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# USDA ARS 2nd International Biosafety & Biocontainment Symposium

# APHIS Risk Assessment

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# APHIS Mission

***Protect the health and value of U.S. agricultural, natural, and other resources***

- Safe trade
- Effective and efficient programs
- Sound, science-based decision making
- Transparent, collaborative processes

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# International Framework

- WTO-Agreement on the Application of Sanitary and Phytosanitary Measures
  - Since 1994
  - Encourages harmonization (int'l standards)
    - International Plant Protection Convention (IPPC)
    - World Organization for Animal Health (OIE)
    - Codex Alimentarius Commission (Codex)
  - Binding dispute settlement

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# APHIS Operational Programs

**APHIS Administrator**

- Plant Protection and Quarantine
- Biotechnology Regulatory Services
- International Services
- Animal Care
- Veterinary Services
- Wildlife Services

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# Plant Protection and Quarantine (PPQ)

- Pest Risk Analysis in APHIS-PPQ
  - Conducted by:

    Center for Plant Health Science and Technology (CPHST)

    Plant Epidemiology and Risk Analysis Laboratory (PERAL)

    Raleigh, NC
- Pursuant to the Plant Protection Act

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# Risk Analysis

- Plant protection = Pest Risk Analysis (PRA)
- Consistent with IPPC standards where affecting trade
- Principles and processes applied to risk analysis for other than trade
- Wide variety of analytical applications

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# Biological Model

## Likelihood X Consequences = Risk

- Common for WTO-SPS applications
- Applies to living organisms as hazards
- Usually no (or poor) exposure data
- Usually not a static hazard
- Uncertainty high and variable

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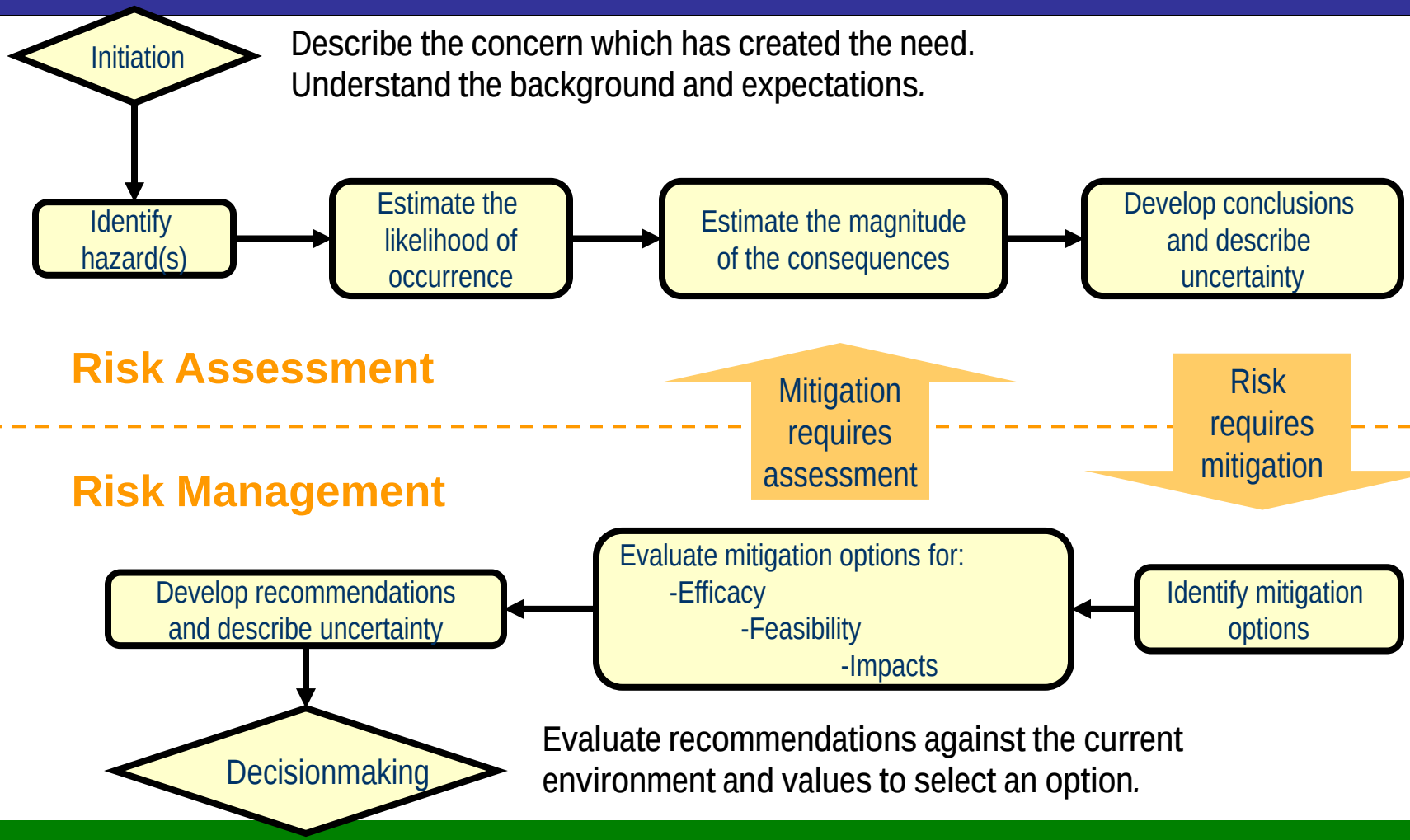
# Process Overview



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# Regulatory Decisions

Risk Assessments and complete Risk Analyses are conducted to serve a variety of needs in regulatory decision-making

In PPQ…

# USDA-APHIS-PPQ-CPHST-PERAL

## PRA productivity

| PRAs 2004 to 2011 | |
|---|---|
| Fruit and vegetable import | 337 |
| Plants and misc products import | 62 |
| New pests | 477 |
| Export | 162 |
| Organism | 124 |
| Operational | 134 |
| Pathway | 84 |

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# PERAL Personnel Resources

- Entomologists
- Plant Pathologists
- Botanists
- Ecologists
- Economists
- Modelers
- Writer/Editor, Librarian, Trainer, Admin.

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# PERAL Information Resources

- Internal
  - Global pest and disease database
  - PRA archives
  - 4,000+ hard references
  - 14,000+ electronic references
- External
  - National Agricultural Library
  - Network of experts/specialists

Lucy Reid
PERAL Information Specialist

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# PRA Guidelines

- Ver. 5.02 Guidelines used since 1997
- Approximately 400 PRAs archived
- Revision process completed in 2011
- Adapted to:
  - Provide technical and conceptual correctness
  - Account for WTO jurisprudence
  - Streamline and automate processes

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# Key Changes: Likelihood

- Separate entry and establishment events
- Make provision for “negligible” likelihood
- Multiplicative model means that if a certain event cannot take place or specific conditions do not exist, the risk is negligible

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# Key Changes: Consequences

- More structured and transparent
- Linked to spread potential
- Based on the concept of pests meeting a threshold for significance
- Once done, analyses do not need to be repeated

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# Key Changes: Uncertainty

- Consistent with SPS
- Separated from evidence
- Addressed at each stage
- Suggestions are made on evaluating evidence in relation to uncertainty

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# “Organizational adaptations”

- Risk management “notes”
- Actionable pest
  - Practical reality
  - Legal requirement
  - Account for official control

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# PPQ Summary

- APHIS-PPQ performs risk assessment across a broad spectrum of regulatory issues in its mandate.
- Much of the work is trade-related and must be consistent with international guidelines.
- Substantial resources are devoted to providing the credible, high-quality products.

# Plant Epidemiology and Risk Analysis Laboratory


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# Biotechnology Regulatory Services

- Plant Pest Risk Assessment in APHIS-BRS
  - Pursuant to the *Plant Protection Act* (statutory authority)
  - *Title 7 Code of Federal Regulations Part 340* (7 CFR 340, regulatory authority)

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# Regulatory Decision

- The exact nature of a risk assessment depends on the regulatory decision that needs to be made
- For BRS (genetically engineered organisms), the decision is:

  In response to a petition, should APHIS grant Nonregulated status for the requested genetically engineered organism?

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# BRS PPRA for Nonregulated Status

- Plant Pest Risk Assessments (PPRA) conducted by BRS include considerations of whether the GE organism could:
  - exhibit plant pathogenic properties
  - become a weed
  - Transmit the genes to organisms with which it does not normally interbreed.
  - increase the weediness of sexually compatible plants
  - harm non-target organisms (beneficial, endangered)

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# Questions ?