Updates for the Pesticide Program Dialogue Committee

Office of Pesticide Programs
U.S. Environmental Protection Agency

February 25, 2015

Welcome and Opening Remarks

Jack Housenger, Director
Office of Pesticide Programs

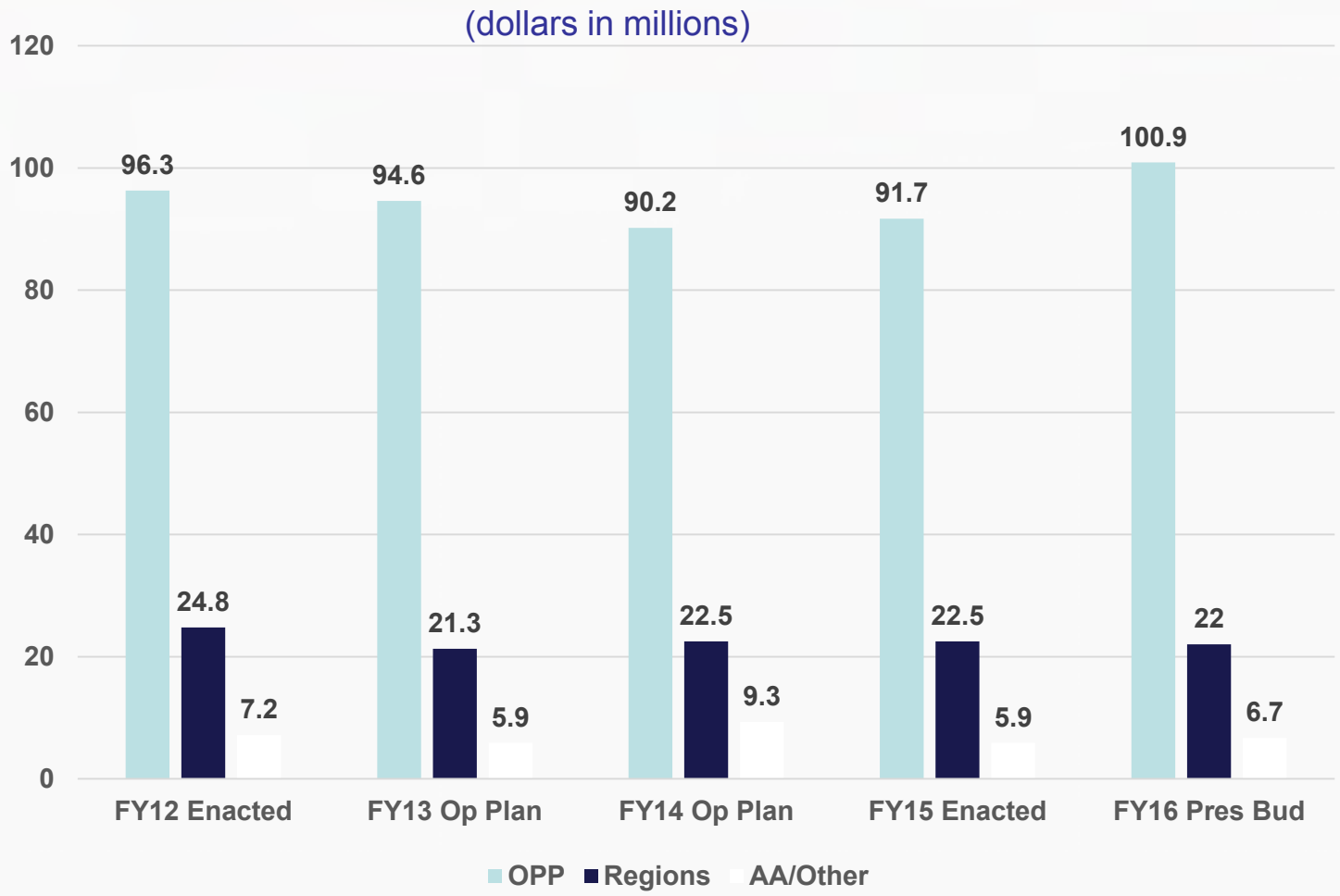
Agenda topics:

- Budget Update
- Chlorpyrifos: Revised Human Health Risk Assessment
- Pollinator Protection Activities
- Enlist & Managing Herbicide Resistance
- Corn Rootworm: EPA's Proposal
- Regulatory Look Back Initiative
- Membership Information
- Closing Thoughts

Budget Update

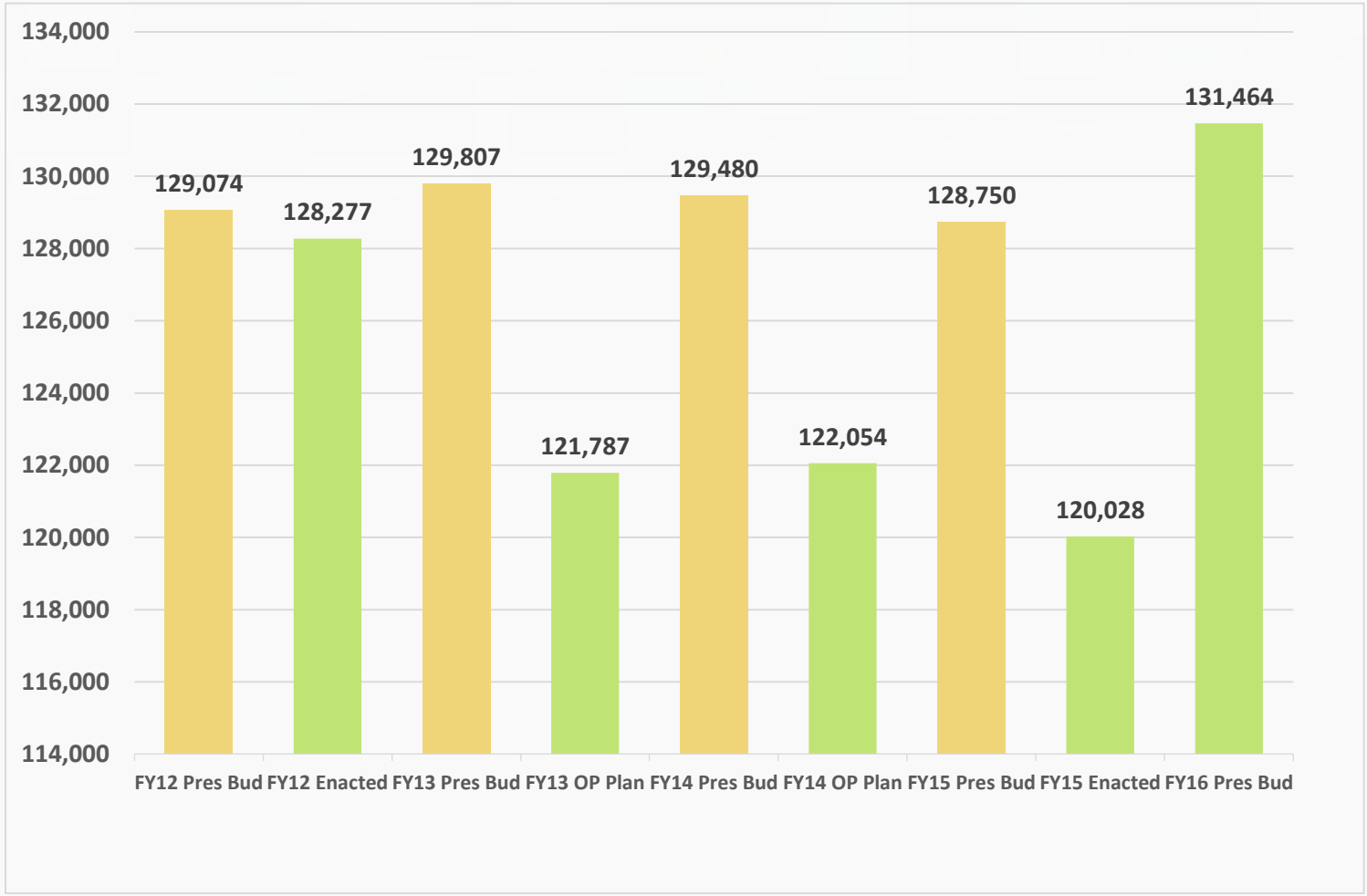
Marty Monell, Deputy Director
Office of Pesticide Programs

FY 2012 – FY 2016 Appropriation's Budget

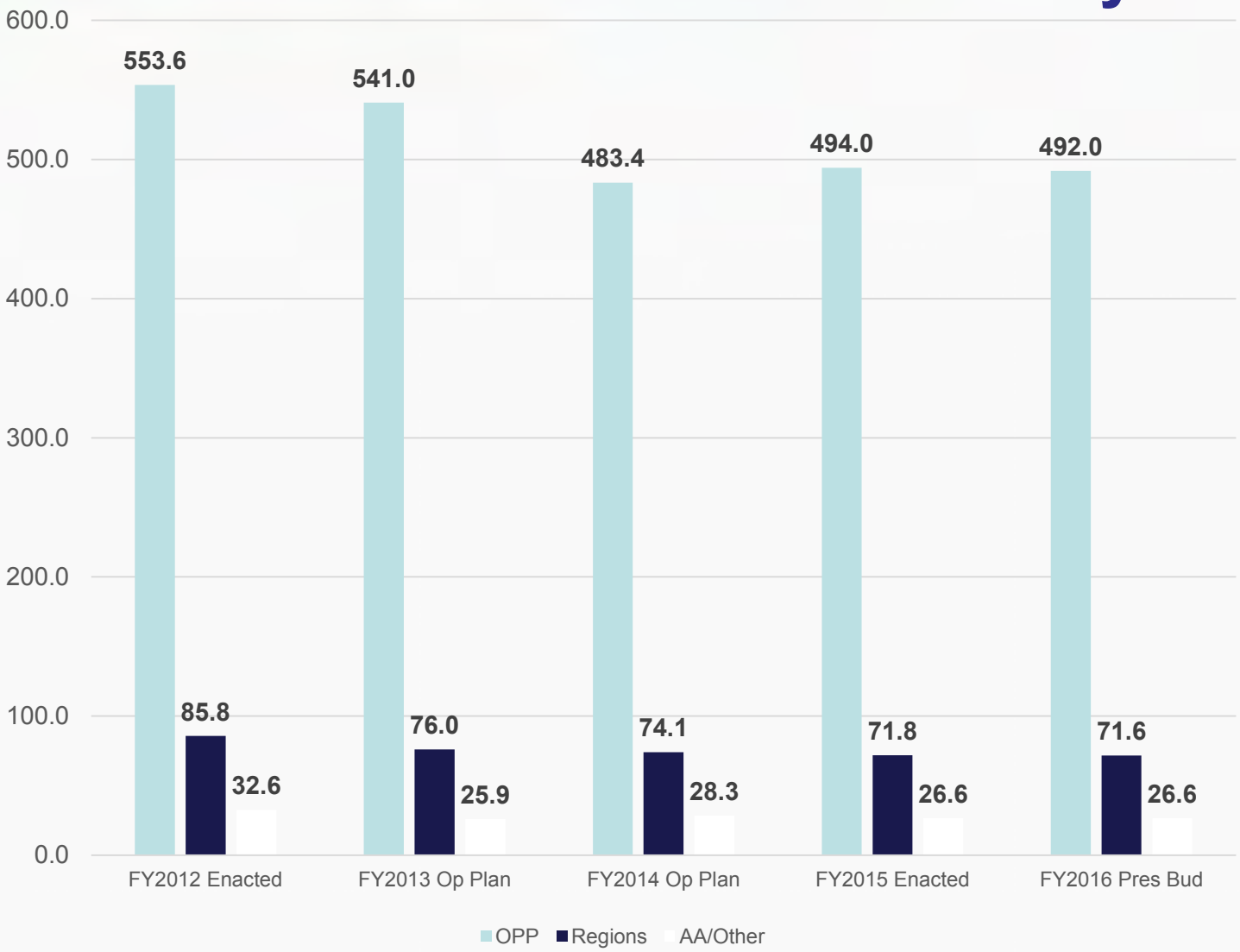


FY 2012 – FY 2016 Minimum Appropriations

(in thousands)



FY 2012 – FY 2016 FTE Summary

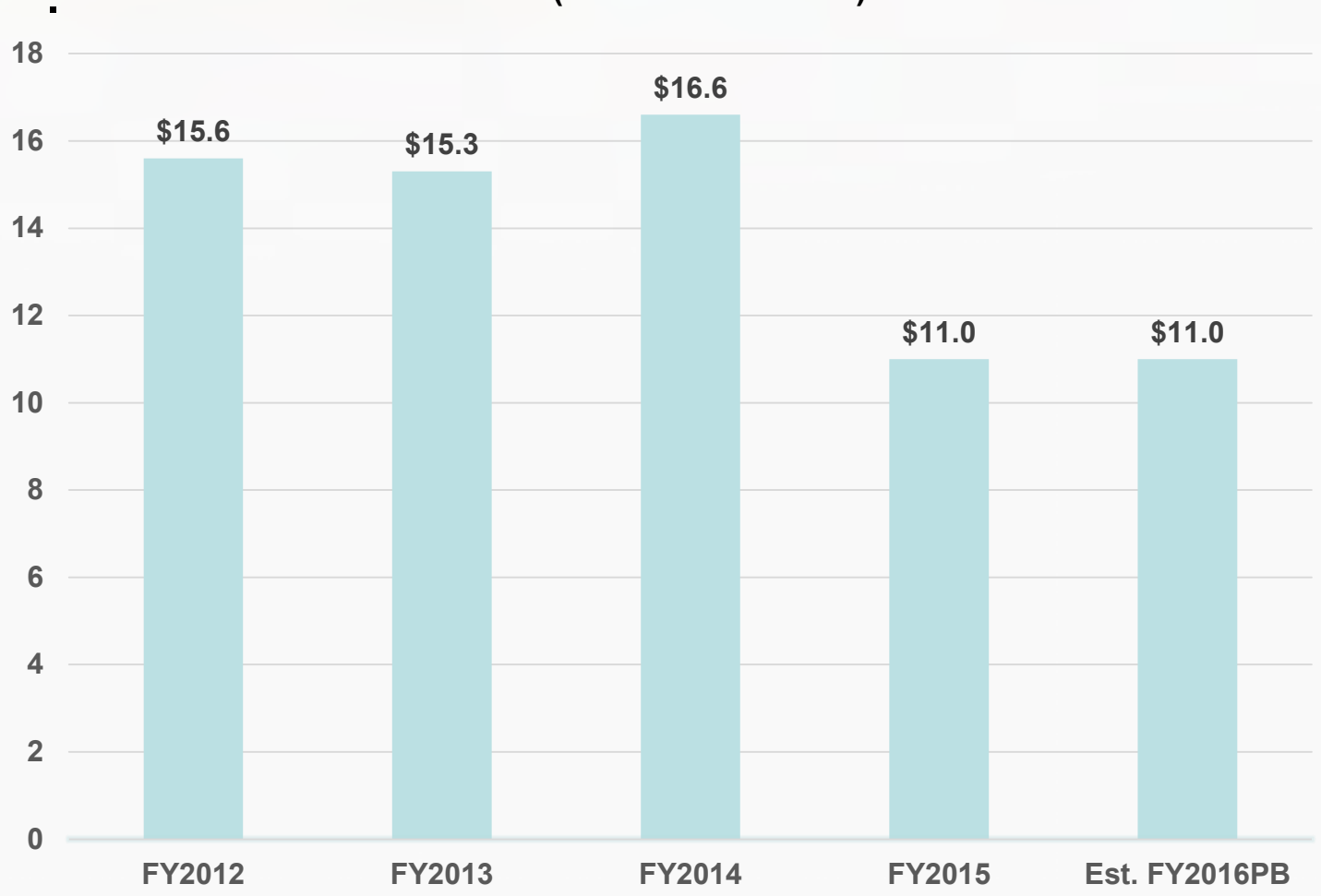


Authorized Pesticide Fees

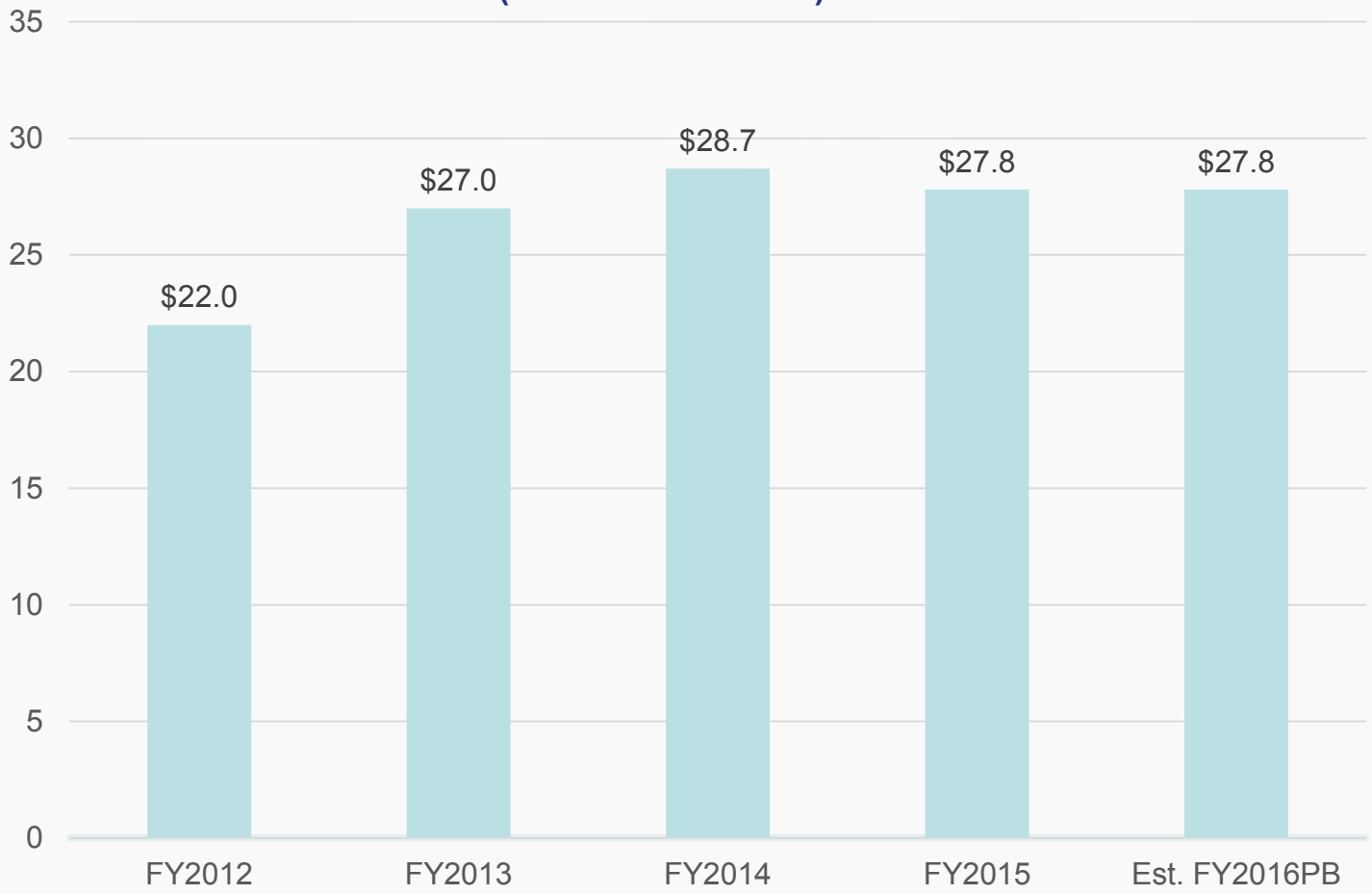
Fee	$ collections	Comments
Registration Service Fees	$15.6M in FY12; $15.4M in FY13; $16.6M in FY14; estimated collections in FY15 ~$11.0M	●Funds both tolerance petitions and other registrations. ●Collections depend on number of applications. ●Contains minimum appropriation provision. ●Deposited into 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	$22.0M in FY12; $27.0M in FY13; $28.3M in FY14; estimated collections in FY15 $27.8M	●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) o reviews of inerts and expedited processing of similar applications. ● $.8M authorized for IT Improvements

FY 2012 – FY 2016 PRIA Fee Collections

(dollars in millions)



FY 2012 - FY 2016
FIFRA Maintenance Fees Collected
(dollars in millions)



Next Topic:
Chlorpyrifos: Revised Human Health Risk Assessment

Joel Wolf, CRM, Pesticide Re-evaluation Division
Anna Lowit, Senior Scientist, Health Effects Division
Dana Spatz, Chief, ERB III, Environmental Fate and Effects Division

Introduction

Chlorpyrifos Revised Human Health Risk Assessment (RHHRA)

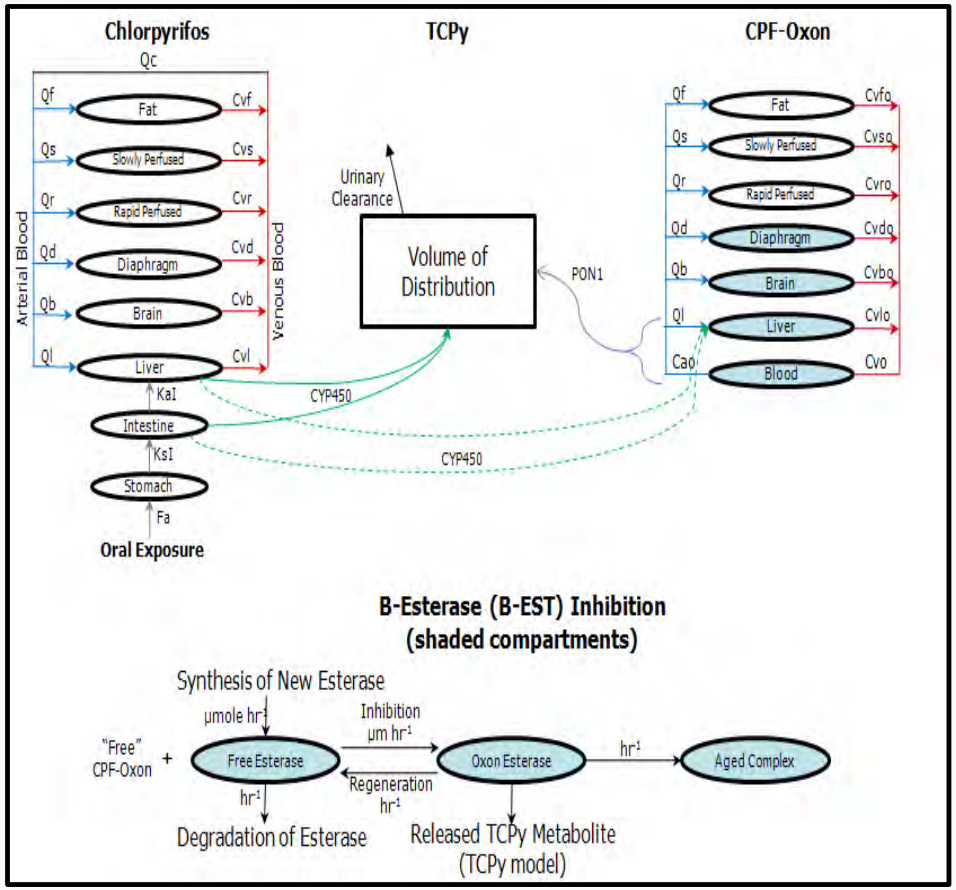
- –Released for 60-day public comment period, 1/14/15
- –Among 1st Assessments
  - Informed by PBPK/PD model
  - Utilizing water intake watershed approach for drinking water
    - –National level assessment with 2 regional screens (Pacific NW & South Atlantic Gulf)

Introduction cont.

RHHRA shows:

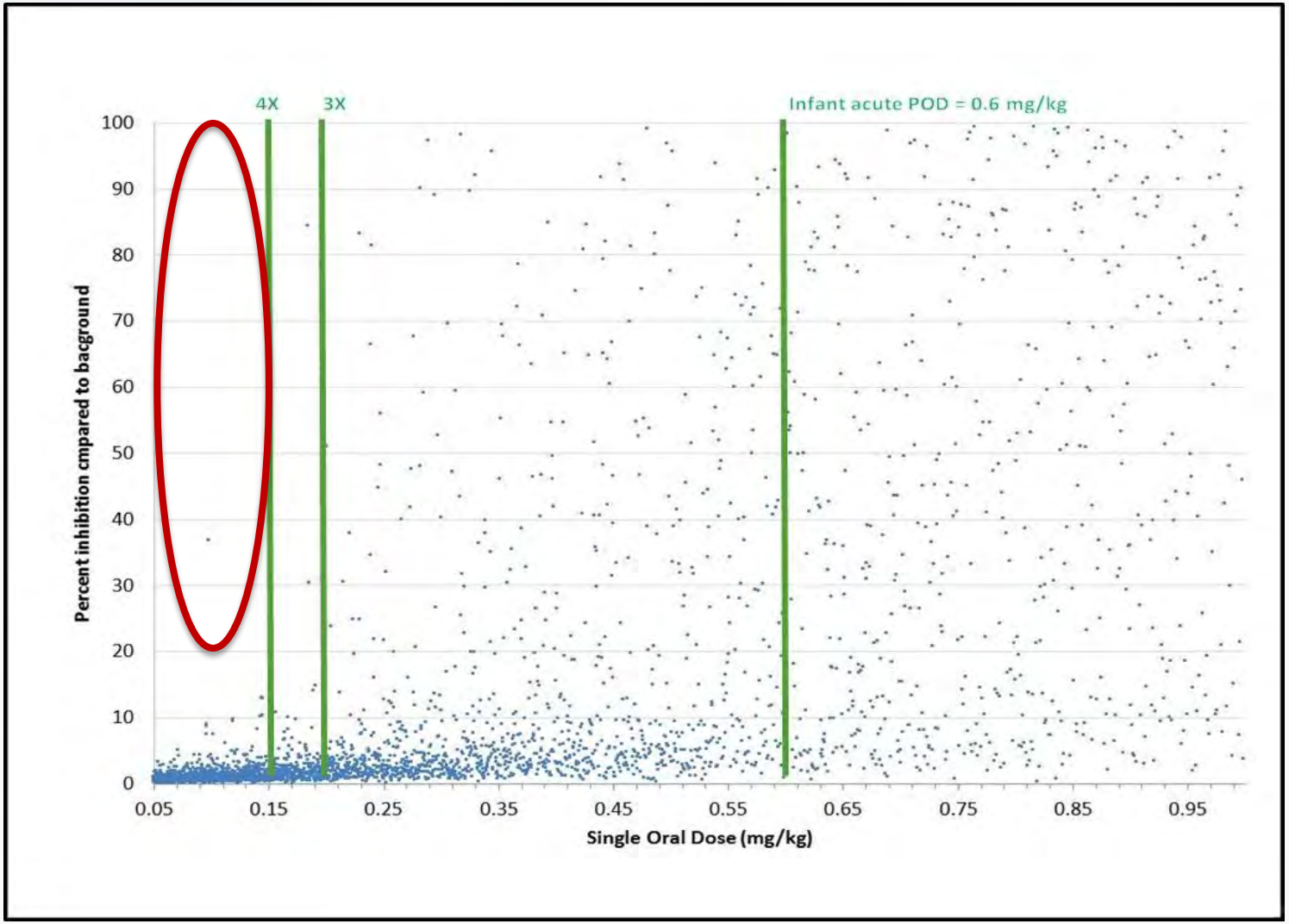
- Risk concerns
  - –Workers - mixers, loaders, and applicators
  - –Drinking water – small watersheds
- No additional risks
  - –Dietary (food only)
  - –Bystanders from airborne chlorpyrifos

Chlorpyrifos PBPK-PD Model



- Descriptions of metabolism to account for the key moieties (chlorpyrifos, the oxon, TCPy) in liver, blood, brain, small intestine, lungs, diaphragm, and skin.
- Parameterization for cholinesterase activities and inhibition in brain, diaphragm, liver, lungs, plasma, and RBC.
  - >120 parameters
- Variation model produces a range of responses that reflect differences in physiology, metabolism, and activity levels.
- Quantitatively integrates age-dependent parameters which allows for simulations of human exposures to chlorpyrifos across for infants, toddlers, adults.

- Based on the 99th-%ile of the simulations, intraspecies extrapolation is 4X for chlorpyrifos and 5X for the oxon



Intra-species Extrapolation

- With respect to the pregnant dam during gestation:
  - Metabolic activities and physiological parameters can be altered during pregnancy.
- The changes in physiology associated with pregnancy require completely different equations that are not included.

  - We are using a 10X intra-species extrapolation factor for pregnant women.

FQPA 10X Safety Factor

- Based largely on epidemiology studies, exposure to chlorpyrifos contributes to adverse neurodevelopmental outcomes in humans.
- The lack of an established MOA/AOP and timing of exposure measurements makes quantitative use of the epidemiology study in risk assessment challenging, particularly with respect to dose-response, duration of exposure, and window(s) of susceptibility.
- The cord blood levels in the range measured in the epidemiology studies (pg/g) are likely low enough that is unlikely to result in AChE inhibition
  - supported by the dose reconstruction analysis of residential use prior to 2000
- Remaining uncertainties preclude definitive causal inference.
- However, there is sufficient uncertainty in the human dose-response relationship for neurodevelopmental to *retain the FQPA 10X Safety Factor*

PBPK-PD Model and Risk Assessment

- PBPK-PD model was used to establish an exposure scenario- and route-specific PoD predictive of 10% RBC AChE inhibition
  - Dietary (food, drinking water), residential, and occupational exposures modeled
- Varying inputs on types of exposures and populations exposed
  - Duration [acute, 21 day (steady state)]
  - Route: dermal, oral, inhalation
  - Body weights vary by lifestage
  - Exposure Time: hours per day, days per week
  - Exposure Frequency: events per day (eating, drinking)

Residential Assessment

- Residential assessments were performed for golf course turf & mosquito adulticide
- Bystander scenarios were also considered
- No risk concerns were identified which require further mitigation
  - E.g., no change needed for existing bystander buffer distances.

Occupational Handler Assessment

- A total of 285 handler exposure (dermal and inhalation) scenarios assessed:
  - 132 scenarios are not of concern (i.e., MOEs are ≥ 100) at current product label requirements.
  - 27 scenarios can be mitigated with personal protective equipment (PPE) or engineering controls.
  - **126 scenarios out of 285 remain a concern** regardless of the PPE and engineering controls considered.
    - Risk mitigation could involve the use of additional PPE, engineering controls, and other options such as changing application rates or limiting equipment.

Occupational Post-Application Assessment

- Occupational post-application risks were assessed for all registered crops.
- Currently labeled Restricted Entry Intervals (REIs) range from 24 hours to up to 5 days after application.
- Based on the assessment, the current REIs are sufficient for most crop scenarios (43 of 55).
- However, some crop/formulation combinations will require an REI increase.

Dietary Assessment

- Acute and steady state dietary (food only; parent chlorpyrifos only) assessments were performed using DEEM and Calendex models.

- Refinements include:
  - USDA's PDP monitoring data
  - Percent crop treated estimates
  - Empirical food processing factors
  - Probabilistic analysis

- Results: Acute and steady state dietary (food) risk estimates are not of concern (<100% of PAD) for any population subgroup at the 99.9th percentile of exposure.

Aggregate Assessment

- A Drinking Water Level of Comparison (DWLOC) approach was used to calculate the amount of exposure which could occur without exceeding the risk level of concern (i.e., the available space in the total aggregate risk cup for exposures to chlorpyrifos oxon in drinking water after accounting for exposures to parent chlorpyrifos from food and residential uses).

- The calculated DWLOCs are compared to the estimated drinking water concentrations (EDWCs) of oxon modeled under a variety of conditions.

- The lowest DWLOC calculated was 3.9 ppb (for infants <1 year old).

- Several screening level EDWCs exceeded 3.9 ppb. The highest exposures generally occur in small hydrologic regions where there is a high percent cropped area of chlorpyrifos use.

Drinking Water Assessment

Background

- Update to the June 2011 Drinking Water Assessment
- Chlorpyrifos and chlorpyrifos-oxon
- Rapid conversion to chlorpyrifos-oxon upon disinfection (e.g., chlorination)

"A range of chlorpyrifos uses can lead to high levels (>100 ppb; peak) of chlorpyrifos in surface water that could be used by community water systems to supply drinking water."

77 currently labeled uses

21-day average concentration

DWLOC: 3.9 ppb (oxon)

Brief Use Profile Summary	
Maximum Single Application Rate (lb a.i./A)	
6	citrus
4	orchards, peanut
3	orchards, corn
2.3	citrus, turnip
2	orchards, peanut, mint, strawberry, grapes, pineapple…
1	alfalfa, corn, soybean, wheat…

National Screening Level Assessment

Bulb onion - does not exceed the DWLOC

Tart cherry - exceeds the DWLOC

When only one application is considered, there are still a number of use scenarios that exceed the DWLOC

EDWCs are not expected to be uniform across the country – variations in use scenarios and site vulnerability

Regional Screening Assessment

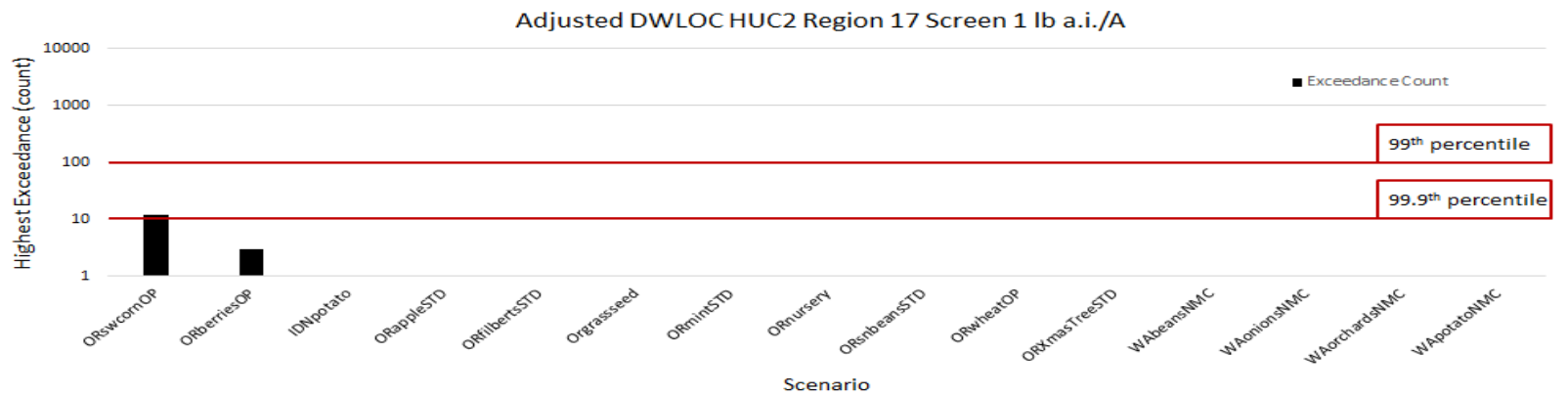
South Atlantic-Gulf (HUC2 Region 3)

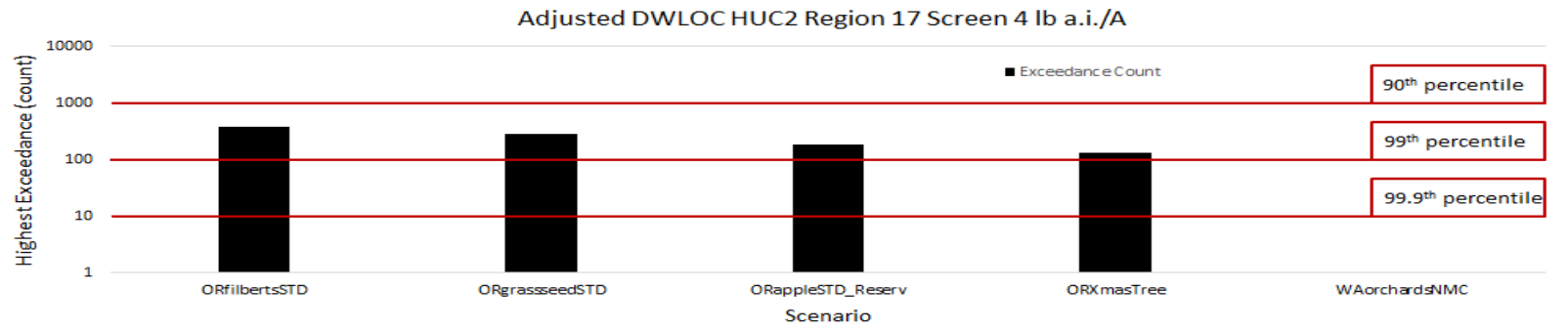
Regional DWI PCA = 0.65

Pacific Northwest (HUC2 Region 17)

Regional DWI PCA = 0.74

Regional Screening Assessment: Pacific Northwest





Exposure Conclusions

Modeled concentrations exceed the DWLOC many times for a wide range of chlorpyrifos uses

Factors that influence concentrations

- –Site vulnerability (regional variability)
- –Application rate

When model inputs are adjusted to reflect actual use scenarios, the results compare well with monitoring data

Next Steps

- Engaging registrants and growers on mitigation
- Comment period extension anticipated
- Ecological assessment in Aug/Sept timeframe

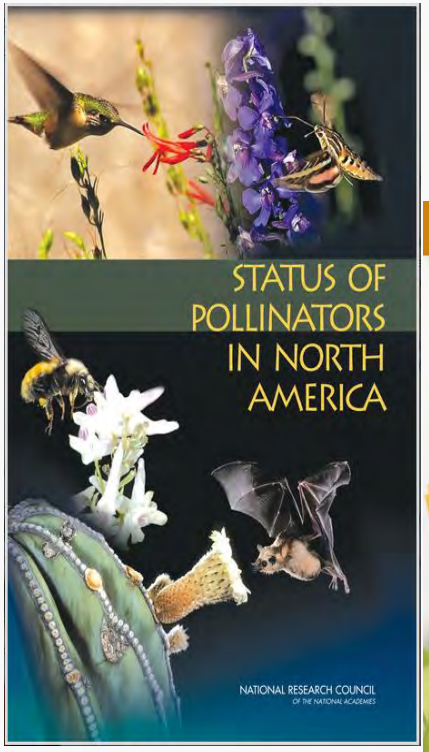
Next Topic:
Pollinator Protection Activities

Marietta Echeverria, Chief, Invertebrate-Vertebrate Branch
Registration Division

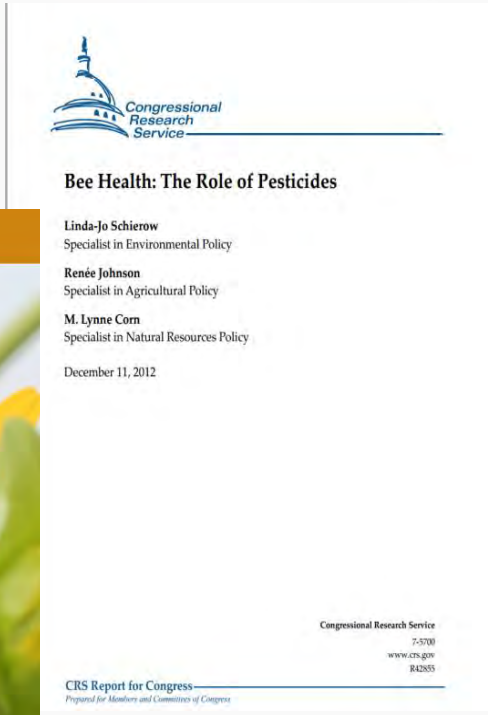
Michael Goodis, Associate Director
Pesticide Re-evaluation Division

Background

- Multiple federal reports have identified pollinator declines



http://www.nap.edu/openbook.php?record_id=11761



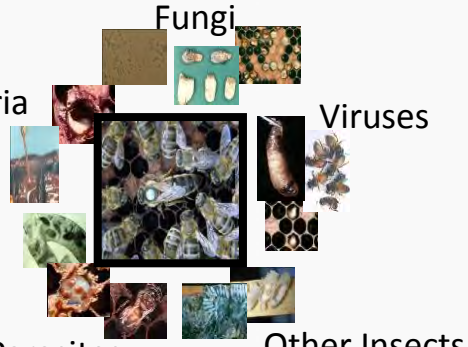
https://www.fas.org/sgp/crs/misc/R42855.pdf

http://www.nap.edu/openbook.php?record_id=11761

Background

USDA has identified multiple factors associated with pollinator declines; no single factor identified as “cause”

Disease/Parasites



Agricultural Practices

Urbanization

Bee Management Practices

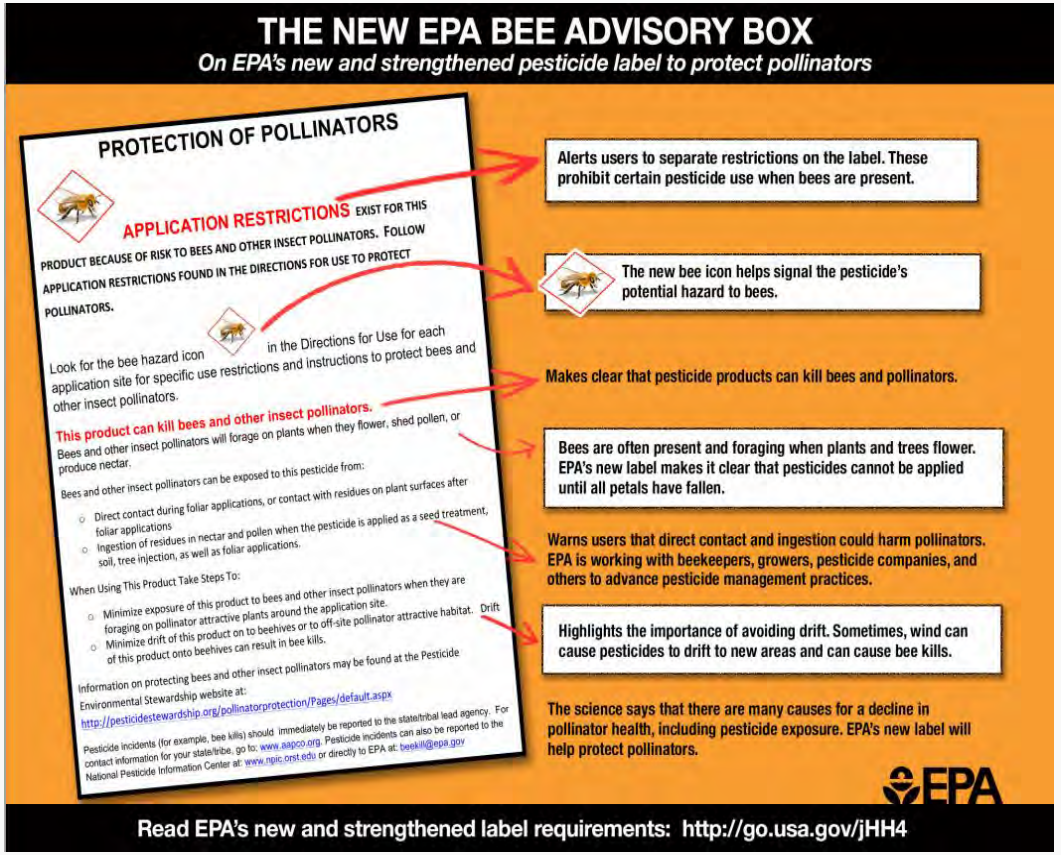
Pesticides

Nutrition

Source: USDA Agricultural Research Service

Improved Labeling

- In response to stakeholder concerns regarding improved label language, EPA developed pollinator protection language that has been applied to the neonicotinoid insecticides
- Pesticide labels on these products will continue to retain more restrictive language
- EPA committed to evaluating whether similar measures should be taken for other pesticides acutely toxic to bees



Presidential Memorandum

- On June 20, 2014, President Obama issued a memorandum directing the executive branch to develop a pollinator health strategy
- The memorandum also created a Pollinator Health Task Force chaired by USDA and EPA
  - Membership on the task force includes the State Department, DOD, DOI, HUD, DOT, DOE, Education, FEMA, NASA, the Smithsonian, OMB, and other parts of the Executive Office of the President
- Strategy is being developed
  - Research Plan
  - Education Plan
  - Public-private partnerships

EPA Requirements in the Presidential Memorandum

- **Assess the effects of pesticides on pollinator health**
- **Engage states and tribes in the development of pollinator protection plans**
- Encourage the incorporation of pollinator protection and habitat planting activities into green infrastructure and Superfund projects
- Expedite review of registration applications for new products targeting pests harmful to pollinators
- Increase habitat plantings around Federal facilities

State Pollinator Protection Plans

- Several states have been working through this issue prior to the Presidential memo by engaging stakeholders and developing state pollinator protection plans
  - Key stakeholders include growers, applicators and beekeepers
  - Input from researchers
  - Examples of states with pollinator protections plans: California, Colorado, Florida, North Dakota, Mississippi
  - Many other states are starting the stakeholder process to develop plans
- These plans serve as examples of effective communication and collaboration between stakeholders at the local level
- Plans can establish local and appropriate agreements and best practices for managing needs of agriculture and beekeepers

Engaging Co-Regulators – States and Tribes

- Actively engaged in understanding how they may contribute to and complement federal efforts on pollinator protection
- Recent meetings with SFIREG have focused on proposed label changes related to pollinator protection and pollinator protection plans
- Letter to AAPCO President, SFIREG chair, TPPC chair expressing interest working with these groups
- Similar discussion with the Tribal Pesticide Program Council

Mitigation Options

- EPA is considering label restrictions to protect bees under contracted services at the treatment site
- EPA is considering alternative mitigation and role of pollinator protection plans to protect bees in the vicinity of other treatment sites
- Considering methods to evaluate effectiveness of pollinator protection plans
- SFIREG drafted guidance document for states to develop plans

Mitigation Options

- EPA will seek public input on proposed mitigation
- Goal is for states/tribes to start pollinator protection plan development where appropriate in 2015
- EPA will continue to conduct chemical-specific risk assessment according to risk assessment framework for bees and will consider additional mitigation as needed

Next Topic:
Enlist & Managing Herbicide Resistance

Daniel Kenny, Chief
Herbicide Branch
Registration Division

Introduction

- EPA's goal is to extend the useful life of chemicals used for pest control by slowing the development of resistance to herbicides (and other pesticides)
- Weed resistance is a complicated issue
  - Competing interests and multiple stakeholders
  - Economic issues
  - Social issues
  - Everyone is a stakeholder, including EPA, and part of the solution

Legal Authority Under FIFRA

- USDA/APHIS/Biotechnology Regulatory Services makes deregulation decision on genetically modified crops
- FIFRA is a risk and benefit statute
  - Risk of resistance may be considered as part of the regulatory decision
- OPP licenses the pesticide for use on genetically modified or conventionally bred crops
  - Establishes terms and conditions of the registration with the registrant
  - Approves product label for users (growers, applicators, and consultants)

Aspects for Consideration in a Successful Weed Resistance Management Framework

- Involves all stakeholders
- Allows flexibility to local conditions
- Growers utilize Best Management Practices, e.g. those developed by WSSA and HRAC
- Promotes early detection and containment
- Involves open communication among all parties
  - Education and training programs are readily available to growers
  - Materials provide a consistent approach that reflects the latest information
  - Communication about where resistance is occurring
- Extends the useful life of the pesticide and preserves the technology

Aspects for Consideration in Growers' or Consultants' Roles in Resistance Management

- Growers and consultants must be proactive
- Identification of "likely resistance"
  - Scouting before application for identification and growth stage
  - Scouting after herbicide application to look for poor performance or likely resistance
- Investigation and follow up for cases of "likely resistance"
- Remediation of the problem
- Communication to registrant or representative when problems are found
- Utilize education and training materials (e.g. from registrant, WSSA, Extension, etc)

Aspects for Consideration in a Registrants' Roles in Resistance Management

- Registrants must be proactive
  - Registrant must follow terms and conditions of registration
- Labels must include MOA and generally agreed upon best practices
- Establish and implement stewardship plan which includes resistance management elements designed by the registrant
- Communication to growers/stakeholders when problems are found
  - Report to growers/stakeholders (facilitate behavior change)
  - Report to EPA (are regulatory actions working)
- Develop educational materials and promote adoption of BMPs
- Develop and implement remediation plan when likely resistance is found
- Work to develop rapid diagnostic tests for resistance

EPA's Emerging Role

- EPA seeks more collaborative interactions on resistance management with societies, RACs, consultants, extension, NGOs, registrants, researchers, state and federal partners
- Gain an understanding of resistance management that can be applied to weeds (and other pesticides)
- Common understanding of resistance and its causes
  - For example a better appreciation what each group can contribute towards managing resistance
- EPA will require specific measures to address weed resistance on all new registration actions for herbicide resistant crops
- Utilize the registration review process to strengthen resistance management for pesticides including glyphosate

Label: Proposed Resistance Management Elements

- Because early identification of problems is critical to managing resistance the following items will be placed with the directions for use so that they are clearly visible
- User or consultant:
  - –Scout before application to identify weed and size
  - –Scout after application determine if application was effective
  - –Report of poor performance / likely resistance to registrant or their representative

Terms of Registration - Proposed Resistance Management Elements

- Develop a Stewardship Program
- Develop Training and Education materials
- Investigate cases of non-performance
  - Use Norsworthy et al. criteria for determining likely herbicide resistance
- Develop a Remediation Plan for use if resistance is suspected
  - Registrant must take immediate action to control likely resistant weeds
  - Thorough follow up to make sure problem is addressed

Terms of Registration - Proposed Resistance Management Elements (cont'd)

- Annual reporting of likely and confirmed resistance to EPA
  - Enough information to describe nature and extent of infestation
  - Early notification is important
  - Separate from 6(a)(2) reporting (adverse effects) but this would report confirmed resistance - too late
- Reporting of likely and confirmed resistance to other stakeholders
- Work to develop a rapid diagnostic system for resistance

Next Steps

- EPA will require specific measures to address weed resistance on all new registration actions for herbicide resistant crops
- Other pending registration actions include:
  - –2,4-D resistant cotton
  - –Dicamba resistant soybean and cotton
- Pending registration review
  - –Glyphosate

Next Topic:
Corn Rootworm: EPA's Proposal for Addressing Resistance and Public Participation

Kimberly Nesci, Chief, Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division

Jeannette Martinez, Biologist
Biopesticides & Pollution Prevention Division

5 Elements of EPA proposal to Improve CRW IRM Program for Bt corn

1. Utilize IPM approach to CRW resistance management
2. Implement proactive strategy to detect unexpected damage
3. Remove random sampling from annual monitoring requirement
4. Adopt on-plant assay methodology for resistance confirmation
5. Enhance current remedial action plans

1) IPM for CRW RM w/low dose toxins

Rationale:

- Refuge alone is insufficient at managing resistance to LD Bt toxins;
- SAP recommended EPA adopt an IPM + IRM approach
  - To reduce selection pressure, delay need to remediate

Goals:

- IPM stewardship program implemented by registrant: Bt-use no more than two consecutive years, crop rotation, multiple Bt MoA, preferably pyramids; non-Bt corn w/insecticide use
- Adoption targets: EPA proposes a two-tiered system – IPM adoption targets should reflect adoption of CRW protected Bt maize

1) IPM for CRW RM w/low dose toxins

IPM adoption measured as % of total acres

	High Risk Areas	Low Risk Areas
Overall IPM participation	70%	50%
Tactics to be used:		
Crop rotation	50%	33%
Multiple MoAs/ pyramids	25%	33%
Non-Bt with SAI	25%	33%
Use of single PIPs	≤10%	≤20%

1) IPM for CRW IRM w/low dose toxins

Goals:

- **Reporting requirement:** communicate annually success of meeting IPM targets (i.e. % growers using which IPM and/or IRM tool). BPPD analyzes & tabulates data across industry, reports results to public
- **Single PIPs:** EPA requests progress towards phase out
- **SAI with Bt:** not allowed for prophylactic use with Bt for CRW control

2) Proactive strategies needed to detect UXD

Rationale:

- First indicator of potential resistance;
- To date, cases of resistance documented by collecting from field failures; Timely, effective response may aid remediation.

Goals: Changes in CRW Bt registrations:

- Uniform damage thresholds for products expressing one vs. more Bt toxins;
- Adult insect collections to investigate possible resistance must originate from problem site/field; testing must utilize on-plant assays;
- Immediate response to field failure paramount –crop rotation preferred but also different MoA/pyramided Bts;
- Establish target adoption levels for mitigation ($\geq$ 75%).

3) Remove random sampling requirement

Rationale:

- Current data not meaningful because CRW populations not tracked over time;
- Even if tracked over time, unlikely to detect resistance before field failures occur;
- More effective to focus on UXD sites and better detection methods (e.g. active scouting)

Goals:

- Modify CRW Bt registrations to remove random sampling requirement;
- Strengthen language to improve proactive detection (e.g. frequent scouting)

4) Resistance confirmation with on-plant assays

Rationale:

- Diet-bioassays for LD toxins have not been helpful for regulatory purposes;
  - Reliable action levels needed at EPA; too much variability and uncertainty with DBA; reactionary
- On-plant assays provide more realistic exposure scenario and can serve as diagnostic tools;
- Use of single on-plant assay and sublethal seedling assay

Goals:

- Change terms of registration to mandate on-plant assay with resistance confirmation criteria

5) Enhancement of current Remedial Action plans

Rationale:

- Specific remedial action plan needs to be in place before resistance develops;
- Contain resistance and/or maintain durability of PIPs in other areas.

Goals:

- Registrants submit RA plan prior to resistance development;
- Industry-wide standards for actions needed for UXD:
  - Immediate action after field failure and continue in subsequent season unless no resistance
  - RA plan must require: Beetle bombing in UXD site same season; preferably crop rotation, use of alternate MoA (pyramid)

5) Enhancement of current Remedial Action plans

Goals (continued):

- Industry-wide standards for action needed when resistance is confirmed:
  - Remedial action plan must define scope of remediation;
  - Area must go beyond resistant site (surrounding fields) and be decided based on CRW dispersal distance (e.g. use UXD reports in area – CDX data base)
  - Research needed addressing dispersal in simulation models; assess spread of resistance
  - Notification system;
    - Publicly reporting documented cases of resistance on website
    - Helps growers make decisions about corn rootworm management in their areas

EPA proposal to improve CRW IRM program

EPA proposal available for 45 days open comment period starting 1-29-15:

http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2014-0805

Next Topic:
Regulatory Look Back Initiative

William Jordan, Deputy Director
Office of Pesticide Programs

Next Topic:
PPDC Membership

Dea Zimmerman, PPDC DFO
Field and External Affairs Division

PPDC Membership

- FR Notice Published February 13th
- Nominations to include:
  - Contact information
  - Brief statement of interest and availability
  - Resume or short bio, with no more than 2 paragraphs describing relevant activities or experience
  - Letter of recommendation
- Membership nominations due to Dea Zimmerman March 16th zimmerman.dea@epa.gov; (p) 312-353-6344

Closing Thoughts

- Next in-person meeting May 14-15

  -Workgroup meetings may occur on May 13th

- Topic suggestions for May meeting to Dea Zimmerman, zimmerman.dea@epa.gov