Implementing the Pesticide Registration Improvement Act - Fiscal Year 2016

Thirteenth Annual Report

March 1, 2017

Table III

Number of PRIA Actions Completed in fiscal year 2013, 2014, 2015, and 2016

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 2013	FY 2014	FY 2015	FY 2016	FY 2013	FY 2014	FY 2015	FY 2016
R010	New active ingredient, food use	20	10	23	8	731	1087	917	1186
R020	New active ingredient, food use, reduced risk		16	10			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	1		1	1024	478		327
R123	New active ingredient, seed treatment only	2	2			718	861		
R124	Conditional ruling on pre-application study waivers; applicant-initiated	5	5	10	6	175	159	199	104
R125	New active ingredient, seed treatment, EUP		1				491		
R140	Additional food use; indoor; food/food handling	6	1	8	2	455	456	494	1119
R150	New use, first food use		4	2	1		1161	1554	2040
R170	New use, additional food use	138	82	82	122	524	515	486	562
R175	Additional food uses covered within a crop grouping/conversion		14	38	65		325	433	527
R180	New use, additional food use; reduced risk	27	13	2	14	277	306	494	607
R190	New use, additional food uses; 6 or more submitted in one application	32	40	30	52	526	488	533	519

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2013	FY 2014	FY 2015	FY 2016	FY 2013	FY 2014	FY 2015	FY 2016
R200	New use, additional food uses; 6 or more submitted in one application; reduced risk	17	4		3	425	743		359
R210	Additional food use; experimental use permit application; establish temporary tolerance; no credit toward new use registration	2				389			
R230	New use, additional use; non-food; outdoor	9	4	11	12	442	511	476	632
R250	New use, additional use; non-food; outdoor; EUP; no credit toward new use registration	4		1	2	122		198	264
R251	EUP, non-crop destruct, no change to tolerance		1	3	1		358	259	695
R260	New use; non-food; indoor	5	2	5	7	606	390	482	611
R270	New use; non-food; indoor; reduced risk		1		1		272		359
R272	Review of study protocol; applicant-initiated; excludes DART, pre-registration conferences, rapid response review, DNT protocol review, protocols needing HSRB review	21	25	25	29	99	89	77	70
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	3	9	1	10	300	354	360	458
R280	Establish import tolerance; new active ingredient or first food use	1	3	1	2	632	716	854	635
R290	Establish import tolerance; additional food use	7	10	7	2	357	643	416	473
R292	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated	14	10	4	13	324	561	759	462
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		1		560		616
R296	Establish rotational crop tolerances; 6 or more crops			1				491	
R298	Amend established tolerance and amended labels		14	19	18		380	428	571
R299	Amend 6 or more tolerances and amended labels			4				541	
R300	New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data;	157	118	127	108	92	115	107	101

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2013	FY 2014	FY 2015	FY 2016	FY 2013	FY 2014	FY 2015	FY 2016
	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.	59	33	49	60	108	130	110	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: • product chemistry and/or • acute toxicity and/or • public health pest efficacy	178	96	90	73	186	248	224	207
R311	New product; requires approval of new food-use inert; applicant-initiated; excludes approval of safeners	1		1		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	33	236	235	233	264
R315	New end use, non-food animal product with 2 animal safety studies	2	9	5	14		345	271	223
R320	New product; new physical form; requires data review in science divisions	14	10	21	15	382	390	367	403
R330	New manufacturing-use product; registered active ingredient; selective data citation	12				313			
R331	New product; repack of identical registered end-use product as a manufacturing-use product; same registrant uses only	23	2	3	3	61	94	38	51

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2013	FY 2014	FY 2015	FY 2016	FY 2013	FY 2014	FY 2015	FY 2016
R333	New product with unregistered source of AI;cite-all or selective data citation where applicant owns all required data	1	29	24	34	220	305	264	270
R334	New product with unregistered source of AI; selective data citation	1	13	22	21	5	302	354	318
R340	Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient)	193	142	117	90	108	126	107	92
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)	54	42	60	48	279	372	343	335
R351	Amendment adding new unregistered source of AI	15	83	89	73	147	215	204	203
R352	Amendment adding already approved uses;		6	6			193	237	
R371	Amendment to EUP		1	2	2		184	99	141
R370	Cancer reassessment; applicant-initiated	2		3	1	349		386	665
R.30	Footnote 3 – 30 calendar days to reach agreement on label				4				63
R.LR	Footnote 3 – Agency label review within 2 business days				15				23
A380	New active ingredient, food use; establish tolerance exemption		1				332		
A400	New active ingredient; non-food use; outdoor; FIFRA §2(mm)	1				1692			
A420	New active ingredient, non-food use, indoor FIFRA §2(mm) uses	4		1	12	1204		2075	997
A460	Additional food use; establish tolerance exemption		2	1			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		1	1239	835		405
A500	New use, additional use; non-food; indoor; FIFRA §2(mm) uses	9	6	5	1	365	389	1082	276
A510	New use, additional use; non-food; indoor; non-FIFRA §2(mm) uses				1				323
A521	Review of public health efficacy study protocol within AD; per AD Internal Guidance for the Efficacy Protocol Review Process; applicant-initiated; Tier 1	12	13	7	8	204	255	184	90
A522	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; applicant-	1	4		2	829	460		420

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2013	FY 2014	FY 2015	FY 2016	FY 2013	FY 2014	FY 2015	FY 2016
	initiated; Tier 2								
A523	Protocol review; other than public health efficacy				1				268
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.	64	39	36	28	112	113	107	104
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.	14	21	16	21	119	124	120	121
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	17	13	17	8	139	152	147	147
A540	New end use product; FIFRA §2(mm) uses only	74	58	84	80	192	200	179	167
A550	New end-use product; uses other than FIFRA §2(mm); non-FQPA product	8		8	3	263		173	209
A560	New manufacturing-use product; registered active ingredient; selective data citation	7	1	2	14	368	369	347	393
A570	Label amendment requiring data submission	108	124	139	134	129	127	117	119
A572	New product or amendment (REI, PPE, use rate changes)	1	2		2	38	334		365
A.30	Footnote 3 – 30 calendar days to reach agreement on label				18				21
A.LR	Footnote 3 – Agency label review within 2 business days				19				2
B590	New active ingredient; food use; establish tolerance exemption, microbial/biochemical	21	21	25	17	771	772	553	600
B600	New active ingredient; non-food use, microbial/biochemical	9	4		5	469	576		786

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2013	FY 2014	FY 2015	FY 2016	FY 2013	FY 2014	FY 2015	FY 2016
B610	New AI EUP; establish temporary tolerance or exemption				4				308
B612	New AI; no change to permanent tolerance exemption				9				405
B614	Conditional ruling on pre-application study waivers			1	3			73	84
B620	Non-food use; experimental use permit application	2	1	2	1	326	231	132	210
B621	Extend or amend EUP, microbial/biochemical	3	7	6	3	33	106	113	153
B630	First food use; establish tolerance exemption, microbial/biochemical		1	6	4		567	530	851
B631	Amend established tolerance exemption, microbial/biochemical	4				393			
B641	Amend established tolerance				1				332
B643	New food use; petition to amend tolerance exemption			3	5			301	293
B644	New use, no change to tolerance		1	1			336	241	
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	6	12	15	16	85	113	110	75
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	17	22	21	32	211	235	210	165
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	11	11	11	9	358	496	389	333

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2013	FY 2014	FY 2015	FY 2016	FY 2013	FY 2014	FY 2015	FY 2016
	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								
B673	New product; unregistered source; citation of TGAI data previously reviewed	1	7	5	2	192	267	354	267
B674	New product; MUP; repack of identical end-use product; same uses				1				89
B680	Label amendment requiring data submission, microbial/biochemical	12	13	18	8	115	125	139	116
B681	Label amendment; unregistered source of active ingredient; supporting data require scientific review, microbial/biochemical	3	3	6	5	183	196	229	148
B682	Protocol review; applicant-initiated; excludes time for HSRB review (pre-application), microbial/biochemical	2	3	5	2	79	58	61	59
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			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		3		1		135		100
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	12	9		147	136	128
B721	SCLP, new product; unregistered source of active ingredient	2			2	176			149
B730	SCLP, label amendment requiring data submission	1		1	1	111		113	147
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	

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2013	FY 2014	FY 2015	FY 2016	FY 2013	FY 2014	FY 2015	FY 2016
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	2	1	1	2	90	95	92	86
B773	Amend or extend an EUP; extend temporary tolerance or exemption				2				147
B780	New PIP; non-food/feed				1				399
B790	New PIP; non-food/feed; SAP review				1				300
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				265
B880	PIP, new product; no SAP review required	7	7	1	3	270	245	268	316
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	2		276	273	262
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)	4				142			
B902	PIP protocol review	1				84			
B903	Inert ingredient tolerance exemption; reviewed in BPPD	1				184			
I001	New food use inert		5	13	17		389	463	509
I002	Amend currently approved inert tolerance; new data	2	1	1	2	254	528	349	447
I003	Amend currently approved inert tolerance; no new data	1	3	2	1	273	324	290	233
I004	New non-food use inert		6	18	7		136	200	210
I006	Amend approved non-food use inert		1		1		34		135
I007	Substantially similar non-food use inert		5	1	1		110	120	121

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2013	FY 2014	FY 2015	FY 2016	FY 2013	FY 2014	FY 2015	FY 2016
I008	Approval of new polymer inert; food use	4	6	8	14	124	166	171	155
I009	New polymer inert ingredient		4	12	4		94	90	87
I010	Amend tolerance exemption descriptor to add CASRNs		2	1	2		268	253	182
M001	Human Studies protocol review - HSRB			1	1			105	213
M002	Completed human study HSRB review			2	6			273	128
M005	New product, combination of AIs across divisions		2	1	3		240	253	265
M006	Gold Seal letter	561	570	611	639		-15	-6	-3
M007	Extend exclusive use of data 3(c)(1)(F)(ii)	1	2	6	1		313	369	363
M008	Extend exclusive use of data 3(c)(1)(F)(vi)		1	1	4		454	488	474
	TOTAL	2048	1919	2111	2174				