



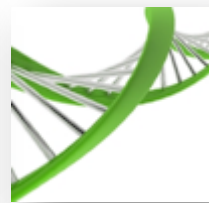
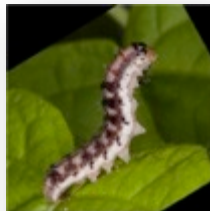
Insecticide Resistance Action Committee

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# Integrating IRM

## Brainstorming Session

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# Integrated IRM

## Key questions

- What is the problem to be solved?
- What are the main barriers to solving those problems?
- Tools available to implement
- Developing metrics to measure adoption
- Assigning accountability to certain functions

# Problem: Growers not planting refuge in Brazil

## Goal: 70% adoption of refuge

**Barriers:** Company commitment (planning, processes, programs, measurement)  
Lack of industry commitment/alignment/accountability  
Lack of enforcement (regulatory)

Solution Elements	What Metrics	Accountability
<ul style="list-style-type: none"><li>• Refuge seed production</li><li>• Refuge seed distribution</li></ul>	<ul style="list-style-type: none"><li>• Refuge seed availability/publish</li><li>• Training metrics</li><li>• Grower refuge adoption</li><li>• Insect monitoring</li></ul>	<ul style="list-style-type: none"><li>• Internal company</li><li>• Industry orgs (global &amp; regional)</li><li>• Public sector</li><li>• Regulators</li></ul>

**Resources Available:** Company roadmaps (IRAC-Biotech); Global orgs (CLI, ETS, Stewardship, Regulatory, Communications); Regional orgs (ABRASEM, AgroBio, CIB, APPS, IRAC-BR, Grower orgs, GBIO), Universities

# How to achieve grower adoption goal?

- Education/Training
- Incentives
- Penalties

# Strategy: Sustainable insecticide use

## Goal: 80% rotation implementation??

### Solution Elements

- MOA rotation
- Moderation

### What Metrics

- Labeling adoption
- Grower adoption
- Available MOAs
- ET limits
- Monitoring

### Accountability

- Internal
- Cross-company
- Public sector
- External (i.e. regulatory)

**Foundational: MOA labeling framework**

# ETS IRM Guide Outline

## Module 1: Risk Assessment

- Organizational structure
- Target geography, regulatory regime
- Target pest(s)

## Module 2: IRM Plan Development

- Product characteristics and pest management practices
- Resistance management options
- Monitoring plans

## Module 3: IRM Plan Implementation

- Market deployment strategy
- Education and training
- Stakeholder communication

## Module 4: IRM Program Maintenance and Compliance

- Monitoring procedures
- Complaint handling
- Resistance mitigation

# Module 1: Risk Assessment

- Identify individuals in the organization responsible and accountable for IRM
  - Technical, commercial and stewardship
- Identify the intended geographies and existing pest management programs
- Identify regulatory requirements and industry guidance for intended geographies
- Identify use patterns and pests most at risk for resistance
  - Where resistance would have greatest impact on value of the product to users and company
- Identify key internal and external stakeholders
- Establish and implement procedures for record keeping and documentation

# Module 2: IRM Plan Development (2-3 yrs pre-launch)

- Evaluate product performance
- Establish baseline susceptibility for key target pest(s)
- Develop IRM guidelines based on product characteristics, use patterns, and prior pest management practices
- Develop strategies to evaluate effectiveness of the IRM plan
  - Product performance
  - Insect resistance monitoring
  - Grower adherence to IRM guidelines
  - Education and training
- Communicate with key stakeholders
  - Licensees, government regulators, grower associations, trade associations, local academic/scientific experts, crop consultants, employees, and food & feed value chains



# Module 3: IRM Plan Integrated into Business Activities

- Grower implementation programs
  - Consider activities to enhance grower implementation, such as sales incentives (dealers, sales reps), use incentives (growers)
  - Measure and understand grower adoption of IRM practices
- Education/training programs
  - Product Use Guides, technical bulletins, etc
  - Tools to promote IRM
- Communicate broadly and transparently regarding IRM plans and implementation
  - Employees
  - Distributors, retailers, growers, licensees
  - Others
- Assess initial IRM implementation efforts
- Establish and implement record keeping & documentation procedures

# Module 4: On-going Stewardship for Life of Product

- Establish and implement monitoring procedures
  - Product adoption and use patterns
  - Implementation of IRM programs including BMPs
    - Identification of barriers to implementation
    - May include grower surveys
    - Refine educational programs based on feedback
    - Review practicality of IRM requirements
  - Resistance monitoring
    - Assessment of technology's performance in the field
    - Process for investigating performance inquiries
- Establish and implement complaint handling procedures
- Establish mitigation plans for potential and confirmed resistance
- Maintain record keeping and documentation

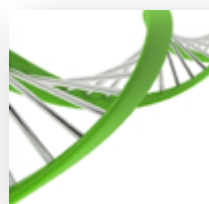
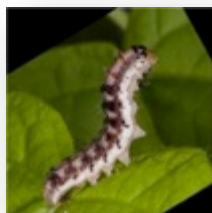


Insecticide Resistance Action Committee

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## Integrating IRM

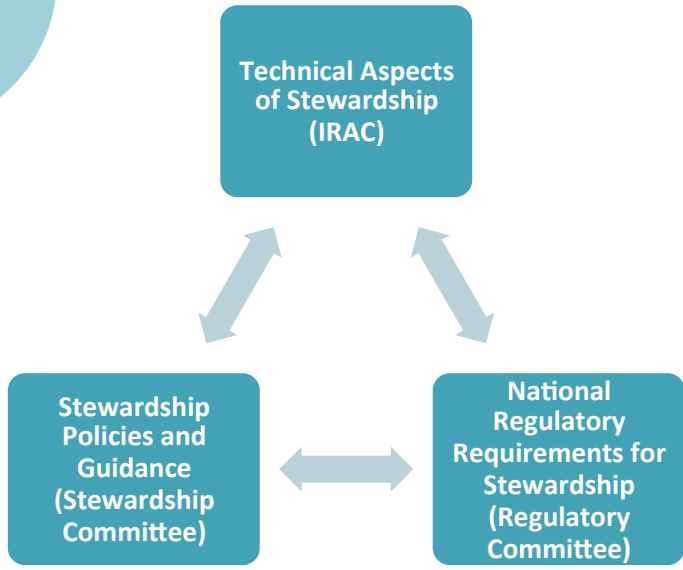
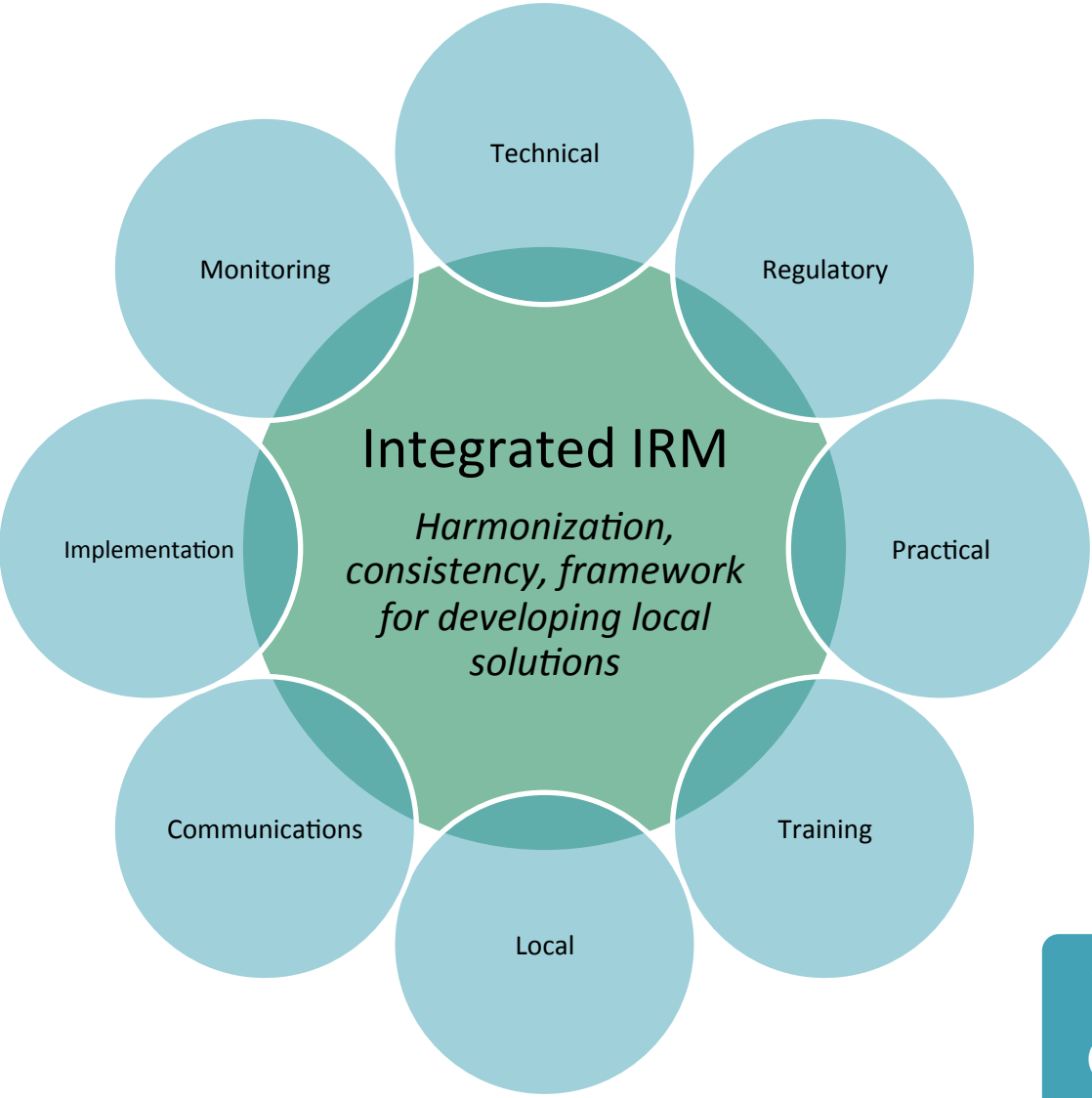
- Operational application
  - Scientific application
  - Moving forward
- 



# IRAC Mission

- Facilitate **communication and education** on insecticide and traits resistance.
- **Promote the development and facilitate the implementation of insecticide resistance management strategies** to maintain efficacy and support sustainable agriculture and improved public health.
- **Question: Are we effectively facilitating the implementation of IRM strategies?**

# Integrated IRM Approach

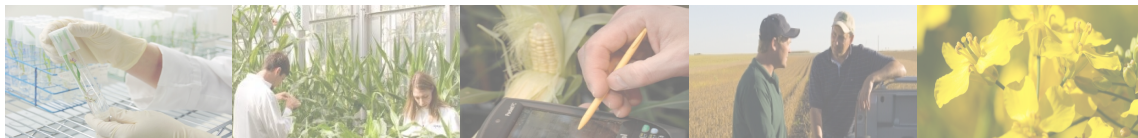


# Roles/Responsibilities

IRAC Biotech Team	Regulatory Committee	Product Stewardship PT	Communications Committee	ETS	National Associations & Stakeholders
Clint Pilcher DuPont	Matthias Pohl BASF	Jenny Dowil DuPont	Deb Carstoiu	Chris Holdgreve	
Develop technical advice on development and implementation of IRM strategies; improve cross-industry cooperation on resistance management	Work with regulators to determine how stewardship and regulations intersect	Develop outreach tactics aligned with ETS IRM modules including education of IRM with growers, academia, researchers, and government officials; IRM compliance assessment considerations	Develop outreach materials (for internal and external use) on IRM and industry stewardship programs	Develop IRM guides and audits for industry (public and private sector)	Regulator, farmer outreach and education; definition of compliance assessment program for the country

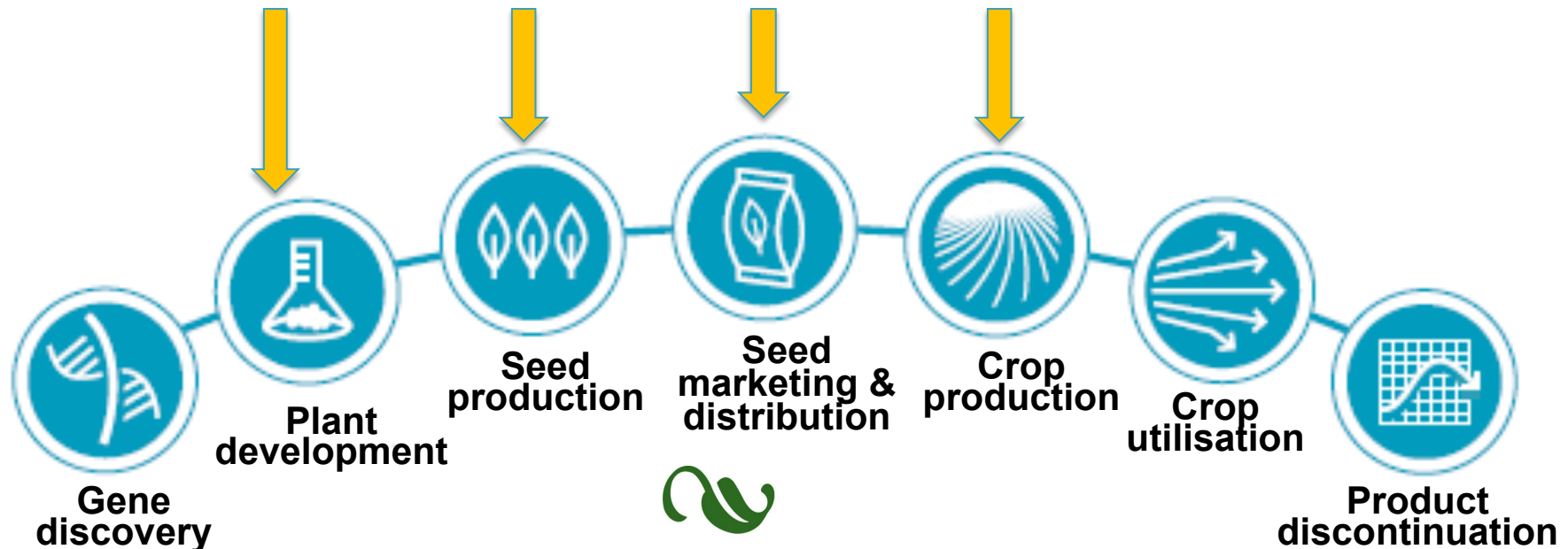
# Excellence Through Stewardship®

- A global industry-coordinated organization that promotes adoption of stewardship programs & quality management systems for the full **biotech plant** life cycle
- Focuses on the responsible management of the technology to support regulatory compliance, achieve product integrity, and assist in the prevention of trade disruptions
- Membership is open to any organization that engages in discovering, developing, handling, or commercializing **biotech plant** products
- Develops and promotes best management practice guides
- Members commit to third-party audits to improve & strengthen their programs



# Recognition of IRM being integral to biotech product life cycle

## IRM is Stewardship



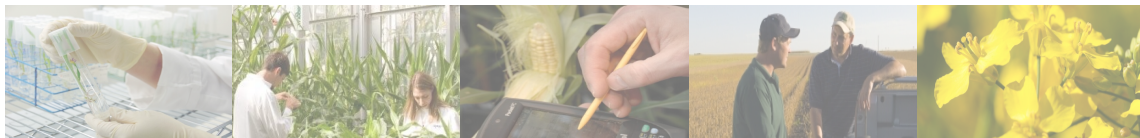
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# Industry Commitment to Durable Technology Deployment

- Insect Resistance Management (IRM) is fundamental to technology stewardship
- IRM practices are embraced throughout R&D, regulatory, and commercial operations and organizations
- Marketplace does not undermine technology sustainability

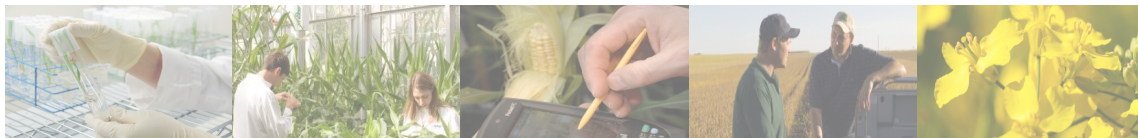


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# IRM Component

- Ensure member companies adhere to **IRM principles** in product development & commercialization of biotech-derived plant products
- Published, in collaboration with CLI & IRAC, a **Guide** for the development and implementation of IRM programs
- Developed an **Audit Checklist** for the IRM component
- **Implement IRM component** in key geographies in 2015
- Commitment by ETS members to successfully **complete audits** of IRM component by December 31, 2016



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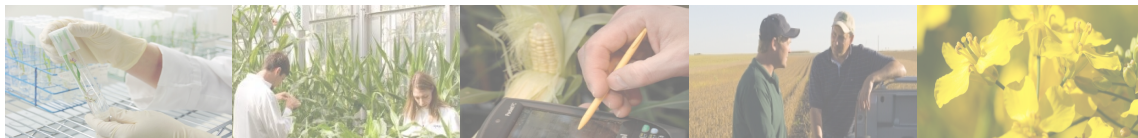
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# ETS Audits

**ETS auditors will verify member companies have processes and programs for IRM in place, including:**

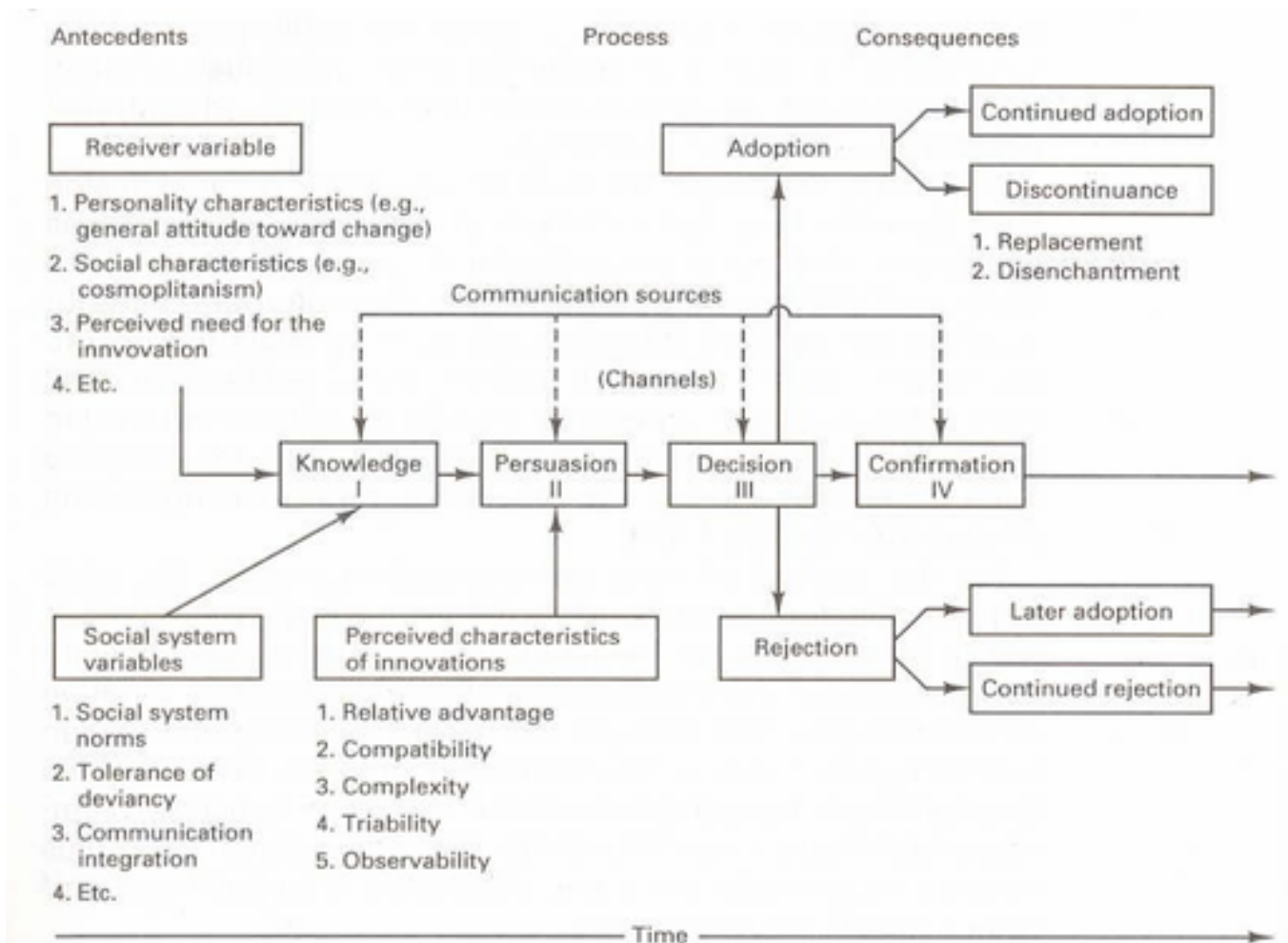
- Management accountability
- Addressing applicable regulatory requirements
- Developing and implementing product-specific IRM plan
- Implementing market deployment and IRM awareness strategy
  - Employees
  - Retailers
  - Growers
- Implementing compliance programs
- Implementing resistance monitoring
- Handling reports of potential resistance
- Records and documentation

**ETS does not  
audit growers**



# Diffusion of IRM (Innovation)

Innovation = “an idea perceived as new by the individual”



# Moving Forward - Discussion

- Is IRAC facilitating effective implementation?
- Who are our customers?

## Ideas:

- Technical industry alignment
  - Position papers on a general roadmap of IRM/BMPs
- Internal company alignment
  - Specific messaging directed to company/industry leadership
- Regional alignment and messaging
  - Identify regional/country industry orgs, regulators, grower orgs (unify on messaging)
  - Brazil example
- Utility of global and regional implementation resources
  - ETS 2.0: Potential Broadening Scope & Responsibilities
  - CLI Stewardship: Redefining Scope & Responsibilities

# IRAC International Ideas/ Actions



- What actions do we want our customers to take?
  - Company leadership? Industry organizations? Regulators? academics?
  - **Idea:** Expand on ETS IRM guide as blueprint to follow?
- Are industry organizations as reactive as farmers when it comes to IRM? In order for farmers to change, we need to change.....
  - Individual company agendas
  - Varying levels of interest, depending upon market share in certain geographies
  - Silos between research (technical) and commercial members in a company; silos among biotech and crop protection WGs
  - **Idea:** Use professional consultants to reach resolution
  - **Idea:** Comprehensive industry driven regulations
  - **Idea:** ETS scope broadened beyond biotech to include IPM
  - **Idea:** IRAC work to influence HRAC and FRAC

# Appendix



- **Considerations for the RM value of using insecticidal chemistry on transgenic crops expressing insecticidal proteins (2014)**
  - Combined use of chemistry and insecticidal proteins can offer the potential for an IRM tactic that could preserve the susceptibility of target insects to both components
  - IRM benefit will only occur with simultaneous exposure to lethal doses of both the insecticide chemistry and insecticidal protein(s).
  - IRM benefit will only occur if insecticide is applied to transgenic crop, but not the refuge.
  - Refuge in Bag strategy for insecticidal proteins does not allow for selective application of chemical insecticides only to transgenic plants and therefore, chemical applications to both the transgenic plants and refuge is unlikely to provide an IRM benefit.
  - Area-wide IRM benefits may be realized if insecticides are used to slow the geographic spread of target pests that may be resistant to the transgenic crop.
  - Combined effects of the chemical insecticide and the expressed insecticidal protein will be less effective and potentially detrimental if resistance has or is already developing to either the chemical or the protein(s).



# 2015/16 Biotech WG Goal

- Continue to characterize the interaction between traits & chemistry as it relates to durability of IC products and further define the coordination of related initiatives and activities