EPA's Perspective on Resistance Management with a Focus on Herbicides and Bt Crops

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Waterhemp in corn

Outline

- Provide brief background on pesticide resistance
- Present overview of two draft Pesticide Registration Notices (PRNs) to be released for public comment
- Discuss changes to EPA's corn rootworm (CRW) resistance management strategy for Bt corn
- Questions?

Glyphosate resistant Kochia

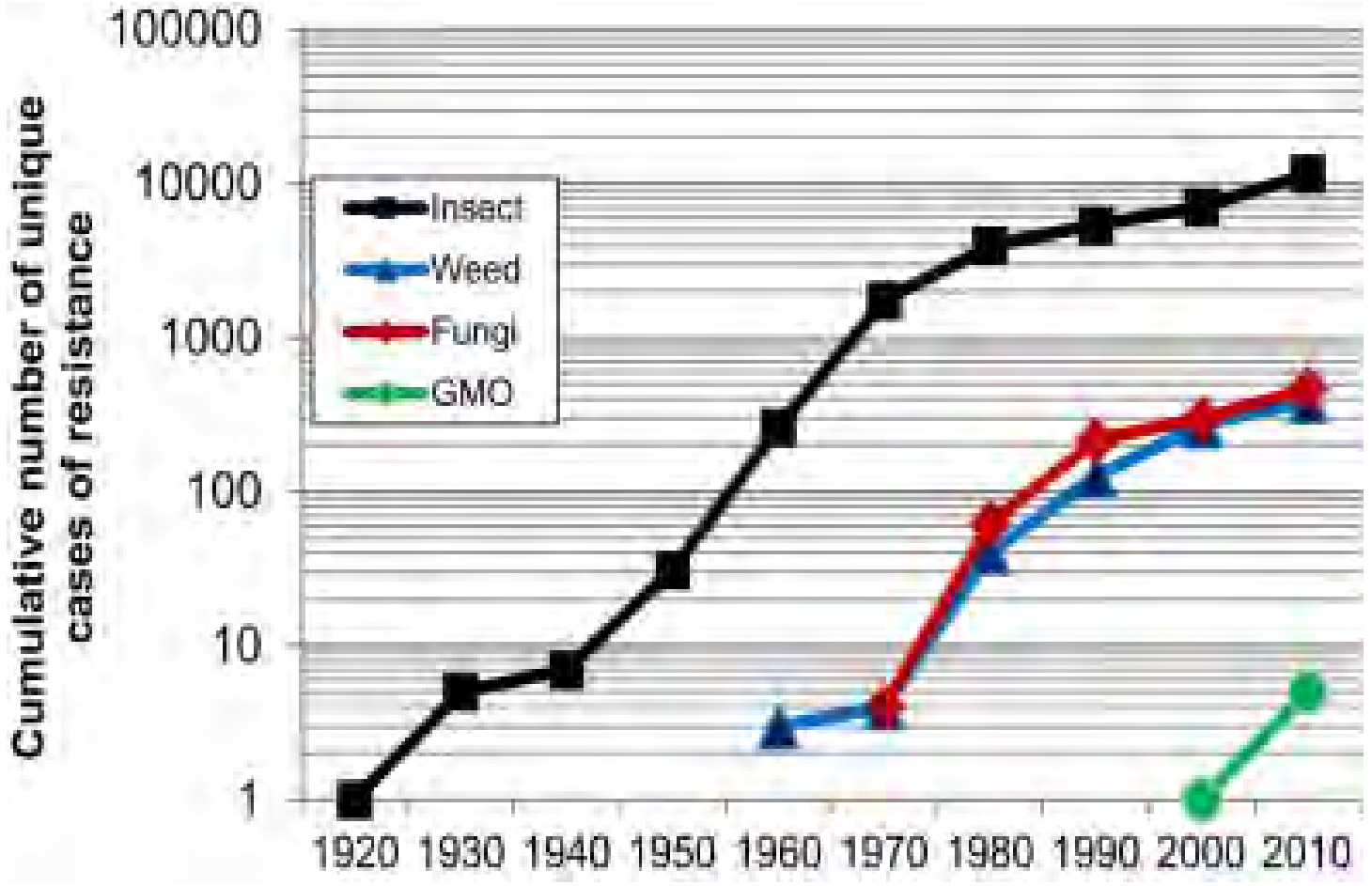
Pesticide Resistance – What do we mean?

Palmer amaranth, *Amaranthus palmeri*

Diamondback moth, *Plutella xylostella*

- Over time, agricultural pests can become resistant to a pesticide, much like human pathogens become resistant to antibiotics.
- The process is greatly accelerated when pesticides with the same Mode of Action (MOA) are repeatedly used on the same pest population or when other tactics to slow resistance are not deployed.

Increase in Pesticide Resistance is a Global Problem



- In the U.S., at least 155 weed species are resistant to one or more herbicide MOAs.
- Globally, at least 580 species of insects are resistant to one or more insecticides.

Source: Sparks and Nauen. 2015. IRAC: Mode of action classification and insecticide resistance management, Pesticide Biochemistry and Physiology, Vol. 121: 122-128

Example: Economic Impact of Glyphosate-Resistant Weeds

- By 2010, ~33 million U.S. acres infested with glyphosate resistant weeds
- By 2012, > 61 million U.S. acres infested with glyphosate resistant weeds
- USDA* reported in 2010 that corn and soybean growers with glyphosate-resistant weed problems spent more money/acre for weed control:
  - Corn growers spent an extra $67 per acre
  - Soybean growers spent an extra $23 per acre
- In 2010 and 2011, growers in Georgia spent >$100 million annually to control glyphosate-resistant Palmer amaranth in cotton fields.

From: * USDA, ERS 2015. Economics of glyphosate resistance management in corn and soybean production.

Why manage pesticide resistance?

- Extend the useful life of pesticide products
- Provide growers with information on how to slow the development or spread of resistant pests
- Help reduce economic losses due to resistance
- Potentially reduce pesticide usage and thus unnecessary pesticide loading in the environment

What is EPA Doing to Address Resistance?

- Beginning to embark on a more widespread effort aimed at combating and slowing the development of pesticide resistance.

- Releasing and requesting public comment on two PRNs:
  1) "Guidance for Pesticide Registrants on Resistance Management Labeling" - Updates an existing PRN (2001-5) and recommends additional resistance management information for pesticide labels.
  2) "Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship"- Focuses on the overall strategy to manage herbicide resistance during registration and registration review.

What are Pesticide Registration Notices (PRNs)?

- Provide non-binding guidance to pesticide registrants and EPA personnel regarding pesticide registration activities and decisions.

- Inform pesticide registrants and other interested persons about important policies, procedures, general registration related decisions, and provide information that facilitates registration-related activities.

- Support EPA's commitment to be transparent in its decision-making for pesticide registrations.

- Reduce burden and costs for both registrants/applicants and EPA by providing guidance that facilitates compliance with statutory and regulatory requirements.

1st Draft PRN - Updates to PR Notice 2001-5

- Focuses on label language for all conventional agricultural pesticides
- Has three categories of updates:
  - Provides additional guidance, and a recommended format, for resistance management statements or information to place on labels
  - Includes references to external technical resources for guidance on resistance management
  - Updates instructions on how to submit changes to existing labels in order to enhance resistance management language.
- Updates developed in collaboration with Canada's Pest Management Regulatory Authority (PMRA), which has a very similar regulatory directive already in place.

2nd Draft PRN - Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship

- Applies only to herbicides
  - No new MOA's in 30 years
  - The most widely used type of pesticide
  - Herbicide resistant weeds are increasing rapidly
  - Consultants, grower groups, and researchers asked the Agency to address the problem
- Provides strategy to address resistance during registration and registration review
- Uses tiered approach based on potential for resistance to develop
- Promotes use of 11 key elements (*adapted from Weed Science Society of America*) that focus on:
  - Clear label information and directions
  - Training and education
  - Locally-developed resistance plans
  - Early detection, investigation, and remediation

Glyphosate resistant Italian ryegrass

Proposed Tiered Approach for Addressing Herbicide Resistance*

Low Concern	Moderate Concern	High Concern
MoA with no resistance weed species in the U.S.	MoA with a few resistant weed species in the U.S.	• Any new MoA or • MoA with many resistant weed or • Herbicide resistant crops (GM or conventional breeding).
1. MoA on Label 2. List seasonal and annual maximum number of applications and pounds 3. Resistance language from PRN or BMP or HRAC 4. Scout before and after application	Elements 1 through 4 plus 5. Define likely and confirmed resistance 6. Farmer report lack of performance to registrant or its agent 7. List confirmed resistant weeds in a separate table and list effective or recommended rates for these weeds with the table 8. Registrant report new cases of likely and confirmed resistance to EPA and users yearly	Elements 1 through 8 plus 9. Provide growers with: Resistance Management Plan, Remedial Action Plan, Educational materials on resistance management 10. For combination products with multiple MoAs, list which herbicide is controlling which weed and minimum recommended rate (could be on a website) 11. Any additional specific requirements (e.g. crop rotation, unique agronomic aspects, additional training, time limited registration, etc.)

* If new resistant weed species are found a MoA may move to higher level of concern

Examples of Actions That Included Herbicide Resistance Management Measures

- For Enlist Duo - 2, 4-D and glyphosate resistant corn and soybean
  - Registrant incorporated herbicide resistance management plan
  - 2014 registration addresses most of the current elements
- Dicamba Xtend – dicamba resistant cotton and soybean
  - Proposed decision will close on May 31, 2016
  - Herbicide resistance management plan addresses current elements

Next Steps for These Two Draft PRNs

Glyphosate resistant & susceptible horseweed

- Release PRNs for a 60 day public comment period.
- Evaluate and consider comments.
- Finalize both PRNs in late fall 2016.

Overview of Changes to EPA's Corn Rootworm (CRW) Resistance Management for Bt Corn

- EPA became aware of reports of CRW resistance in Corn Belt in 2011
- As a result, EPA initiated discussions with CRW entomologists, developed white paper, and received advise from SAP (2013)
- EPA developed an initial proposal to enhance resistance management and mitigation of resistance
- EPA received public comments on proposed framework, made refinements to address comments
- Goals of framework: Extend Bt corn durability and benefits as well as future CRW Plant-Incorporated Protectant (PIP) corn that reduce conventional pesticides in environment and to humans

New Framework for CRW Resistance Management and Bt Corn

Terms and Conditions of Bt Corn Registrations. 2016. EPA-HQ-OPP-2014-0805;
http://www.regulations.gov/#!searchResults;rpp=25;po=0;s=EPA-HQ-OPP-2014-0805;fp=true;ns=true

- Integrated Pest Management (IPM) stewardship for Bt corn
- Investigation and response to reports of unexpected damage (UXD) by CRW
- Investigation of populations of concern: resistance detection assays
- Mitigation of CRW populations meeting EPA's resistance criteria
- Annual reporting

New Framework for CRW Resistance Management and Bt Corn

- Proactive Integrated Pest Management (IPM) with IRM
  - Biotech companies develop and implement educational outreach program
  - Develop and implement multi-year CRW management plan for growers using Bt corn consistent with good IPM practices
  - IPM with Bt use is important and will reduce likelihood of resistance
  - IPM tools encouraged include rotation to non-Bt corn every few years, planting of pyramided Bt corn, non-Bt corn with a soil-applied insecticide

New Framework for CRW Resistance Management and Bt Corn

- Response to UXD to Bt corn
  - CRW damage to Bt corn can be an early indication of developing resistance
  - Proactive and robust actions may lessen (or eliminate) impact of resistance in CRW
  - Biotech companies (B.C.) investigate complaints, use standardized thresholds for single and pyramided Bt corn to determine if field is a UXD case and CRW are resistant (bioassays)
  - B.C. must implement Best Management Practices (BMPs) based on good IPM

    1. Rotation to a non-crop host (area will be considered mitigated; no further actions needed)

    2. Use of pyramided Bt corn, different single Bt trait, non-Bt corn + SAI

    3. As last option, SAI, ST, chemigation can be used if additional management tools beyond options 1 and 2 are needed

New Framework for CRW Resistance Management and Bt Corn

- Enhanced and corn rootworm specific mitigation strategies will be implemented for confirmed cases of resistance
  - B.C. must notify affected companies, neighboring customers, extension specialists and crop consultants where CRW are resistant
  - ½ mile radius around resistant site = mitigation action area (MAA)
  - Discontinue sales and planting of compromised single trait until resistance is mitigated
  - Monitor resistant population until mitigation complete
  - Pyramids with resistant trait require a 20% refuge until mitigation complete
  - Encourage mitigation practices such as crop rotation, pyramids

Who Does the New Framework Apply to?

- Legally binding for biotechnology companies selling Bt seed
  - Annual assessment of IPM adoption
  - Grower education
- Permits flexibility for growers and encourages adaptive multi-year CRW management plan
- Burden on growers should be minimal

Questions?

Palmer amaranth in soybean

Pesticide Registration Notices - webpages

https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year

https://www.epa.gov/pesticide-registration/pesticide-registration-notices-category

https://www.epa.gov/pesticide-registration/prn-2016-x-guidance-pesticide-registrants-pesticide-resistance-management

https://www.epa.gov/pesticide-registration/prn-2016-xx-guidance-herbicide-resistance-management-labeling-education