



Update on EPA's Pesticide Program Activities

CPDA Regulatory Policy Conference
March 13, 2018

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Director, Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency



Discussion Topics

- Leadership and Organizational Changes
- Update on PRIA
- Registration Review Update
- Endangered Species Act
- Pollinator Protection Update
- Managing Pesticide Resistance
- Registration Actions for 2018
- Registration Efficiencies

Leadership and Organizational Changes





Office of Pesticide Programs

Rick Keigwin, Director
Arnold E. Layne, Deputy Director

Antimicrobials Division
Anita Pease, Acting Director
Steve Weiss, Acting Deputy Director

**Biological and Economic Analysis
Division**
Wynne Miller, Director

**Biopesticides and Pollution
Prevention Division**
Robert McNally, Director
Anne Overstreet, Acting Director

**Environmental Fate and Effects
Division**
Marietta Echeverria, Director
Kimberly Nesci, Associate Director
Mark Corbin, Acting Associate
Director

Field and External Affairs Division
Jackie Mosby, Director
George (Jeff) Herndon, Acting
Deputy Director

Health Effects Division
Dana Vogel, Director
Jeff Dawson, Deputy Director
Elissa Reaves, Associate Director

**Information Technology and
Resources Management Division**
Delores Barber, Director
Hamaad Syed, Deputy Director

Pesticide Re-evaluation Division
Yu-Ting Guilaran, Director
Billy Smith, Associate Director

Registration Division
Mike Goodis, Director
Dan Rosenblatt, Deputy Director
Donna Davis, Acting Deputy Director



Director – Michael Goodis

Immediate Office

Deputy Director - Dan Rosenblatt

Associate Director – Donna Davis (acting)

Amer Al-Mudallal, Tony Britten, Sherada Hobgood, Angela Hollis

<p>Invertebrate and Vertebrate Branch 1 Chief: Catherine Aubee <u>PM 3:</u> Kable Bo Davis <u>PM 4:</u> Beth Fertich -Matt Aubuchon -Julie Breeden-Alemi -Tim Ciarlo -Jennifer Gaines -Helen Hull-Sanders -Letu Kassa (Student) -Autumn Metzger -Maggie Ruddick -Jennifer Saunders (S.Ent.²)</p>	<p>Invertebrate and Vertebrate Branch 2 Chief: Marion Johnson <u>PM 10:</u> Richard Gebken <u>PM 11:</u> Michael Walsh -Eric Bohnenblust (on detail) -Byron Everhart (SEE¹) -Carlyn Petrella -Debra Rate(SRS³) -Carmen Rodia -Matthew Sellner -Betty Williams</p>	<p>Invertebrate and Vertebrate Branch 3 Chief: Meredith Laws <u>PM 1:</u> Venus Eagle <u>PM 7:</u> Gene Benbow -Melody Banks -Dee Colby -Marianne Lewis -Jackie Herrick -Vacant (SRS³)</p>	<p>Fungicide Branch Chief: Cynthia Giles-Parker <u>PM 21:</u> Hope Johnson <u>PM 22:</u> Tony Kish -Heather Garvie (SRS³) -Marcel Howard -Maryam Muhammad -Craig Reeves (SEE¹) -Lindsay Roe -Fatima Sow</p>	<p>Fungicide and Herbicide Branch Chief: Rachel Holloman <u>PM 20:</u> Shaja Joyner <u>PM 24:</u> Erik Kraft -Bewanda Alexander (SEE¹) -Aswathy Balan -Driss Benmhend -Nathan Mellor -Lisa Pahel -Eleanor Thornton -Vacant (SRS³)</p>	<p>Herbicide Branch Chief: Dan Kenny <u>PM 23:</u> Grant Rowland (acting) <u>PM 25:</u> Reuben Baris -Shanta Adeeb -Sarah Meadows -Mindy Ondish -Emily Schmid -Vacant (SRS³)</p>
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Chemistry, Inerts and Toxicology Assessment Branch
Chief: PV Shah

<p><u>Toxicology Team Leader:</u> Anwar Dunbar (acting) -Bonaventure Akinlosotu -Byron Backus -Princess Campbell -Tracy Keigwin -Eugenia McAndrew</p>	<p><u>Chemistry Team</u> Leader: Shyam Mathur -Akiva Abramovitch -Bruce Kitchens -Maria Rodriguez <u>SEE Employees</u> -Bill Herald -Linda Mascal -Sylvester George</p>	<p><u>Inerts Team Leader:</u> Kerry Leifer (PM 8) -Lisa Austin -Alga Debesai -David Lieu -Deirdre Sunderland -Janet Whitehurst</p>
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Minor Use and Emergency Response Branch
Chief: Tawanda Maignan (acting)

Minor Use Team Leader: Nancy Fitz (acting)
 Andy Ertman
 Sidney Jackson

Emergency Response Team Leader: Nikhil Mallampalli (acting)
 Stacey Groce
 Andrea Conrath
 Tamica Cain

1. SEE: Senior Environmental Employment Program. 2. S.Ent: Senior Entomologist. 3. SRS: Senior Regulatory Specialist.



FY 2018 OPP Priorities

Protecting Human Health and the Environment

- Meeting PRIA statutory deadlines
- Progressing the registration review program
- Advancing critical science and policy issues
- Working collaboratively with state partners and other stakeholders to implement program

Update on PRIA





Update on PRIA

- The expiration date of PRIA 3 was extended through the continuing resolution through late March 2018.
- The PRIA 4 legislation pending in the Senate extends the authorization to collect maintenance fees, at \$31M/yr through FY'20.
- H.R. 1029 passed unanimously in the House on March 20, 2017.
- On June 29, 2017, the Senate Agriculture Committee unanimously forwarded an amended bill extending authorization for 3 years. Currently, a hold is delaying vote by the full Senate.

Registration Review Updates





What is Registration Review?

- Statutory Mandate – FIFRA Section 3(g)
 - Requires review of each registered pesticide every 15 years
- Scope – ~725 “cases” encompassing over 1,100 pesticide active ingredients (A.I.)
 - Conventional, antimicrobial, and biopesticides
- Statutory Deadline – EPA must complete review of all pesticides by 10/1/2022



Registration Review Progress

- **Conventionals**
 - 277 draft risk assessments completed (~39% remaining)
 - 203 proposed interim decisions complete (~56% remaining)
 - 179 final or interim decisions complete (~61% remaining)
- **Antimicrobials**
 - 48 draft risk assessments completed (~66% remaining)
 - 44 proposed interim decisions complete (~68% remaining)
 - 39 final or interim decisions complete (~72% remaining)
- **Biopesticides**
 - 42 draft risk assessments completed (~67% remaining)
 - 42 proposed interim decisions complete (~67% remaining)
 - 37 final or interim decisions complete (~71% remaining)



Registration Review Status

- **Registration Review Deliverables**
 - 54 Draft Risk Assessments anticipated (15 In FY18 Q1)
 - 55 Proposed interim Decisions anticipated (2 In FY18 Q1)
 - 40 Interim Decisions anticipated (17 In FY18 Q1)
- **2018 High Profile Draft Risk Assessments**
 - Glyphosate, atrazine, paraquat, soil fumigants, neonicotinoids (final pollinator)
- **2018 High Profile Proposed Interim Decisions**
 - Glyphosate, neonicotinoids

Endangered Species Act





EPA Endangered Species Act

- In January 2017, EPA initiated consultation, issuing Biological Evaluations for chlorpyrifos, diazinon, and malathion.
- On December 29, 2017, NMFS issued the final Biological Opinion on potential effects of chlorpyrifos, diazinon, and malathion.
- The BiOp reaches “jeopardy” and “adverse modification” conclusions for 38 federally listed threatened or endangered species and 37 critical habitat units.



ESA Interagency Working Group

- On January 31, 2018, a Memorandum of Agreement was signed by EPA, DOI (includes FWS), DOC, and NMFS, establishing an Interagency Working Group.
- The Working Group will provide recommendations to EPA, FWS and NMFS leadership on improving the ESA consultation process for pesticide registration and registration review.

Pollinator Protection Update





EPA's Final Acute Mitigation Policy

EPA's Policy to Mitigate the Acute Risk to Bees from Pesticide Products - issued January 12, 2017

- Two Mitigation Strategies:
 1. **Label Restrictions for Contract Pollination Services**
 2. **State and Tribal Managed Pollinator Protection Plans (MP3s) for Bee Colonies Not under Contract Pollination Services**
- Prohibits pesticide applications under certain conditions
- Also provides some flexibility for growers in some circumstances

<https://www.epa.gov/pollinator-protection/policy-mitigating-acute-risk-bees-pesticide-products>



Acute Risk Mitigation Policy

- Applies to Products:
 - With outdoor foliar uses;
 - That are registered for crops that may use pollination services; and,
 - With uses that have application rates that exceed the EPA Tier I acute risk Level of Concern (LOC) for bees
- Policy Applies When:
 - The target crop is in bloom;
 - A contract exists for pollination services to the target crop; and,
 - Managed bees are present under contract for pollination services to the target crop

Managing Pesticide Resistance





EPA New Guidance

- **PRN 2017-1, entitled “Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling:”**
 - provides general guidance on resistance management labeling for all conventional agricultural insecticides, fungicides and herbicides
 - revises an existing Notice (2001-5), that provides general guidance to registrants of all pesticides, except Bt crops and homeowner-use products
- **PRN 2017-2, entitled “Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship:”**
 - new Notice that focuses on guidance for herbicide registrants
 - provides guidance for labels, terms of registration, education, training and stewardship



Next Steps

- **For registration review** - implementing herbicide-resistance measures for existing herbicides:
 - Registration review will include herbicide-resistance elements in every herbicide proposed interim and final decision
- **For registration actions** - implementing herbicide-resistance measures for all end-use herbicide products:
 - commercial turf and sod farms
 - ornamental production and non-agricultural use
 - aquatic vegetation
 - rights-of-way and vegetation management

Continuing to Move Registration Actions Forward in FY18





FY'18: On-Time Completion Rates

Type of decision	FY'18 Late Completions (through February)	FY'18 Rate of on-time Completions (through February)	FY'17 Rate of on-time Completions	FY'16 Rate of on-time Completions	FY'15 Rate of on-time Completions
Antimicrobial	0	100%	99.7%	99.4%	96%
Biopesticide	0	100%	98.8%	97.4%	98%
Conventional	2	99.5%	98.7%	98.6%	99%
Inert	0	100%	95.2%	95.9%	96%
Misc	1	99.5%	99.8%	99.8%	99%
Total	3	99.6%	99.1%	98.9%	98%



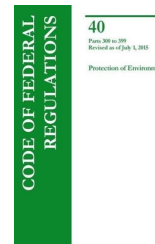
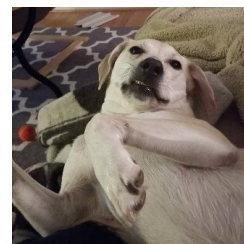
PRIA Renegotiations

FY	Antimicrobials	Biopesticides	Conventionals	Misc.	Inerts
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%
2017	26/338 = 7.7%	22/163 = 13.5%	197/937 = 21.0%	0/544 = 0%	16/42 = 38.1%
2018 thru 2/18	2/146 = 1.4%	7/63 = 11.1%	93/404 = 23.0%	0/201 = 0%	7/15 = 46.7%



Efficacy Activities Related to PRIA 4

- Draft premises and fire ant guidelines are available for public comment until 3/30/18 and will go to the SAP in May 2018 (PRIA 4 due date 9/30/20 and 3/30/21, respectively)
 - Will be more specific than the current 1998 guidelines and will include additional study types (e.g. Hymenoptera nests, fly baits)
- Draft pests of pets guideline is under internal review with the goal of going to the SAP by June 2019 (PRIA 4 due date 3/30/20)
 - Will include more modern technologies not found in the 1998 guideline (e.g. spot ons)
- Product performance rule reg text is being drafted based on public and SAP comments (PRIA 4 due date 9/30/20)
 - Will include performance standards and representative species for efficacy testing





Pet Spot-On Enhanced Reporting Pilot

- Objectives:

- Develop standardized templates that can be used by registrants for submission of enhanced incident reporting and sales information
- Template acts to ensure the submission of incident data is in a consistent format using consistent terminology making statistical analysis of the data achievable

- Results:

- Pilot results demonstrate that use of the standardized templates is feasible, and provides data in a format that can be analyzed in a meaningful way.

- Next Steps:

- May 10, 2018 from 1:00-3:00 PM EST: Planned open stakeholder webinar to conclude the Pilot and discuss implementation of standardized template use.



Updates to Pesticide Registration Notice 98-10

- Status of Updated PRN on Notifications
 - Updated PRN published in Federal Register on 9/5/17, comment period extended for 60-days to 12/5/17.
 - Agency requested comments on use of PRN to address product ingredient disclosure
 - Agency requested impacted parties to provide through comments available information on projected cost implications of this draft updated guidance.
- Next Steps
 - Consider comments received
 - Revise PRN as needed
 - Brief OMB on revised PRN
 - Finalize and publish PRN

Registration Efficiencies





SmartLabel Project Deployment and Implementation

- Production ready system is near completion
- Field test with Pilot participants in 2018
 - Will inform and prepare for official launch of SmartLabel
 - Objective: 2018 Launch
- Methodical implementation
 - Integration of SmartLabel applications into current workflows (Label + Use Index)
 - Build database of all registrations (~20,000 products)
 - Improvements in review and approval
 - Develop requirements for submission of SmartLabels for all registrations



Chemistry and Acute Toxicology Science Advisory Council (CATSAC)

CATSAC's mission: Formerly the "Similarity Clinic"

- To ensure that current standard practices and policies are consistently applied to similarity decisions and in reviews of product chemistry, acute toxicity, and alternative assays across OPP's registering divisions (RD, AD, BPPD).
 - saves animals and resources by eliminating unnecessary testing of animals and review of redundant acute studies.
- CATSAC consists of:
 - Chemists/Toxicologists/Regulatory Scientists
 - RD/AD/BPPD
- Waiver rationales that are in the "grey" area or for which a denial is recommended are **required** to go to CATSAC. Waivers accepted by reviewer are not typically taken to CATSAC, the reviewer has option of bringing questions concerning waivers to the group



CATSAC

- Standard Operating Procedure (SOP) is final;
 - Divisions have been following SOP;
 - All rejections are reviewed by CATSAC;

- Standard Evaluation Procedure (SEP) development continues;
 - purpose is to give guidance on both product chemistry and acute toxicity evaluation process;
 - provide common definitions and terminology such as 100% repack, identical products, substantially similar products, and potential for bridging data;
 - SEP will require multiple levels of review;



Group B- Physical/Chemical Properties Self-Certification

- Pesticide Registration (PR) Notice 98-1
 - Self-Certification Program
 - Applicants can submit one-page summary physical/chemical properties
 - No longer required to submit study upon which the summary is based
 - <https://www.epa.gov/pesticide-registration/prn-98-1-self-certification-product-chemistry-data-attachments>



Group B- Physical/Chemical Properties Self-Certification

- Simplifies and accelerates processing of applications
- Reduction of paperwork
- Saves time, effort, and resources
- Currently, RD receives ~30% self-certifications with new registrations



Thank You!