



National Plant Disease Recovery System - HSPD#9 U.S. EPA Role

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EPA Core Mission Related to Pesticides

- Provide Safe and Effective Pesticides Through Agency Licensing Program
- Ensure Protection of Human Health From Exposures to Pesticides – treated foods, drinking water, residential uses
- Mitigate Risks to Non-target Species and Environment



Main Role for EPA Under HSPD#9

- Item 18B – “NPDRS shall include... pesticide control measures to prevent, slow, or stop the spread of a high consequence plant disease, such as wheat smut or soybean rust.”
- Pesticide Licensing Program – Labels
- Food Safety Finding – Tolerances on Crop for Trade Purposes

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FIFRA Regulatory Avenues

- National Label (section 3 registration)
- Special Local Need (section 24c registration)
- Addition of “New” Pest to Existing Label (section 2(ee))
- Emergency Exemption (section 18)
- Treated Food in Commerce Needs Tolerance (FFDCA section 408)

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EPA Review Areas

- Mammalian Toxicology
- Residue Chemistry
- Exposure Evaluation
- Ecological Hazard and Fate
- 100+ Studies and \$200 M Investment for R&D and Registration for New Pesticide
- Food Safety Finding
- Pesticide Worker Risk Assessment
- Structure Labeling Terms to Ensure Protection of Public, Non-target Species and Environment

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Review Timelines

- New Ingredient – 24 Months
- First Food Use – 21 Months
- New Food Use – Old Chemical – 15 Months
- Amendment to Existing Label – 8 Months
- Emergency Exemption Request – 50 Days
- “Surprise” Emergency Exemption (aka Crisis) – 1-2 Days

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Collaboration = Success

- USDA, DHS, FDA, CDC, EPA
- State lead agencies (DoA's, DEQ's, NASDA, etc.)
- Registrants
- Commodity Organizations
- Crop Advisers, Producers, Applicators

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Soybean Rust Working the Process

- Develop Candidate Product List
- Build Appropriate Use Terms
- Coordinate with Registrant(s) for Support and Product Inventory Investment
- Resistance Management Considerations
- Food Residues/Trade
- When Detected – Sec. 3 and Section 18 Products Available 25 States
- Now – New Sec. 3's Approved and Section 18s Granted to 33 States
- Multiple Registrants Carry Label w/ SBR claim
- Varied Tool Box – Involving Different FRAC Group Pesticides
- 3X/season; pre-mix and tank mix products
- Tolerances for Triazole Fungicides Permit Trade – Domestic and Export (i.e. Japan)

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Goals for Each Select Agent

- If Pesticide Needed – Initiate Trials to Determine Best Fit for Efficacy and Safety
- Collectively, Put Together Regulatory Approach to Address Gaps
- May Involve Mix of Authorities Necessary for Covering Short and Long-Term Control Needs
- EPA Regulatory Decision and Tolerance – In Advance of Disease Control

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Summary Points/Wrap Up

- EPA Plays Support Role to USDA, DHS and Others for HSPD#9
- Work is High Priority for EPA and Fits into Mission for Protection of Health and the Environment
- Up-Front Coordination In Advance of a Field Control Need is Critical
- EPA Interested in Scoping/Trouble-Shooting Options for Each Select Agent

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