Alternatives to Rulemaking

Flexible Approaches to Advance Animal and Plant Health and Animal Welfare
Alternatives to Rulemaking: Overview

- APHIS will always have a regulatory role, **BUT**

- It often won’t be the only or even the primary way we contribute to agricultural health and animal welfare
Considerations

- **Policy:**
  - **Executive Order 13563:** Identify and use the best, most innovative and least burdensome tools for achieving regulatory ends

- **Practical:**
  - **Copeland Report on Rules:** Regulatory review time has increased dramatically in recent years
Average review time by OIRA = 140 days in 2013

USDA Rules:

* Partial year data
APHIS’ Exploration

A cross-unit senior-level team:

- **Reviewed** international literature
- **Interviewed** representatives from other Federal Agencies
- **Sought examples** in APHIS where alternatives already used
Alternatives to Rulemaking – APHIS Commitment

- Use non-regulatory approaches as the preferred solutions when they protect agricultural health or animal welfare.

- Ensure all actions are based on risk, maintain or enhance agricultural production and trade (domestic, import, and export), are environmentally sound, and pose minimal burdens on stakeholders.
Alternatives to Rulemaking

Three components:
1) Use process to consider non-regulatory solutions for emerging issues
2) Continue work on issuing more flexible regs
3) Determine where we can/should interpret existing regs more flexibly
Systematic Process for Considering Alternatives

- Risk-based
- Includes stakeholder input and support
- Balances risk with economics
- Considers human behavior
- Considers civil rights, environment, tribal consultations, environmental justice
- Uses flexible approaches, data and adaptive management
## Spectrum of Solutions

<table>
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<tr>
<th>No intervention</th>
<th>Education and outreach</th>
<th>Industry self-regulation with government involvement</th>
<th>State/local/international program with Federal support</th>
<th>Working with other Federal regulatory programs</th>
<th>Voluntary or mandatory Federal regulatory program</th>
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National Animal Health Monitoring System

- National studies of domestic livestock
- Statistically valid estimates of management practices
  - Disease risk
  - Production yield
- Gives producers data about choices
Secure Food Supply Plans

- Safely move eggs, broilers, turkeys, milk, and pork during disease outbreaks/quarantines
- Minimize disease risks, safely operate, maintain food supplies ... and reduce economic losses
- Industry, State, Federal, university collaboration
Pilot Test for Process in APHIS

- Seed summit
  Meeting with stakeholders to develop approach to address seed imports and virus risks

- Aquaculture
  - Meeting with the aquaculture industry to develop an approach for safe trade of fish susceptible to disease.
Create Performance-based Regs

- Continue process of creating more flexible regulations
  - More flexibility in the long term
  - Gives stakeholders options to reduce agricultural health or animal welfare risk
  - Potentially reduce need for future rulemaking
Seek input from staff – where do we see little risk and an opportunity to be “smarter”?
Seek input from stakeholders – what’s hampering business?
Explore language in regulations to see where we have “room”
Pilot tests to explore approaches
Project:
Develop U.S.-based dipping stations for Mexican cattle
- Regulations require tick dips in Mexico
- Safety considerations
- Ongoing project
Project:
Develop more consistent potency standards for biologics

- Regulations and policy documents regarding manufacturers’ roles are inconsistent/outdated
- Internal review of potency testing guidelines
- Work with international regulators and manufacturers
Other RegFlex Pilot Projects

- Take a *de minimis* approach for animal welfare licensees
- Proactively determine “similar to” for biotechnology deregulations
- Exempt processed citrus peel from import restrictions
- Facilitate limited imports of Canadian Ash logs for Tribal use
- Grant a general permit for EPA-registered microbial biopesticides