indoor; uses other than FIFRA section 2(mm)	1				748			
A520	Experimental use permit application	4	1			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	11	8	12	13	143	177	204	255
A522	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; applicant-initiated; Tier 2		3	1	4		622	829	460
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.	55	89	64	39	95	91	112	113
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.	19	19	14	21	186	128	119	124
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	15	15	17	13	130	143	139	152
A540	New end use product; FIFRA §2(mm) uses only	66	69	74	58	159	193	192	200
A550	New end-use product; uses other than FIFRA §2(mm); non-FQPA product	7	7	8		179	218	263	
A560	New manufacturing-use product; registered active ingredient; selective data citation	8	7	7	1	262	385	368	369

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2011	FY 2012	FY 2013	FY 2014	FY 2011	FY 2012	FY 2013	FY 2014
A570	Label amendment requiring data submission	151	99	108	124	136	180	129	127
A572	New product or amendment (REI, PPE, use rate changes)			1	2			38	334
B590	New active ingredient; food use; establish tolerance exemption, microbial/biochemical	10	38	21	21	734	692	771	772
B600	New active ingredient; non-food use, microbial/biochemical	6	14	9	4	681	541	469	576
B620	Non-food use; experimental use permit application	2	3	2	1	103	143	326	231
B621	Extend or amend EUP, microbial/biochemical	4	8	3	7	69	37	33	106
B63	New use, first food use, with tolerance exemption microbial/biochemical,	3				1233			
B630	First food use; establish tolerance exemption, microbial/biochemical	12			1	614			567
B631	Amend established tolerance exemption, microbial/biochemical	2	6	4		389	243	393	
B641	Amend established tolerance		1				276		
B644	New use, no change to tolerance				1				336
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	12	22	6	12	61	85	85	113
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	16	13	17	22	262	189	211	235
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				1				512

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2011	FY 2012	FY 2013	FY 2014	FY 2011	FY 2012	FY 2013	FY 2014
	scientific rationales, microbial/biochemical								
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	6	16	11	11	334	374	358	496
B673	New product; unregistered source; citation of TGA1 data previously reviewed			1	7			192	267
B680	Label amendment requiring data submission, microbial/biochemical	20	13	12	13	103	89	115	125
B681	Label amendment; unregistered source of active ingredient; supporting data require scientific review, microbial/biochemical	5	6	3	3	263	281	183	196
B682	Protocol review; applicant-initiated; excludes time for HSRB review (pre-application), microbial/biochemical	1	4	2	3	52	64	79	58
B690	SCLP, new active ingredient; food or non-food use	1	1		1	169	140		272
B700	SCLP, experimental use permit application; new active ingredient or new use			1	1			120	310
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		3		67		135
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	3	2		3	130	141		147
B721	SCLP, new product; unregistered source of active ingredient	4	2	2		185	160	176	
B730	SCLP, label amendment requiring data submission	3	1	1		158	122	111	
B740	Plant-incorporated protectants (PIP), EUP; registered active	2			1	208			112

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2011	FY 2012	FY 2013	FY 2014	FY 2011	FY 2012	FY 2013	FY 2014
	ingredient; non-food/feed or crop destruct basis; no Scientific Advisory Panel (SAP) review required								
B771	PIP, experimental use permit application; new active ingredient; establish temporary tolerance or tolerance exemption; no SAP review required			1				280	
B772	PIP, amend or extend EUP; minor changes to experimental design; established temporary tolerance or tolerance exemption is unaffected	3	1	2	1	54	90	90	95
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		8				773		
B820	New PIP with tolerance petition				2				527
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	5	6	7	7	274	259	270	245
B881	PIP, new product; SAP review required	3	3			458	456		
B885	Registration application, registered PIP, seed increase, breeding stack of approved PIPs				1				276
B890	Application to amend a seed increase registration, converts to commercial registration				2				272
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)	6	1	4		179	178	142	
B902	PIP protocol review			1				84	
B903	Inert ingredient tolerance exemption; reviewed in BPPD			1				184	
I001	New food use inert				5				389

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2011	FY 2012	FY 2013	FY 2014	FY 2011	FY 2012	FY 2013	FY 2014
I002	Amend currently approved inert tolerance; new data			2	1			254	528
I003	Amend currently approved inert tolerance; no new data			1	3			273	324
I004	New non-food use inert				6				136
I006	Amend approved non-food use inert				1				34
I007	Substantially similar non-food use inert				5				110
I008	Approval of new polymer inert; food use			4	6			124	166
I009	New polymer inert ingredient				4				94
I010	Amend tolerance exemption descriptor to add CASRNs				2				268
M005	New product, combination of AIs across divisions				2				240
M006	Gold Seal letter			561	570			-13	-15
M007	Extend exclusive use of data 3(c)(1)(F)(ii)			1	2			226	313
M008	Extend exclusive use of data 3(c)(1)(F)(vi)				1				454
	TOTAL	1554	1574	2048	1919				