

PRIA 3 Quarterly Stakeholder Meeting

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Office of Chemical Safety and Pollution Prevention

Office of Pesticide Programs

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AGENDA

- Introductions
- PRIA 4 Update
- Government Shutdown and Impacts
- Follow-up from previous Stakeholder Quarterly Meeting
- PRIA 3 Summary
- Renegotiation rates
- On-time completion rates
- Pending Non-PRIA Fast Tracks & Notifications
- Fees collected
- 2-day label approval
- Electronic label reviews
- Electronic Submissions
- 45/90 Preliminary technical screen
- Next Meeting Dates
- Stakeholder issues



PRIA 4 – The Long and Winding Road

- PRIA 4 bill (H.R. 1029), reauthorizing PRIA for 7 years through fiscal year 2023, passed unanimously in the House in March 2017;
- The Senate passed an amended PRIA 4 bill in June 2018 extending PRIA for 5 years through 2023;
- The Senate unanimously passed S.483, referencing back to the June 2018 H.R. 1029 amendment, on February 14, 2019;
- The House unanimously passed an amended S.483 on February 25, 2019 (amendments incorporated the text and charts from the 2018 Senate amendment);
- The Senate passed the amended PRIA 4 bill by unanimous consent on February 28, 2019;
- The bill was signed and enacted into law on March 8, 2019.



Government Shutdown, PRIA Lapses, and Other Good Times

- Federal government was shut down from 12/22/18 through 1/25/19; EPA stayed open with additional funding through 12/28/18;
- At time of shutdown, over 1,400 PRIA applications were pending;
- Approximately 450 actions (PRIA and non-PRIA) were submitted electronically to the Pesticide Submission Portal during the shutdown;
 - These applications were “received” once EPA re-opened on 1/28/19;
- No paper submissions were received during the shutdown.



Government Shutdown (cont'd)

- Between paper and portal submissions, around 460 submissions (PRIA and non-PRIA) were received the first week EPA reopened;
- Overall, EPA received over 1,700 submissions electronically or in paper through February;
- EPA's front end processing group is still working to catch up on processing this incoming slug of applications;
- AD, BPPD, and RD have been reaching out to registrants regarding PRIA actions affected by shutdown.
 - Discussion of divisional approaches on renegotiations, technical screens



PRIA Lapses

- PRIA lapsed from 12/22/18 to 1/25/19;
 - EPA was only operational for three business days during that period;
 - The continuing resolution signed 1/25/19 retroactively reinstated PRIA 3 authority for that duration;
- PRIA authority lapsed again after 2/15/19, when the appropriations bill funding EPA through the rest of the fiscal year did not include language extending the PRIA 3 expiration date;
- That period of lapse ended with signing of PRIA 4 on 3/8/19.



PRIA Lapses (cont'd)

- Per the phase out provisions described in FIFRA section 33(m)(2)(B), new applications received from February 15, 2019, through March 7, 2019, were subject to reduced registration service fees (70% from the fiscal year 2017 levels) but did not receive the decision review time frames specified in PRIA 3;
 - Applications received on or prior to February 15, 2019, continue to be reviewed under the decision time frames specified in PRIA 3;
- Applicants who submitted applications during the PRIA lapse period but now wish to have a statutory decision time period would need to withdraw their application and submit again under PRIA 4.



PRIA Lapses (cont'd)

- Preliminary analysis of electronic submissions through the PSP during the period in which PRIA lapsed suggests a lower than normal volume of PRIA applications, the exception being Gold Seal letter requests;
- This trend is also reflected in paper submissions.



Previous Stakeholder Meeting Follow-up – CATSAC

- New rotating Co-Chairs
 - Lindsay O'Dell and Tara Flint
 - Updated standing membership
- Standard Evaluation Procedure (SEP) currently going thru final steps of internal peer review
 - purpose is to give guidance on both product chemistry and acute toxicity evaluation process;
 - provide common definitions and terminology such as 100% repack, identical products, substantially similar products, and potential for bridging data;



Previous Stakeholder Meeting Follow-up – CATSAC (cont'd)

- FY2018 CATSAC summary:
 - 13 packages for review;
 - Waived/Bridged 20 studies;
 - > 200 animals saved;
 - > \$180,000 on study cost saved.
- PRIA 4 MO10: Conditional ruling on pre-application, product substantial similarity, 4 months, \$2,363



Previous Stakeholder Meeting Follow-up (cont'd) – Notifications PR Notice

- Status of updated PR Notice on notifications
 - Comments received in response to the updated PR Notice announcement have been reviewed by EPA;
 - EPA is considering comments and is preparing the update to the Notifications PR Notice.

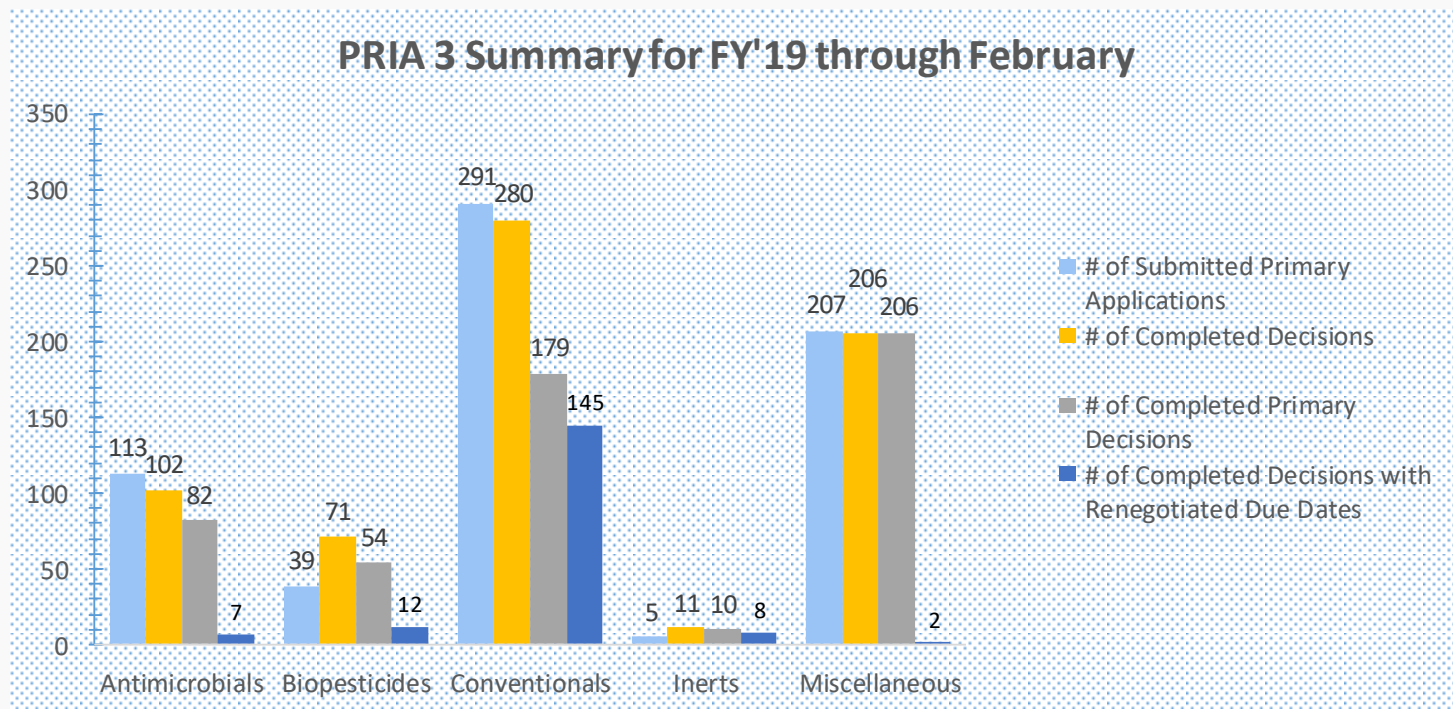


Previous Stakeholder Meeting Follow-up (cont'd) – Outreach and Training for Pesticide Submission Portal (PSP)

- Follow-up to this issue will occur at the July meeting;
- PRIA Coalition will canvas stakeholders on their experiences submitting to the PSP and provide that information to EPA;
- Once stakeholder feedback is received and assessed, EPA will develop training materials and schedule training, still targeting the 3 training modules being presented twice each within a 6 month timeframe, as previously described.



FY'19 PRIA Submissions, Completions, and Renegotiations through February





Historical % of Completed PRIA Decisions with Renegotiated Due Dates

FY	Antimicrobials	Biopesticides	Conventionals	Misc.	Inerts
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	6/328 = 1.8%	40/214 = 18.7%	310/1044 = 29.7%	2/578 = 0.3%	16/35 = 45.7%
2019 thru Feb.	7/102 = 6.9%	12/71 = 16.9%	145/280 = 51.8%	2/206 = 0.9%	8/11 = 72.7%



FY'19 through February: On-Time Completion Rates

Type of decision	FY'19 Late Completions (through February)	FY'19 Rate of on-time Completions (through Feb.)	FY'18 Rate of on-time Completions	FY'17 Rate of on-time Completions	FY'16 Rate of on-time Completions
Antimicrobial	9	91.2%	99.7%	99.7%	99.4%
Biopesticide	3	95.8%	100%	98.8%	97.4%
Conventional	9	96.8%	99.7%	98.7%	98.6%
Inert	1	90.9%	100%	95.2%	95.9%
Misc	0	100%	99.7%	99.8%	99.8%
Total	22	96.7%	99.7%	99.1%	98.9%



FY'19 (through 3/4/19) Non-PRIA Fast-Track Amendments & Notifications

Non-PRIA Activity	Antimicrobials	Biopesticide	Conventional
Fast Track Amendments:			
- Completed	135	80	233
- Pending	296	72	912
- > 90d	241	44	839
Notifications:			
- Completed	321	110	449
- Pending	305	37	512
- > 30d	301	35	497



Non-PRIA Fast-Track Amendments & Notifications

- As part of priority setting conversations leading out of the shutdown, registrants were invited to include non-PRIA actions among their priorities,
- Divisions have also been seeking confirmation from registrants that pending amendment requests are still needed;
- Registrants can help EPA tackle this backlog by not submitting separate label amendments (PRIA or non-PRIA) when they can be bundled together as one submission;
- EPA will be continuing its efforts to address the backlog of non-PRIA actions.



Fees Collected in FY'19 through 3/7/19



PRIA Fees: \$7.2M

Maintenance Fees: \$26M



FY'19 through February: Two-Day Label Review Approval Tracking Report Summary

Table 1: Completed Decisions Resulting in New or Amended Product Label Approvals

	Antimicrobial Decisions (A)	Conventional Decisions (R & M005)	Total
Completed Decisions	97	280	377
Completed PRIA 3 Decisions	97	280	377
PRIA 3 Decisions Involving Label Approvals	97	241	338

Table 2: Timing for Completion of PRIA 3 Label Reviews & Approvals

	Antimicrobial Label Reviews & Approvals (A)	Conventional Label Reviews & Approvals (R & M005)	Total
After the PRIA Due Date	9 (9%)	2 (<1%)	11 (3%)
On the PRIA Due Date	35 (36%)	63 (26%)	98(29%)
Before the PRIA Due Date but after the Pre-decisional Determination due date	41 (43%)	127 (53%)	168 (50%)
On or before the Pre-decisional Determination Due Date	12 (12%)	49 (20%)	61 (18%)
Total	97	241	338



FY'19 through February: 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: 90% - 94%;
- % of labels reviewed electronically in AD: 91% - 96%;
- % of labels reviewed electronically in BPPD: 79% - 94%.



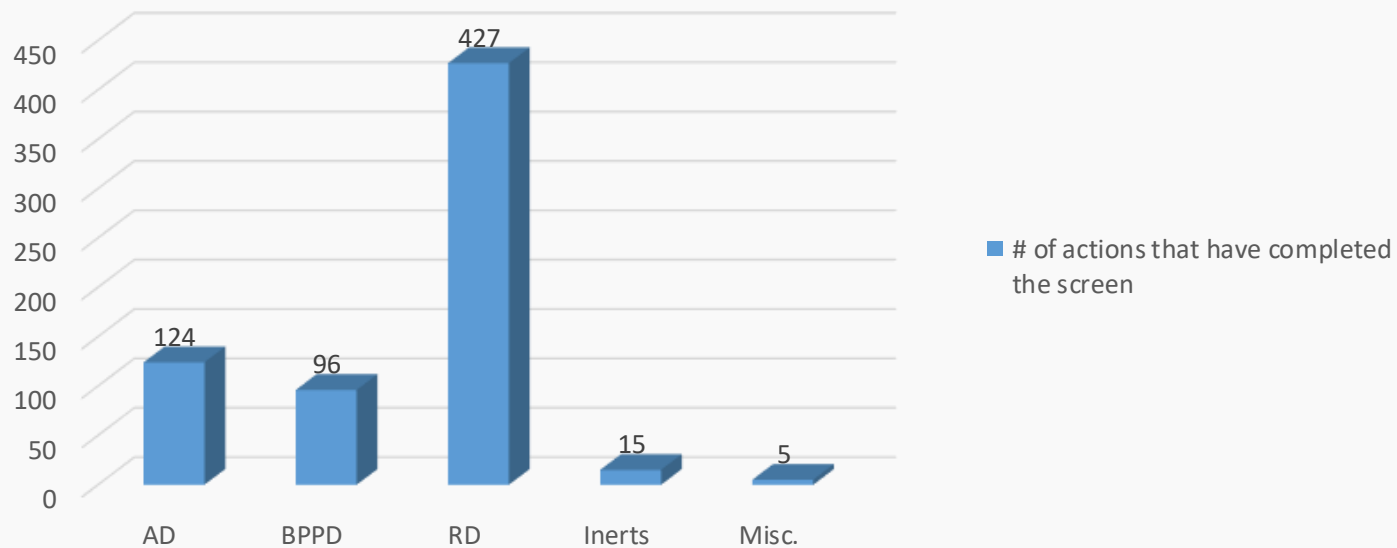
FY'19 through February: All Stakeholder Registration Submissions by Type of Product

Type of Product	Total # of Submissions	# Paper Submissions	# CD/DVD Submissions	# of Portal Submissions	% Paper Submission	% CD/DVD Submission	% Portal Submission
Conventional	2,112	950	4	1,158	45%	<1%	55%
Antimicrobial	999	476	1	522	48%	<1%	52%
Biopesticide	409	134	8	267	33%	2%	65%
total	3,520	1,560	13	1,947	44%	<1%	55%



FY'19 through February: 45/90-day Preliminary Technical Screen

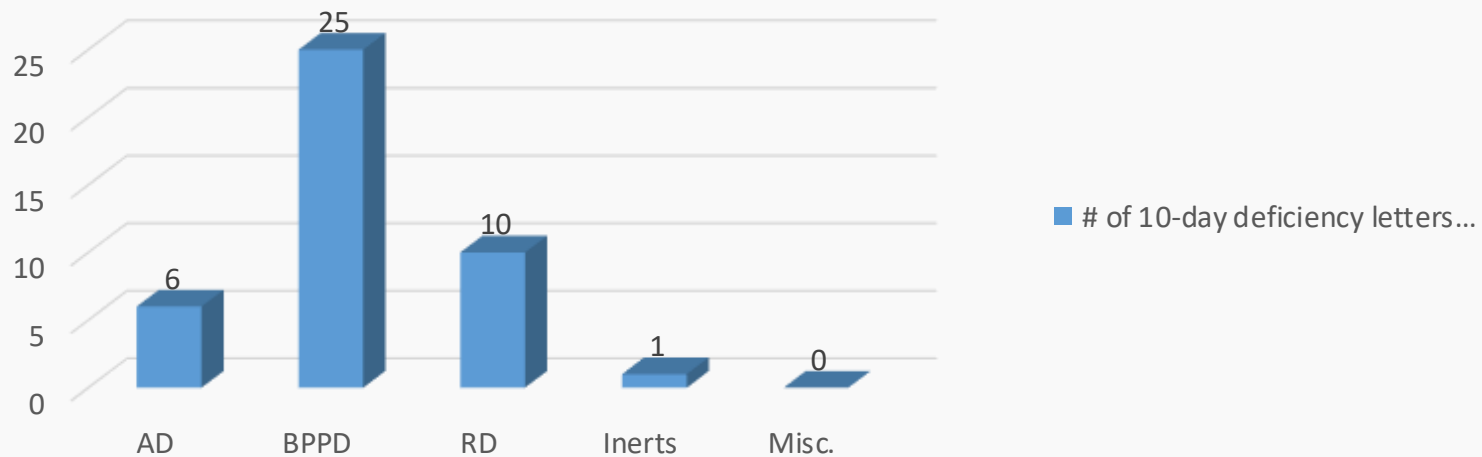
Actions That Have Completed the Screen





FY'19 through February: 45/90-day Preliminary Technical Screen (*cont'd*)

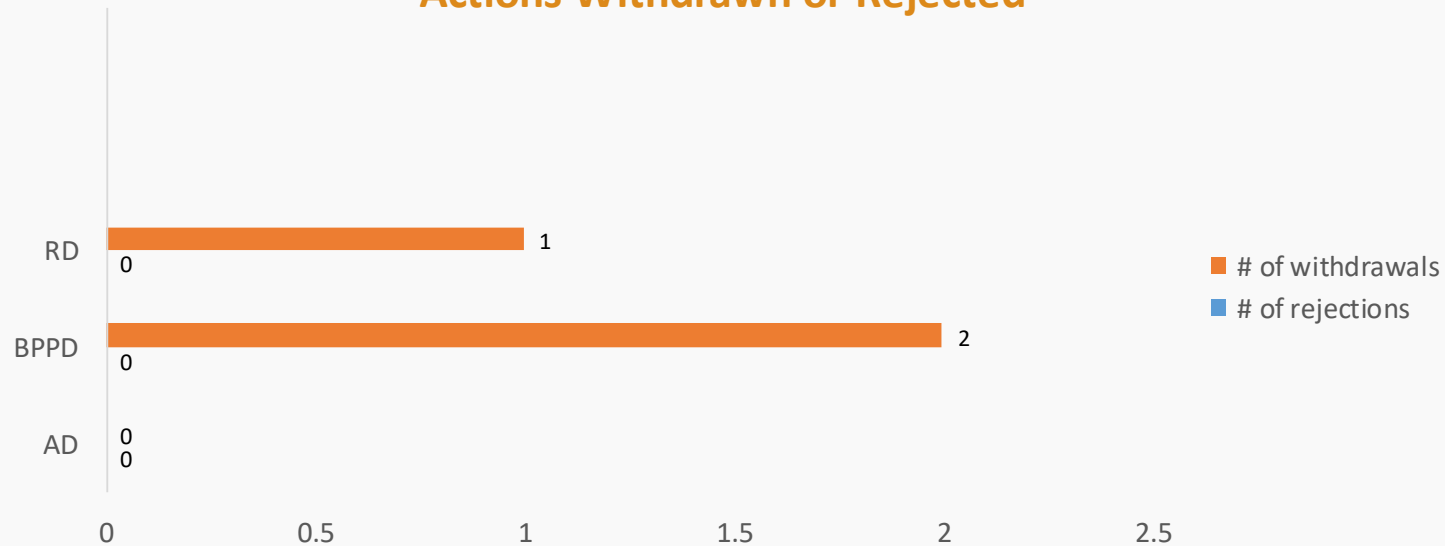
10-day Deficiency Letters Sent Out





FY'19 through February: 45/90-day Preliminary Technical Screen (*cont'd*)

Actions Withdrawn or Rejected





Future PRIA Stakeholder Meeting Date

- Wednesday, July 10, 2019
- Wednesday, November 13, 2019
- Meetings will be held on the 1st floor conference room from 1:00PM – 4:00PM,



PRIA Points of Contact

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