Implementing the Pesticide Registration Improvement Act - Fiscal Year 2015

Twelfth Annual Report

March 1, 2016

Table III

Number of PRIA Actions Completed in fiscal year 2012, 2013, 2014, and 2015

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 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015
R010	New active ingredient, food use	51	20	10	23	910	731	1087	917
R020	New active ingredient, food use, reduced risk	6		16	10	587		940	690
R060	New active ingredient, non-food use, outdoor				10				727
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	1	5	5	10	164	175	159	199
R125	New active ingredient, seed treatment, EUP			1				491	
R140	Additional food use; indoor; food/food handling	7	6	1	8	548	455	456	494
R150	New use, first food use	11		4	2	673		1161	1554
R170	New use, additional food use	108	138	82	82	467	524	515	486
R175	Additional food uses covered within a crop grouping/conversion			14	38			325	433
R180	New use, additional food use; reduced risk		27	13	2		277	306	494
R19	New use, additional new food uses, bundled, 6 or more	3				1548			

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015
R190	New use, additional food uses; 6 or more submitted in one application	59	32	40	30	519	526	488	533
R200	New use, additional food uses; 6 or more submitted in one application; reduced risk	5	17	4		328	425	743	
R210	Additional food use; experimental use permit application; establish temporary tolerance; no credit toward new use registration	3	2			341	389		
R230	New use, additional use; non-food; outdoor	19	9	4	11	481	442	511	476
R250	New use, additional use; non-food; outdoor; EUP; no credit toward new use registration		4		1		122		198
R251	EUP, non-crop destruct, no change to tolerance			1	3			358	259
R260	New use; non-food; indoor	6	5	2	5	205	606	390	482
R270	New use; non-food; indoor; reduced risk			1				272	
R272	Review of study protocol; applicant-initiated; excludes DART, pre-registration conferences, rapid response review, DNT protocol review, protocols needing HSRB review	22	21	25	25	72	99	89	77
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	6	3	9	1	588	300	354	360
R280	Establish import tolerance; new active ingredient or first food use	2	1	3	1	694	632	716	854
R290	Establish import tolerance; additional food use	4	7	10	7	431	357	643	416
R292	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated	6	14	10	4	385	324	561	759
R293	Establish tolerance(s) for inadvertent residues in one crop, applicant initiated			1				497	
R295	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; applicant-initiated	5		5		448		560	
R296	Establish rotational crop tolerances; 6 or more crops				1				491
R298	Amend established tolerance and amended labels			14	19			380	428
R299	Amend 6 or more tolerances and amended labels				4				541
R300	New product; identical or substantially similar in composition and use	194	157	118	127	73	92	115	107

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015
	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.								
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.	24	59	33	49	131	108	130	110
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	225	178	96	90	190	186	248	224
R311	New product; requires approval of new food-use inert; applicant-initiated; excludes approval of safeners	3	1		1	353	365		1043
R312	New Product; requires approval of new non-food use inert; applicant initiated		1				179		
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	44		236	235	233
R315	New end use, non-food animal product with 2 animal safety studies		2	9	5			345	271
R320	New product; new physical form; requires data review in science divisions	15	14	10	21	380	382	390	367
R330	New manufacturing-use product; registered active ingredient; selective data citation	6	12			354	313		
R331	New product; repack of identical registered end-use product as a manufacturing-use product; same registrant uses only	2	23	2	3	22	61	94	38

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015
R333	New product with unregistered source of AI;cite-all or selective data citation where applicant owns all required data		1	29	24		220	305	264
R334	New product with unregistered source of AI; selective data citation		1	13	22		5	302	354
R340	Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient)	228	193	142	117	116	108	126	107
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)	43	54	42	60	284	279	372	343
R351	Amendment adding new unregistered source of AI		15	83	89		147	215	204
R352	Amendment adding already approved uses;			6	6			193	237
R371	Amendment to EUP			1	2			184	99
R370	Cancer reassessment; applicant-initiated	1	2		3	535	349		386
A380	New active ingredient, food use; establish tolerance exemption			1				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		1	736	1204		2075
A460	Additional food use; establish tolerance exemption	4	1	2	1	740	-5	454	485
A480	New use, additional use; non-food; outdoor; FIFRA §2(mm) uses		7	1	3		406	274	268
A490	New use, additional use; non-food; outdoor; uses other than FIFRA §2(mm)		1	2			1239	835	
A500	New use, additional use; non-food; indoor; FIFRA §2(mm) uses	6	9	6	5	244	365	389	1082
A520	Experimental use permit application	1				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	8	12	13	7	177	204	255	184
A522	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; applicant-	3	1	4		622	829	460	

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015
	initiated; Tier 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.	89	64	39	36	91	112	113	107
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	14	21	16	128	119	124	120
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	17	13	17	143	139	152	147
A540	New end use product; FIFRA §2(mm) uses only	69	74	58	84	193	192	200	179
A550	New end-use product; uses other than FIFRA §2(mm); non-FQPA product	7	8		8	218	263		173
A560	New manufacturing-use product; registered active ingredient; selective data citation	7	7	1	2	385	368	369	347
A570	Label amendment requiring data submission	99	108	124	139	180	129	127	117
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	38	21	21	25	692	771	772	553
B600	New active ingredient; non-food use, microbial/biochemical	14	9	4		541	469	576	
B614	Conditional ruling on pre-application study waivers				1				73
B620	Non-food use; experimental use permit application	3	2	1	2	143	326	231	132
B621	Extend or amend EUP, microbial/biochemical	8	3	7	6	37	33	106	113

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015
B630	First food use; establish tolerance exemption, microbial/biochemical			1	6			567	530
B631	Amend established tolerance exemption, microbial/biochemical	6	4			243	393		
B641	Amend established tolerance	1				276			
B643	New food use; petition to amend tolerance exemption				3				301
B644	New use, no change to tolerance			1	1			336	241
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	22	6	12	15	85	85	113	110
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	13	17	22	21	189	211	235	210
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			1	1			512	518
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	16	11	11	11	374	358	496	389
B673	New product; unregistered source; citation of TGAI data previously reviewed		1	7	5		192	267	354

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015
B680	Label amendment requiring data submission, microbial/biochemical	13	12	13	18	89	115	125	139
B681	Label amendment; unregistered source of active ingredient; supporting data require scientific review, microbial/biochemical	6	3	3	6	281	183	196	229
B682	Protocol review; applicant-initiated; excludes time for HSRB review (pre-application), microbial/biochemical	4	2	3	5	64	79	58	61
B683	Label amendment; requires update of RA (REI, PPE, PHI changes)				1				117
B690	SCLP, new active ingredient; food or non-food use	1		1	1	140		272	217
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	2		3	12	141		147	136
B721	SCLP, new product; unregistered source of active ingredient	2	2			160	176		
B730	SCLP, label amendment requiring data submission	1	1		1	122	111		113
B740	Plant-incorporated protectants (PIP), EUP; registered active ingredient; non-food/feed or crop destruct basis; no Scientific Advisory Panel (SAP) review required			1	1			112	182
B771	PIP, experimental use permit application; new active ingredient; establish temporary tolerance or tolerance exemption; no SAP review required		1		5		280		315
B772	PIP, amend or extend EUP; minor changes to experimental design; established temporary tolerance or tolerance exemption is unaffected	1	2	1	1	90	90	95	92
B800	PIP, new active ingredient; establish permanent tolerance or	8				773			

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015
	tolerance exemption based on temporary tolerance or tolerance exemption; no SAP review required								
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			
B880	PIP, new product; no SAP review required	6	7	7	1	259	270	245	268
B881	PIP, new product; SAP review required	3				456			
B884	New PIP, seed increase, acreage cap, time-limited reg, tol exemption				3				365
B885	Registration application, registered PIP, seed increase, breeding stack of approved PIPs			1	1			276	273
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)	1	4			178	142		
B902	PIP protocol review		1				84		
B903	Inert ingredient tolerance exemption; reviewed in BPPD		1				184		
I001	New food use inert			5	13			389	463
I002	Amend currently approved inert tolerance; new data		2	1	1		254	528	349
I003	Amend currently approved inert tolerance; no new data		1	3	2		273	324	290
I004	New non-food use inert			6	18			136	200
I006	Amend approved non-food use inert			1				34	
I007	Substantially similar non-food use inert			5	1			110	120
I008	Approval of new polymer inert; food use		4	6	8		124	166	171
I009	New polymer inert ingredient			4	12			94	90
I010	Amend tolerance exemption descriptor to add CASRNs			2	1			268	253
M001	Human Studies protocol review - HSRB				1				105

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2012	FY 2013	FY 2014	FY 2015	FY 2012	FY 2013	FY 2014	FY 2015
M002	Completed human study HSRB review				2				273
M005	New product, combination of AIs across divisions			2	1			240	253
M006	Gold Seal letter		561	570	611		-13	-15	-6
M007	Extend exclusive use of data 3(c)(1)(F)(ii)		1	2	6		226	313	369
M008	Extend exclusive use of data 3(c)(1)(F)(vi)			1	1			454	488
	TOTAL	1574	2048	1919	2111				