

US EPA ARCHIVE DOCUMENT



PRIA 3 Quarterly Stakeholder Meeting

Peter Caulkins

U.S. Environmental Protection Agency

Office of Chemical Safety and Pollution Prevention

Office of Pesticide Programs



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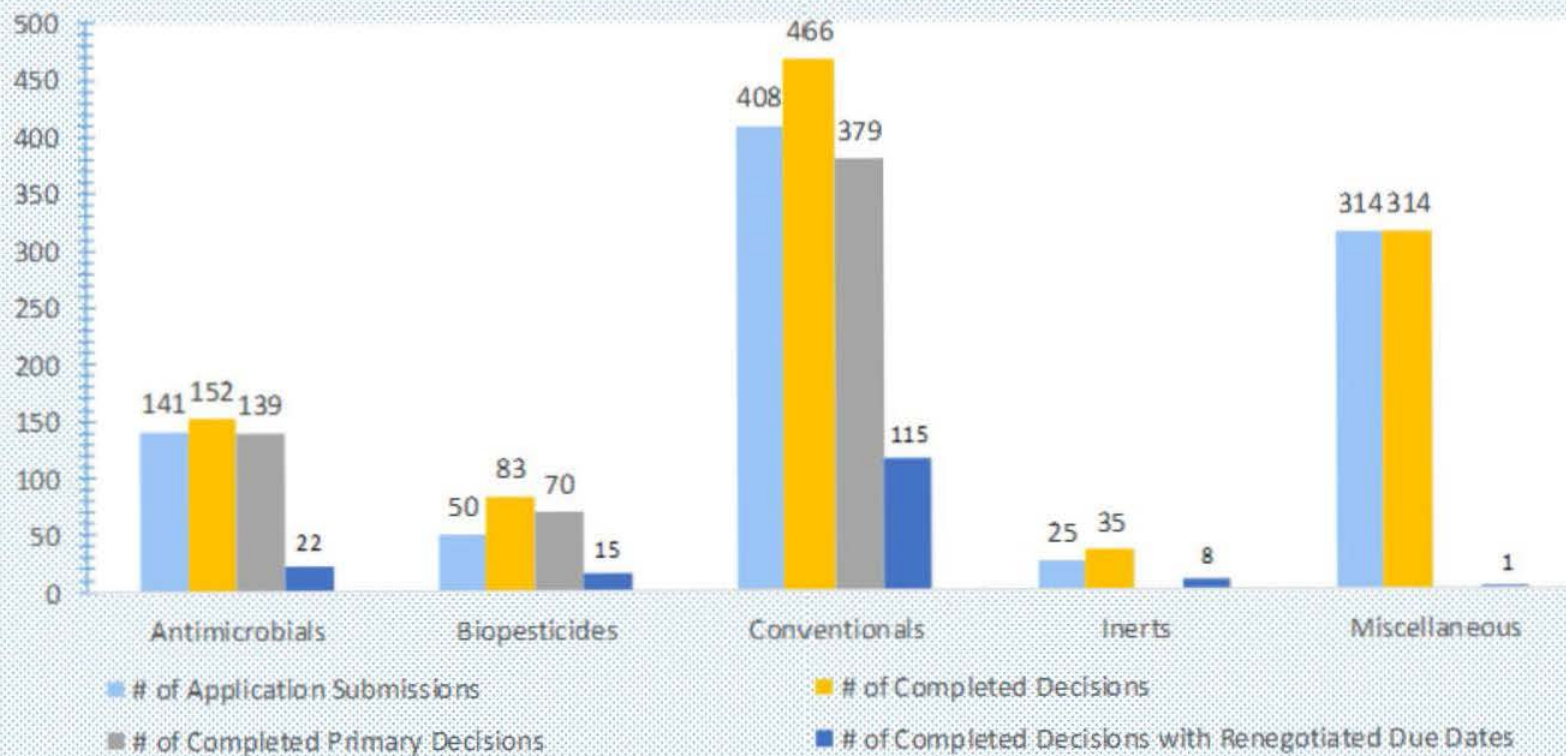


Agenda

- ☐ Introductions
- ☐ PRIA 3 Summary for FY'15 (October 1, 2014 – March 31, 2015)
- ☐ 45/90 Preliminary Technical Screen
- ☐ Fast Track Amendment & Notification Backlogs
- ☐ Milestone Notification Email Tracking Summary
- ☐ Policy Changes for the Collection of User Fees
- ☐ Past Quarterly PRIA3 Stakeholder Meeting materials on PRIA Webpage



PRIA 3 Summary for FY'15





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	22/152 = 14.4%	15/83 = 18.1%	115/466 = 24.7%	1/314 = 0.3%	8/35 = 22.8%



Number of Late PRIA Decisions

Branch	Late Completions	Rate of on-time Completions
Antimicrobials	12	92.1%
Biopesticides	3	96.4%
Conventionals	6	98.7%
Inerts	1	97.1%
Misc	2	99.4%
Total	24	97.7%



Fees Collected in FY15 to Date



PRIA Fees: \$7.5M

Maintenance Fees: \$27.1M



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	152	466	618
Completed PRIA 3 Decisions	151	458	609
PRIA 3 Decisions Involving Label Approvals	149	375	524

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	12 (8%)	2 (<1%)	14 (3%)
On the PRIA Due Date	44 (30%)	41 (11%)	85 (16%)
Before the PRIA Due Date; Pre-decisional Determination Due Date is null	4 (3%)	0 (%)	4 (<1%)
Before the PRIA Due Date but after the Pre-decisional Determination due date	66 (44%)	192 (51%)	258 (49%)
On or before the Pre-decisional Determination Due Date	23 (15%)	140 (37%)	163 (31%)
Total	149	375	524



45/90 Preliminary Technical Screen

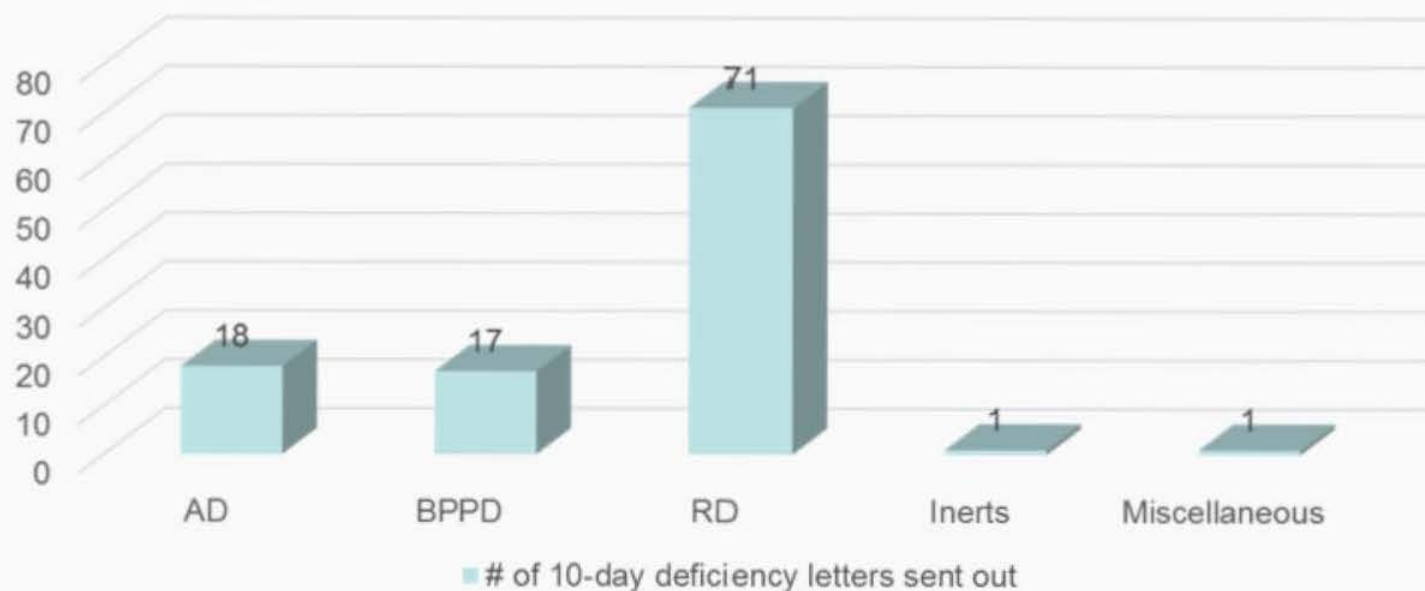
Actions That Have Completed the Screen





45/90 Preliminary Technical Screen *continued...*

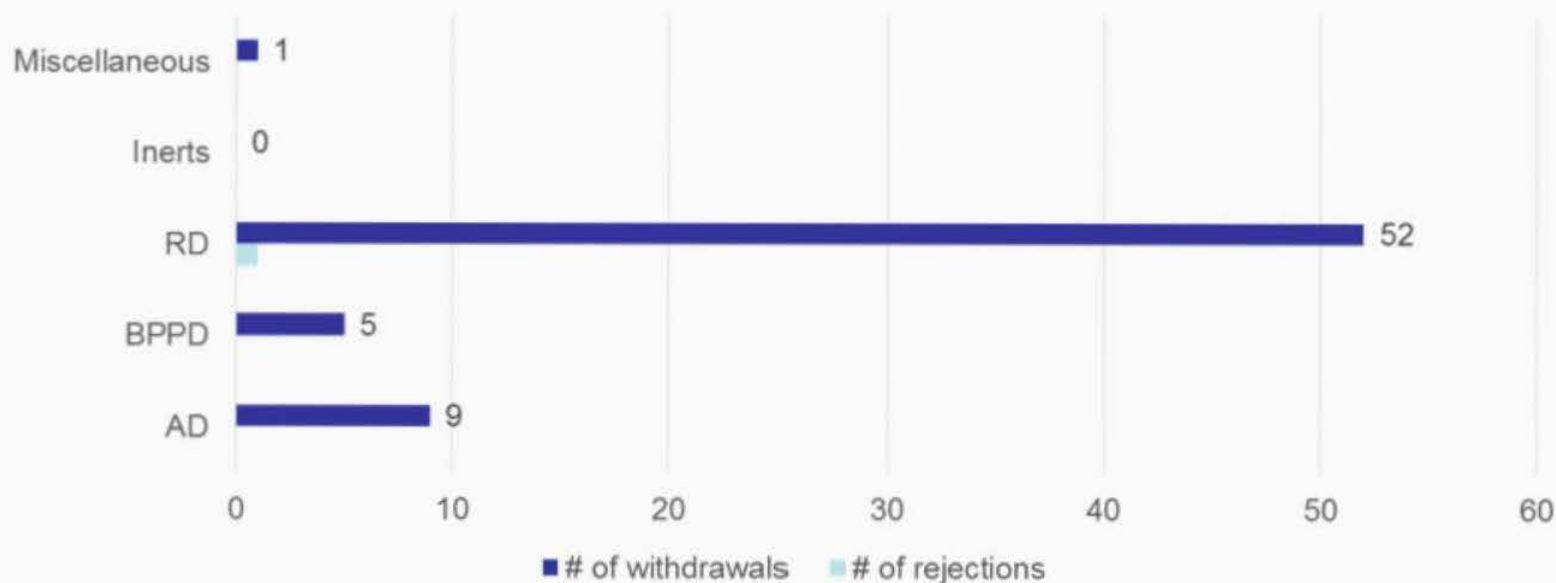
10-day Deficiency Letters Sent Out





45/90 Preliminary Technical Screen *continued...*

Actions Withdrawn or Rejected





Reason for Rejections/Withdrawals

- ☐ Not substantially similar
- ☐ Missing data
- ☐ Data deficiencies
- ☐ Uncleared inerts
- ☐ Inadequate acute toxicity data
- ☐ Waiver request missing or inadequate
- ☐ Data matrix/data comp issues
- ☐ Unregistered source for active ingredient
- ☐ Revised CSF significantly different from accepted CSF
- ☐ Inadequate package for exclusive use petition
- ☐ Bridging argument inadequate



Fast Track Amendment & Notification Backlogs

AD

- 116 fast track amendments pending, and 5 were in backlog status (i.e. more than 90 days have elapsed)
- 111 notifications pending, and 32 were in backlog status (i.e. more than 30 days have elapsed)

BPPD

- 66 fast track amendments pending, and 13 were in backlog status
- 33 notifications pending, and 24 were in backlog status

RD

- 276 fast track amendments pending, and 40 were in backlog status
- 178 notifications pending, and 100 were in backlog status



Milestone Notification Email Tracking Summary

Most Active Companies

Company	Email Notifications Sent
ANTIMICROBIALS	
Mason Chemical Company	39
Ecolab	35
Enviro Tech Chemical Services, Inc.	30
Stephan Company	27
Lonza Inc.	22
W.M. Barr & Company, Inc.	16
Goodrich	15
AgroFresh	13
Thor GMBH	13
Arch Chemicals, Inc.	12



Most Active Companies *continued...*

Company	Email Notifications Sent
BIOPESTICIDES	
Great Lakes Fishery Commission	12
Semiosbio Technologies, Inc.	12
Bio-Ferm GMBH	9
Bayer	9
Monsanto	8
Marrone Bio Innovations	8
Terramera, Inc.	8
Falcon Lab LLC	8
Emery Oleochemicals LLC	7
Agro Logistic Systems	6



Most Active Companies *continued...*

Company	Email Notifications Sent
CONVENTIONALS	
Syngenta	142
Valent	67
BASF	65
Dow	64
Dupont	60
Agracity Crops & Nutrition	59
FMC	44
Albough LLC	43
McLaughlin Gormley King	42
Bell Labs	40



Most Active Companies *continued...*

Company	Email Notifications Sent
INERTS	
BASF	8
Stephan Company	6
Nalco	6
BYK Additives Inc.	5



Most Active PRIA Categories

	PRIA Category	Category Description	# of Email Notifications Sent
ANTIMICROBIALS			
1	A570	Amendment; non-fast track	264
2	A540	New Product; non-fast track	171
3	A530	New Product; me-too, fast track	81
4	A531	New Product; substantially similar	32
BIOPESTICIDES			
1	B680	Amendment; microbial	56
2	B720	New Product; SCLP	26
3	B670	New Product; microbial	20
4	B682	Protocol review	16
CONVENTIONALS			
1	R300	New Product; substantially similar, cite all	361
2	R340	Amendment; non-fast track	351
3	R310	New Product; registered source	159
4	R301	New Product; substantially similar, selective citation	138
INERTS			
1	I001	New Food use inert clearance	22
2	I009	New Polymer, non-food use inert clearance	15
3	I004	New non-food use inert clearance	10
4	I008	New Polymer, food use inert clearance	10



Payments for User Fees

In the past two years, there have been 3,179 **PRIA payments** made, with 736 of these payments (~23%) made by check, bank drafts or money orders through the PRIA lockbox

In the past two years, there have been 3,065 **maintenance fee payments** made with 1,939 of these payments (~63%) made by check, bank drafts or money orders through the maintenance fee lockbox



Policy Changes for the Collection of User Fees

- ☐ Treasury has mandated the closure of EPA lockboxes by the end of FY'15
 - ☐ Will eliminate check payments for both PRIA and maintenance fees
- ☐ Checks, bank drafts and money orders will no longer be processed through the lockboxes effective September 30, 2015
 - ☐ Last day that checks should be sent to the lockboxes should be September 15, 2015 to allow time to be processed
- ☐ Treasury will no longer accept credit card payments above \$25,000 beginning June 1, 2015
- ☐ Any payments above \$25,000 must be made by electronic funds transfer (ACH) via pay.gov
 - ☐ PayPal and Dwolla are being added as payment options in May but only have a maximum payment amount of \$10,000



PRIA 3 Quarterly Stakeholder Meeting materials can be found at:

<http://www2.epa.gov/pria-fees>

– Click on “Related Topics” box