



PRIA Summary to the PPDC FY'18 at Mid-Year



**U.S. Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs**

May, 2018

AGENDA

- PRIA 4 Update
- PRIA Submissions and Completions
- Renegotiation Rates
- On-Time Completions
- Fees Collected (through April 19, 2018)
- Electronic Submissions
- Electronic Label Reviews
- Preliminary Technical Screens Summary
- PRIA Points of Contact

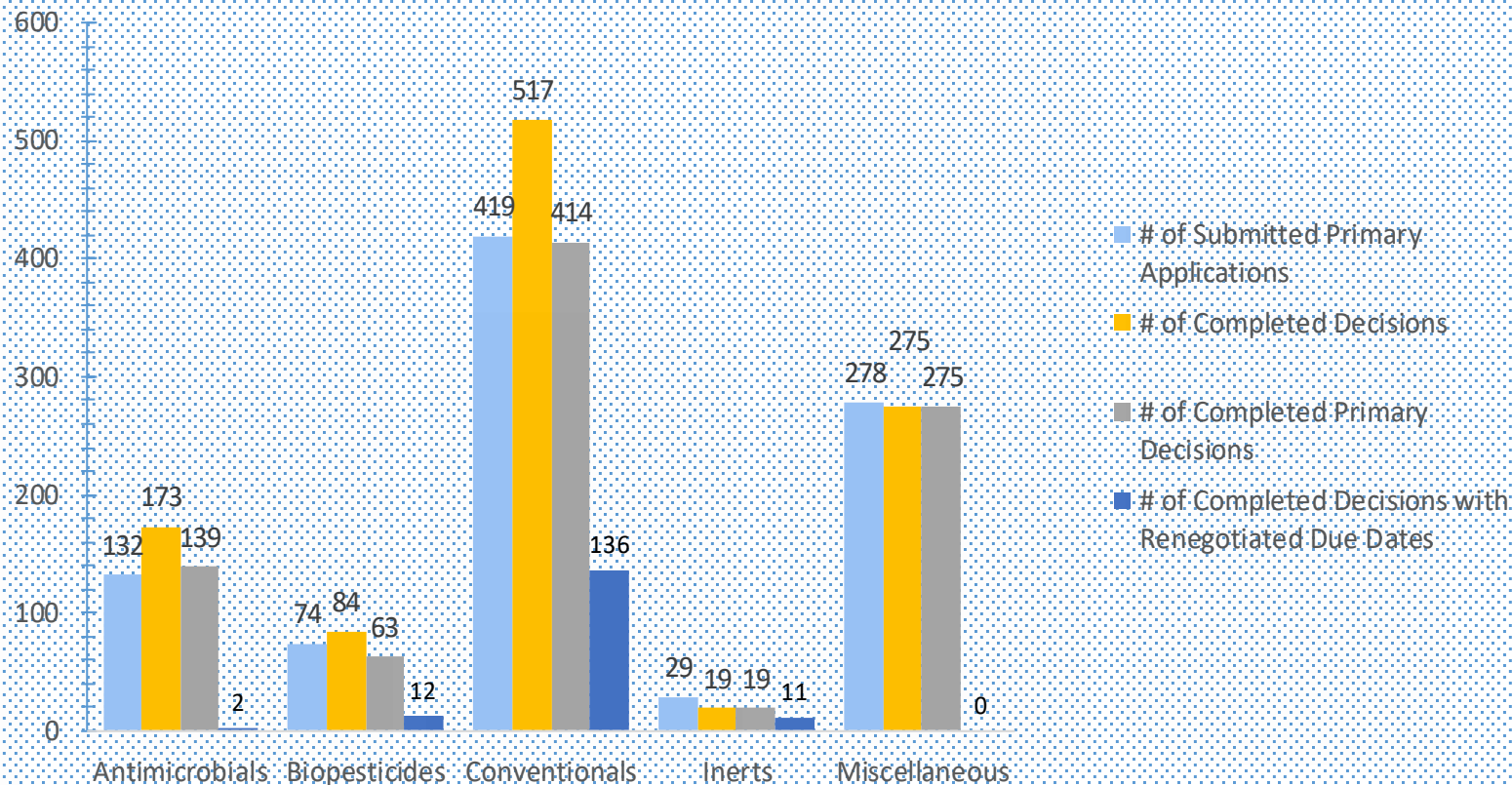


PRIA Summary

- PRIA 3 expiration date was extended through the end of fiscal year 2018 by the Consolidated Appropriations Act of 2018.
- PRIA 4 bill reauthorizing PRIA beyond FY 17 passed unanimously in the House in March 2017 and advanced out of the Senate Agriculture Committee in June 2017.
- The Farm Bill (H.R. 2) introduced in the House includes a provision enacting the House version of PRIA 4 (H.R. 1029), which reauthorizes PRIA through fiscal year 2023.



PRIA 3 Summary for FY'18 through March 2018





Historical % of Completed PRIA Decisions with Renegotiated Due Dates

FY	Antimicrobials	Biopesticides	Conventionals	Misc.	Inerts
2010	108/310 = 34.8%	85/138 = 61.6%	277/1069 = 25.9%		
2011	85/346 = 24.6%	48/134 = 35.8%	236/1074 = 22.0%		
2012	86/333 = 25.8%	74/133 = 42.8%	235/1068 = 22.0%		
2013	73/329 = 22.2%	34/111 = 30.6%	205/1039 = 19.7%	0/562 = 0%	1/7 = 14.3%
2014	41/287 = 14.3%	30/129 = 23.2%	259/895 = 28.9%	1/575 = 0.2%	9/45 = 20%
2015	44/319 = 13.8%	28/154 = 18.2%	229/960 = 23.8%	2/622 = 0.3%	18/56 = 32.1%
2016	31/350 = 8.9%	22/151 = 14.6%	254/977 = 26.0%	2/643 = 0.3%	21/49 = 42.9%
2017	26/338 = 7.7%	22/163 = 13.5%	197/937 = 21.0%	0/544 = 0%	16/42 = 38.1%
2018, midyear	2/173 = 1.2%	12/84 = 14.3%	136/517 = 26.3%	0/275 = 0%	11/19 = 57.9%



FY'18: On-Time Completion Rates

Type of decision	FY'18 Late Completions (through mid-year)	FY'18 Rate of on-time Completions (through mid-year)	FY'17 Rate of on-time Completions	FY'16 Rate of on-time Completions	FY'15 Rate of on-time Completions
Antimicrobial	0	100%	99.7%	99.4%	96%
Biopesticide	0	100%	98.8%	97.4%	98%
Conventional	2	99.6%	98.7%	98.6%	99%
Inert	0	100%	95.2%	95.9%	96%
Misc	1	99.6%	99.8%	99.8%	99%
Total	3	99.7%	99.1%	98.9%	98%



Fees Collected in FY18 through April 19, 2018



PRIA Fees: \$9.58M

Maintenance Fees: \$27.76M



FY'18 through March 2018: All Stakeholder Registration Submissions by Type of Product

Type of Product	Total # of Submissions	# Paper Submissions	# CD/DVD Submissions	# of Portal Submissions	% Paper Submission	% CD/DVD Submission	% Portal Submission
Conventional	3,855	1,943	9	1,903	50%	<1%	49%
Antimicrobial	1,260	402	1	857	32%	<1%	68%
Biopesticide	542	250	28	264	46%	5%	49%
Total	5,657	2,595	38	3,024	46%	<1%	53%



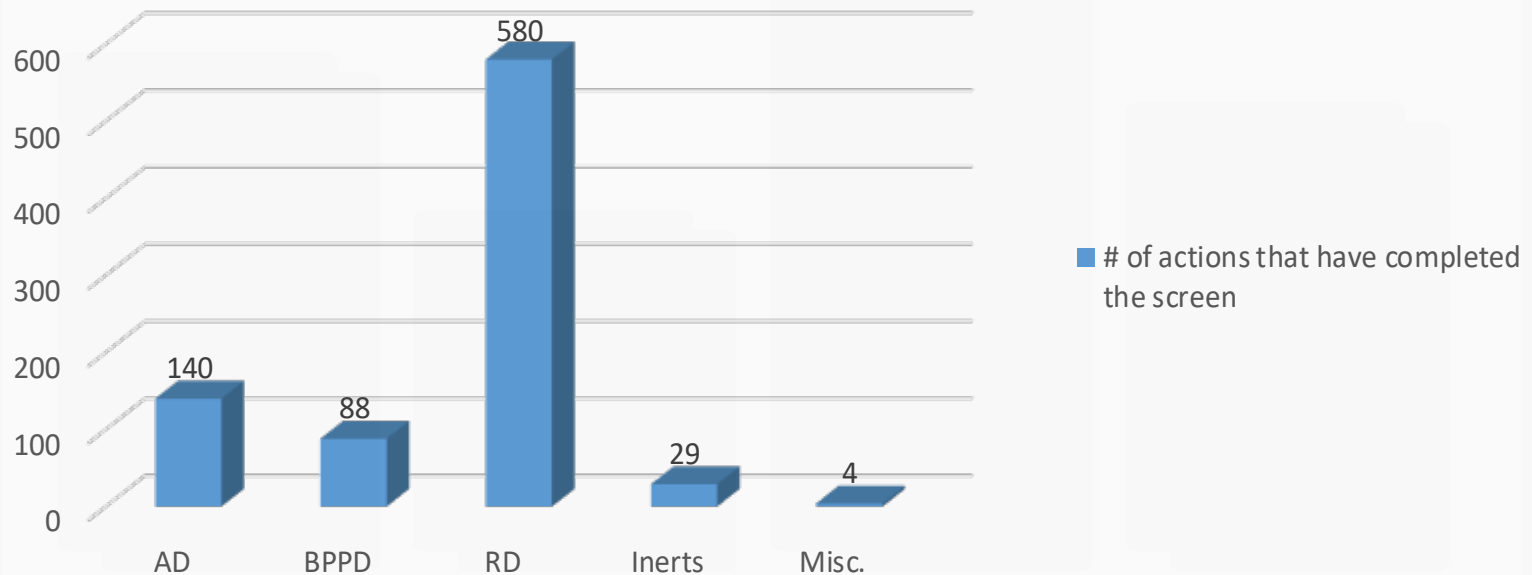
FY'18 through March 2018: Electronic Label Reviews

- Tracking the use of electronic comparison software in conducting label reviews requires input from reviewers;
- Lack of necessary input increases uncertainty;
- % of labels reviewed electronically in RD: 87% - 92%;
- % of labels reviewed electronically in AD: 89% - 95%;
- % of labels reviewed electronically in BPPD: 76% - 88%.



FY'18 through March 2018: 45/90-day Preliminary Technical Screen

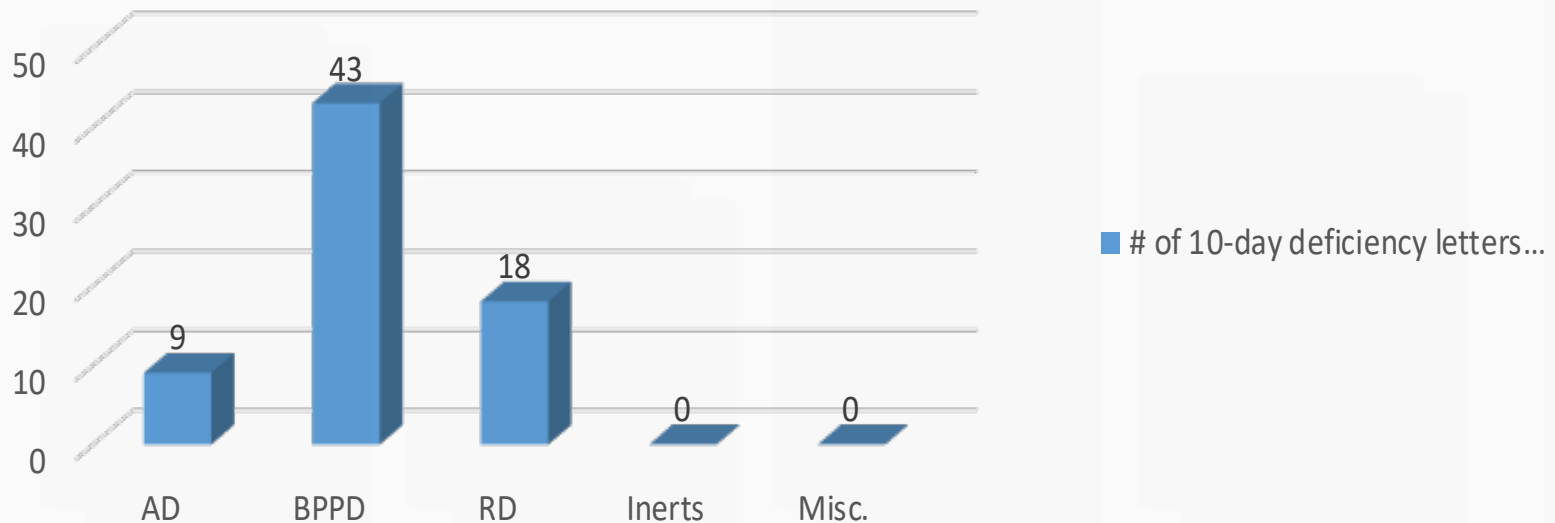
Actions That Have Completed the Screen





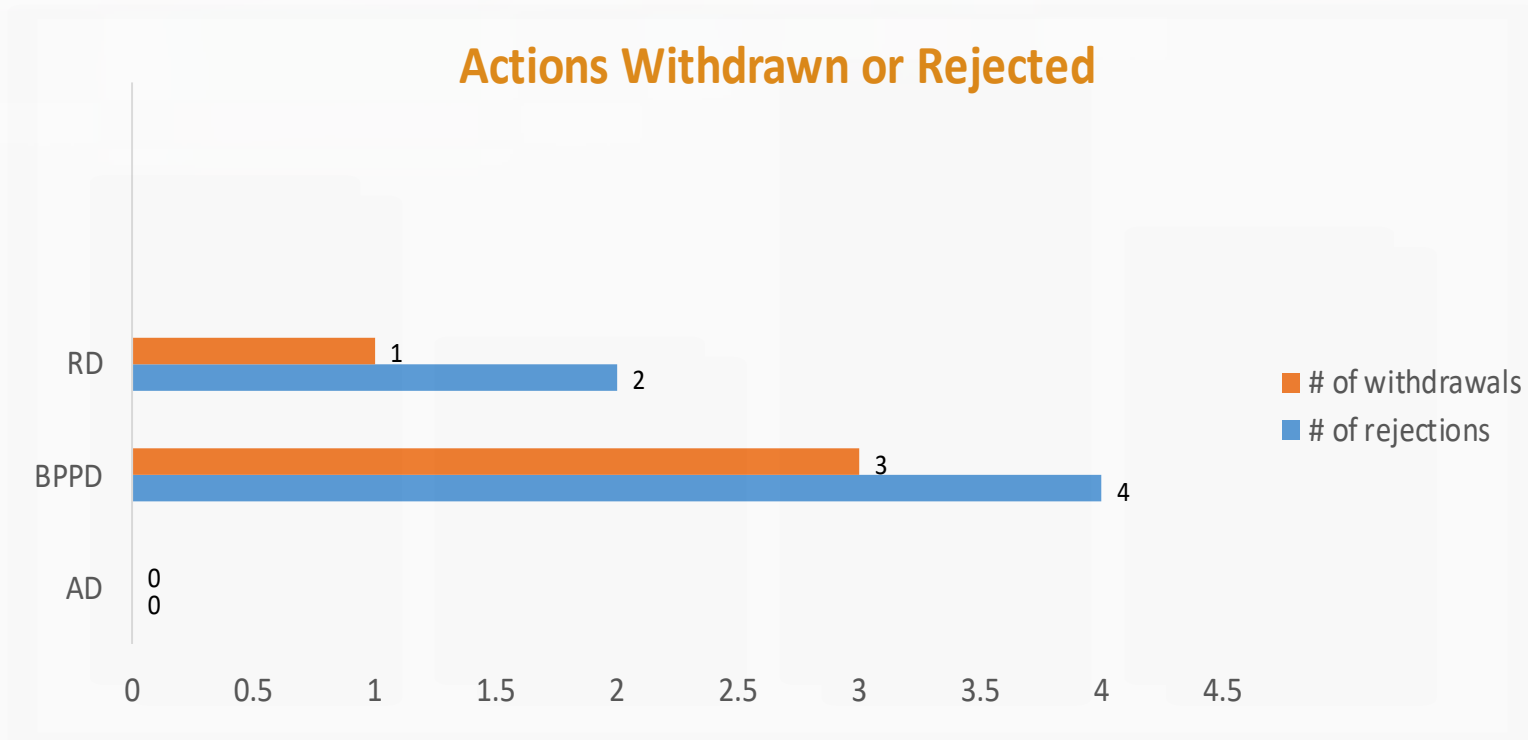
FY'18 through March 2018: 45/90-day Preliminary Technical Screen (*cont'd*)

10-day Deficiency Letters Sent Out





FY'18 through March 2018: 45/90-day Preliminary Technical Screen (cont'd)





FY'18 through March 2018 : Reasons for 45/90 Screen Rejections/Withdrawals

- Not substantially similar (both label and formulation)
- Data deficiencies/ Missing data or rationale
- Inadequate efficacy data to support claims
- Uncleared inerts/ missing inert data
- Inert ingredient misidentified
- Data matrix/data compensation issues
- Bridging argument unacceptable



PRIA Points of Contact

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