



# Alternatives to Rulemaking

Flexible Approaches to Advance Animal and  
Plant Health and Animal Welfare

# Alternatives to Rulemaking: Overview

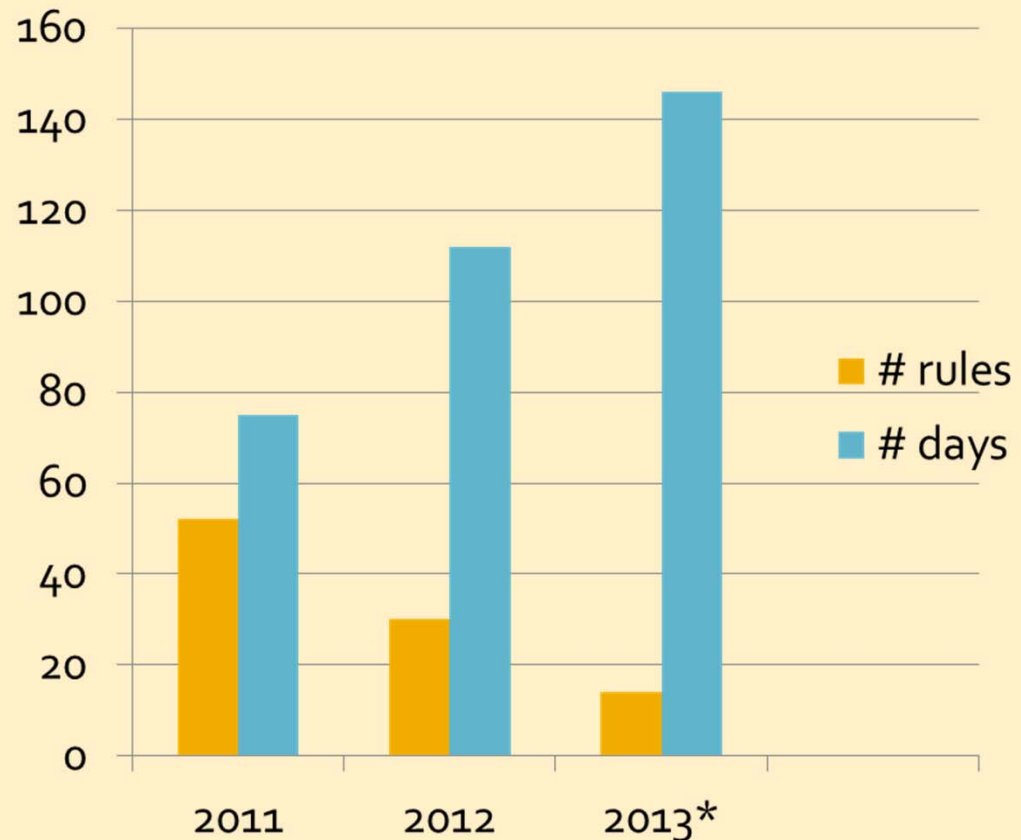
- APHIS will always have a regulatory role, **BUT**
- It often won't be the only or even the primary way we contribute to agricultural health and animal welfare

# 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

# Copeland Report on Rules

- 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



**No  
intervention**

**Education  
and outreach**

**Industry self-  
regulation  
with  
government  
involvement**

**State/local/  
international  
program with  
Federal  
support**

**Working with  
other Federal  
regulatory  
programs**

**Voluntary or  
mandatory  
Federal  
regulatory  
program**

# Example – Education and Outreach

## 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

# Example – Industry Self-Regulation

## 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

# Flexibility with Existing Regs

- 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

# RegFlex Pilot Projects: VS (1 of 2)

## Project:

Develop U.S.-based dipping stations for Mexican cattle

- Regulations require tick dips in Mexico
- Safety considerations
- Ongoing project





# RegFlex Pilot Projects: VS (2 of 2)

## 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