Implementing the Pesticide Registration Improvement Act - Fiscal Year 2017

Fourteenth Annual Report

March 1, 2018

Table IV

Number of PRIA Decisions Pending at the End of the Fiscal Year (FY 2014 through FY 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

Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year					
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**			
		2014	**2015**	**2016**	**2017**
R01	New Active Ingredient, Food Use	1			
R010	New Active Ingredient, Food Use	40	20	27	36
R020	New Active Ingredient, Food use; reduced risk	10	26	20	20
R060	New Active Ingredient, Non-food use, outdoor	9		6	10
R090	New Active Ingredient, Non-food use, outdoor, EUP			1	1
R110	New Active Ingredient, Non-food use; indoor	2	3	2	2
R124	Conditional Ruling on Pre-application Study Waivers; applicant-initiated	7	2	5	5
R140	Additional food use; Indoor; food/food handling	10	2		
R150	New Use, First food use	10	10	6	3
R17	New Use, Each Additional New Food Use	5	5	5	5
R170	New Use, Additional Food Use	209	202	190	198
R175	Additional food uses covered within a crop grouping resulting from the conversion of an existing approved crop grouping	73	76	56	85
R180	New Use, Additional food use; reduced risk	12	16	33	23
R190	New Use, Additional food uses; 6 or more submitted in one application	54	73	50	49
R200	New Use, Additional food uses; 6 or more submitted in one application; reduced risk	8	10	12	

Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year					
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**			
		2014	**2015**	**2016**	**2017**
R210	New Use, Additional food use; EUP; establish temporary tolerance; no credit toward new use registration	2			
R23	New use, Non-food, outdoor	1			
R230	New Use, Additional use; non-food; outdoor	20	19	13	17
R240	New Use, Additional use; non-food; outdoor; reduced risk		3	4	
R250	EUP, new use; no credit toward new use registration		1		
R251	EUP which requires no changes to tolerance; non-crop destruct	3	1		
R260	New use; non-food; indoor	10	8	2	5
R270	New use; non-food; indoor; reduced risk		2	1	
R271	New use; non-food; indoor; EUP			1	
R272	Review of Study Protocol; applicant-initiated; excludes DART, pre-registration conferences, Rapid Response review, DNT protocol review, protocols needing HSRB review	4	3	4	7
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	12	7	4
R280	Establish import tolerance; new active ingredient or first food use	3	2	3	5
R29	Import tolerance, Additional new food use	1	1	1	1
R290	Establish import tolerance; additional food use	10	7	18	14
B291	Establish import tolerances; additional food uses; 6 or more crops submitted in one petition	2	2	2	
R292	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated	7	18	9	10
R294	Establish tolerances for inadvertent residues; 6 or more		1	1	1
R295	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; applicant-initiated	1	1		1
R296	Establish tolerances for residues in rotational crops in response to specific petition; 6 or more crops submitted in one application	1			
R298	Amend established tolerance, submission of amended labels	39	28	22	21
R299	Amend 6 or more established tolerances; submission of amended labels.	4			11

Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year					
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**			
		2014	**2015**	**2016**	**2017**
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, 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.	37	47	32	76
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.	18	27	30	42
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	65	46	52	67
R311	New product; requires approval of new food-use inert; applicant-initiated; excludes approval of safeners	1			
R314	New product with 2 or more registered AIs never before registered as this combination	32	30	17	38
R315	New product, non-food, animal product with 2 animal safety studies	4	9	13	2
R320	New product; new physical form; requires data review in science divisions	23	25	18	17
R331	New product, repack of identical end-use product as a MUP		2		
R333	New product with unregistered source of AI, cite-all	15	29	21	37
R334	New product with unregistered source of AI, selective citation	26	22	48	43
R340	Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient)	49	38	28	49
R345	Amendment; non-food animal product with animal safety data			1	
R35	Amendment, Non-fast track (changes to REI, PPE, PHI, rate and number of applications, add aerial application, modify GW/SW advisory statement)	2	2	2	2
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)	72	50	31	39

Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year					
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**			
		2014	**2015**	**2016**	**2017**
R351	Amendment adding new unregistered source of AI	45	51	47	65
R352	Amendment adding already approved uses,	5	5	2	3
R370	Cancer reassessment; applicant-initiated	3	1	4	5
A420	Non-food use; indoor; FIFRA section 2(mm) uses	7	17	5	2
A440	New Use, First food use; establish tolerance exemption	2	4	1	1
A460	New Food Use, Additional food use; establish tolerance exemption	4	5	5	3
A480	New use, Additional use; non-food; outdoor; FIFRA §2(mm) uses	2			2
A490	New use, Additional use; non-food; outdoor; uses other than FIFRA §2(mm)		1		
A500	New use, Additional use; non-food; indoor; FIFRA §2(mm) uses	5	2		2
A510	Additional use; non-food; indoor; uses other than FIFRA section 2(mm)	3	4		
A521	Review of public health efficacy study protocol within AD; per AD Internal Guidance for the Efficacy Protocol Review Process; applicant-initiated; Tier 1	3	1	3	4
A522	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; applicant-initiated; Tier 2	1	3	3	
A523	Review of protocol other than public health efficacy study	1	1		1
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.	11	11	10	9
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.	8	11	4	7
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	5	5	1
A540	New end use product; FIFRA §2(mm) uses only	45	41	47	41

Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year					
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**			
		2014	**2015**	**2016**	**2017**
A550	New end-use product; uses other than FIFRA §2(mm); non-FQPA product	4	1	3	3
A560	New manufacturing-use product; registered active ingredient; selective data citation	5	16	9	9
A570	Label amendment requiring data submission	44	62	54	82
A571	Science reassessment: cancer; eco; ESA			1	1
A572	New product or amendment requiring data review	1	3	2	1
B590	New active ingredient; food use; establish tolerance exemption, Microbial/Biochemical,	47	29	46	136
B600	New active ingredient; non-food use, Microbial/Biochemical,	4	5	4	6
B610	Food use; EUP; establish temporary tolerance exemption, Microbial/Biochemical	3	2		
B612	New active ingredient; no change to permanent tolerance exemption.	2	10	1	1
B614	Conditional ruling pre-application study waiver		1	1	1
B620	Non-food use; Experimental Use Permit application, Microbial/Biochemical		1		
B621	Extend or amend Experimental Use Permit, Microbial/Biochemical		2		1
B630	First food use; establish tolerance exemption, Microbial/Biochemical,	14	9		2
B640	New food use; petition to amend an established tolerance				4
B641	Amend established tolerance (e.g., decrease or increase)		1		
B643	New food use; petition to amend tolerance exemption	3	5	4	
B644	New use, no change to existing tolerance or tolerance exemption	1	1	1	
B650	New use; non-food			4	1
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	10	3	6	4
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	15	9	15	13

Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year					
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**			
		2014	**2015**	**2016**	**2017**
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	2			2
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	13	8	6	12
B673	New product, unregistered source of AI; citation of TGAI previously approved	4	7	2	5
B674	New product; MUP; repack of identical end-use product as MUP		1		
B676	New product, more than 1 active ingredient where one is an unregistered source	1		1	
B680	Label amendment requiring data submission, Microbial/Biochemical	5	6	8	8
B681	Label amendment; unregistered source of active ingredient; supporting data require scientific review, Microbial/Biochemical	5	3	12	4
B682	Protocol review; applicant-initiated; excludes time for HSRB review				1
B683	Label amendment; update of previous risk assessment; no new data			1	2
B690	SCLP, New active ingredient; food or non-food use	1			
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	
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	4	5		2
B721	SCLP, New product; unregistered source of active ingredient			2	3
B730	SCLP, Label amendment requiring data submission	1	1		

Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year					
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**			
		2014	**2015**	**2016**	**2017**
B740	Plant-Incorporated Protectants (PIP), EUP; registered active ingredient; non-food/feed or crop destruct basis; no Scientific Advisory Panel (SAP) review required	1			
B771	PIP, Experimental Use Permit application; new active ingredient; establish temporary tolerance or tolerance exemption; no SAP review required;	5		2	2
B772	Amend or extend EUP		1		
B773	Amend or extend EUP with temporary tol exemption extension		2		
B780	New PIP; non-food/feed		1		
B790	New PIP; non-food/feed; SAP review		1		
B800	New PIP; establish tol or exemption based on temporary tol			4	
B851	PIP, New active ingredient; different genetic event of a previously approved active ingredient; same crop; no tolerance action required; no SAP review required		1		
B880	PIP, New product; no SAP review required	1	2	7	2
B881	New PIP product; new terms of registration; additional data; SAP review			2	
B883	New PIP, seed increase with negotiated acreage cap and time-limited registration with petition to establish a permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption				2
B884	New PIP, seed increase with negotiated acreage cap and time-limited registration with petition to establish permanent tolerance/tolerance exemption	3			
B885	PIP, seed increase, breeding stack of previously approved PIPs, same crop		2	9	1
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
B903	Inert tolerance exemption, reviewed in BPPD				1
I001	New food-use inert	23	26	18	18
I002	Amend existing inert tolerance or exemption, new data	1	2	5	2
I003	Amend existing inert tolerance or exemption, no new data	1	1	1	4
I004	New non-food use inert	13	3	6	4

Progress in Meeting Decision Times – Number of PRIA Decisions Pending at End of Fiscal Year					
PRIA Category	**Description of Category**	**Number of PRIA Decisions Pending at the End of Fiscal Year**			
		2014	**2015**	**2016**	**2017**
I005	Amend currently approved non-food use inert with new use pattern, no new data				1
I006	Amend existing non-food use inert with new use pattern, no new data		1		
I007	Substantially similar non-food use inert	1			
I008	New polymer inert, food use	5	8	4	4
I009	New polymer inert, non-food use	6	3	1	4
I010	Amend a tolerance exemption descriptor to add CASRNs, no new data	1			
M001	Protocol review by HSRB		1	2	4
M002	Completed study requiring HSRB review	2	1		
M005	New product, combination of AIs from AD, BPPD, RD	1	3	2	1
M006	Gold seal letters	1	36		160
M007	Extension of Exclusive use of data 3(c)(1)(F)(ii)	6	2	1	4
M008	Exclusive use of data for a minor use 3(c)(1)(F)(vi)	3	4		