



Biopesticides Program: Looking at Today and Tomorrow

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Using sound science as a compass, OCSPP's mission is to protect you, your family, and the environment from potential risks from pesticides and toxic chemicals.



To protect human health and the environment by ensuring the availability of properly regulated biopesticides, and encouraging sustainable pollution prevention practices

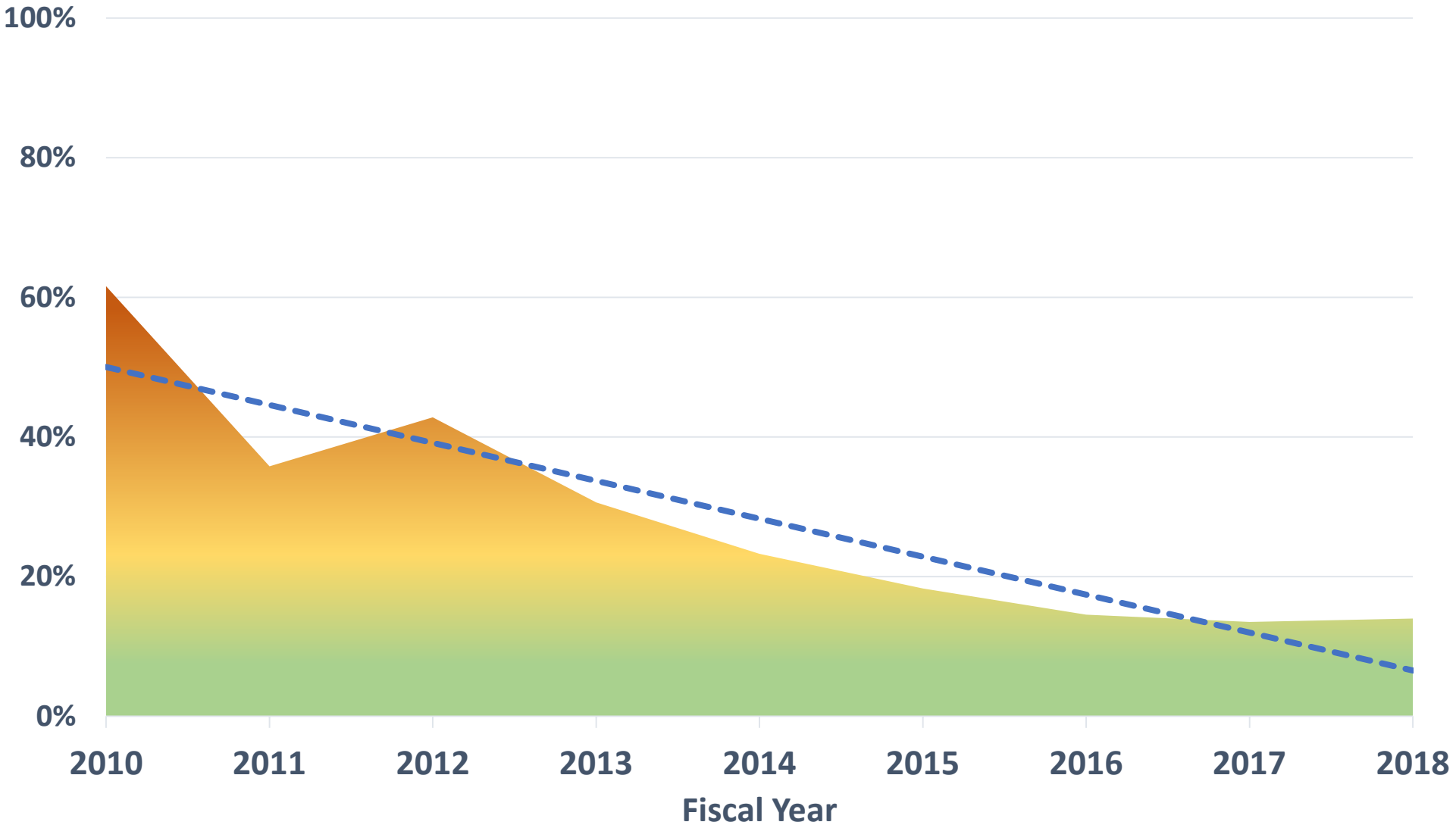
Biopesticides and



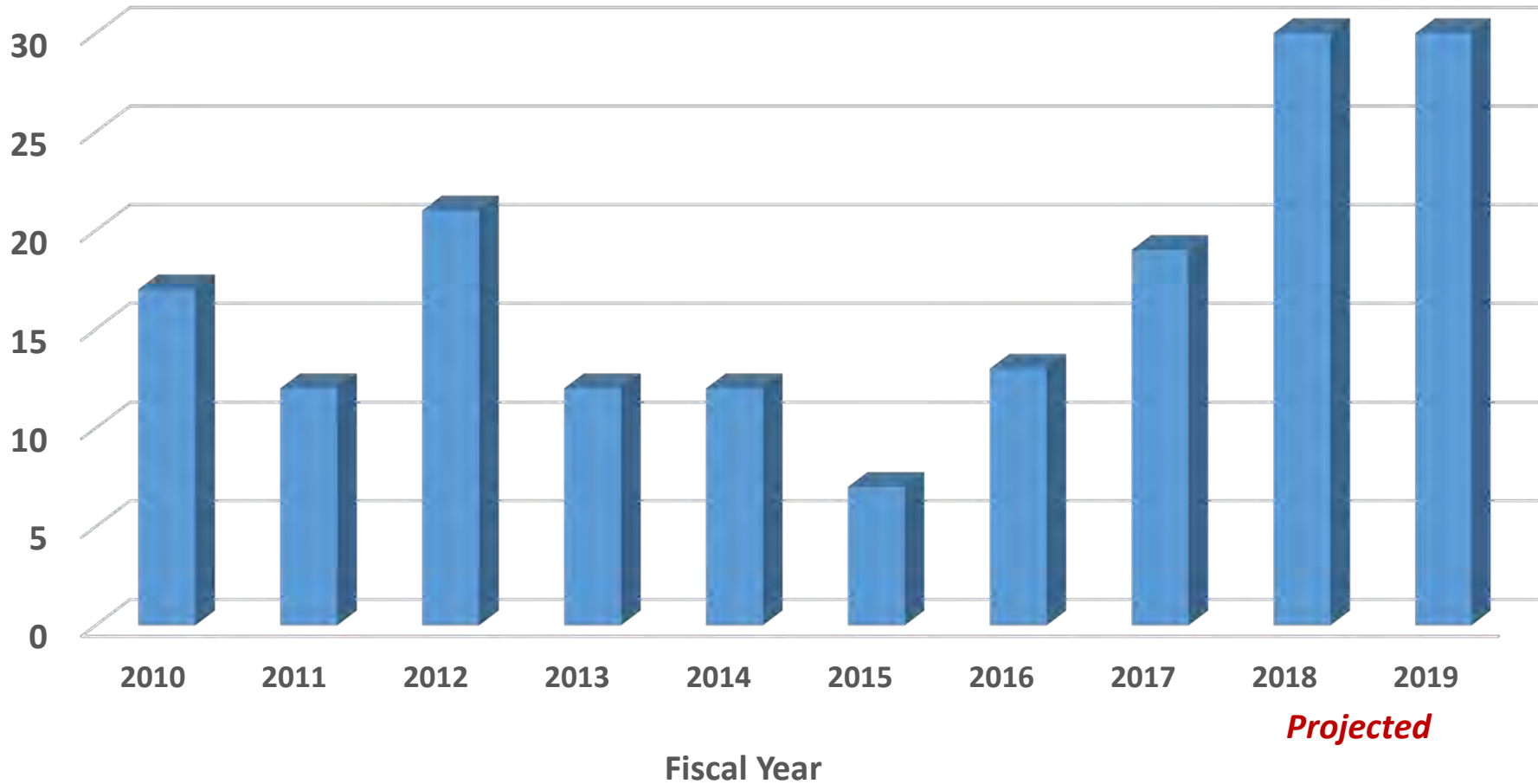
**Pollution Prevention
Division**

- Registration
 - 9 new active ingredients
 - 8 new uses
 - 13% renegotiation rate for 163 completed PRIA decisions
 - 99% of 163 PRIA decisions completed on time
- Registration Review
 - 25 Preliminary Work Plans
 - 11 Final Work Plans
 - 3 Final Decisions/Case Closures
- Electronic Label Submissions
 - 524 biopesticide submissions

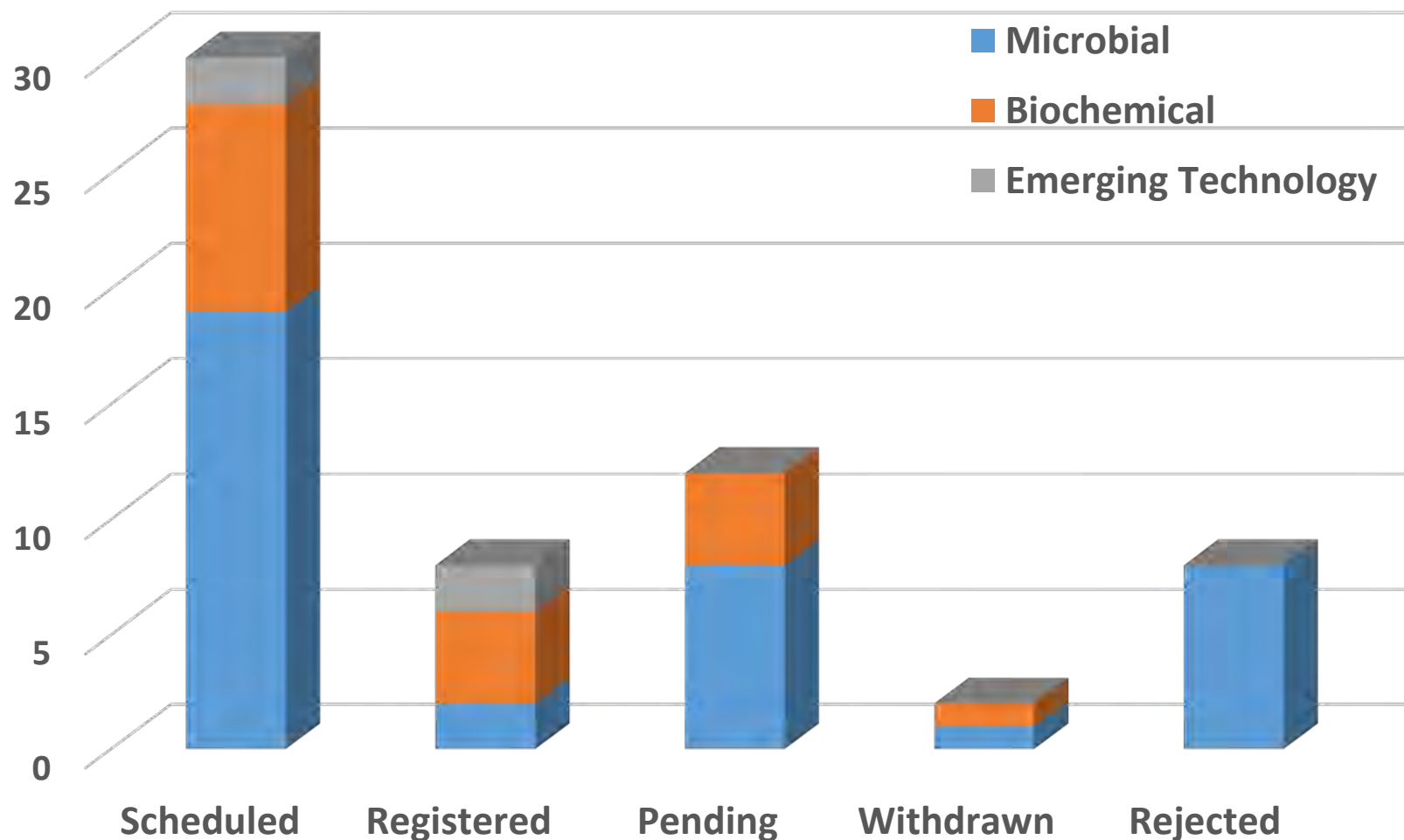
Renegotiation Rate (for Decisions)



New Active Ingredient Registration Decisions



New Active Ingredient Decisions (FY2018)

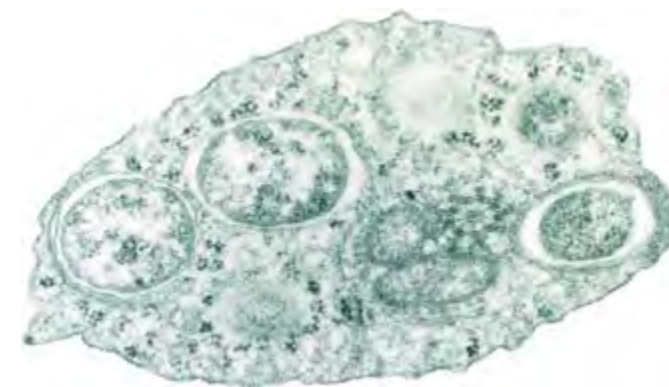


Registrations Granted

- *Wolbachia*
- Calcium salts of phosphorous acid
- Calcium disodium EDTA dihydrate
- *Bacillus amyloliquefaciens* F727
- *Bacillus subtilis* BU814
- mCry51Aa2 protein in cotton
- Alpha methyl mannoside
- LCO (lipo-chitooligosaccharide)

- ~410 registered biopesticide active ingredients
- Use trending up significantly for several years (8 M lbs AI in 2015)
 - *Bacillus thuringiensis* (Bt)
 - *Bacillus firmus*
 - Gibberellic acid
 - Kaolin clay
- Several crops have high % treated with biopesticides
 - 80% of table grapes treated with gibberellic acid
 - 45% of strawberries treated with Bt
 - 55% of mosquito larvacide treatments are biopesticides (*Bt israelensis* and *B. sphaericus*)

- November 2017 FIFRA Section 3 registration for ZAP Males[®], a *Wolbachia pipientis* product targeting population suppression of *Aedes albopictus*, a carrier of Zika virus
- EUP amendment/extension for *Wolbachia pipientis* targeting population suppression of *Aedes aegypti*, a carrier of Zika virus
- *Wolbachia* bacteria is carried within male mosquitoes released to the wild
- *Wolbachia*-carrying males that successfully mate with wild females will result in non-viable offspring



Credit: [Public Library of Science](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2811111/) / Scott O'Neill

Increasing Use of Expert Committees

- Hazard Science Policy Council (HASPOC)
 - Develops and provides guidance to risk assessors on overarching science policy issues related to pesticide toxicity
- Toxicology Scientific Advisory Council (TOXSAC)
 - Reviews hazard characterization documents and supports endpoint selection and FQPA findings
- Chemistry Scientific Advisory Council (CHEMSAC)
 - Considers proposals and approaches for conducting field trials, potential departures from field trials guidance, and acceptability of analytical methods
 - Conducts secondary reviews of residue chemistry documents



- **2012 Guidance: Waivers may be granted for pesticides and pesticide products (biochemical, conventional, and antimicrobial) if any of these criteria are met:**
 - Test material Toxicity Category I for primary dermal irritation
 - Test material is corrosive to skin, or has pH <2 or >11
 - Product design (e.g., childproof insect baits and rodent bait boxes) prevents dermal exposure
- **2016 Guidance: Waivers may be granted for acute dermal toxicity studies for formulated products**
- **Goals: Reduce animal testing and save resources**



US Environmental Protection Agency
Office of Pesticide Programs

Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide
Formulations & Supporting Retrospective Analysis

November 9, 2016

- Biopesticides typically exempt from the requirement of a tolerance, sometimes with limitations
 - When a biopesticide has potential endpoints of concern, a tolerance, instead of a tolerance exemption, may be necessary
- Consistency
 - Hazard-based vs. risk-based
 - Weight of evidence approach
- Limitations
 - Implications in enforcement
 - Implications for expanding product labels/uses

- February 14, 2018
- Goals
 - Highlight the importance of tolerance exemptions to the industry
 - Clarify EPA's tolerance-related processes
 - Increase industry's ability to prepare successful submissions
- Outcomes
 - Increased EPA's understanding of exemption issue
 - Better industry understanding of EPA tolerance-related processes
 - BPIA members encouraged to engage EPA in pre-submission meetings for products with hazard endpoints but with exemption rationales



PRIA 4

- PRIA 3 extended until September 30, 2018
- New legislation (PRIA 4) being considered by Congress
- Possible changes to biochemical and microbial timeframes and fees

FY18 Budget

- Approved by Congress and the President
- EPA awaiting its final FY18 operating plan

FIFRA [Sec 2(v)] Plant Regulator Definition

- Through physiological action, does the substance or mixture of substances:
 - Accelerate or retard the rate of growth?
 - Accelerate or retard the rate of maturation?
 - Alter the behavior of plants or the produce thereof?
- A plant biostimulant may be considered to be a plant regulator if known activity and/or product label claims fit within the FIFRA definition of plant regulator



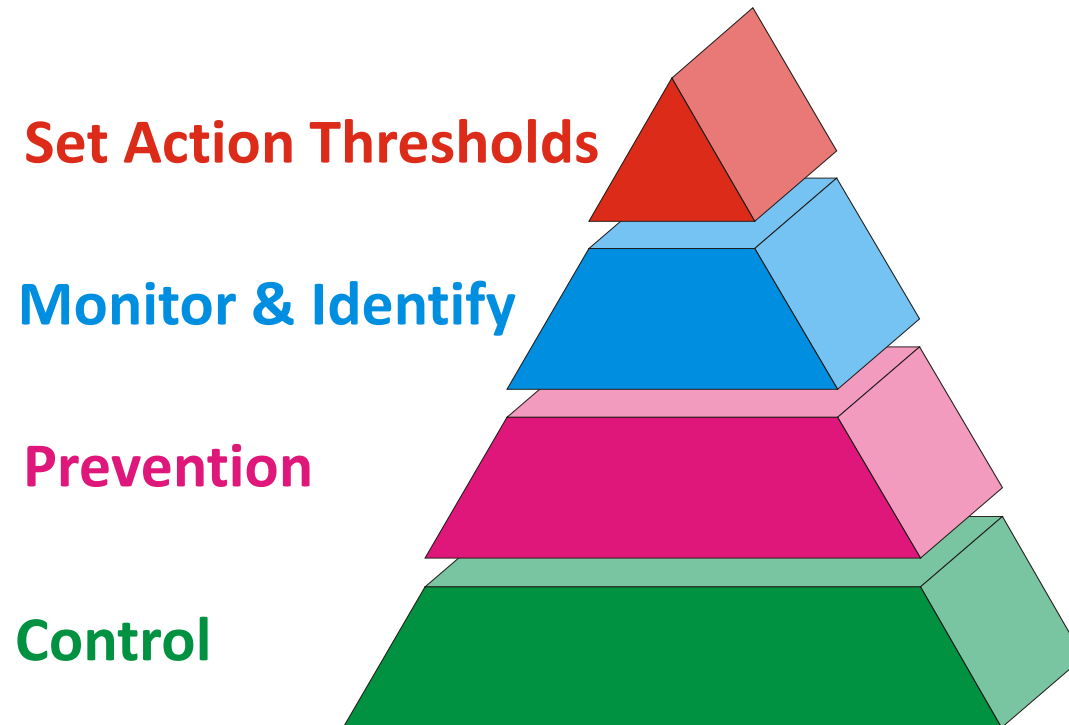
- Growing importance of plant biostimulants in environmentally sound agricultural practices
- Developing guidance for plant biostimulant products and associated label claims that may be included in, or excluded from regulation under FIFRA
- Provides clarity on label claims
 - Plant growth regulator claims
 - Exemptions claims (soil amendment, plant inoculant, plant nutrient)
 - Other non-pesticidal claims
- Definitional issues to be addressed in the future

- Exclusions based on substances excluded from regulation by FIFRA*
 - Vitamin-hormone products
 - Plant macronutrient or micronutrient trace elements
 - Plant inoculants
 - Soil amendments
- Includes guidance for generic product label claims for products not covered by the exclusions from the FIFRA Section 2(u) plant regulator definition

**(40 CFR 152.6 (f)(1) & (2) and (g)(1), (2) & (3) and FIFRA Section 2(u))*

Integrated Pest Management (IPM)

Environmentally sensitive approach to pest management that relies on information on the life cycles of pests and their interaction with the environment to determine the most effective pest control methods.



How EPA Promotes IPM in the Agricultural Community

- Connecting growers with other stakeholder networks that are knowledgeable about the benefits and return on investment of IPM
- Providing online training and technical resources available to assist with developing or reinvigorating an IPM programs
- Recognition opportunities for agricultural stakeholders:
Pesticide Environmental Stewardship Program

- Surge in biopesticide applications
 - Nearly 60 new active ingredient decisions due in FY2018/2019
- Implement PRIA 4 (*if enacted*)
- Emerging technologies and innovations in biotech are advancing in ways presenting policy and assessment challenges:
 - GE mosquitoes
 - Gene editing (e.g., CRISPR)
 - Non-PIP RNA interference technologies
- Biostimulant guidance





Don't judge each day by the
harvest you reap but by the
seeds you plant.

- *Robert Louis Stevenson*