# Increasing Understanding of Pesticide Safety - PPDC

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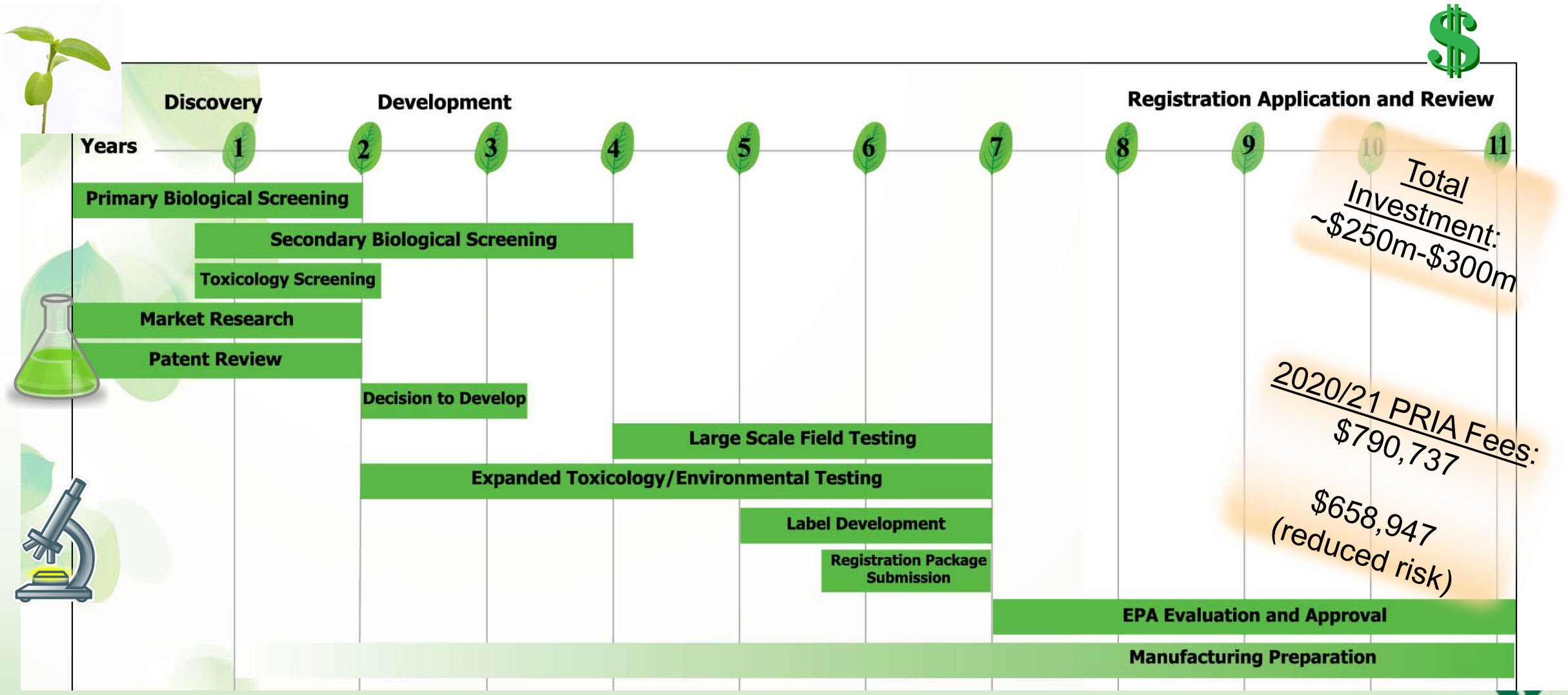
CropLife AMERICA

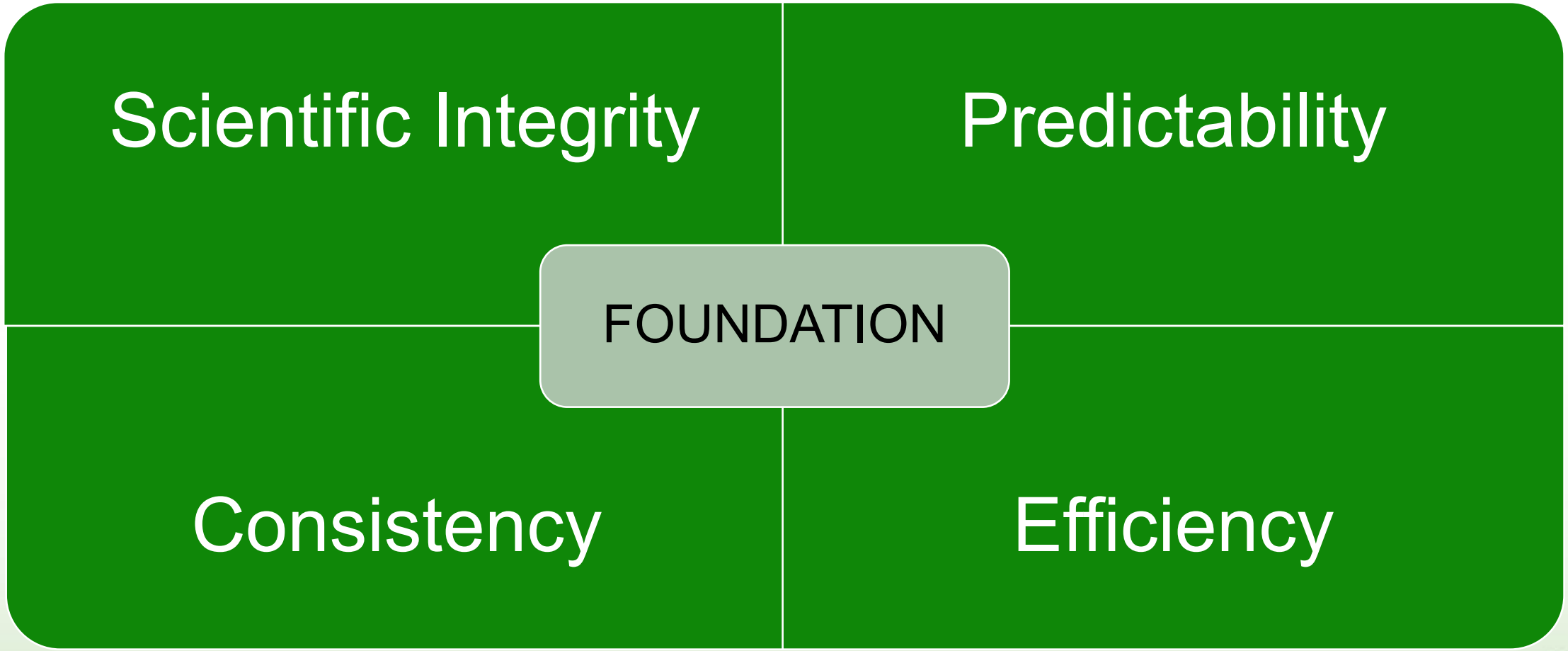
# Outline

- Industry Product Development overview
- CropLife America – Strategic Priorities
  - Improving Environmental Sustainability
  - ESA Approach

# New a.i. - from Discovery to Market



# Expectations of a Sound Regulatory Process



# FIFRA Regulation of Pesticides Is Data Driven

Specific Requirements for:

- Acute and chronic toxicology - to address human health effects
- Ecological effects, - what is impact on wildlife, & nontarget organisms
- Environmental fate – how long does it last, how does it break down
- Residue chemistry – what residues remain on treated crops
- Product chemistry – composition, manufacturing process
- Proposed label – use directions, caution statements

*Studies must meet specific quality assurance standards (GLP)*

# Good Laboratory Practice

## What is GLP?


40 CFR 160

| **Quality system of controls for research laboratories & organizations** | | |
|---|---|---|
| • Uniformity | • Reliability | • Quality |
| • Consistency | • Reproducibility | • Data integrity |
| Applies to field and laboratory studies generated for purposes of U.S registration of crop protection products | | |



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# GLP Elements

- **Organization and Personnel**
  - Quality Assurance staff
  - Responsibilities for:
    - Management
    - Sponsor
    - Study Director
    - Principal Investigator
    - Study Personnel
- **Facilities**
  - Test System Facilities
  - Facilities for Test and Reference Items
- **Equipment**
  - Design, maintenance, calibration
- **Testing Facilities Operation**
  - Standard operating procedures
  - Reagents & solutions
  - Animal & other test system care
- **Test, Control and Reference Substances**
- **Protocol for and Conduct of a Study**
- **Records and Reports**
  - Reporting of study results
  - Storage & retrieval of records & data
  - Retention of records

# Established Study Protocol

- Full and detailed study protocol is agreed upon prior to conducting a study

- Changes to the study protocol require a clear record of when, how, and why the study was changed; and must be signed off by the Study Director

# Recordkeeping

- Standard Operating Procedures (SOPs)
- Written, management-approved descriptions of how a specific task is to be performed, and by whom

# Recordkeeping

- Fully auditable study record
- Maintained for long periods, maybe decades
- Procedures for original recording of, and changes to, raw data
- Secure archive, designed for expedient retrieval

# Audits

- Independent audits of all internal studies
- Study reports are audited to ensure compliance
- Audits of CROs hired by sponsor companies are conducted by sponsor QAU
- Audits by EPA/OECA are done periodically of studies and facilities

# Sample GLP Statement in Study Report

**STATEMENT OF COMPLIANCE WITH GOOD LABORATORY PRACTICE**

**Study No.**: 181/17-215CD

**Study Title**: ABC Herbicide 25 EC: Validation of the Analytical Method

**Test Item**: ABC Herbicide 25 EC

This study was conducted in compliance with U.S. Environmental Protection Agency (EPA) Good Laboratory Practice (GLP) standards as set forth in 40 CFR Part 160 and as compatible with the OECD Principles of Good Laboratory Practice (OECD, 1998a; OECD 1998b) and regulatory authorities throughout the European Community and the Japan Ministry of Agriculture Test Guidelines for Pesticide Registration (JMAFF, 2012).

Johnson Labs

_____ _____

Joseph Jones — Date
Study Director

XYZ Company

_____ _____

Sponsor — Date

_____ _____

Submitter — Date

(Johnson Labs = CRO)

(XYZ Company = Registrant)

# CropLife America (CLA)

## Who we are:

Established in 1933, CLA represents the developers, manufacturers, formulators, and distributors of pesticides and plant science solutions for agriculture and pest management in the United States.

## Strategic Imperatives:

1. Increase collaboration and deepen partnerships with our members, our farmers, our customers, our value chain, and our food and environmental stakeholders, and decision-makers. (**Environmental Sustainability**)

2. Communicate in a proactive and consumer-oriented manner. (**Industry Perception**)

3. Ground our efforts in data and science to share knowledge and measure impact. (**Regulatory Integrity**)

# Improving Environmental Sustainability

Continually improve our environmental outcomes through voluntary conservation measures and innovative technologies

# Agricultural Sustainability

1. Defining Sustainability
2. Partnerships
3. Communication

## UN SDGs

- Members, grower groups, NGO, other associations, Food industry, and Hill Staff Surveys
- 3 U.N. SDGs selected: Innovation and Agricultural Productivity, Biodiversity, and Climate Change

## Engagement

- Outreach to Academics, Environmental NGOs, and conservation organizations

## Pesticides & Sustainability

- Amplifying member stories
- Fact Sheets (GHG Emissions Habitats Restored, Soil Health, productivity)
- Life Cycle Analysis
- Monitoring and Reporting

# Defining Sustainability

| Biodiversity | Climate Change | Innovation & Productivity |
| --- | --- | --- |
| • Improving soil health and resiliency<br>• Reducing topsoil erosion<br>• Improving pollinator health<br>• Promoting conservation | • Lowering GHGs<br>• Cutting fuel consumption<br>• Promoting reduced-till practices | • Newer chemistries<br>• Robotics and Precision Ag<br>• Decreasing yield loss<br>• Enhancing farmer education |

# Conservation

Last year, Corteva Agriscience announced a two-year agreement to support the efforts of the Nature Conservancy, working to help farmers grow more sustainably while protecting water quality.

# Pollinator Health

Since 2011, Bayer's Bee Care Program has supported more than 30 collaborative projects addressing local and regional threats and opportunities facing pollinators.



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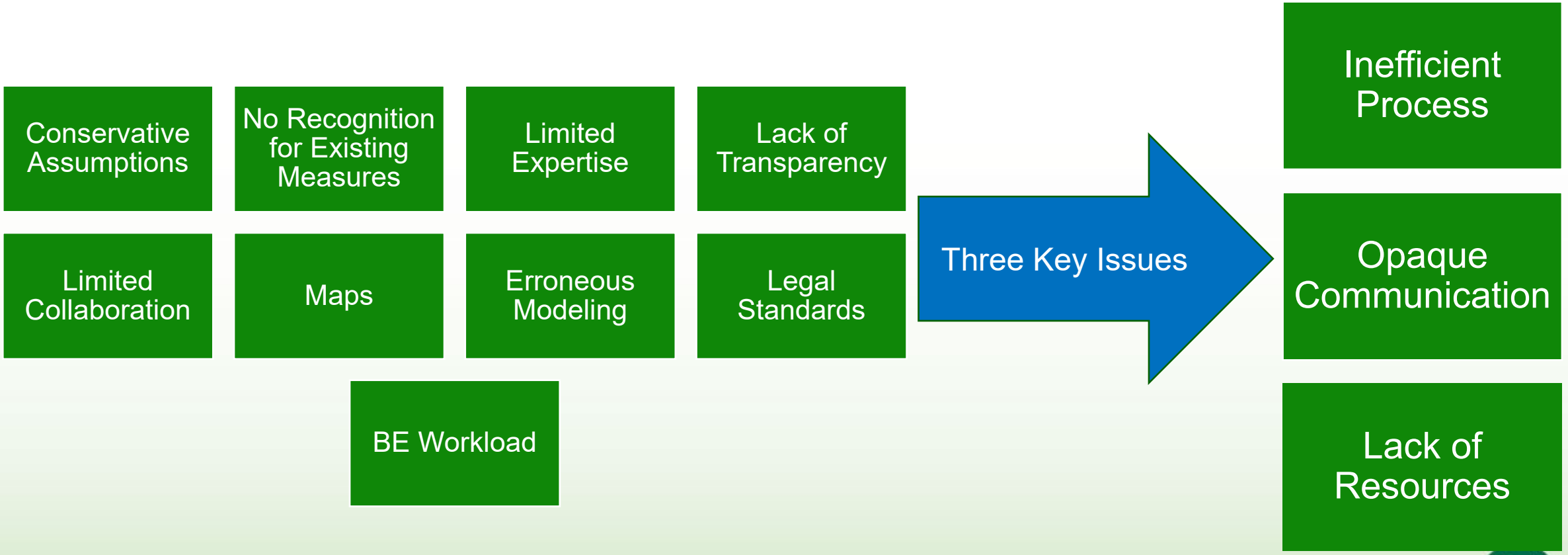
# Rescuing Farmland

Through the Syngenta Good Growth Plan, Syngenta has benefited 26.7 million acres of farmland on the brink of degradation - roughly the size of Tennessee.

# Regulatory Integrity

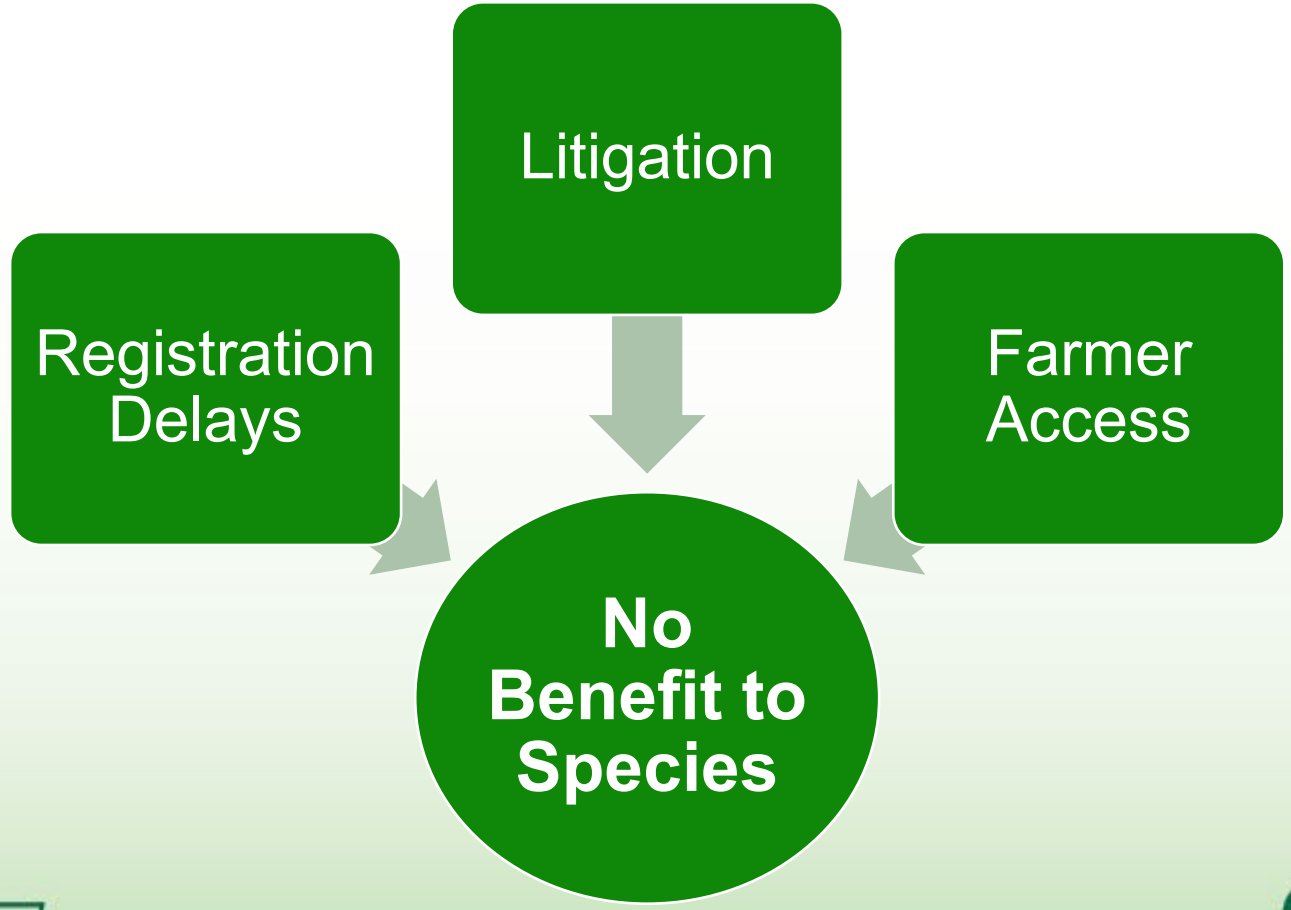
Preserve the statutory commitment to a transparent and reliable federal risk-based pesticide regulatory process and market policies that help ensure farmer and consumer access to needed tools and technologies.

# Endangered Species - Current Challenges:

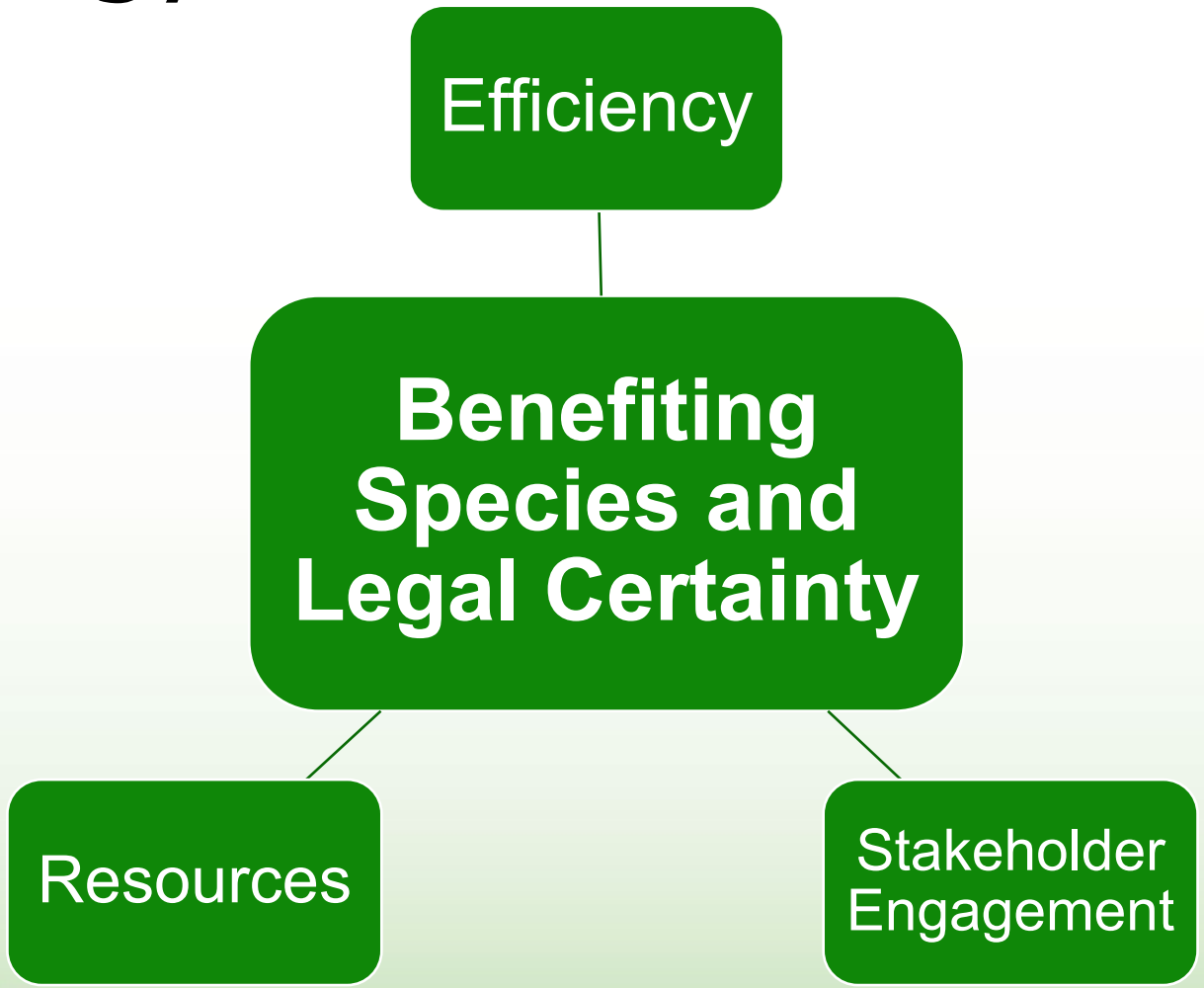



* Not the full list

# The Outcome of these Challenges:



# CLA's Strategy



# Key Takeaways

- CropLife America Supports
  - **More Collaboration**
    - Between federal family (EPA, Services, and USDA)
    - Stakeholder engagement (Federal Family, Registrants, Farm and Grower Groups, Environmental NGOs, and others)
  - **Better Communication**
    - Between the federal family
    - Explain the limited purpose of the Biological Evaluation, assumptions made, uncertainties in the data, etc. for non-technical audience
    - Explain Avoidance and Minimization aspects of pesticide registration, and the approved uses of a pesticide
  - **Improve Efficiency**
    - Improving Risk Assessment and recognition for existing practices
    - Leveraging existing and seeking additional resources for conservation of listed species

# Questions ?

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