Implementing the Pesticide Registration Improvement Act - Fiscal Year 2018

Fifteenth Annual Report

Table III

Number of PRIA Actions Completed in fiscal year 2015, 2016, 2017, and 2018

Key to the table

- R - Conventional Pesticides
- A - Antimicrobial Pesticides
- B - Biopesticides
- EUP - Experimental Use Permit
- I – Inert Ingredient
- M – Miscellaneous
- 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 2015	FY 2016	FY 2017	FY 2018	FY 2015	FY 2016	FY 2017	FY 2018
R010	New active ingredient, food use	23	8	16	5	917	1186	934	860
R020	New active ingredient, food use, reduced risk	10		6	15	690		711	709
R060	New active ingredient, non-food use, outdoor	10			3	727			737
R090	New active ingredient, non-food use, outdoor, EUP				1				466
R110	New active ingredient, non-food use, indoor		1				327		
R124	Conditional ruling on pre-application study waivers; applicant-initiated	10	6	6	10	199	104	170	116
R140	Additional food use; indoor; food/food handling	8	2			494	1119		
R150	New use, first food use	2	1	3		1554	2040	728	
R170	New use, additional food use	82	122	92	94	486	562	560	640
R175	Additional food uses covered within a crop grouping/conversion	38	65	17	40	433	527	439	566
R180	New use, additional food use; reduced risk	2	14	24	15	494	607	457	396
R190	New use, additional food uses; 6 or more submitted in one application	30	52	25	19	533	519	541	564

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2015	FY 2016	FY 2017	FY 2018	FY 2015	FY 2016	FY 2017	FY 2018
R200	New use, additional food uses; 6 or more submitted in one application; reduced risk		3	12			359	640	
R230	New use, additional use; non-food; outdoor	11	12	8	9	476	632	718	461
R240	New use, additional use; non-food; outdoor; reduced risk			4				421	
R250	New use, additional use; non-food; outdoor; EUP; no credit toward new use registration	1	2		1	198	264		122
R251	EUP, non-crop destruct, no change to tolerance	3	1		1	259	695		140
R260	New use; non-food; indoor	5	7	1	5	482	611	369	384
R270	New use; non-food; indoor; reduced risk		1	1	2		359	437	
R272	Review of study protocol; applicant-initiated; excludes DART, pre-registration conferences, rapid response review, DNT protocol review, protocols needing HSRB review	25	29	40	20	77	70	61	61
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	1	10	4	4	360	458	687	456
R275	Rebuttal of agency reviewed protocol; applicant-initiated				1				21
R280	Establish import tolerance; new active ingredient or first food use	1	2		3	854	635		613
R290	Establish import tolerance; additional food use	7	2	14	7	416	473	471	536
R291	Establish import tolerance; additional food uses; 6 or more crops submitted in one petition			2				1083	
R292	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated	4	13	4	4	759	462	399	437
R295	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; applicant-initiated		1		1		616		462
R296	Establish rotational crop tolerances; 6 or more crops	1				491			
R298	Amend established tolerance and amended labels	19	18	11	13	428	571	435	661
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;	127	108	128	204	107	101	106	111

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2015	FY 2016	FY 2017	FY 2018	FY 2015	FY 2016	FY 2017	FY 2018
	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.	49	60	65	89	110	108	119	118
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	90	73	86	97	224	207	207	214
R311	New product; requires approval of new food-use inert; applicant-initiated; excludes approval of safeners	1				1043			
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	44	33	21	37	233	264	234	260
R315	New end use, non-food animal product with 2 animal safety studies	5	14	14	2	271	223	242	255
R320	New product; new physical form; requires data review in science divisions	21	15	15	11	367	403	347	372
R331	New product; repack of identical registered end-use product as a manufacturing-use product; same registrant uses only	3	3	3	2	38	51	79	58
R333	New product with unregistered source of a.i..; cite-all or selective data citation where applicant owns all required data	24	34	28	38	264	270	271	299
R334	New product with unregistered source of a.i.; selective data citation	22	21	50	42	354	318	321	326
R340	Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient)	117	90	108	91	107	92	111	110

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2015	FY 2016	FY 2017	FY 2018	FY 2015	FY 2016	FY 2017	FY 2018
R345	Amending non-food animal product that includes submission of target animal safety data; previously registered			1				213	
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)	60	48	39	24	343	335	254	304
R351	Amendment adding new unregistered source of AI	89	73	82	96	204	203	208	215
R352	Amendment adding already approved uses;	6		3	6	237		203	133
R370	Cancer reassessment; applicant-initiated	3	1		3	386	665		698
R371	Amendment to EUP	2	2			99	141		
R.30	Footnote 3 – 30 calendar days to reach agreement on label		4		7		63		11
R.LR	Footnote 3 – Agency label review within 2 business days		15	4	25		23	2	2
A420	New active ingredient, non-food use, indoor FIFRA §2(mm) uses	1	12	1	1	2075	997	732	182
A440	New use, first food use, establish tolerance exemption			1				532	
A460	Additional food use; establish tolerance exemption	1		1	3	485		456	1594
A480	New use, additional use; non-food; outdoor; FIFRA §2(mm) uses	3			2	268			273
A490	New use, additional use; non-food; outdoor; uses other than FIFRA §2(mm)		1				405		
A500	New use, additional use; non-food; indoor; FIFRA §2(mm) uses	5	1		2	1082	276		271
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	7	8	6	10	184	90	94	85
A522	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; applicant-initiated; Tier 2		2	2			420	355	
A523	Protocol review; other than public health efficacy		1		1		268		212

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2015	FY 2016	FY 2017	FY 2018	FY 2015	FY 2016	FY 2017	FY 2018
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.	36	28	42	26	107	104	100	109
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.	16	21	11	18	120	121	119	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	17	8	8	6	147	147	155	150
A540	New end use product; FIFRA §2(mm) uses only	84	80	85	69	179	167	166	151
A550	New end-use product; uses other than FIFRA §2(mm); non-FQPA product	8	3	3	3	173	209	216	211
A560	New manufacturing-use product; registered active ingredient; selective data citation	2	14	7	9	347	393	315	341
A570	Label amendment requiring data submission	139	134	132	132	117	119	116	116
A572	New product or amendment (REI, PPE, use rate changes)		2	3	3		365	266	233
A.30	Footnote 3 – 30 calendar days to reach agreement on label		18	17	22		21	9	14
A.LR	Footnote 3 – Agency label review within 2 business days		19	19	21		2	1	3
B590	New active ingredient; food use; establish tolerance exemption, microbial/biochemical	25	17	11	110	553	600	605	361
B600	New active ingredient; non-food use, microbial/biochemical		5	3	2		786	417	507
B610	New AI EUP; establish temporary tolerance or exemption		4				308		
B612	New AI; no change to permanent tolerance exemption		9	1			405	479	
B614	Conditional ruling on pre-application study waivers	1	3	9	1	73	84	74	94

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2015	FY 2016	FY 2017	FY 2018	FY 2015	FY 2016	FY 2017	FY 2018
B620	Non-food use; experimental use permit application	2	1			132	210		
B621	Extend or amend EUP, microbial/biochemical	6	3	3	3	113	153	140	171
B630	First food use; establish tolerance exemption, microbial/biochemical	6	4		2	530	851		217
B641	Amend established tolerance		1				332		
B643	New food use; petition to amend tolerance exemption	3	5	3		301	293	302	
B644	New use, no change to tolerance	1		2		241		119	
B650	New use, non-food			4	1			211	212
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	15	16	17	9	110	75	100	83
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	21	32	22	18	210	165	210	194
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				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	11	9	7	9	389	333	374	380

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2015	FY 2016	FY 2017	FY 2018	FY 2015	FY 2016	FY 2017	FY 2018
B673	New product; unregistered source; citation of TGAI data previously reviewed	5	2	6	6	354	267	281	294
B674	New product; MUP; repack of identical end-use product; same uses		1				89		
B676	New product; more than one active ingredient where one active ingredient is an unregistered source; product chemistry must be submitted			1				345	
B680	Label amendment requiring data submission, microbial/biochemical	18	8	19	15	139	116	190	127
B681	Label amendment; unregistered source of active ingredient; supporting data require scientific review, microbial/biochemical	6	5	11	14	229	148	169	198
B682	Protocol review; applicant-initiated; excludes time for HSRB review (pre-application), microbial/biochemical	5	2	6	3	61	59	78	29
B683	Label amendment; requires update of RA (REI, PPE, PHI changes)	1		1	2	117		351	137
B690	SCLP, new active ingredient; food or non-food use	1		2		217		208	
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			100	99	
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	12	9	3	4	136	128	123	119
B721	SCLP, new product; unregistered source of active ingredient		2	3	4		149	211	203
B730	SCLP, label amendment requiring data submission	1	1	1	1	113	147	43	92
B740	Plant-incorporated protectants (PIP), EUP; registered active ingredient; non-food/feed or crop destruct basis; no Scientific Advisory Panel (SAP) review required	1				182			

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2015	FY 2016	FY 2017	FY 2018	FY 2015	FY 2016	FY 2017	FY 2018
B771	PIP, experimental use permit application; new active ingredient; establish temporary tolerance or tolerance exemption; no SAP review required	5		2	2	315		305	318
B772	PIP, amend or extend EUP; minor changes to experimental design; established temporary tolerance or tolerance exemption is unaffected	1	2	1		92	86	89	
B773	Amend or extend an EUP; extend temporary tolerance or exemption		2	1	2		147	146	212
B780	New PIP; non-food/feed		1				399		
B790	New PIP; non-food/feed; SAP review		1				300		
B800	New PIP, with petition to establish permanent tolerance/tolerance exemption based on an existing tolerance/tolerance exemption			4				405	
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	1	3	7	2	268	316	302	277
B881	PIP; new product; SAP review			2				436	
B883	PIP; seed increase with negotiated acreage cap and time-limited registration; petition to establish permanent tolerance/ tolerance exemption based on temporary tolerance/ tolerance exemption				2				287
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	2	9	1	273	262	276	248
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	1			95	156
B903	Inert Ingredient tolerance exemption; reviewed in BPPD				1				304
I001	New food use inert	13	17	11	8	463	509	474	643
I002	Amend currently approved inert tolerance; new data	1	2	2	3	349	447	401	531
I003	Amend currently approved inert tolerance; no new data	2	1	1	2	290	233	376	350
I004	New non-food use inert	18	7	10	7	200	210	202	259
I005	Amend currently approved non-food use inert ingredient with new use pattern; new data				1				238
I006	Amend approved non-food use inert		1				135		
I007	Substantially similar non-food use inert	1	1	5	1	120	121	117	121

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2015	FY 2016	FY 2017	FY 2018	FY 2015	FY 2016	FY 2017	FY 2018
I008	Approval of new polymer inert; food use	8	14	7	9	171	155	201	193
I009	New polymer inert ingredient	12	4	5	8	90	87	108	108
I010	Amend tolerance exemption descriptor to add CASRNs	1	2	1		253	182	235	
M001	Human Studies protocol review - HSRB	1	1	1	4	105	213	256	260
M002	Completed human study HSRB review	2	6			273	128		
M005	New product, combination of AIs across divisions	1	3	4	1	253	265	270	294
M006	Gold Seal letter	611	639	540	571	-6	-3	2	1
M007	Extend exclusive use of data 3(c)(1)(F)(ii)	6	1	1	3	369	363	337	407
M008	Extend exclusive use of data 3(c)(1)(F)(vi)	1	4			488	474		
	TOTAL	2111	2174	2026	2206				