PRIA 3 Quarterly Stakeholder Meeting

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Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs

November 9, 2016

AGENDA

- Introductions
- Follow-up from previous Stakeholder Quarterly Meeting
- PRIA 3 Summary for FY'16
- Renegotiation rates: FY'16
- Late completions FY'16
- Pending Non-PRIA Fast Tracks & Notifications
- Fees collected: FY'16
- 2-day label approval: FY'16
- Electronic label reviews: FY'16
- Electronic Submissions: FY'16
- 45/90 Preliminary technical screen: FY'16
- Worker Protection Update
- Next Meeting Dates
- Stakeholder issues

Follow-up from Previous Stakeholder Meetings

- Status of guidance for substantially similar submissions

  - An internal assessment of the substantially similar process in AD & RD indicated that development of guidance materials alone would not adequately address the problems;
  - Formal process for selection of clinic members completed;
  - Work on SOP & SEP will follow;

- Status of FRN on Notifications
  - Draft PRN 98-10 on Notifications has been completed;
  - Completed Division Director and Office Director Review;
  - Awaiting OMB non-significant determination

Follow-up from Previous Stakeholder Meetings – (con't)

- **Request for Electronic Portal Submission Training**
  - Conducted training sessions for ACC, BPIA, CSPA, and IR-4;
  - Conducted several webinars for individual companies [which allows for more specific and private discussion of the company's particular types of submissions];
  - ITRMD will accommodate any further training requests [contact Dominique White, email: white.Dominique@epa.gov; phone: 703 347-8159]

Follow-up from Previous Stakeholder Meetings – (con't)

- **Registration Transfer Timeframe**

  - a registration transfer request that contains a **complete** set of transfer documents should take 60-90 days;

  - incomplete applications take longer

  [see Pesticide Registration Manual (The Blue Book), chapter 16 "Transfer of Product Registration and Data Rights"; https://www.epa.gov/pesticide-registration/pesticide-registration-manual];

Follow-up from Previous Stakeholder Meetings – (con't)

- **Development of 2-way portal capability**

  - request to expand current portal capabilities to allow for access to available DERs;

  - given current queue of development priorities, this request is deemed a long-term priority

Follow-up from Previous Stakeholder Meetings – (con't)

- **Presidential Innovation Fellows PRIA Update:**

  They listened - In the Spring of 2016, a team of Presidential Innovation Fellows working with OPP spoke with 8 PRIA companies for background conversations on how they experience the current PRIA registration process. Several themes emerged:

  1. There is support for the electronic data initiatives currently happening in OPP;
  2. There was a desire for more consistency across decisions;
  3. The Portal has provided important functionality for PRIA actions

Follow-up from Previous Stakeholder Meetings – (con't)

Presidential Innovation Fellows PRIA Update (con't):

4. There is a strong desire for an easier way to find the **status** of an application and **who** they can reach out to to get accurate information.

Next Steps

OPP and the Presidential Innovation Fellows team are working together to move forward several initiatives in the areas of—

1. Improvements to support more flexibility internally for working with OPP's data and providing consistency and visibility across OPP;

Follow-up from Previous Stakeholder Meetings – (con't)

- **Presidential Innovation Fellows PRIA Update**

  Next Steps (con't):

  2. Several initiatives to develop a more intuitive system for customers registering products with OPP;

  3. Building applications that are able to work with data and provide interactions that was previously difficult within OPP to enhance communication and consistency;

Follow-up from Previous Stakeholder Meetings – (con't)

- **Circumstances Associated with Issuance of "Not Grants"**

  - "not grants" process requires senior management approval; vetting first @ PRIA Bi-Weekly followed by approval only by Office Director or Deputy Office Director;

  - In FY'15 & FY'16 21 "not grant" letters were issued covering 60 decisions (out of 4,264 decisions; 1.4%)
    - AD – 7 decisions (out of 664; 1.0%)
    - BPPD – 10 decisions (out of 304; 3.3%)
    - Inerts – 3 decisions (out of 105; 2.8%)
    - RD – 40 decisions (out of 1,934; 2.1%)

Follow-up from Previous Stakeholder Meetings – (con't)

- **Circumstances Associated with Issuance of "Not Grants" (con't)**
- AD circumstances included:

  - aquatic studies unacceptable; tox data waivers for dermal, inhalation, reproduction, developmental, prenatal & mutagenicity studies denied;

  - potential dermal and inhalation risks of concern; to refine risk assessment (RA) additional information was required including: transfer of residues to skin, dermal sensitization surrogate study to HSRB to determine its appropriateness for use; expected production volume;

Follow-up from Previous Stakeholder Meetings – (con't)

- **Circumstances Associated with Issuance of "Not Grants" (con't)**
- AD circumstances included (con't):

  - potential ecological risk of concern; to refine RA additional information was required including: volume of paper treated at a site, % sorption of AI onto treated paper, volume of effluent per production day, limit of detection of AI in effluent, information on engineering controls to pre-treat effluent before release;

Follow-up from Previous Stakeholder Meetings – (con't)

- **Circumstances Associated with Issuance of "Not Grants" (con't)**
- BPPD circumstances included:

  - lack of adequate bridging rationale to use surrogate strain data for tox & non-target species requirements; cited data previously classified by EPA as invalid, lacked honey-bee study;

  -unacceptable bridging argument as 2 substances not substantially similar; inadequate developmental tox, avian dietary, freshwater fish; no dermal exposure, fate, or residue profile data submitted;

Follow-up from Previous Stakeholder Meetings – (con't)

- **Circumstances Associated with Issuance of "Not Grants" (con't)**
- BPPD circumstances included (con't):

  - deficiencies regarding 3 AIs including – product chemistry, acute tox fish, aquatic invertebrate tox, lacks honey bee study;

- Inerts circumstances included:

  - chromatogram not submitted, incomplete chemical structure, discrepancy regarding molecular weight, lacks rationale on why compound not likely to degrade, identity of test substance not provided, applicant could not provide response until pending patent granted;

Follow-up from Previous Stakeholder Meetings – (con't)

- **Circumstances Associated with Issuance of "Not Grants" (con't)**

- Inerts circumstances included (con't):

  - lack of data on potential adverse effects of nano-inert on pollinators;

  - potential unacceptable risk concerns due to unusable dermal absorption study;

Follow-up from Previous Stakeholder Meetings – (con't)

- **Circumstances Associated with Issuance of "Not Grants" (con't)**
- RD circumstances included:

  - 28 decisions due to lack of data on potential adverse impacts on pollinators from "neonics" which were identified and DCI'ed under registration review; can't make a no unreasonable adverse effects determination until data submitted, reviewed and RAs conducted in registration review;

  - Lacks a benefits analysis demonstrating that control of target pests outweighs potential risks to birds;

Follow-up from Previous Stakeholder Meetings – (con't)

- **Circumstances Associated with Issuance of "Not Grants" (con't)**
- RD circumstances included (con't):

  - Petition received from another registrant to deny application stating that submitter had not obtained AI as claimed; initial response to petition by submitter deemed insufficient;

  - Unacceptable acute inhalation, dermal sensitization, product identity & composition, certified limits for product with multiple AIs;

Follow-up from Previous Stakeholder Meetings – (con't)

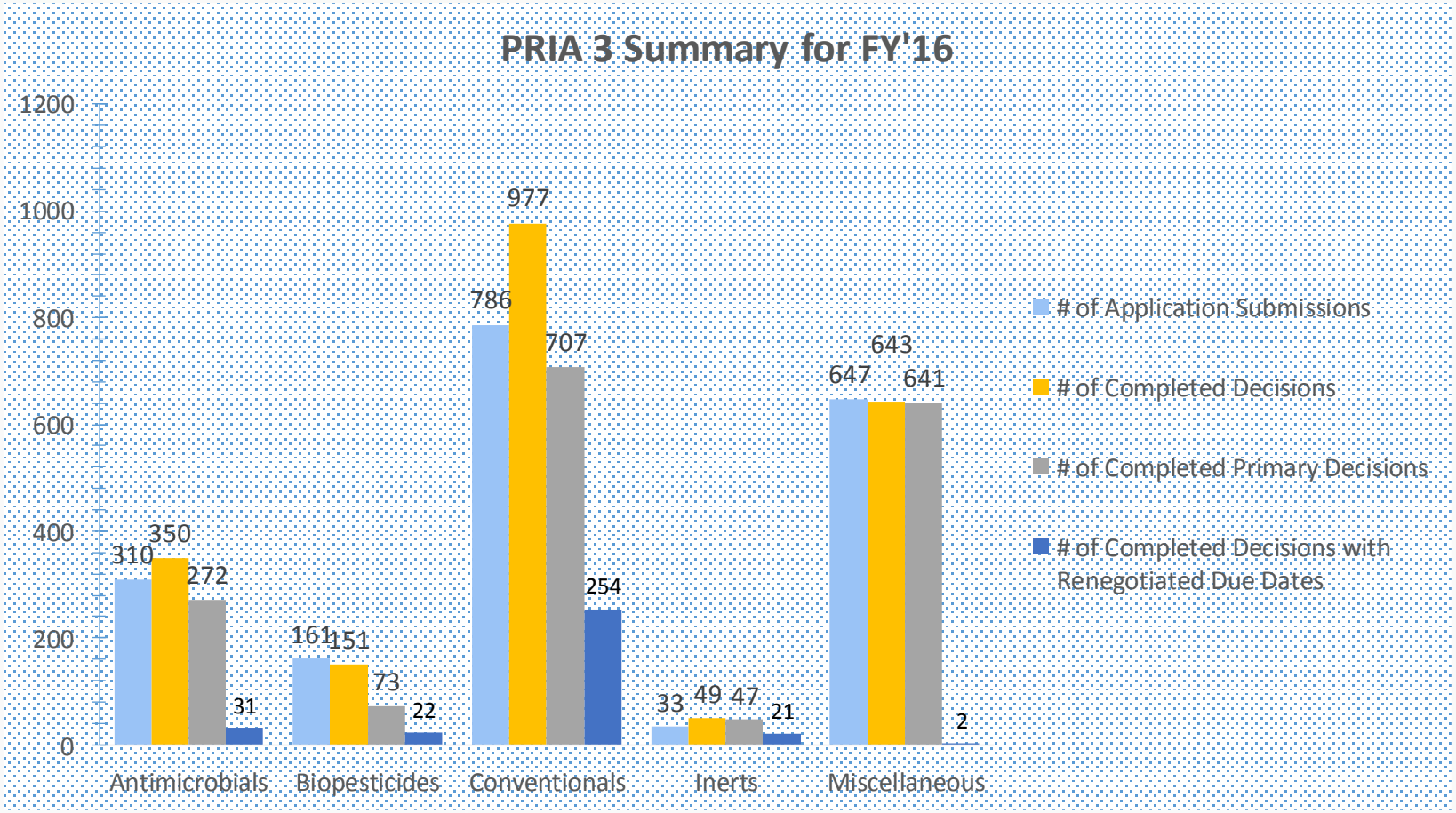
- **Circumstances Associated with Issuance of "Not Grants" (con't)**

- Summary of Circumstances associated with "not grants"

  - A plausible probability exists that a registration could be granted once the necessary information has been submitted and reviewed;

  - typically the PRIA due date had been previously renegotiated;

  - substantial uncertainty regarding when the necessary information would be submitted and/or when the review and RA's would be completed.


PRIA 3 Summary for FY'16
1200
1000
800
600
400
200
0
310
350
272
31
161
151
73
22
786
977
707
254
33
49
47
21
647
643
641
2
Antimicrobials
Biopesticides
Conventionals
Inerts
Miscellaneous
# of Application Submissions
# of Completed Decisions
# of Completed Primary Decisions
# of Completed Decisions with Renegotiated Due Dates

Historical % of Completed PRIA Decisions with Renegotiated Due Dates

FY	Antimicrobials	Biopesticides	Conventionals	Misc.	Inerts
2009	68/342 = 19.9%	42/124 = 33.9%	193/1104 = 17.5%		
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%

FY'16: Number of Late PRIA Decisions

Type of decision	FY'16 Late Completions	FY'16 Rate of on-time Completions	FY'15 Rate of on-time Completions	FY'14 Rate of on-time Completions	FY'13 Rate of on-time Completions
Antimicrobial	2	99.4%	96%	78%	99%
Biopesticide	4	97.4%	98%	79%	98%
Conventional	14	98.6%	99%	78%	99%
Inert	2	95.9%	96%	91%	100%
Misc	1	99.8%	99%	99%	99%
Total	23	98.9%	98%	85%	99%

FY'16 Non-PRIA Fast-Track Amendments & Notifications

- In FY'16 **AD** completed 592 non-PRIA fast track amendments. As of 9/30/16 AD had 41 non-PRIA fast-track amendments pending, 11 of which were in backlog status (pending > 90 days) which for comparative purposes represents 1.8% of the number of completed decisions. In FY'16 AD also completed 1,181 notifications; and as of 9/30/16 57 notifications were pending, 56 of which were in backlog status (pending > 30 days) which represents 4.7% of the number of completed decisions;

- In FY'16 **BPPD** completed 260 non-PRIA FT amendments. As of 9/30/16 BPPD had 39 non-PRIA fast-track amendments pending, 16 of which were in backlog status which represents 6% of the number of completed decisions. In FY'16 BPPD also completed 220 notifications, and as of 9/30/16 27 notifications were pending, 13 of which were in backlog status which represents 5.9% of the number of completed decisions;

FY'16 Non-PRIA Fast-Track Amendments & Notifications (con't)

- In FY'16 **RD** completed 1,328 non-PRIA FT amendments. As of 9/30/16 RD had 352 non-PRIA fast-track amendments pending, 26 of which were in backlog status which represents 2% of the number of completed decisions. In FY'16 RD also completed 1,680 notifications, and as of 9/30/16 186 notifications were pending, 68 of which were in backlog status which represents 4% of the number of completed decisions;

Fees Collected in FY16

PRIA Fees: $19.156M

Maintenance Fees: $27.5M

FY'16: 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	350	980	1,330
Completed PRIA 3 Decisions	347	973	1,320
PRIA 3 Decisions Involving Label Approvals	336	821	1,157

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	1 (<1%)	9 (1%)	10 (<1%)
On the PRIA Due Date	132 (39%)	188 (23%)	320 (28%)
Before the PRIA Due Date but after the Pre-decisional Determination due date	166 (49%)	346 (42%)	512 (44%)
On or before the Pre-decisional Determination Due Date	37 (11%)	278 (34%)	315 (27%)
Total	**336**	**821**	**1,157**

FY'16: Electronic Label Reviews

- Tracking the use of electronic comparison software in conducting label reviews requires input from reviewers;

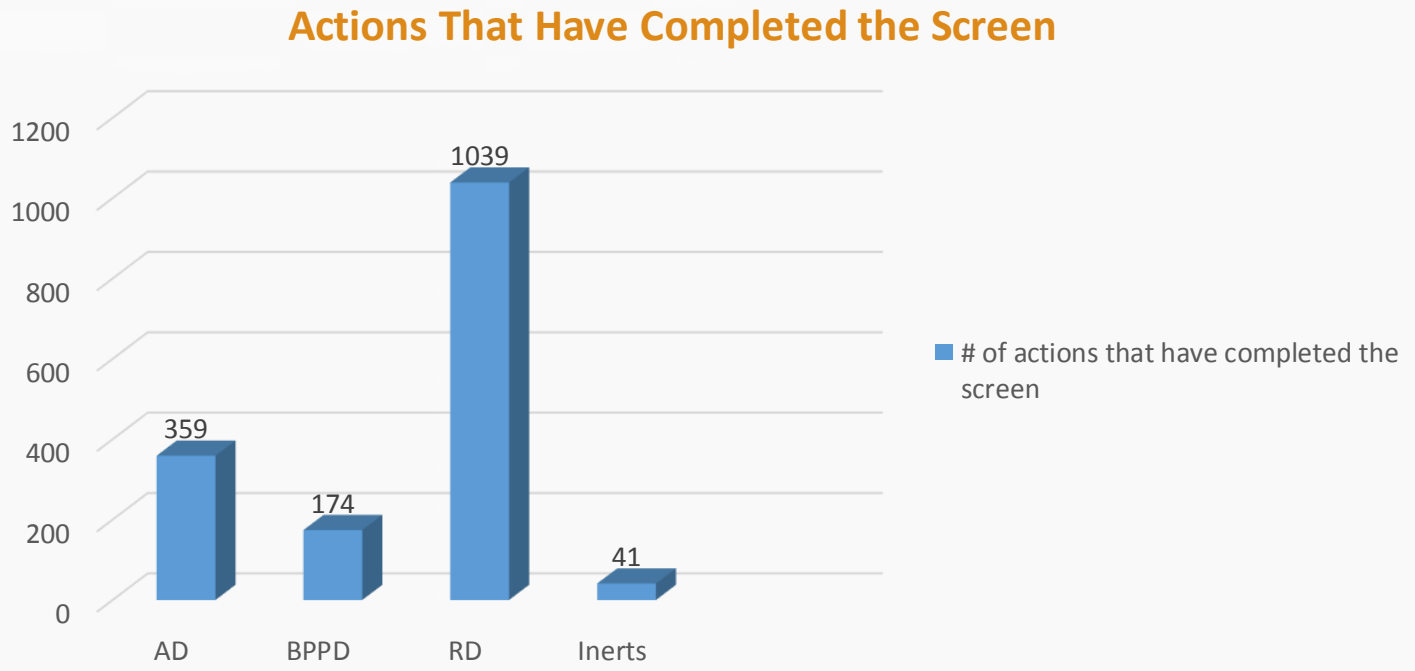
- The number of label reviews where the reviewers have not been providing the necessary input into the tracking system has been reduced but there is still room for improvement: RD – no input for 13% of completed label reviews, AD – no input for 7%, and BPPD no input for 30%;
- Lack of necessary input increases uncertainty;

- % of labels reviewed electronically in RD: 79% - 92%;
- % of labels reviewed electronically in AD: 82% - 91%;
- % of labels reviewed electronically in BPPD: 73% - 95%.

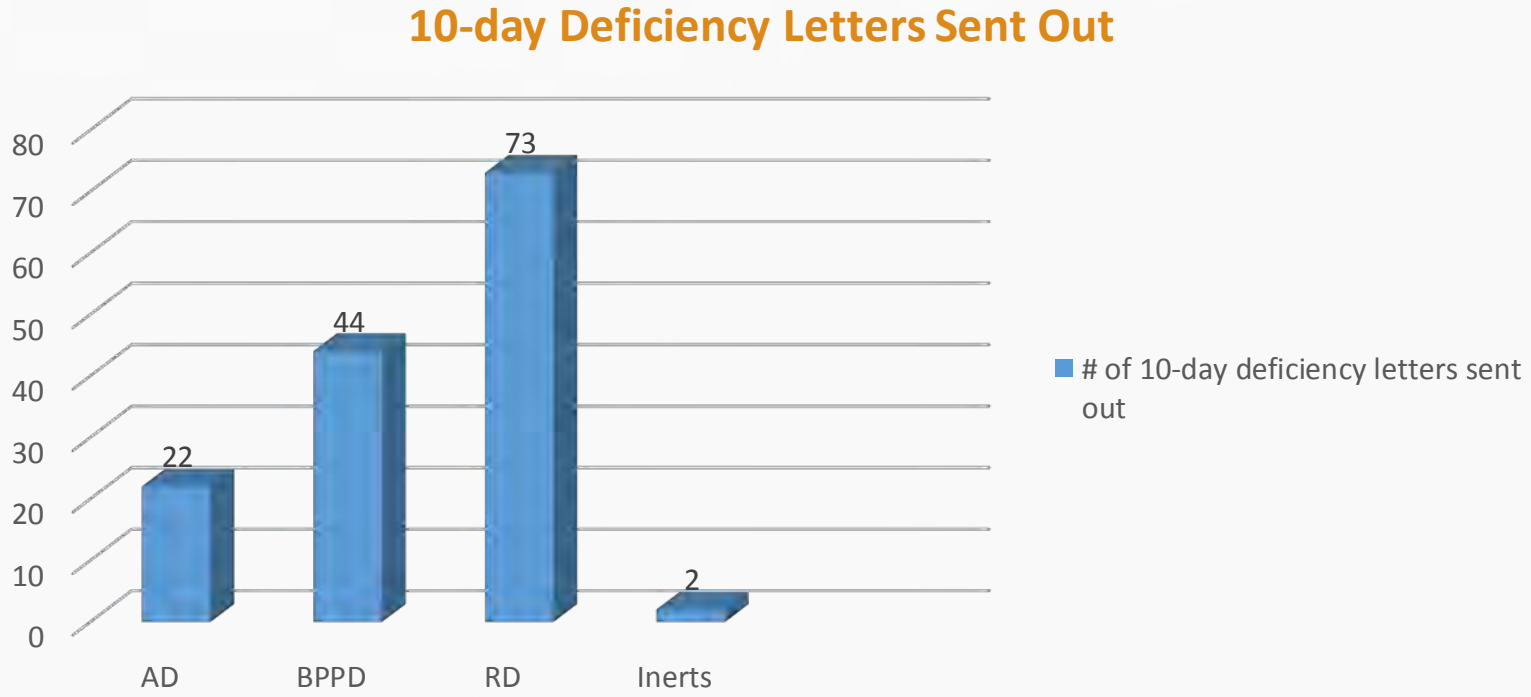
FY'16: All Stakeholder Registration Submissions by Type of Product

Type of Product	Total # of Submissions	# Paper Submissions	# CD/DVD Submissions	# of Portal Submissions	% Paper Submission	% CD/DVD Submission	% Portal Submission
Conventional	9,145	6,277	192	2,676	69%	2%	29%
Antimicrobial	2,806	1,582	78	1,146	56%	3%	41%
Biopesticide	1,203	913	44	246	76%	4%	20%
total	**13,154**	**8,772**	**314**	**4,068**	**67%**	**2%**	**31%**

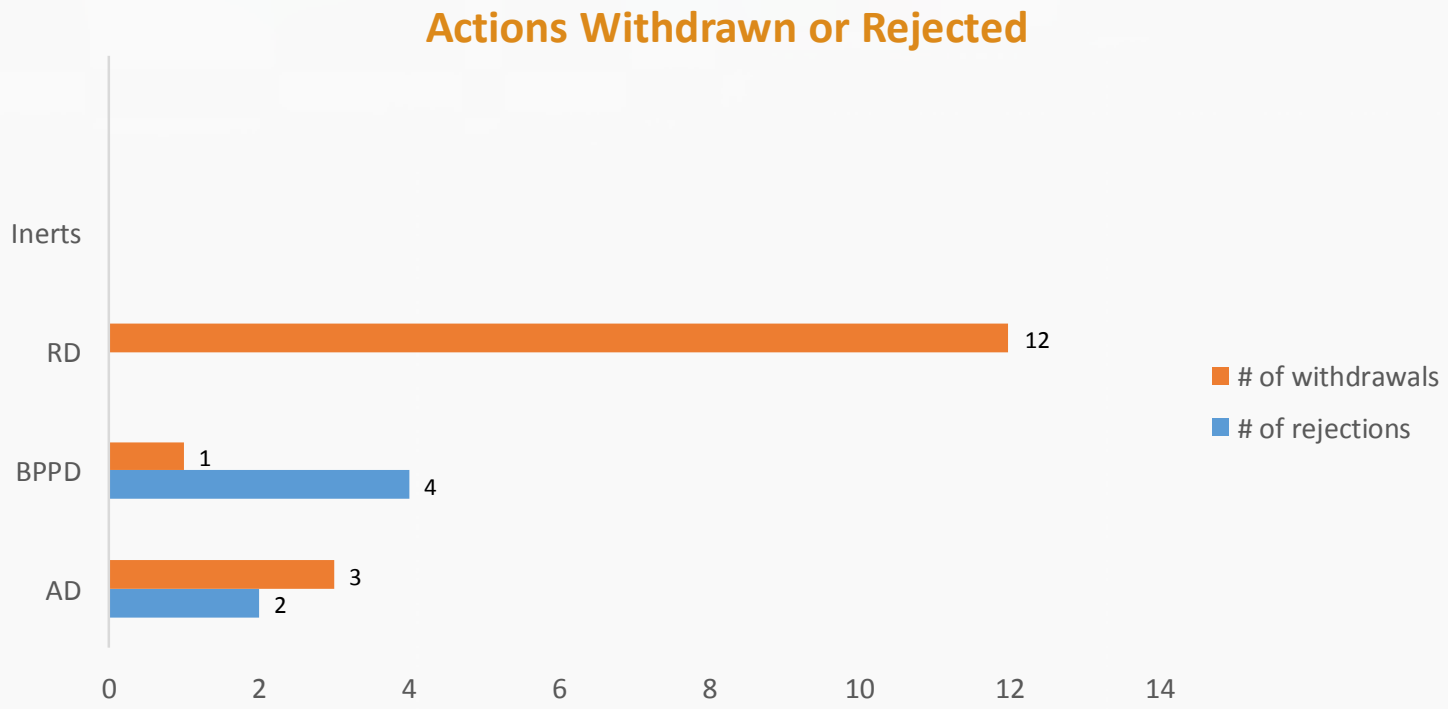
FY'16: 45/90 Preliminary Technical Screen



FY'16: 45/90 Preliminary Technical Screen *continued…*



FY'16: 45/90 Preliminary Technical Screen *continued…*



FY'16: Reasons for 45/90 Screen Rejections/Withdrawals

- ❑ Not substantially similar
- ❑ Data deficiencies/ Missing data
- ❑ Inadequate efficacy data to support claims
- ❑ Uncleared inerts/ missing inert data
- ❑ Inadequate acute toxicity data
- ❑ Data matrix/data comp issues
- ❑ Unregistered source for active ingredient
- ❑ Revised CSF significantly different from accepted CSF
- ❑ Bridging argument inadequate

Update on 2016 – 2017 PRIA Supported Worker Protection Activities

- **Association of Farmworker Opportunity (AFOP) - National Farmworker Training Program - Cooperative Agreement- $500,000**

- AFOP is responsible for developing and administering a pesticide safety training program that will support a national network of pesticide safety trainers providing pesticide worker safety training to migrant and seasonal farmworkers and their families.

Update on 2016 – 2017 PRIA Supported Worker Protection Activities (con't)

- **Pesticide Educational Resources Collaborative (PERC) UC Davis/OR State Cooperative Agreement - $500,000**
- This cooperative agreement will develop or coordinate the development of pesticide education materials. An advisory board and EPA will help in setting national priorities. PERC will use subject matter experts and production professionals. PERC will focus on WPS materials in its first year because of the urgent need for training materials consistent with the newly updated regulation. PERC will focus on C&T materials in its second year in response to anticipated changes in categories/needs nationwide.

Update on 2016 – 2017 PRIA Supported Worker Protection Activities (con't)

- **Pesticide Educational Resources Collaborative (PERC) UC Davis/OR State Cooperative Agreement - $500,000 (con't)**
- Current Projects:
  - How to Comply with the WPS - Manual
  - Train the Trainer Manual
  - Train the Trainer Online Modules
  - WPS Interactive Website
  - Videos for Training Workers
  - Videos for Training Handlers
  - Updated Central Posting Materials
  - Clearinghouse of WPS Training Materials
  - Respirators 101 Training Module

Update on 2016 – 2017 PRIA Supported Worker Protection Activities (con't)

- **National Pesticide Information Center (NPIC) - Cooperative Agreement - $500,000**
- This cooperative agreement facilitates informed decision-making about pesticides and supports the protection of human health and the environment by serving as a bi-lingual, factual source of information for professional and public audiences on pesticide-related issues.

- **Pesticide Safety Education Programs Cooperative Agreement - $1,500,000 <u>NOT DISTRIBUTED</u>**
- The National Association of State Departments of Agriculture won the competition for a 5 Year cooperative agreement and refused to accept the award. This is being re-competed.

Future PRIA Stakeholder Meeting Dates

- Wednesday, March1, 2017; 1st floor conference room, 1:00PM – 4:00PM
- Wednesday, July 12, 2017; 1st floor conference room, 1:00PM – 4:00PM
- Thursday, November 16, 2017; 1st floor conference room, 1:00PM – 4:00PM

Stakeholder Issues

PRIA Points of Contact

- Peter Caulkins, Senior Advisor, PRIA Coordinator: Caulkins.peter@epa.gov
- Steve Schaible, RD PRIA Ombudsperson: Schaible.stephen@epa.gov
- Diane Isbell, AD PRIA Ombudsperson: Isbell.diane@epa.gov
- Linda Hollis, Branch Chief, BPPD: Hollis.linda@epa.gov