



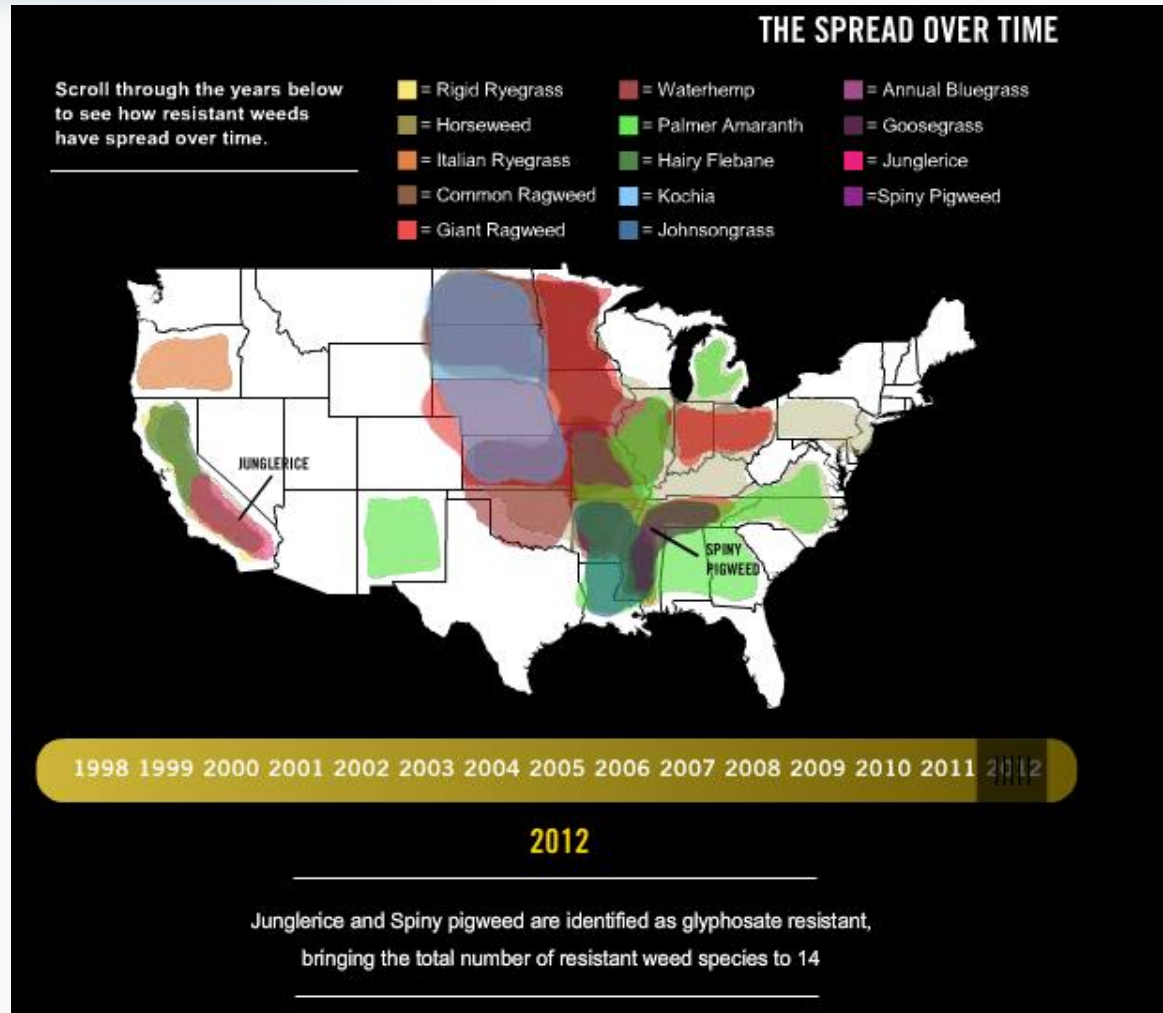
Registering Herbicide Uses on Genetically Engineered (GE) Crops

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Background

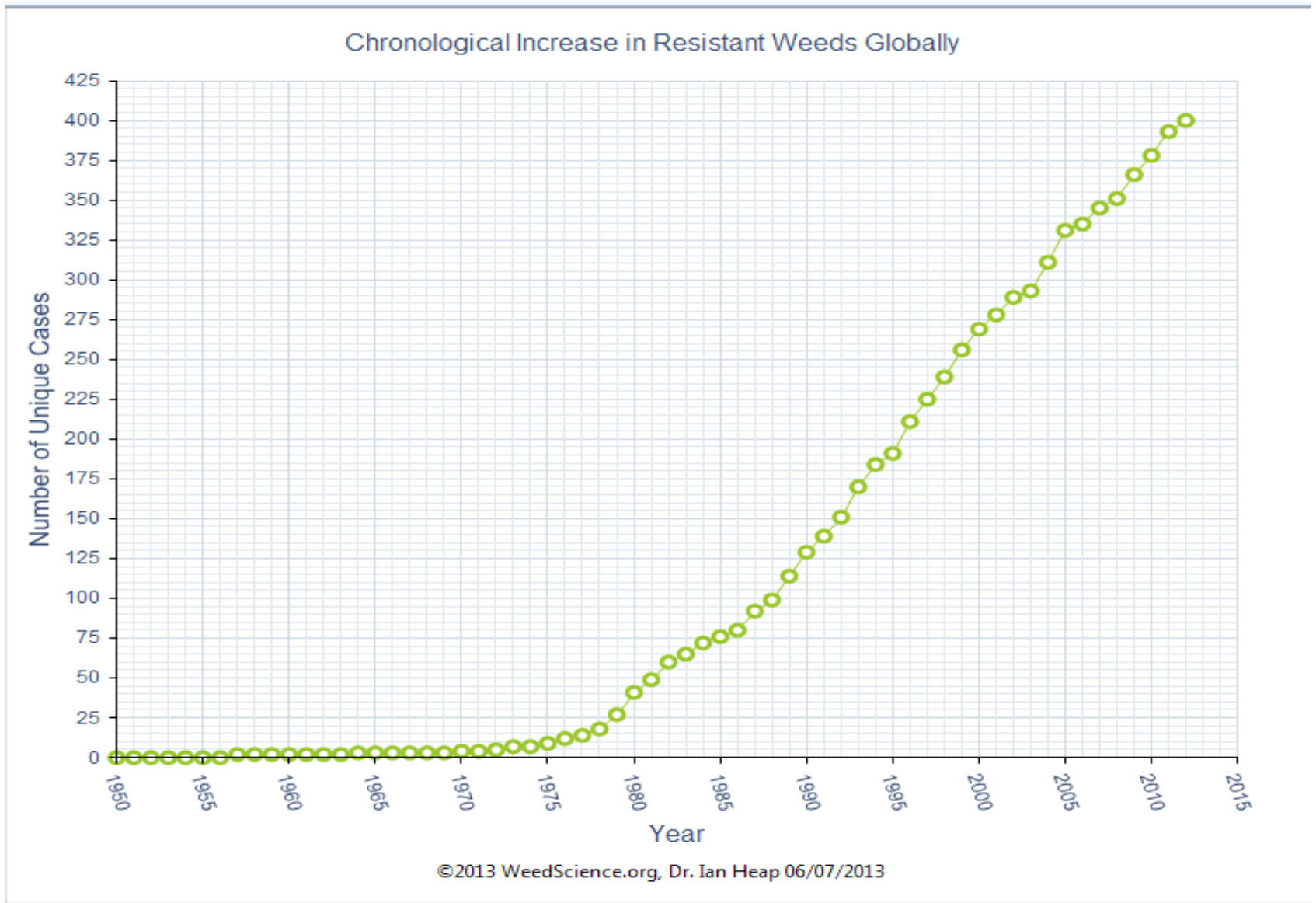
- Herbicide-resistant weeds are an increasing problem
 - Resistance to glyphosate has become a significant economic issue to growers
 - Need for additional tools to manage resistant weeds
 - New herbicide tolerant genes allow crops to be treated with additional herbicides

Current Location of Glyphosate Resistant Weeds



From: <http://www.resistancefighter.com/news.aspx>

Global Increase in Resistant Weeds Over Time



Higher Level of EPA Assessment Required

- Based on wide spread use of GE glyphosate
 - Unique % of crops treated
 - ~98% of soybean is glyphosate resistant
- Anticipation of high level use of other GE traits
 - Increased acreage
 - Potential for higher exposure
- Increasing the scope of assessments accordingly
- Coordination with USDA
 - Share information and assessments

Concerns

- Public concern about genetically modified food
- Growers of sensitive crops, such as vegetables, concerned about increased use of pesticides and damage from spray drift
- NGOs concerned about drift to non-target organisms, including endangered species
- Increase in selection for resistant weeds
- Agency receives more comments submitted to docket for these actions

EPA and USDA Coordinated Effort

- EPA reviews information on the effects of the herbicide on humans and the environment (registration decision for herbicide use)
- USDA reviews information on the gene conferring tolerance to the plant (deregulation decision for seed)
 - Authority to deregulate through the Plant Protection Act
 - Addresses requirements of NEPA
- Agencies share information to inform and strengthen both regulatory decisions

Human Health Risk Assessment Summary

- New or amended tolerances as needed
- Assessment:
 - Aggregate (dietary, residential)
 - Conservative assumptions
 - Occupational Exposure

Human Health Risk Assessment Summary, Continued

- Additional assessments as warranted based on chemical profile
 - Bystander Exposure
 - Spray Drift
 - Most vulnerable exposure scenarios assessed
 - Human Health Impurities Assessment

Environmental Exposure Considerations

- Normal exposure pathways
 - Runoff
 - Spray drift
 - Foliar deposition
- Additional exposure considerations as warranted by chemical
 - Vapor drift and off target deposition
- Non-target organisms including threatened and endangered species

Minimize Off-Target Movement

- Reduce spray drift
 - Properties of the formulation that reduce drift
 - Coarse droplet size restriction (specific nozzle(s) required on label)
- Other methods, as warranted by chemical profile
 - Volatility
 - Run-off
 - Ground water

Stewardship Plan / Resistance Management

- Industry activities include:
 - Providing labeling with Mode of Action and best management practices
 - Promoting resistance management
 - Investigating cases of non-performance
 - Developing remediation plan to control possible resistance
 - Reporting instances of likely resistance
- Grower activities include:
 - Scouting fields
 - Reporting performance problems
 - Adopting drift reduction measures

EPA's Decision Process

- Development of Proposed Decision
 - Discusses findings in risk assessments
 - Proposed regulatory/registration decision
 - If decision to register, introduces proposed risk mitigation strategy (labeling, stewardship)
 - Allows 30-day public comment period
- Implementation of Final Decision