Implementing the Pesticide Registration Improvement Act - Fiscal Year 2017

Fourteenth Annual Report

March 1, 2018

Table III

Number of PRIA Actions Completed in fiscal year 2014, 2015, 2016, and 2017

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 2014	FY 2015	FY 2016	FY 2017	FY 2014	FY 2015	FY 2016	FY 2017
R010	New active ingredient, food use	10	23	8	16	1087	917	1186	934
R020	New active ingredient, food use, reduced risk	16	10		6	940	690		711
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	1		1		478		327	
R123	New active ingredient, seed treatment only	2				861			
R124	Conditional ruling on pre-application study waivers; applicant-initiated	5	10	6	6	159	199	104	170
R125	New active ingredient, seed treatment, EUP	1				491			
R140	Additional food use; indoor; food/food handling	1	8	2		456	494	1119	
R150	New use, first food use	4	2	1	3	1161	1554	2040	728
R170	New use, additional food use	82	82	122	92	515	486	562	560
R175	Additional food uses covered within a crop grouping/conversion	14	38	65	17	325	433	527	439
R180	New use, additional food use; reduced risk	13	2	14	24	306	494	607	457
R190	New use, additional food uses; 6 or more submitted in one application	40	30	52	25	488	533	519	541

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2014	FY 2015	FY 2016	FY 2017	FY 2014	FY 2015	FY 2016	FY 2017
R200	New use, additional food uses; 6 or more submitted in one application; reduced risk	4		3	12	743		359	640
R230	New use, additional use; non-food; outdoor	4	11	12	8	511	476	632	718
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			198	264	
R251	EUP, non-crop destruct, no change to tolerance	1	3	1		358	259	695	
R260	New use; non-food; indoor	2	5	7	1	390	482	611	369
R270	New use; non-food; indoor; reduced risk	1		1	1	272		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	25	29	40	89	77	70	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	9	1	10	4	354	360	458	687
R280	Establish import tolerance; new active ingredient or first food use	3	1	2		716	854	635	
R290	Establish import tolerance; additional food use	10	7	2	14	643	416	473	471
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	10	4	13	4	561	759	462	399
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	11	380	428	571	435
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;	118	127	108	128	115	107	101	106

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2014	FY 2015	FY 2016	FY 2017	FY 2014	FY 2015	FY 2016	FY 2017
	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.	33	49	60	65	130	110	108	119
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	96	90	73	86	248	224	207	207
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	32	44	33	21	235	233	264	234
R315	New end use, non-food animal product with 2 animal safety studies	9	5	14	14	345	271	223	242
R320	New product; new physical form; requires data review in science divisions	10	21	15	15	390	367	403	347
R331	New product; repack of identical registered end-use product as a manufacturing-use product; same registrant uses only	2	3	3	3	94	38	51	79
R333	New product with unregistered source of AI;cite-all or selective data citation where applicant owns all required data	29	24	34	28	305	264	270	271
R334	New product with unregistered source of AI; selective data citation	13	22	21	50	302	354	318	321
R340	Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient)	142	117	90	108	126	107	92	111

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2014	FY 2015	FY 2016	FY 2017	FY 2014	FY 2015	FY 2016	FY 2017
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)	42	60	48	39	372	343	335	254
R351	Amendment adding new unregistered source of AI	83	89	73	82	215	204	203	208
R352	Amendment adding already approved uses;	6	6		3	193	237		203
R371	Amendment to EUP	1	2	2		184	99	141	
R370	Cancer reassessment; applicant-initiated		3	1			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	4			23	2
A380	New active ingredient, food use; establish tolerance exemption	1				332			
A420	New active ingredient, non-food use, indoor FIFRA §2(mm) uses		1	12	1		2075	997	732
A440	New use, first food use, establish tolerance exemption				1				532
A460	Additional food use; establish tolerance exemption	2	1		1	454	485		456
A480	New use, additional use; non-food; outdoor; FIFRA §2(mm) uses	1	3			274	268		
A490	New use, additional use; non-food; outdoor; uses other than FIFRA §2(mm)	2		1		835		405	
A500	New use, additional use; non-food; indoor; FIFRA §2(mm) uses	6	5	1		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	13	7	8	6	255	184	90	94
A522	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; applicant-initiated; Tier 2	4		2	2	460		420	355
A523	Protocol review; other than public health efficacy			1				268	

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2014	FY 2015	FY 2016	FY 2017	FY 2014	FY 2015	FY 2016	FY 2017
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.	39	36	28	42	113	107	104	100
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.	21	16	21	11	124	120	121	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	13	17	8	8	152	147	147	155
A540	New end use product; FIFRA §2(mm) uses only	58	84	80	85	200	179	167	166
A550	New end-use product; uses other than FIFRA §2(mm); non-FQPA product		8	3	3		173	209	216
A560	New manufacturing-use product; registered active ingredient; selective data citation	1	2	14	7	369	347	393	315
A570	Label amendment requiring data submission	124	139	134	132	127	117	119	116
A572	New product or amendment (REI, PPE, use rate changes)	2		2	3	334		365	266
A.30	Footnote 3 – 30 calendar days to reach agreement on label			18	17			21	9
A.LR	Footnote 3 – Agency label review within 2 business days			19	19			2	1
B590	New active ingredient; food use; establish tolerance exemption, microbial/biochemical	21	25	17	11	772	553	600	605
B600	New active ingredient; non-food use, microbial/biochemical	4		5	3	576		786	417
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		73	84	74

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2014	FY 2015	FY 2016	FY 2017	FY 2014	FY 2015	FY 2016	FY 2017
B620	Non-food use; experimental use permit application	1	2	1		231	132	210	
B621	Extend or amend EUP, microbial/biochemical	7	6	3	3	106	113	153	140
B630	First food use; establish tolerance exemption, microbial/biochemical	1	6	4		567	530	851	
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	1		2	336	241		119
B650	New use, non-food				4				211
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	15	16	17	113	110	75	100
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	22	21	32	22	235	210	165	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	11	11	9	7	496	389	333	374

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2014	FY 2015	FY 2016	FY 2017	FY 2014	FY 2015	FY 2016	FY 2017
B673	New product; unregistered source; citation of TGAI data previously reviewed	7	5	2	6	267	354	267	281
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	13	18	8	19	125	139	116	190
B681	Label amendment; unregistered source of active ingredient; supporting data require scientific review, microbial/biochemical	3	6	5	11	196	229	148	169
B682	Protocol review; applicant-initiated; excludes time for HSRB review (pre-application), microbial/biochemical	3	5	2	6	58	61	59	78
B683	Label amendment; requires update of RA (REI, PPE, PHI changes)		1		1		117		351
B690	SCLP, new active ingredient; food or non-food use	1	1		2	272	217		208
B700	SCLP, experimental use permit application; new active ingredient or new use	1				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	1	135		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	3	12	9	3	147	136	128	123
B721	SCLP, new product; unregistered source of active ingredient			2	3			149	211
B730	SCLP, label amendment requiring data submission		1	1	1		113	147	43
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 2014	FY 2015	FY 2016	FY 2017	FY 2014	FY 2015	FY 2016	FY 2017
B771	PIP, experimental use permit application; new active ingredient; establish temporary tolerance or tolerance exemption; no SAP review required		5		2		315		305
B772	PIP, amend or extend EUP; minor changes to experimental design; established temporary tolerance or tolerance exemption is unaffected	1	1	2	1	95	92	86	89
B773	Amend or extend an EUP; extend temporary tolerance or exemption			2	1			147	146
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
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	1	3	7	245	268	316	302
B881	PIP; new product; SAP review				2				436
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	9	276	273	262	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)				1				95
I001	New food use inert	5	13	17	11	389	463	509	474
I002	Amend currently approved inert tolerance; new data	1	1	2	2	528	349	447	401
I003	Amend currently approved inert tolerance; no new data	3	2	1	1	324	290	233	376
I004	New non-food use inert	6	18	7	10	136	200	210	202
I006	Amend approved non-food use inert	1		1		34		135	
I007	Substantially similar non-food use inert	5	1	1	5	110	120	121	117

PRIA Category	Description of Category	Number Completed PRIA Decisions				Average Decision Time in Days			
		FY 2014	FY 2015	FY 2016	FY 2017	FY 2014	FY 2015	FY 2016	FY 2017
I008	Approval of new polymer inert; food use	6	8	14	7	166	171	155	201
I009	New polymer inert ingredient	4	12	4	5	94	90	87	108
I010	Amend tolerance exemption descriptor to add CASRNs	2	1	2	1	268	253	182	235
M001	Human Studies protocol review - HSRB		1	1	1		105	213	256
M002	Completed human study HSRB review		2	6			273	128	
M005	New product, combination of AIs across divisions	2	1	3	4	240	253	265	270
M006	Gold Seal letter	570	611	639	540	-15	-6	-3	2
M007	Extend exclusive use of data 3(c)(1)(F)(ii)	2	6	1	1	313	369	363	337
M008	Extend exclusive use of data 3(c)(1)(F)(vi)	1	1	4		454	488	474	
	TOTAL	1919	2111	2174	2026				