PRIA Coalition Quarterly Stakeholder Meeting

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Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs

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AGENDA

- Introductions
- Follow-up from previous Stakeholder Quarterly Meeting
- PRIA Submission by Type
- PRIA Submissions, Completions, and Renegotiations
- Renegotiation Rates
- On-time Completion Rates
- Fees Collected in FY'19
- 45/90 Preliminary Technical Screen
- Non-PRIA Fast Tracks & Notifications
- Process Improvements- Product Chemistry
- ELMS Activities/ A3 Summaries
- Wrap-Up/Next Meeting Dates

Previous Stakeholder Meeting Follow-up – CATSAC

- CATSAC summary (FY2019):
  - 12 packages for review (AD=9, RD=1, BPPD=2);
  - Waived/Bridged 24 studies;
  - Minimum of 258 animals saved;
  - > $287,000 on study cost saved.
- No M010 PRIA applications received in FY'19.

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

- Status of updated PR Notice on notifications
  - The team has completed its response to comments document and recommended approach for a final PR Notice
  - Division level comments are being received, after which the team will brief senior management

M009 Summary

- “Non-FIFRA Regulated Determination: applicant initiated, per product”;
- OPP received 9 applications in FY’19, completed 2;
- Examples of activities requested in these applications include:
  - Device determination requests
  - Active ingredient determinations
  - Product-specific determinations
  - Insect trap with substance determinations
  - Pesticide determinations (fertilizer vs. plant growth regulator)

M009 Summary- What's Included?

- Activities EPA envisions being evaluated under M009 category:
  - Device determinations
  - New a.i. ingredient determinations
  - Microbial product pesticide determinations
  - Determinations that a product is not a pesticide under 40 CFR 152.10
    - Deodorizers, bleaches, and cleaning agents
    - Products not containing toxicants, intended only to attract pests for survey or detection purposes, and labeled accordingly
    - Barriers- product contains no toxicants
  - Exemptions under 40 CFR 152.25
    - Treated articles or substances
    - Pheromones, pheromone traps
    - Preservatives for biological specimens
    - Foods
    - 25(b) minimum risk determinations
    - Natural cedar

FIFRA-regulated Inquiries Received Outside of PRIA M009 Category

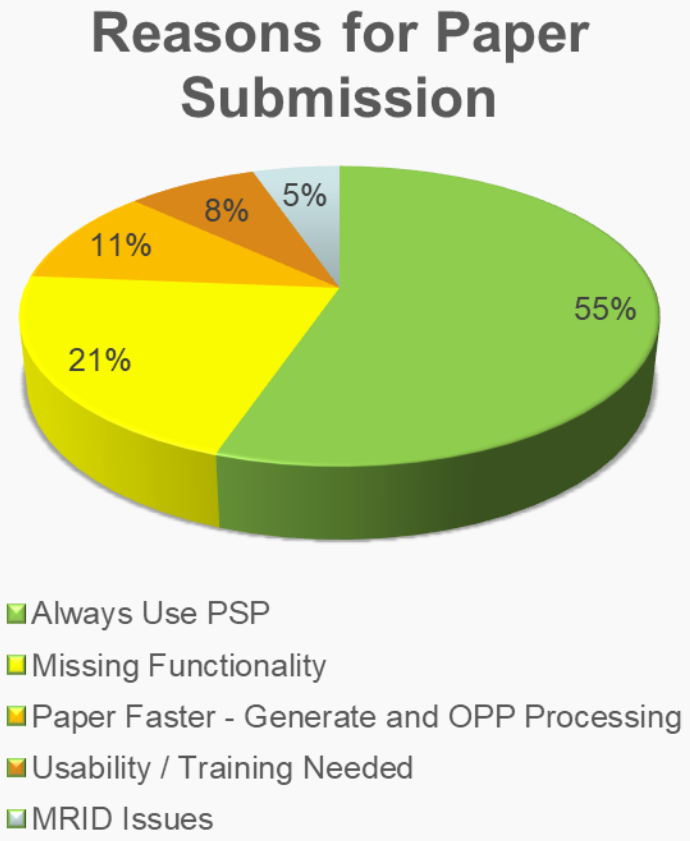
- EPA provides general information on items covered by PRIA category M009 (e.g., pesticide devices, treated articles), referencing EPA's website in an effort to assist the requesters in making their own determinations;
- If the company is interested in an EPA determination regarding the status of their product, requests must be submitted under the PRIA category M009;
- The Agency notes that we can no longer make FIFRA determinations informally outside of the PRIA process;
- Requests from states and regions for enforcement purposes will be handled by OPP staff outside of the PRIA review process.

Pesticide Submission Portal Analysis and Training

- ITRMD evaluated survey results provided in July by PRIA Coalition along with internal performance metrics to identify areas for program improvement and training in order to increase PSP adoption among registrants;
- Fifty registrants were surveyed to identify PSP usage, obstacles to PSP adoption, areas for improvement, and potential user training topics;
- 92% of respondents reported PSP use for at least some of their submissions to OPP;
- Non-users indicated usability and knowledge of the system as the principle hurdles to use.

Why Registrants Make Paper Submissions

- Most respondents (55%) stated that they use PSP for all submissions
- Respondents who make paper submissions indicated that missing functionality and/or submission type is the primary reason
- A quarter of respondents indicated that paper submission is preferable because:
  - it's easier to compile documents,
  - they have limited system knowledge,
  - MRID functionality is complicated,
  - and EPA sometimes processes paper faster



Respondent Challenges and Requests

Usability

- Expand Available Submissions and Existing Functionality
- Improve File Upload Process
- Review MRID Functionality
- Modernize UI/UX
- Review CDX Integrations – Company Number, Agent Registration, Use of Security Questions

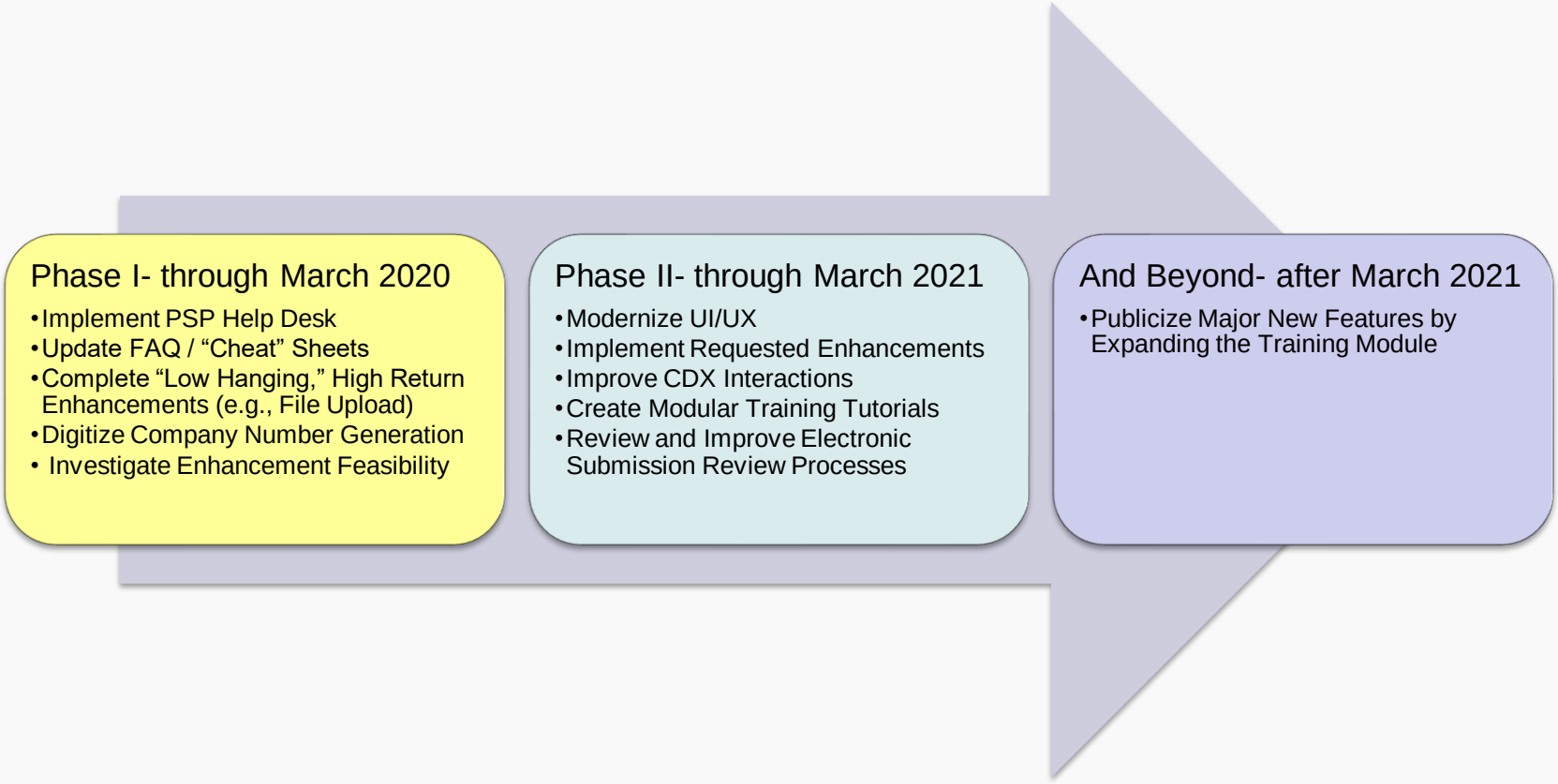
Submission Processing

- Incentivize Usage by Processing PSP Submissions Faster
- Enhance In-Application Statuses to be More Comprehensive and Clear
- Review Submission Routing to OPP Staff
- Centralize Standard Communications in PSP

Help Desk / User Assistance

- Create Recorded Training Modules – Users Learn at Own Pace and Availability
- Clarify Where Submissions Can Be Made and How to Make Them
- Better Route User Questions to Knowledgeable EPA Staff
- Publicize New Features and Provide Tutorials
- Better Communicate System Outages

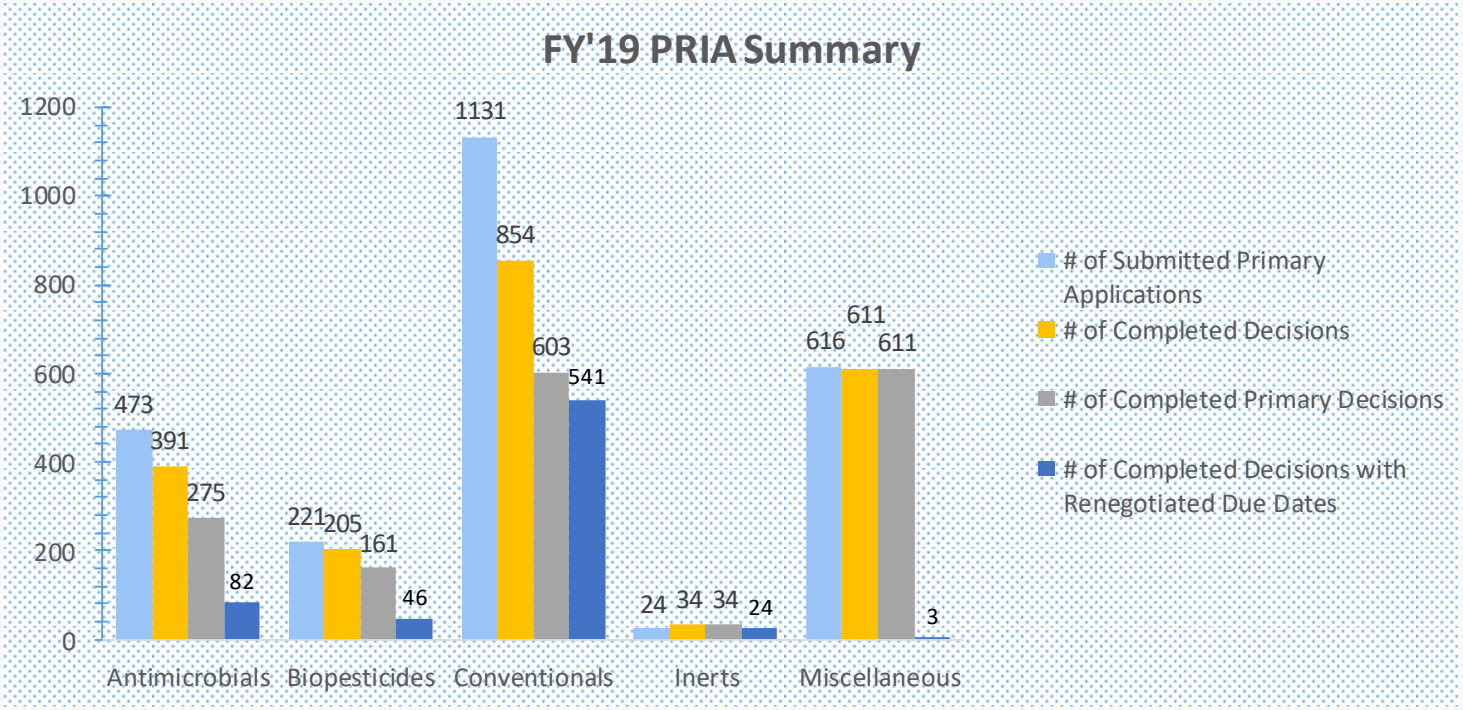
Next Steps / Recommendations



FY'19: 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	7,556	3,529	8	4,019	47%	<1%	53%
Antimicrobial	2,603	926	4	1,673	36%	<1%	64%
Biopesticide	1,093	313	21	759	29%	2%	69%
Total	**11,252**	**4,768**	**33**	**6,451**	**42%**	**<1%**	**57%**

FY'19 PRIA Submissions, Completions, and Renegotiations



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	82/391 = 21.0%	46/205 = 22.5%	541/854= 63.4%	3/611 = 0.5%	24/34 = 70.6%

FY'19: On-Time Completion Rates

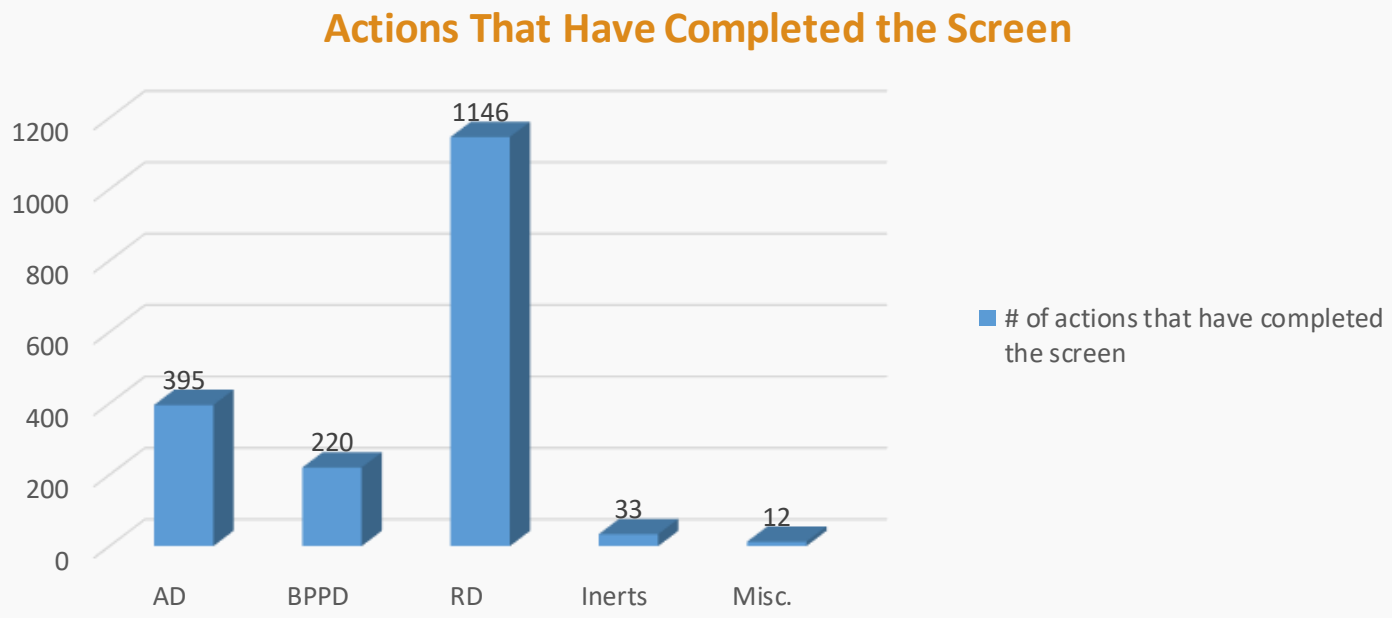
Type of decision	FY'19 Late Completions	FY'19 Rate of on-time Completions	FY'18 Rate of on-time Completions	FY'17 Rate of on-time Completions	FY'16 Rate of on-time Completions
Antimicrobial	15	96.1%	99.7%	99.7%	99.4%
Biopesticide	6	97.0%	100%	98.8%	97.4%
Conventional	21	97.5%	99.7%	98.7%	98.6%
Inert	6	82.3%	100%	95.2%	95.9%
Misc	3	99.5%	99.7%	99.8%	99.8%
Total	51	97.5%	99.7%	99.1%	98.9%

Fees Collected in FY'19

PRIA Fees: $16.5M

Maintenance Fees: $27.8M

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



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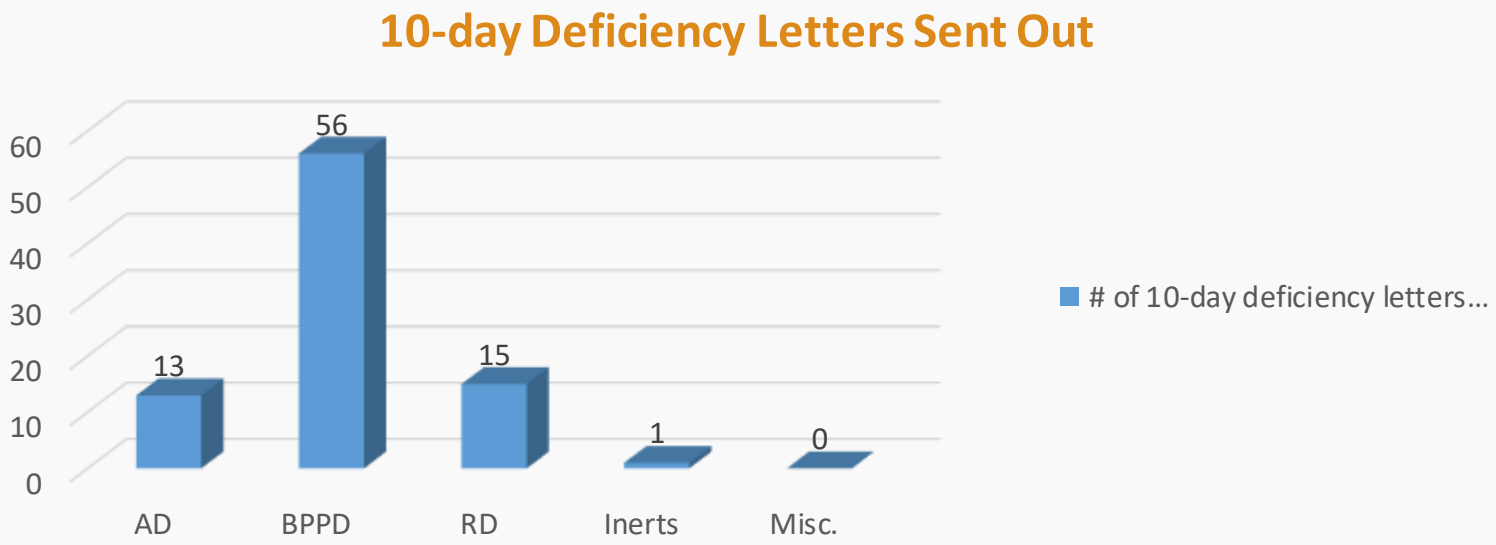

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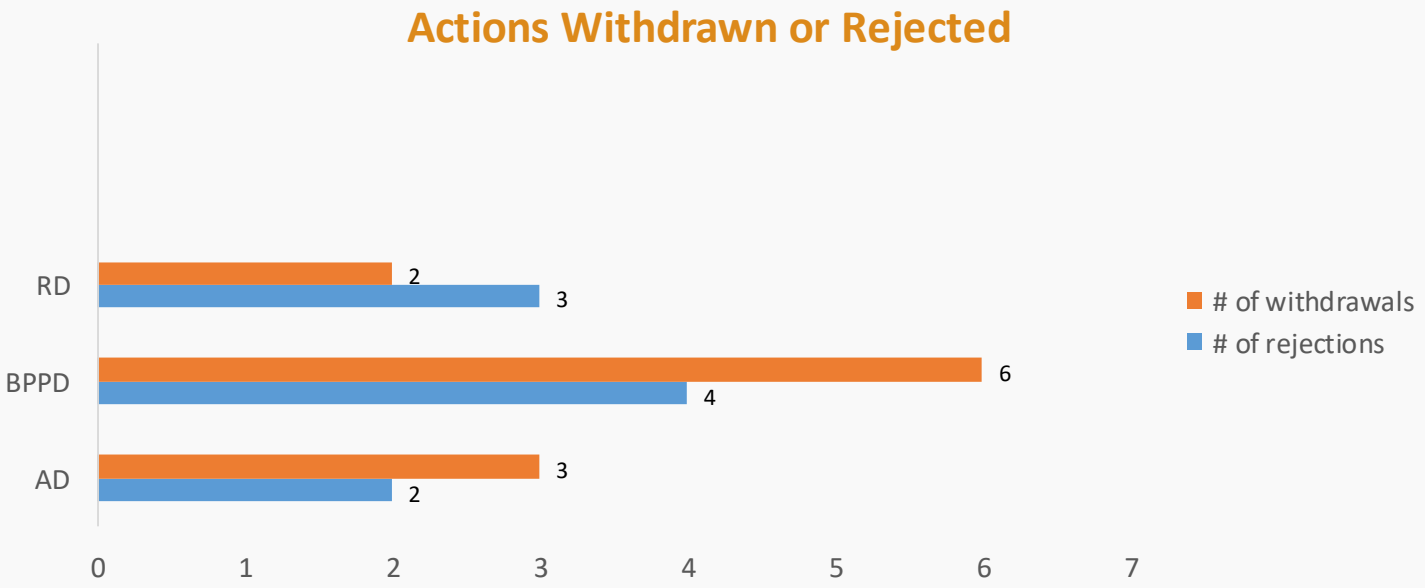

FY'19 Non-PRIA Fast-Track Amendments & Notifications (*FY'18 in Parentheses*)

Non-PRIA Activity	AD	BPPD	RD
Fast Track Amendments: - Completed - Pending - > 90d	440 (*557*) 374 (*289*) 236 (*181*)	208 (*231*) 97 (*88*) 42 (*61*)	667 (*1,069*) 1,109 (*817*) 932 (*625*)
Notifications: - Completed - Completed-Disapproved - Pending - > 30d	890 (*1,042*) 64 187 (*329*) 137 (*278*)	204 (*231*) 10 29 (*62*) 12 (*38*)	1,353 (*1,172*) 65 939 (*438*) 842 (*387*)

Notification & Non-PRIA Backlog: Clarifying the Record

In early October, 2019, RD provided registrants with the opportunity to provide feedback on non-PRIA items still pending with the agency.

Notification & Non-PRIA Backlog (RD): Setting the Record Straight

- A list of pending non-PRIA items was sent to each registrant in order to:
  - Confirm that the list is consistent with what the registrant understands is pending with the agency
  - Withdraw items that are no desired or needed
  - Use the pending list to consider where opportunities to consolidate or bundle pending actions exist for a single product registration

- Registrants were asked to respond within two months from the date of the agency letter to the responsible Product Manager (PM)

Notification & Non-PRIA Backlog (RD): Additional Actions

- RD has begun implementing additional tactics to address backlog situations, such as:
  - Using notification items as training tools for new employees
  - Forming ad-hoc teams to devote dedicated time slots to work on notifications
  - Utilizing additional internal response codes that will aid in tracking trends, problematic notification categories, and failure rates

Process Improvement-
Product Chemistry Challenges

A high percentage of the conventional renegotiations are being driven by delayed completion of product chemistry reviews

- Staffing resources
- Contract review challenges
- Quality of Submissions
- Under utilization of self-certification

Product Chemistry Overcoming the Challenges

- **What steps is EPA taking?**
  - ❑ Recruiting
  - ❑ Better use of contractor resources and development of standard review template
  - ❑ Prioritization of work and enhanced communication with product teams
  - ❑ SWAT teams to quickly build capacity
  - ❑ Pilot project to expand self-certification
  - ❑ Developing a checklist to help submitters improve submissions
- **What the regulated community can do**
  - ❑ Improved submissions (e.g. CSF checklist)
  - ❑ Self-certification statement for Product Chemistry Group A

Improving the Product Chemistry Review Process

- Improvements in the efficiency and capacity of the Agency review process such as identification of review priorities, bundling of reviews for similar actions, and increased use of contractor resources.

- Improvements in the quality of incoming submissions, including greater usage of product chemistry self-certification of “Group B” (physical and chemical property data) as provided under PR Notice 98-1, piloting a self-certification approach for submission of “Group A” (product identity and composition data)

- Development of Product Chemistry Checklist to help identity common deficiencies in product chemistry/CSF submissions

CSF/Product Chemistry Submission Checklist

Confidential Statement of Formula

- ❑ Are certified limits correctly calculated?
- ❑ For the active ingredient(s), are certified limits (in end use products) calculated based on the nominal concentration of the pure AI?
- ❑ Are justifications provided for any proposed non-standard certified limits?
- ❑ Are certified limits included in correct columns?
- ❑ Does the basic CSF have only one source of the active ingredient(s)?
- ❑ Is the CSF Form properly signed and dated?
- ❑ DOES THE TOTAL PERCENTAGE OF ALL COMPONENTS IN THE FORMULATION ADD UP TO 100%?

Product Chemistry: Product Identity and Composition (Group A Data):

- ❑ For products formulated from registered sources of active ingredients, has self- certification of physical/chemical properties been utilized per PR Notice 98-1? https://www.epa.gov/sites/production/files/2014-04/documents/pr98-1.pdf
- ❑ Guideline 830.1600 (Description of materials used to produce the product) – Are MSDS's for all starting materials submitted?
- ❑ Guideline 830.1650 (Description of formulation process) - Do the materials listed in the formulation process concur with those listed in proposed basic CSF?
- ❑ Guideline 830.1800 (Enforcement analytical method) – Is a method validation provided?

CSF/Product Chemistry Submission Checklist (cont)

Physical and Chemical Properties (Group B Data):

- ❑ Guideline 830.6313 (Stability to normal and elevated temperatures, metals, and metal ions) – does the submitted test data include determination of stability in the presence of metals, and metal ions?
- ❑ Guideline 830.6314 (Oxidation/reduction: chemical incompatibility) – Does the submitted test data include compatibility/incompatibility of the proposed product with "commonly used chemicals?"
- ❑ Guideline 830.6317 (Storage stability) – Does the submitted test data demonstrate how long the product will retain the percent active ingredient in its packaging material for a period of a *minimum* of one year?

For substantially similar (me-too) products:

- ❑ In cases where more than one product is cited for substantial similarly in Box #6 of EPA Form 8570-1, has a specific product been cited for product chemistry similarity?
- ❑ Are all cited MRID's in data matrix correct?

Non-applicable data requirements:

- ❑ For any guideline study that is indicated as not applicable, is a justification provided?

Self-Certification of Physical/Chemical Properties Data

- Outlined in PR Notice 98-1
  - Applies only to Group B (Guideline Series 830.6302 – 830.7950)
  - Only non-integrated system products
- Forms
  - 8570-36 – Summary of the physical/chemical properties
  - 8570-37 – Self-certification statement
- Beneficial to companies and EPA
  - Easier submission process for registrant
  - Shorter review time
  - Conserves Agency resources

EPA Review of Self-Certification

- After reviewing the submitted material, EPA may:
  - Accept the self-certification
  - Request to see the actual data which was summarized
  - Request additional information/error correction
- Registrants generally have 30 days to respond if data or other information requested
  - EPA can establish a different time frame
- Regulatory action may be taken in the case of non-compliance
  - Registration actions: show-stopper data gap
  - DCIs/Audits: could result in suspension of the product

Self-Certification Form/Submission Process Improvements

- ITRMD is working with the registering divisions on developing/improving fillable electronic forms
  - 8570-36 (summary of studies), 8570-37 (self-certification), and 8570-38 (summary of chemical properties)
- Also developing process/algorithm for ensuring the forms get properly processed and given an MRID number
  - Treated like a study
  - MRID necessary for tracking and reference on data matrix
- Revising self-certification “regulatory action” language for clarity

Form 8570-37 - Group B Chemistry Self-Certification

Current “regulatory action” language:

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of section 12(a)(2)(N) of FIFRA without opportunity for hearing, if I have not submitted to EPA within thirty (30) days of receipt of a request by the Agency, or within a specified time agreed to by the Agency, test results of studies summarized in the "Summary Form."

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of sections 12(a)(2)(N), 12(a)(2)(Q), or 12(a)(2)(R) of FIFRA without opportunity for hearing, if I fail to provide to EPA within thirty (30) days of receipt of a notification of error, or within a specified time agreed to by the Agency, information that EPA determines is required to correct the error.

ELMS Activities

- What is ELMS?
  - A means to promote continuous improvement.
  - A framework for linking our processes and goals.
  - A system that uses Lean principles and tools, paired with routine monitoring, measurement, and engagement to identify problems, solve problems, and sustain improvements.

- ELMS deployed in OPP 30 September 2019
  - ITRMD, Front-end processing
  - RD: New a.i.s
  - BPPD: 90-day Technical Screen

ITMRD ELMS Activity: Front-End Processing

- Goal - Reduce the amount of time it takes for a PM to receive an incoming submission (including tracking the time it takes to receive and triage a submission, PRIA Coding and 21-day completeness screen).
- Due to the size/scope; only PRIA actions are included in the scope of the project.
- Project is in the early stages and staff has begun to look at the data and develop and implement certain guidelines as they relate to the Front-End ELMS project.

RD New AIs ELMS Activities

Using visual management to track new AIs through each milestone from package receipt through label stamping to find efficiencies to decrease completion time

1st generation flow board

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2nd generation flow board

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RD New A.I.s ELMS Activities

- Encountered issues are documented and problem solving is focused on those that most commonly occur
- Progress is tracked on a performance board
- Preliminary analysis indicates that data deficiencies are often identified after the 90-Day Technical Screen; therefore, we will focus on methods to improve receipt of the data earlier in the process

BPPD ELMS Activity: Preliminary Technical Screen

- Addressing consistency of 90-day technical screens and quality of communication by reducing internal re-work
- Goals:
  - Develop and implement tools to bring better consistency to technical screens
  - Improve written communication
- Tools in development:
  - Detailed checklists for each guideline study
  - Instructions to reviewers
  - Templates for screening memoranda with good examples
- Benefits:
  - Corrects deficiencies earlier in the process
  - Reduces the number of 75-day letters
  - Reduces the number of highly deficient applications

ELMS Deployment Schedule for FY'20

- Nov/Dec
  - HED: New ai Risk Assessments
  - EFED: New ai Risk Assessments
  - AD: Registration Review
- January
  - BEAD: Registration Review Benefits
  - PRD: Registration Review
- February
  - HED: Registration Review Risk Assessments
  - EFED: Registration Review Risk Assessments

A3- Senior Executive Projects in FY'19

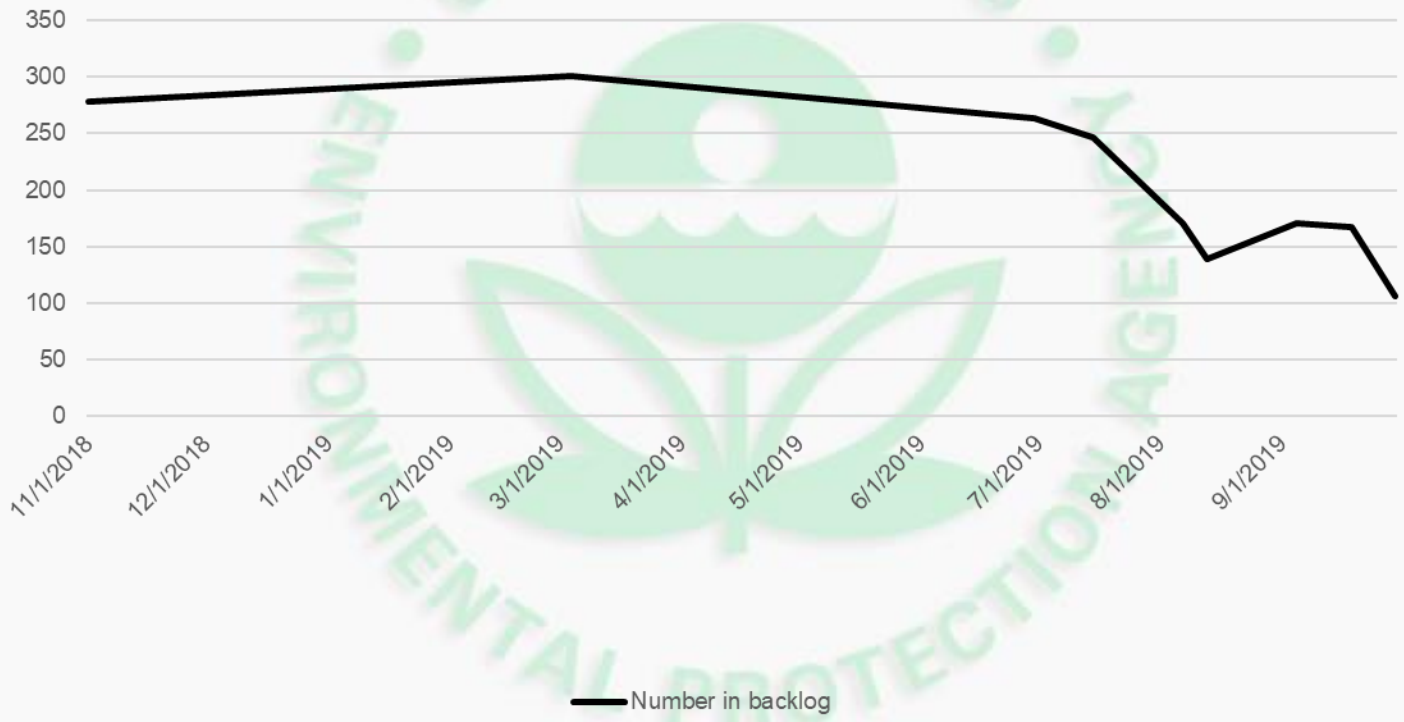
- All senior managers in OPP had to develop an A3 project;
- PRIA-related A3 projects were:
  - Antimicrobials Division- notifications backlog
  - Registration Division; Inert Ingredients Backlog
  - Biopesticides and Pollution Prevention Division- microbial pesticide non-PRIA backlog (notifications, FTAs)
  - Immediate Office/ITRMD- front end processing of PRIA applications; reducing the time it takes applications to reach the risk managers
- Reflecting continual improvement, there will be a new array of A3 projects in FY'20.

AD: Notification Backlog Reduction Effort

Goal: Reduce the number of backlogged notifications by 25% in FY19

- Baseline = 278 in backlog, as of 11/1/18
- Implemented efficiency measures:
  - Internal
    - Delegation of sign-off authority
    - Yes/No only
      - No cycles of revision/review
    - Cleanup of old close codes keeping decisions open as pending actions
    - Work with registrants to withdraw/consolidate
    - Improvements to OPPIN (close codes, “pop-box” for rejection reasons)
  - External
    - More care with submissions (e.g., formatting, appropriate for 98-10)
    - Assist with cleanup of old notifications and consolidation of actions
- As of 9/30/19, the backlog had been reduced to 106, a 62% reduction.

Number of AD Notifications in Backlog Status

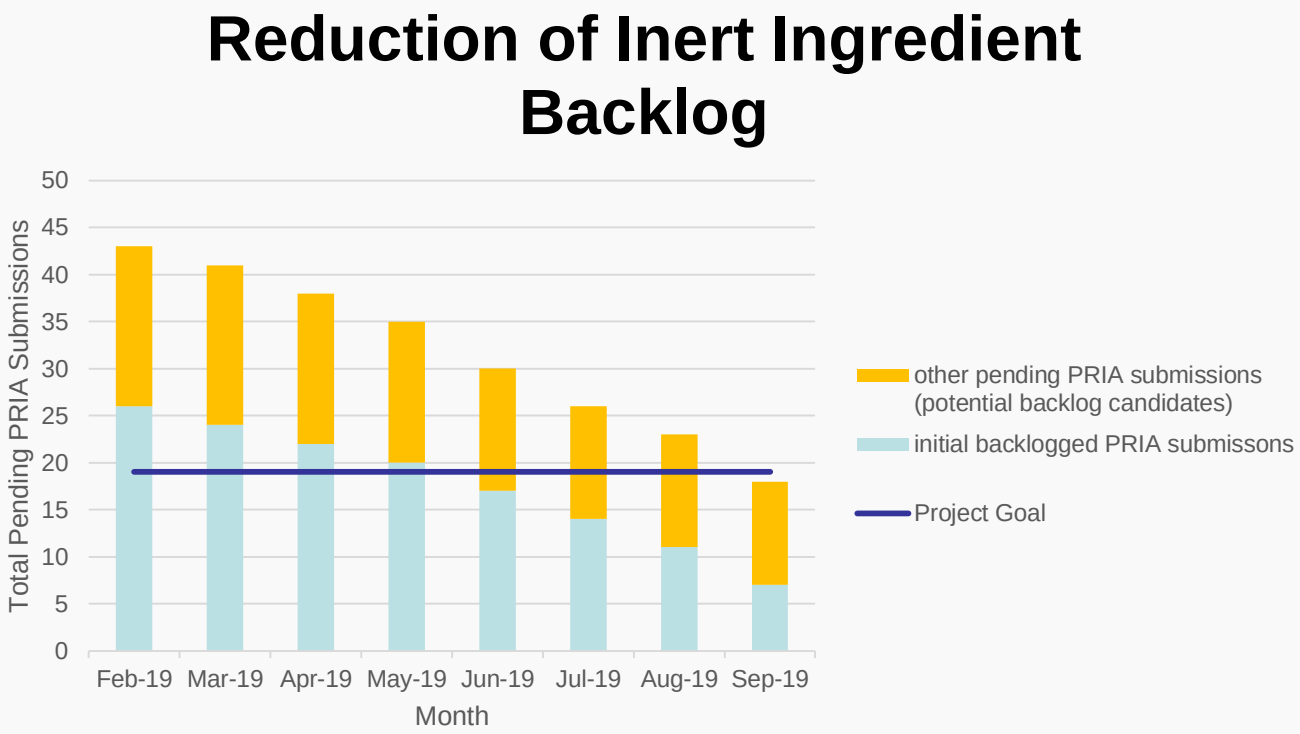


Review of New Inert Ingredient Submissions: The Challenge

- **Goal**: to use Lean tools to identify inefficiencies in the new inert ingredient review process with the goal of reducing the backlog of new inert ingredient submission reviews by 25% in FY ’19.

- **Result:** The project was successfully completed and a 31% reduction in the backlog of new inert ingredient submission reviews was achieved.

Review of New Inert Ingredient Submissions



Review of New Inert Ingredient Submissions: Process Improvement

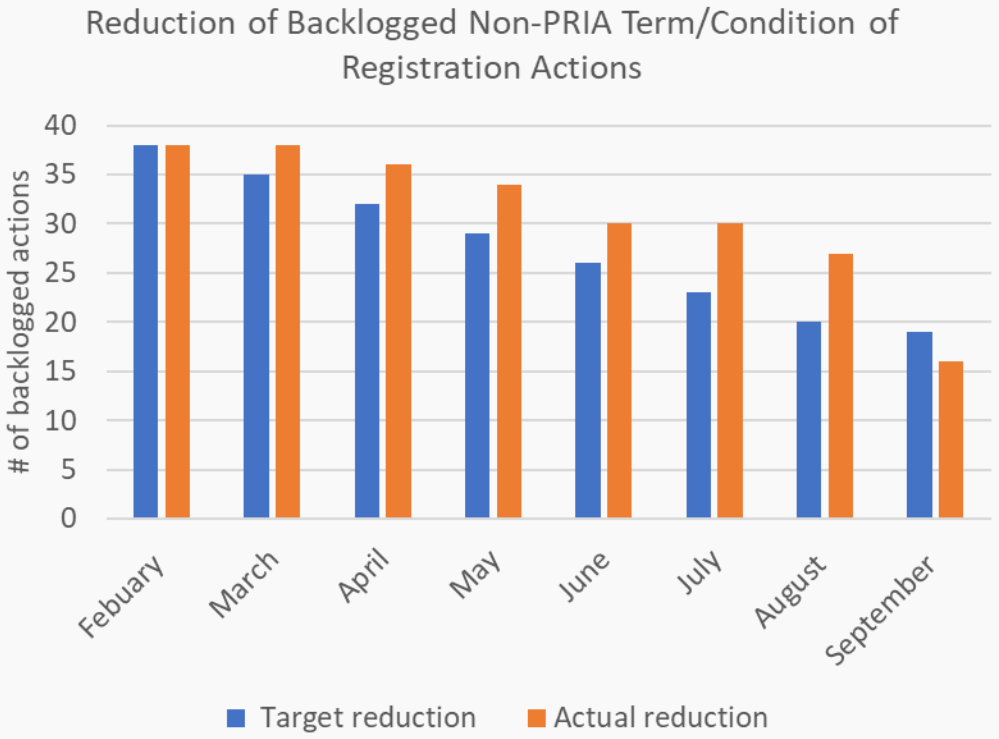
- Principles of value stream mapping were used to identify and remove or reduce waste in the value stream.
- Based on available data regarding the steps and associated timeframes in the existing process, three significant sources of waste were identified and corrected:
  - Waiting--the time periods in which individual inert ingredient submissions and/or reviews were not being actively worked on;
  - Conveyance--the mechanisms used to move between each of the discrete steps involved in the inert ingredient review; and
  - Processing--the overall procedure used to in-process an inert ingredient submission and produce a completed inert ingredient review.

BPPD A3 Project: Reduction of Non-PRIA Microbial Action Backlog

- BPPD developed a strategic approach using Lean management tools to address work on the non-PRIA microbial term of registration action backlog
- Improvement actions included developing a streamlined review (cover memo/DER) template and training an additional science reviewer
- Goal was to reduce the backlog of these actions by a minimum of 50% (starting with 38 backlogged actions) during the A3 project timeframe

BPPD A3 Project: Reduction of Non-PRIA Microbial Action Backlog Results

- BPPD completed 58% of the targeted actions during the project timeframe.
- Improvement actions have been implemented as permanent changes for the review of these actions.



IO/ITRMD A3 Project: Reduction of Time for Front End Processing

- **Goal**: Examine and improve the timeliness for EPA's internal workflow process for electronic pesticide applications submissions, in order to reduce the average time by which OPP staff receive pesticide applications to process;
- Specific to AD and BPPD applications
- Result: While a reduction in the front-end processing time was observed, more robust results are expected to be realized through the ongoing IT modernization effort.
  - Information gathered from this A3 project was utilized in the October front end processing ELMS event

Wrap-Up

- Summary of action items and proposed topics for next meeting;
- Scheduling of FY’20 quarterly stakeholder meetings

PRIA Points of Contact

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