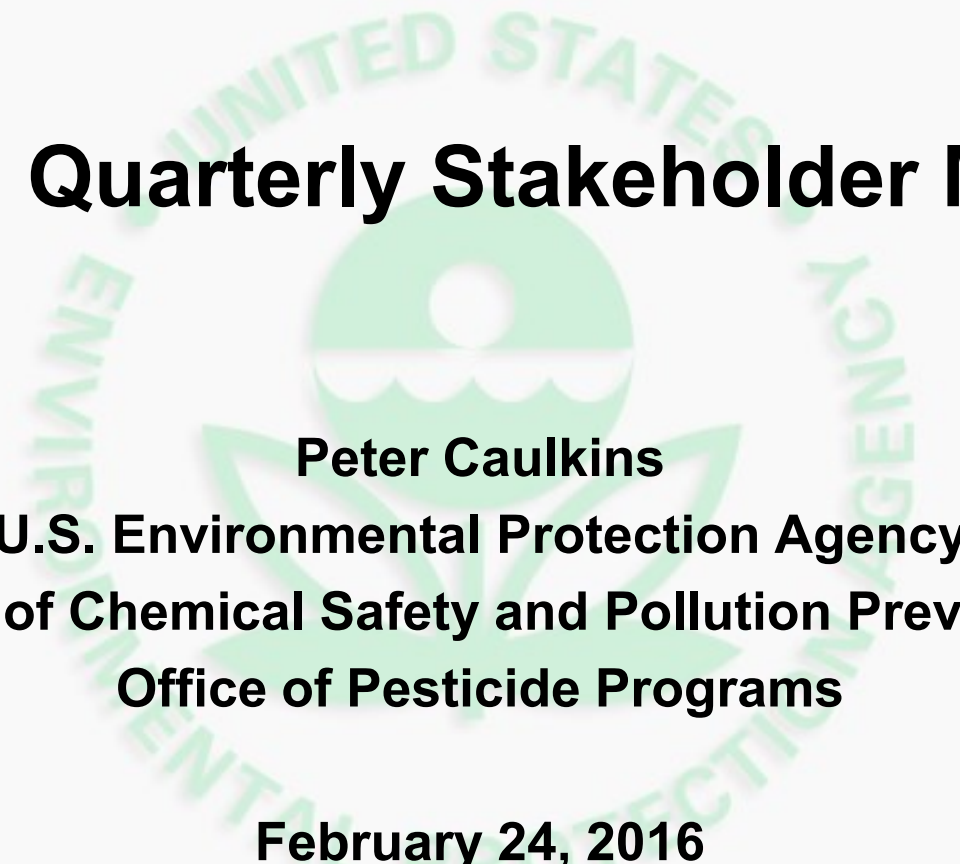


US EPA ARCHIVE DOCUMENT



# **PRIA 3 Quarterly Stakeholder Meeting**



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

**February 24, 2016**

# AGENDA

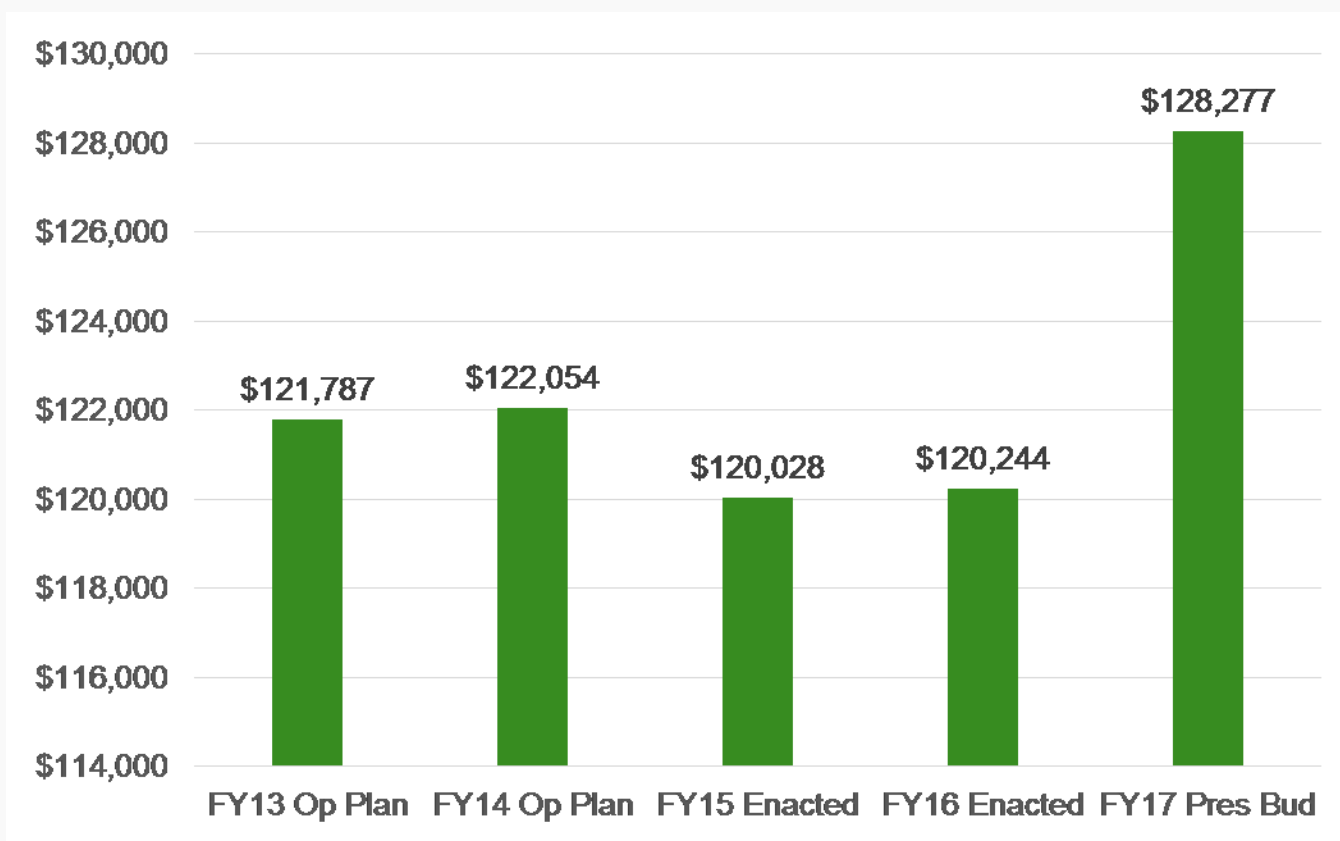
- Introductions
- Budget
- PRIA 3 Summary for FY'15
- Renegotiation rates FY'15
- Late completions FY'15
- Average completion times FY'15
- Major Accomplishments FY'15
- Pending Non-PRIA Fast Tracks & Notifications
- Fees collected FY'15
- 2-day label approval FY'15
- 45/90 Preliminary technical screen FY'15
- Electronic Submissions/ electronic label reviews
- Stakeholder issues



# FY 2013 – FY 2017

## Minimum Appropriations Threshold

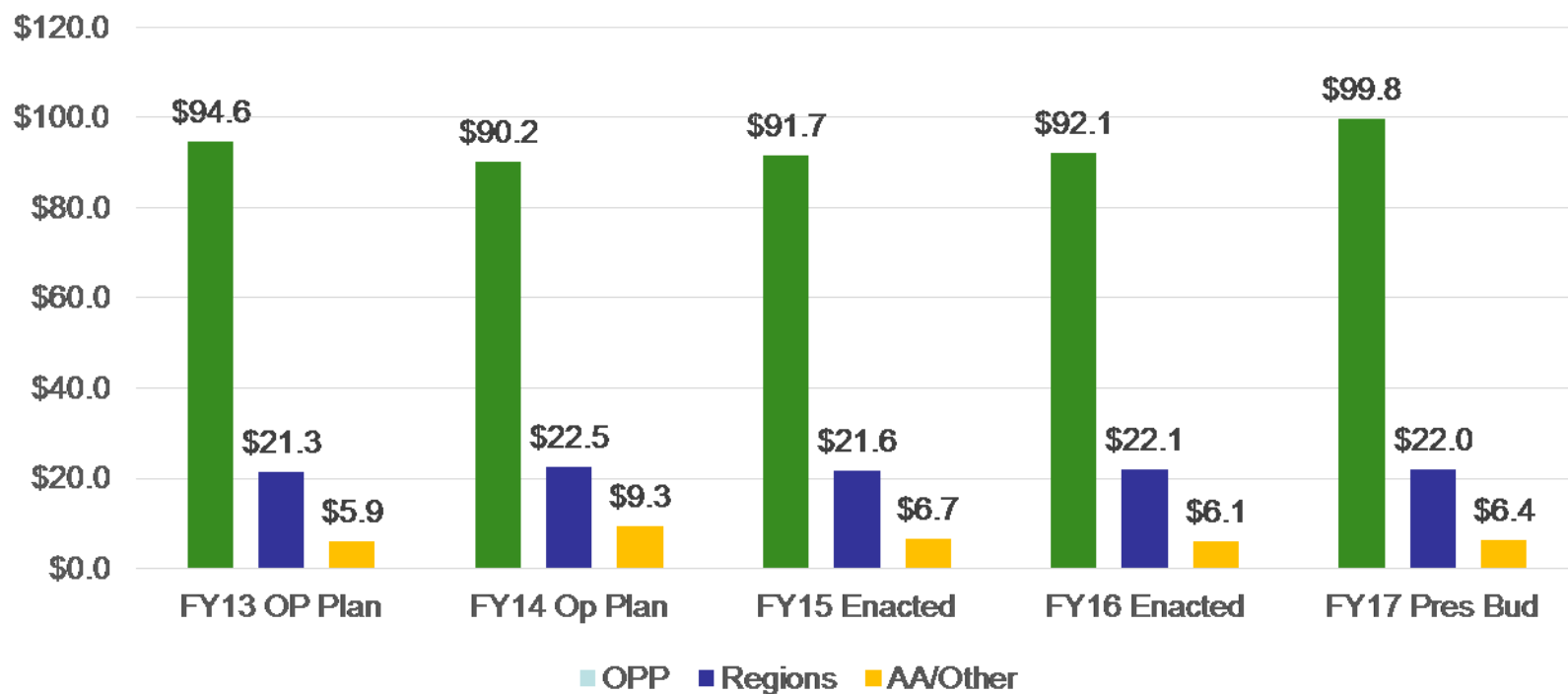
(dollars in thousands)





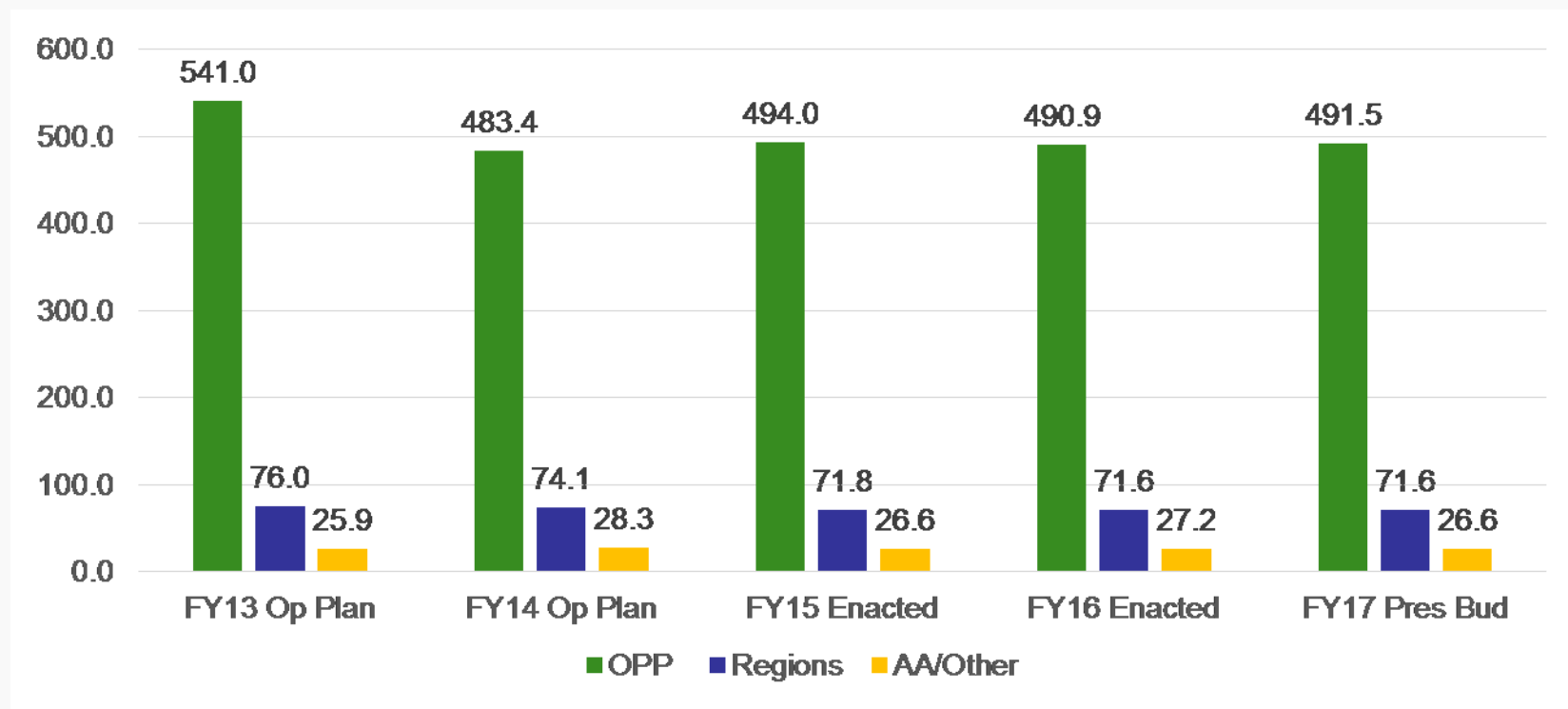
# FY 2013 – FY 2017 Appropriations

(dollars in millions)





# FY 2013 – FY 2017 FTE Summary





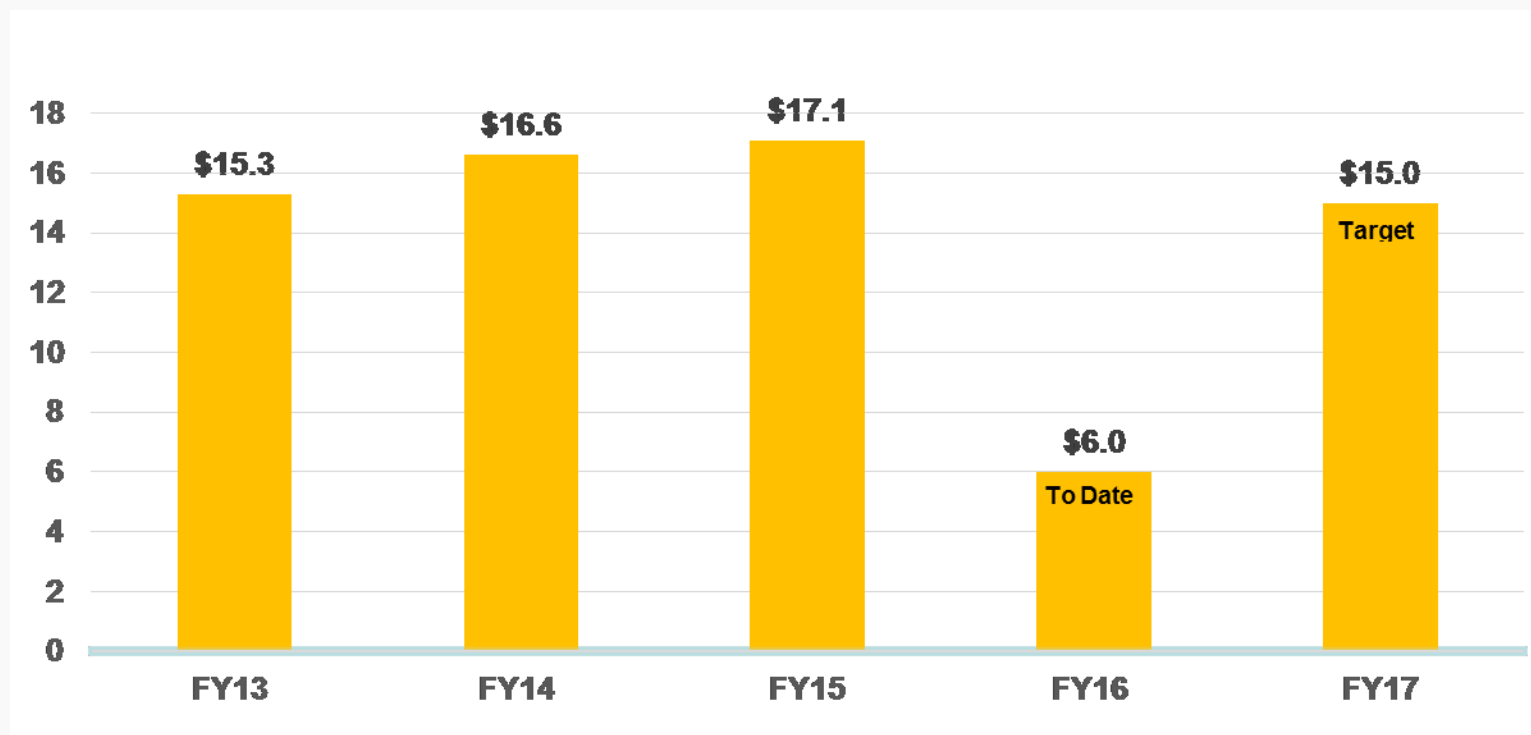
## Authorized Pesticide Fees

Fee	Description
Registration Service Fees	<ul style="list-style-type: none"><li>●Funds both tolerance petitions and other registrations</li><li>●Collections depend on number of applications</li><li>●Contains minimum appropriation provision</li><li>●Deposited into the Pesticide Registration Fund</li><li>●PRIA 3 mandated programs totaled \$2.0M per year for Worker Protection (\$1M); Partnership Grants (\$0.5M); and Pesticide Safety Education Program (\$0.5M)</li></ul>
Maintenance Fees	<ul style="list-style-type: none"><li>●Funds-Registration Review Program</li><li>●PRIA 3 authorizes \$27.8M per year through FY 2017</li><li>●Deposited into the FIFRA Revolving Fund</li><li>● &gt;\$3M (1/9-1/8 of \$27.8M) reviews of inerts and expedited processing of similar applications</li><li>● \$.8M authorized for IT Improvements</li></ul>



## FY 2013 – FY 2017 PRIA Fee Collections

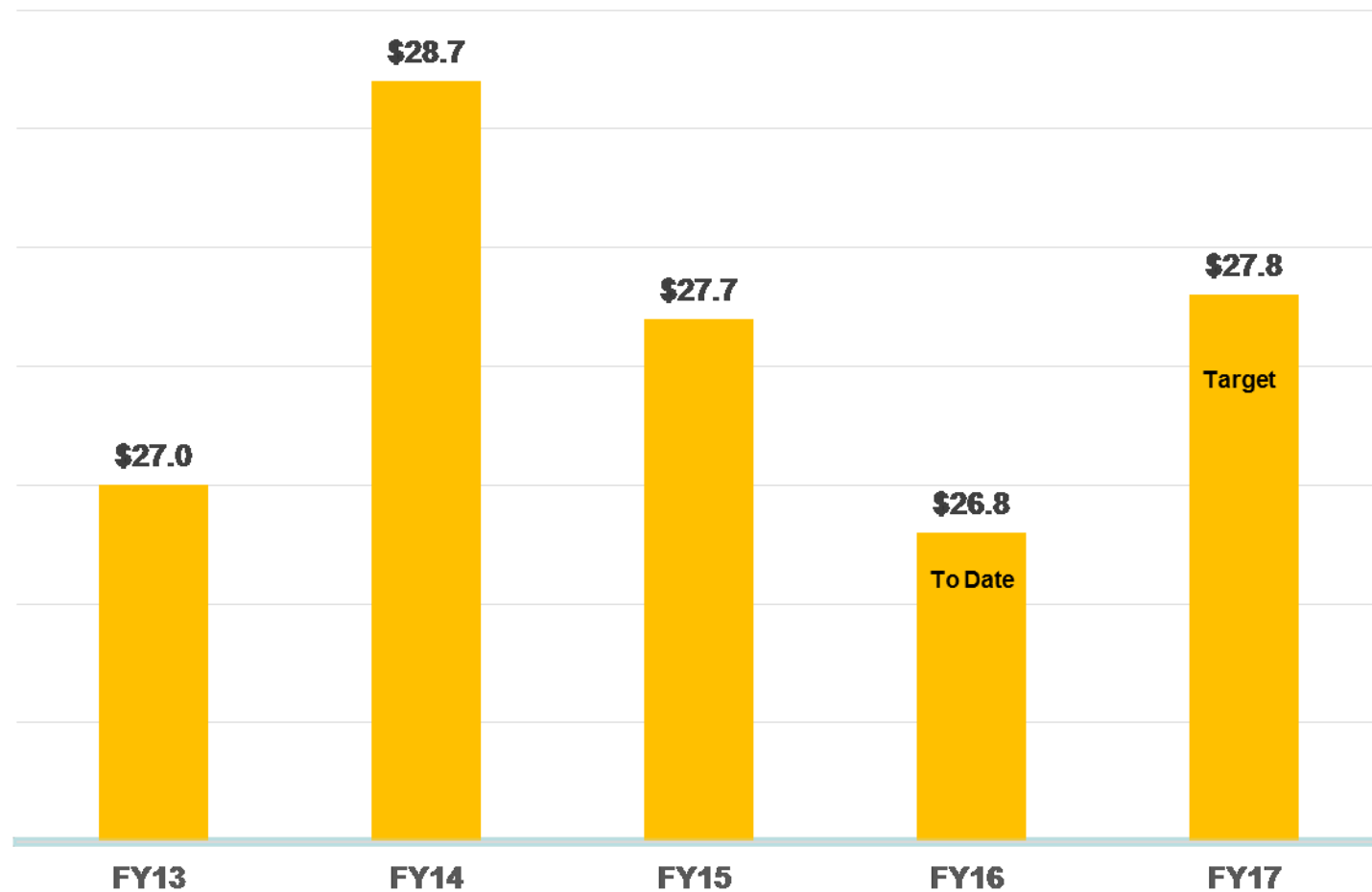
(dollars in millions)





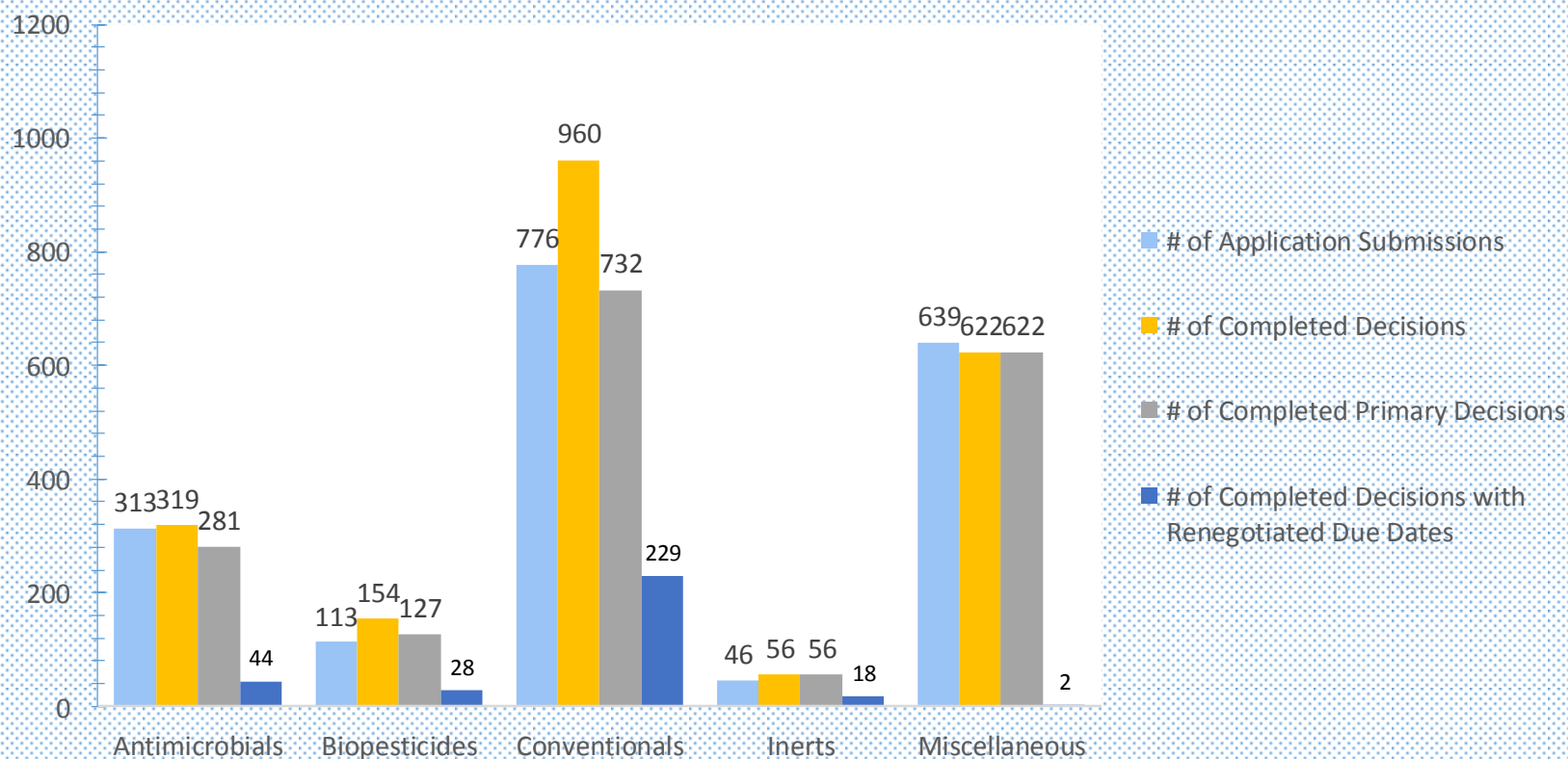


## FY 2013 - FY 2017 FIFRA Maintenance Fee Collections (dollars in millions)





### PIRA 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	44/319 = 13.8%	28/154 = 18.2%	229/960 = 23.8%	2/622 = 0.3%	18/56 = 32.1%



## FY'15 Number of Late PRIA Decisions

Type of decision	FY'15 Late Completions	FY'15 Rate of on-time Completions	FY'14 Rate of on-time Completions	FY'13 Rate of on-time Completions
Antimicrobial	14	96%	78%	99%
Biopesticide	3	98%	79%	98%
Conventional	7	99%	78%	99%
Inert	2	96%	91%	100%
Misc	7	99%	99%	99%
Total	33	98%	85%	99%



# FY'15 Average Decision Times

## FY'15 RD Average Exceedances over PRIA Timeframes

Type of Action	Avg Exceedance of Completed Decisions	PRIA Categories Included	PRIA Categories with Improved Timeframes (compared to FY'14)
New Als	+5.4 months	R010, R020, R060	R010, R020
New Uses	+2.8 months	R140, R150, R170, R175, R180, R190, R230, R260, R273	R170, R230, R273
New Products	-- 3 days	R300, R301, R310, R314, R315, R320, R331, R333, R334	R300, R301, R310, R314, R315, R320, R331, R333
Amendments	-- 2 days	R340, R350, R351, R352, R371	R340, R350, R351, R371



# FY'15 Average Decision Times

## FY'15 BPPD Average Exceedance over PRIA Timeframes

Type of Action	Avg Exceedance of Completed Decisions	PRIA Categories Included	PRIA Categories with Improved Timeframes (compared to FY'14)
New AIs	+1.2 months	B590, B690, B880, B884	B590, B690
New Uses	+2.8 months	B630, B634, B644	B630, B644
New Products	< -- 1 day	B660, B670, B671, B672, B673, B720, B880	B660, B670, B672, B720
Amendments	-- 4 days	B680, B681	



# FY'15 Average Decision Times

## FY'15 AD Average Exceedance over PRIA Timeframes

Type of Action	Avg Exceedance of Completed Decisions	PRIA Categories Included	PRIA Categories with Improved Timeframes (compared to FY'14)
New uses	+15.2 months (outlier included) +18 days (outlier excluded)	A460,A480, A500	A480
New Products	+ 11 days	A530, A531, A532, A540, A550, A560	A530,A531, A532, A540, A560
Amendments	- 3 days	A570	A570



## Major Registration Accomplishments

AD

- Completed 1 new AI; 9 new uses;
- Completed 168 non-fast-track new products; 120 non-fast-track amendments;
- Completed 845 fast-track amendments; 963 notifications;

BPPD

- Completed 8 new AIs; 5 other AIs withdrawn; 1 other AI not granted; 2 other AIs rejected; 4 new uses;
- Completed 75 non-fast track new products; 30 non-fast track amendments;
- Completed 165 fast-track amendments; 114 notifications;

RD

- Completed 7 new AIs ( 2 import tolerances); 100 new uses;;
- Completed 192 non-fast-track new products; 272 non-fast-track amendments;
- Completed 174 fast-track new products; 956 fast-track amendments
- Completed 1,371 notifications





## Major Registration Accomplishments – con't

AD

- Successful negotiated settlement with industry on 158W; issued 158W letter to registrants; interim guidance on food use data requirements; posted Use Site Index for public comment; developed training videos for external stakeholders

BPPD

- Collaborated with DfE program to facilitate submission of biopesticide products into the DfE process

RD

- Completed Phase 1 pilot with stakeholders on the SmartLabel to refine the model; developed vocabularies and processes for standardizing terminology; defined validation rules for structured pesticide label submissions



## End of FY'15 Pending Non-PRIA Fast-Track Amendments & Notifications

- At the end of FY'15 (September 30, 2015) **AD** had 25 non-PRIA fast-track amendments and 25 notifications pending;
- At the end of FY'15 (September 30, 2015) **BPPD** had 27 non-PRIA fast-track amendments and 24 notifications pending;
- At the end of FY'15 (September 30, 2015) **RD** had 255 non-PRIA fast-track amendments and 178 notifications pending;



# FY'15 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	319	961	1,280
Completed PRIA 3 Decisions	314	942	1,256
PRIA 3 Decisions Involving Label Approvals	304	770	1,074

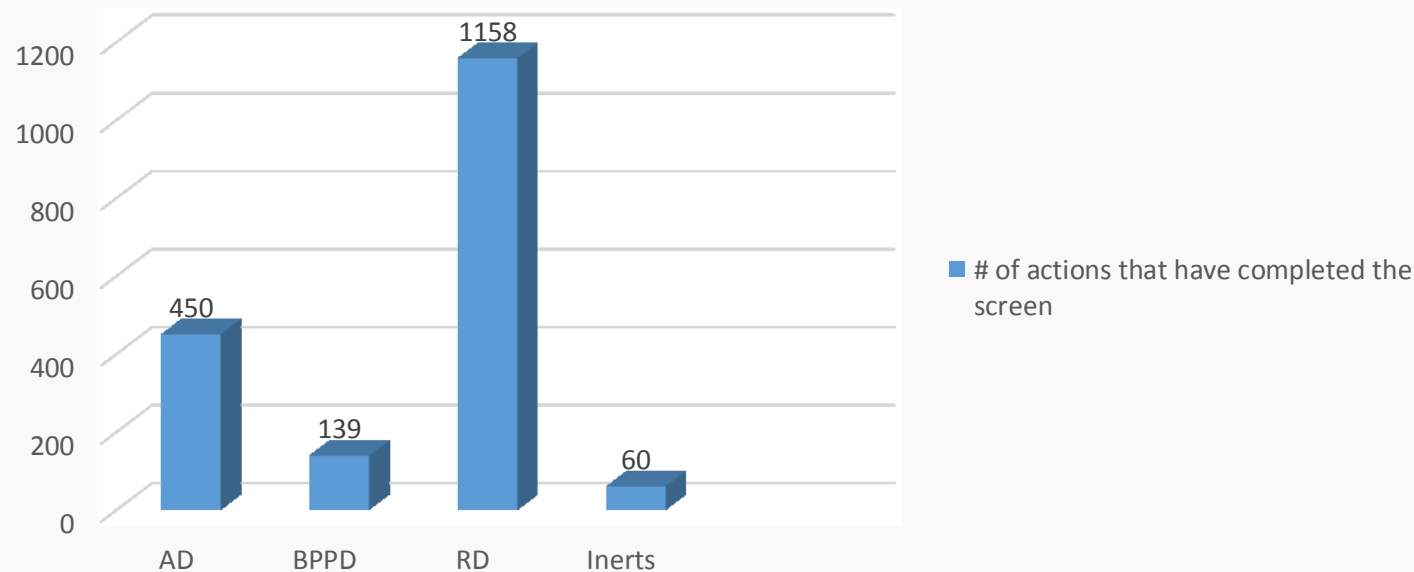
**Table 2: Timing for Completion of PRIA 3 Label Reviews & Approvals**

	Antimicrobial Label Reviews & Approvals (A)	Conventional Label Reviews & Approvals (R & M005)	Total
After the PRIA Due Date	14 (5%)	3 (<1%)	17 (2%)
On the PRIA Due Date	107 (35%)	104 (14%)	211 (20%)
Before the PRIA Due Date but after the Pre-decisional Determination due date	133 (43%)	369 (48%)	502 (46%)
On or before the Pre-decisional Determination Due Date	50 (16%)	294 (38%)	344 (32%)
Total	304	770	1,074



# FY'15 45/90 Preliminary Technical Screen

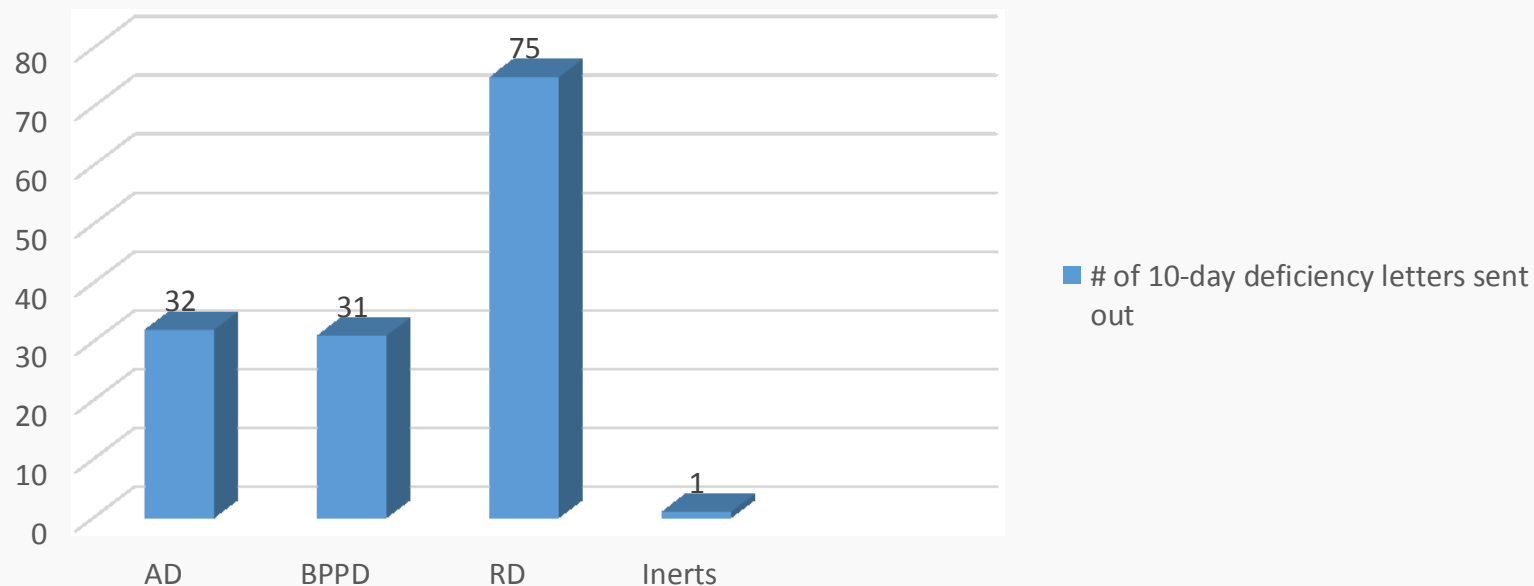
## Actions That Have Completed the Screen





# FY'15 45/90 Preliminary Technical Screen *continued...*

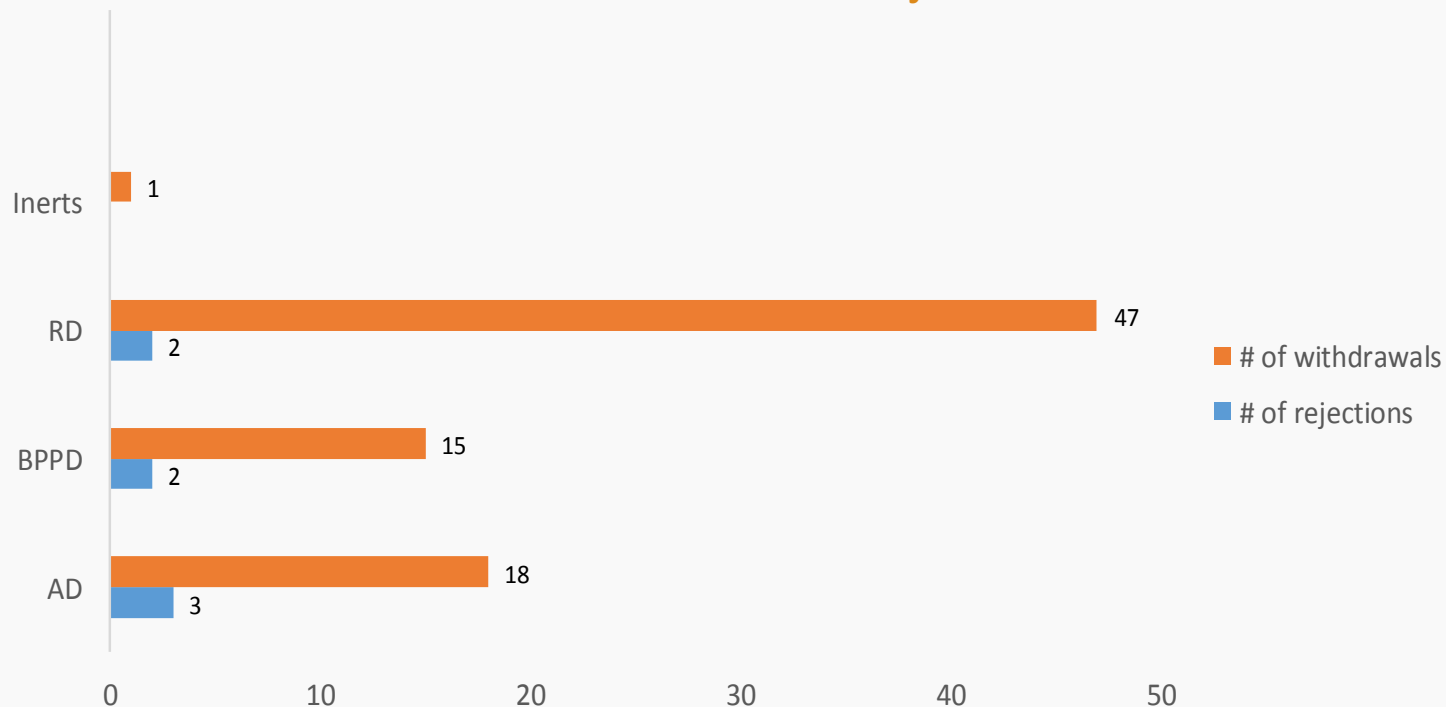
## 10-day Deficiency Letters Sent Out





# FY'15 45/90 Preliminary Technical Screen *continued...*

## Actions Withdrawn or Rejected





# **FY'15 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
- ☐ 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
- ☐ Deficient companion animal study



## FY'15 Electronic Submissions by Type of Product

Type of Product	Total # Packages Submitted	# Paper-Only Packages Submitted	# Electronic-Only Packages Submitted	Both paper & Electronic packages Submitted	% Paper Submission	% Electronic Submission	% both Paper & Electronic Submission
Conventional	2,864	1,504	684	676	52%	24%	24%
Antimicrobial	1,132	735	249	148	65%	22%	13%
Biopesticide	405	315	49	41	78%	12%	10%
total	4,401	2,554	982	865	58%	22%	20%





## **FY'15 Electronic Submissions by Type of Action {Percentage Submitted Electronically}**

<b>Type of Action</b>	<b>Antimicrobial</b>	<b>Biopesticide</b>	<b>Conventional</b>
<b>New AI</b>	67%	49%	92%
<b>New Use</b>	17%		95%
<b>New Product</b>	38%	20%	25%
<b>Amendment</b>	59%	16%	30%
<b>Non-PRIA</b>	12%	4%	16%



# FY'15 Electronic Label Reviews

- Tracking the use of electronic comparison software in conducting label reviews requires input from reviewers;
- A significant number of reviewers have not been providing the necessary input into the tracking system: RD – no input for 27% of completed label reviews, AD – no input for 45%, and BPPD no input for 49%;
- Lack of necessary input increases uncertainty;
- % of labels reviewed electronically in RD: 65% - 92%;
- % of labels reviewed electronically in AD: 51% - 97%;
- % of labels reviewed electronically in BPPD: 39% - 78%.



# Stakeholder Issues



## PRIA Points of Contact

- Peter Caulkins, Senior Advisor, PRIA Coordinator:  
[caulkins.peter@epa.gov](mailto:caulkins.peter@epa.gov)
- Steve Schaible, RD PRIA Ombudsperson:  
[Schaible.stephen@epa.gov](mailto:Schaible.stephen@epa.gov)
- Diane Isbell, AD Acting PRIA Ombudsperson:  
[isbell.diane@epa.gov](mailto:isbell.diane@epa.gov)
- Linda Hollis, Branch Chief, BPPD:  
[hollis.linda@epa.gov](mailto:hollis.linda@epa.gov)