

PRIA 3 Quarterly Stakeholder Meeting

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U.S. Environmental Protection Agency

Office of Chemical Safety and Pollution Prevention

Office of Pesticide Programs

February 24, 2016

AGENDA

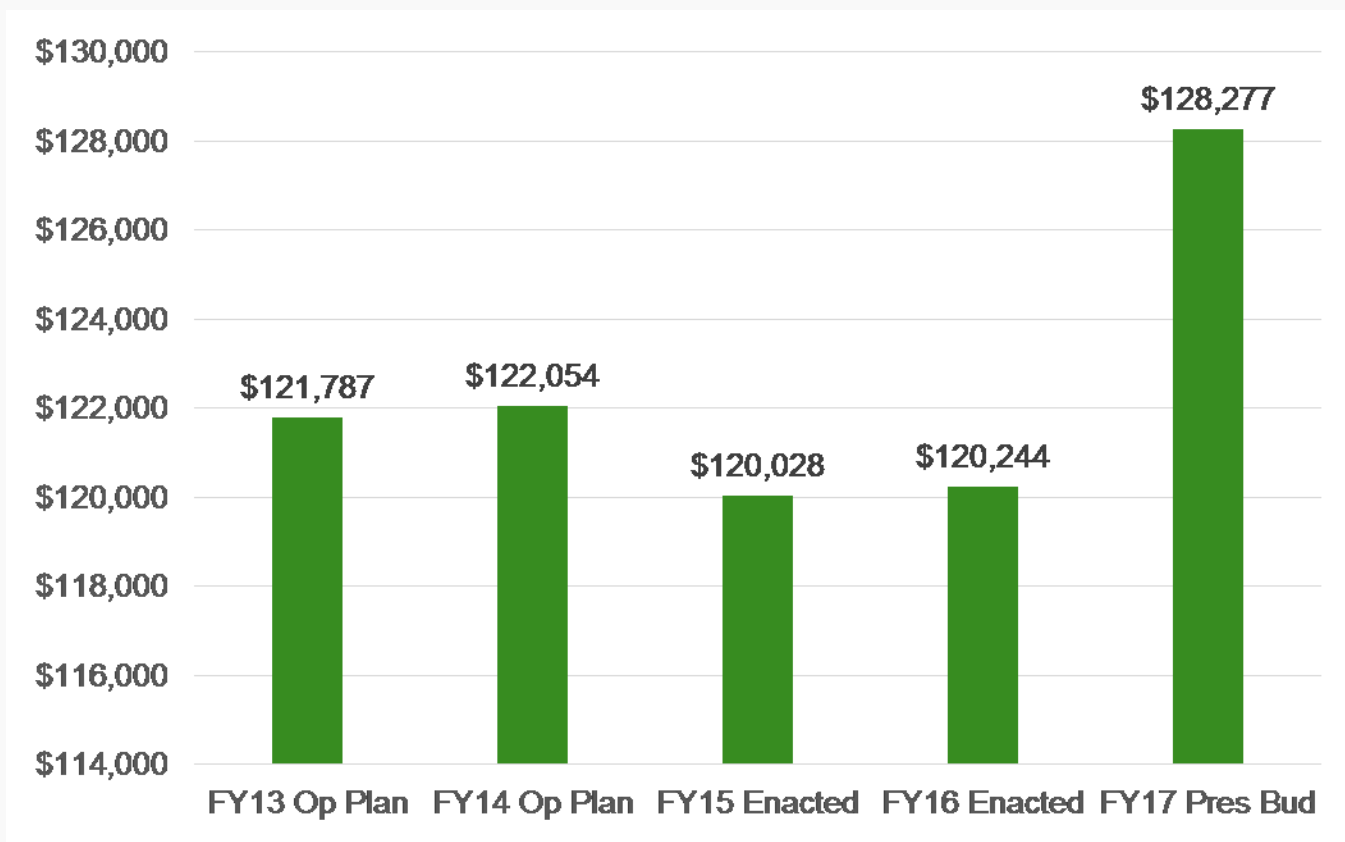
- Introductions
- Budget
- PRIA 3 Summary for FY'15
- Renegotiation rates FY'15
- Late completions FY'15
- Average completion times FY'15
- Major Accomplishments FY'15
- Pending Non-PRIA Fast Tracks & Notifications
- Fees collected FY'15
- 2-day label approval FY'15
- 45/90 Preliminary technical screen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



FY 2013 – FY 2017

Minimum Appropriations Threshold

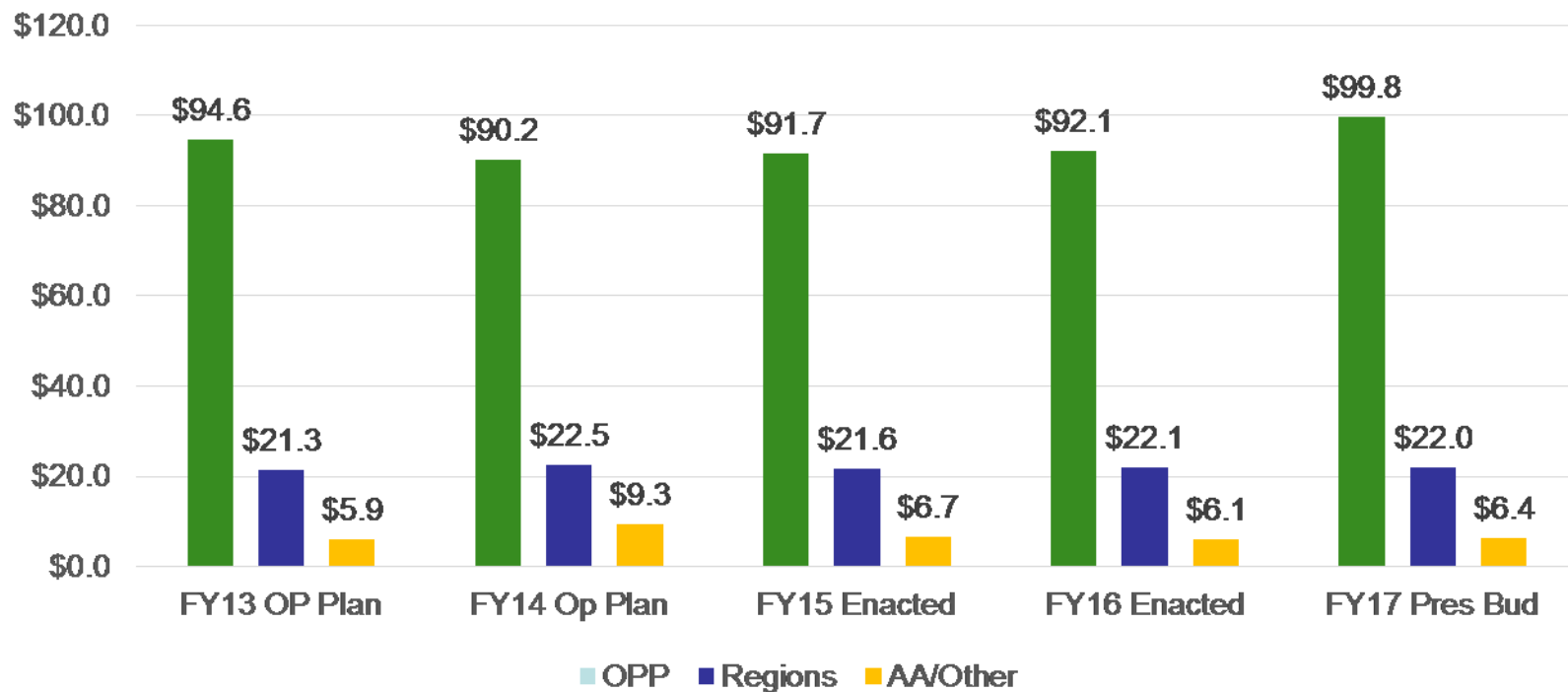
(dollars in thousands)





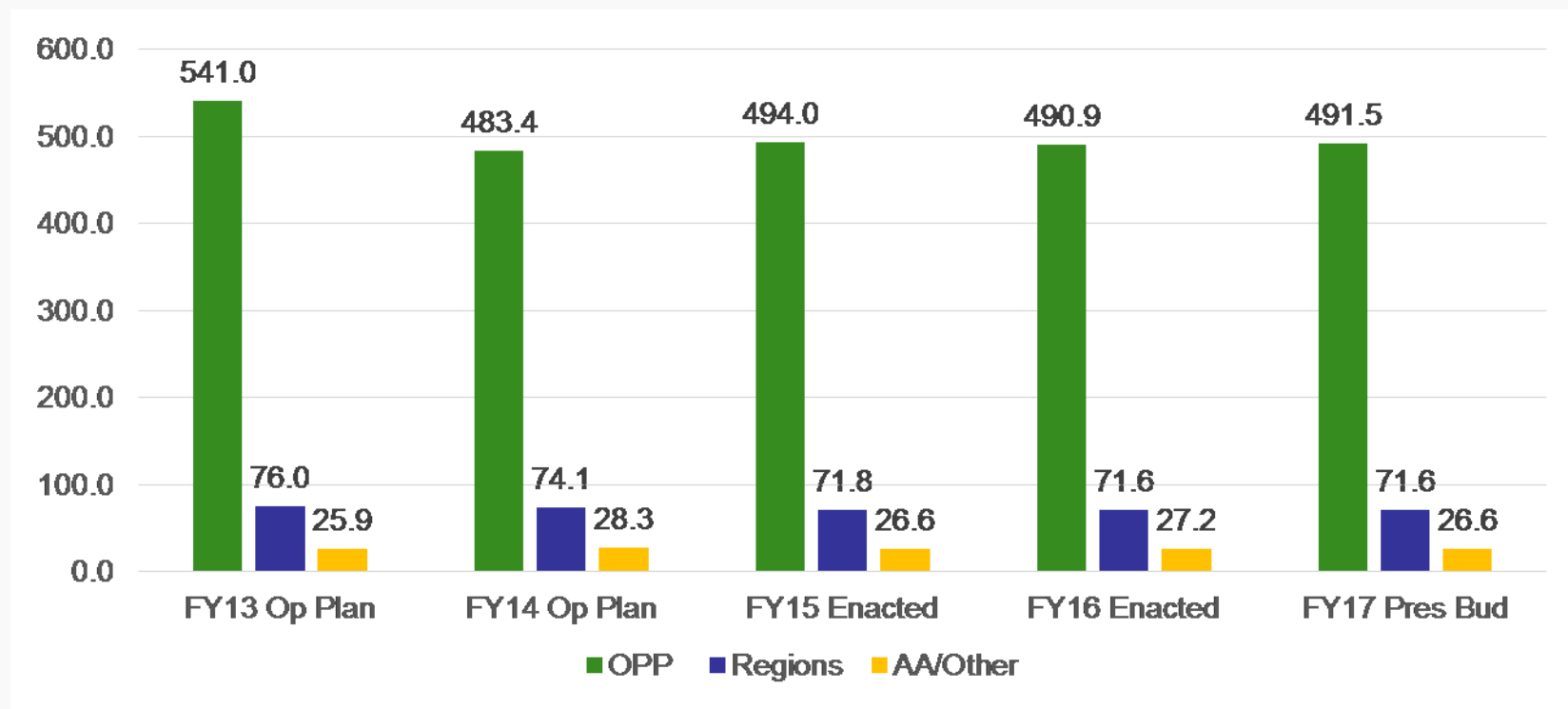
FY 2013 – FY 2017 Appropriations

(dollars in millions)





FY 2013 – FY 2017 FTE Summary





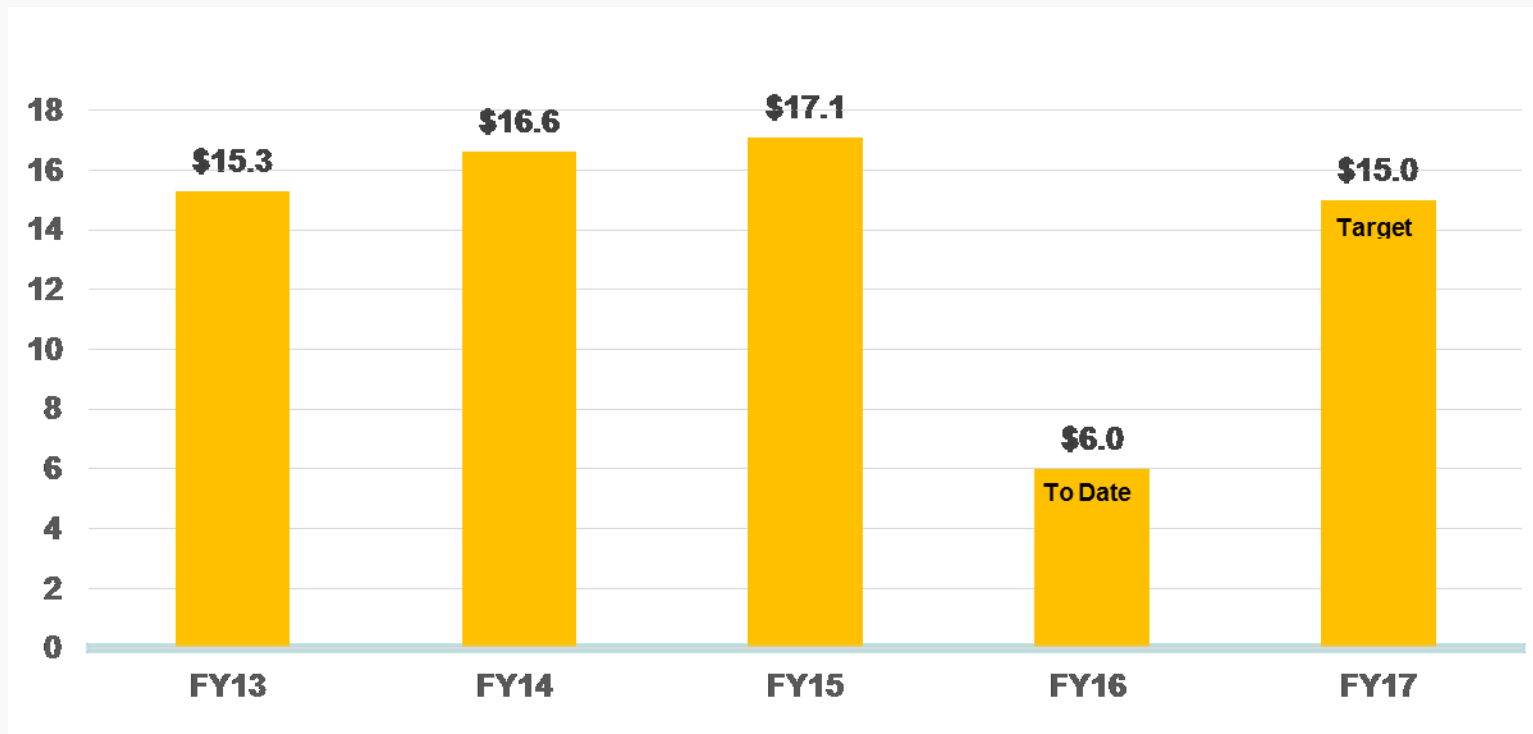
Authorized Pesticide Fees

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



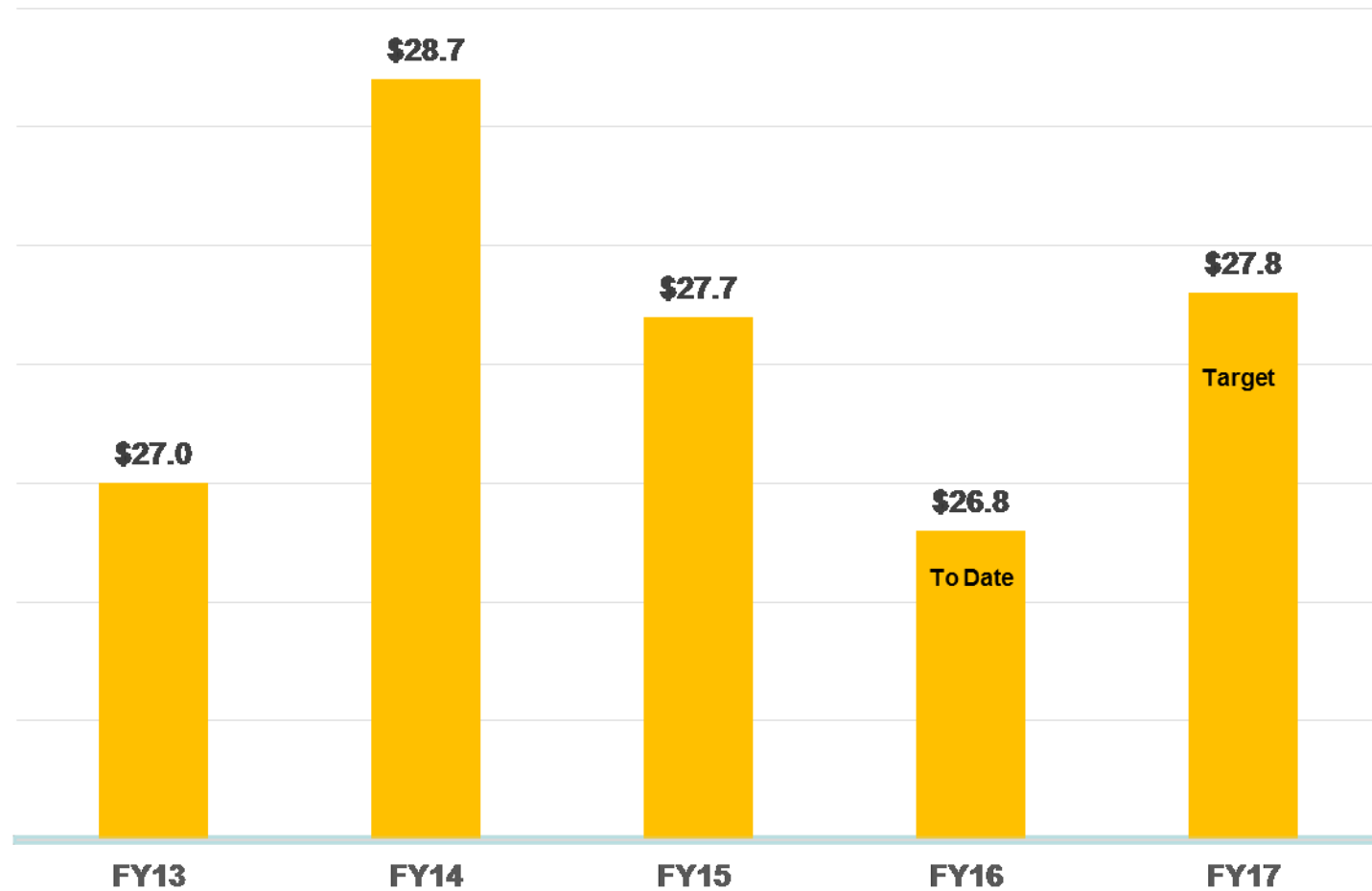
FY 2013 – FY 2017 PRIA Fee Collections

(dollars in millions)



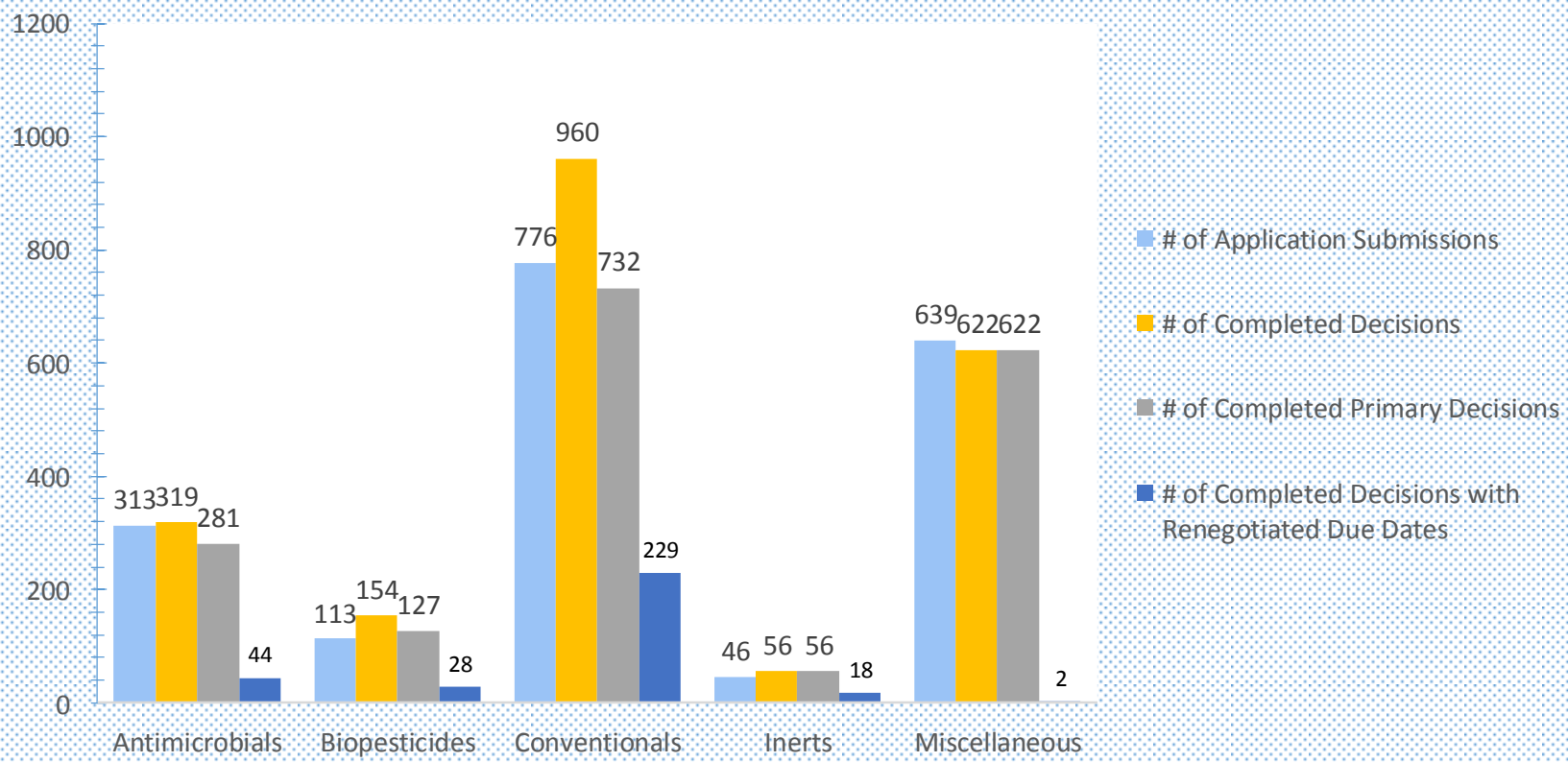


FY 2013 - FY 2017 FIFRA Maintenance Fee Collections (dollars in millions)





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	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

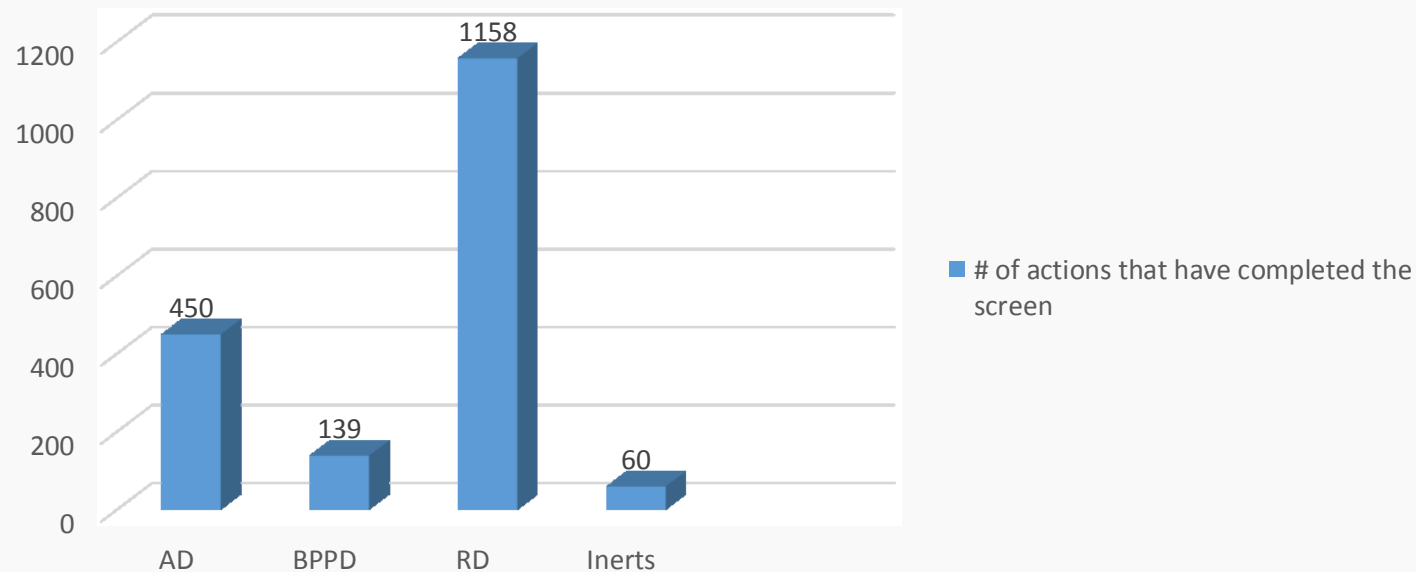
Table 2: Timing for Completion of PRIA 3 Label Reviews & Approvals

	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

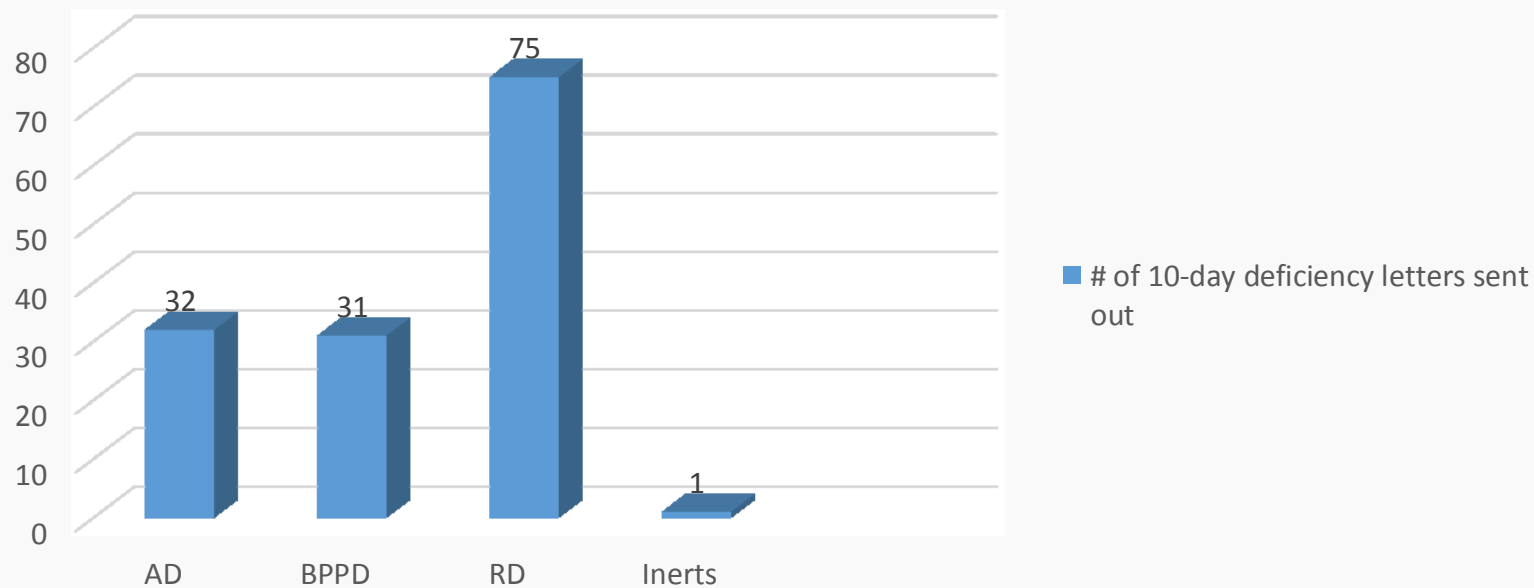
Actions That Have Completed the Screen





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

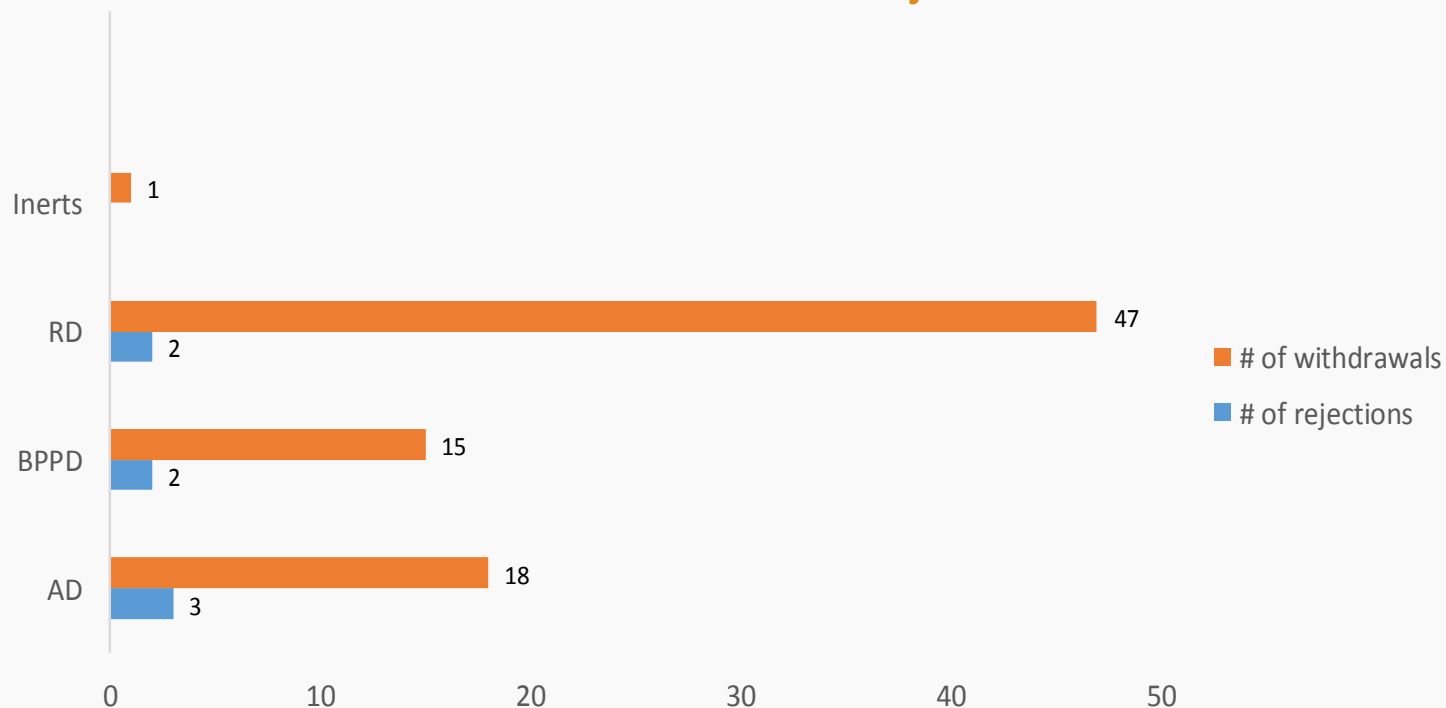
10-day Deficiency Letters Sent Out





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}

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

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