excellence through STEWARDSHIP

Guide For

Insect Resistance Management OF Biotechnology-Derived Plant Products

DISCLAIMER

The *Guide for Insect Resistance Management for Biotechnology-Derived Plant Products* ("Guide") is solely an educational tool and is guidance to assist users in developing and implementing their own organization-specific process for insect resistance management of plant biotechnology products.

The Guide is flexible, and its application will differ according to the size, nature and complexity of the organization and products involved. The Guide is representative and not exhaustive. It is the responsibility of any user of this Guide to consider that user's specific circumstances (1) when developing a process specific to its organization, and (2) in meeting any applicable legal requirements.

This Guide is not, and should not be used as, a substitute for (1) a user's own individual understanding of its legal requirements, (2) consultation by a user with its legal counsel and other advisors, or (3) direct contact with appropriate regulatory agencies.

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INTRODUCTION

Integrated Pest Management (IPM) is a holistic approach to sustainable agriculture that focuses on managing pests using a combination of sound agronomic best management practices that minimizes pest damage and maximizes the availability, effectiveness, and durability of tools needed for pest management. IPM includes the responsible use of crop protection and plant biotechnology products including developing, implementing, and promoting resistance management plans. Growers must be able to maximize production sustainably while minimizing losses and protecting biodiversity and the environment. Key components to be considered in IPM and resistance management strategies include:

- Preventing the build-up of pests and pest resistance.
- Preserving natural enemies within the cropping system (e.g., insect predators).
- Monitoring crops for pests and natural control mechanisms.
- Intervention through use of economically-feasible measures when additional control measures are justified.
- Using multiple complementary control tactics.

Insect Resistance Management (IRM) is a component of Integrated Pest Management (IPM) and requires a diverse set of tools and practices that are best identified and determined based on local farming operations and cultural practices. Resistance management is important to support the increasing global demand for food. An IRM plan should be flexible and updated as necessary based on changes in growing conditions, insect pest pressures and biology, product use patterns, and early indications of resistance development to ensure the continued effectiveness of the IRM plan. Insect resistance for purposes of this Guide is defined as resistance to proteins expressed by biotechnology-derived plant products (i.e., insect protected products) as opposed to chemistry or agricultural practices.

Purpose

This Guide assists developers of insect resistant biotechnology-derived plant products by providing guidance on the development and implementation of an insect resistance management plan(s) as components of an IPM strategy at stages throughout the product life cycle from research and discovery through commercialization and post-market activities[1].

Scope

This Guide addresses considerations for development of IRM Plans when developing and commercializing biotechnology-derived plant products that contain plant insecticidal proteins

[1] These include product discontinuation and incident response.

(PIPs) including assessment of the potential for resistance development and measures that may delay, or otherwise limit resistance development.

This Guide currently focuses on IRM and does not address other types of resistance management (i.e., Herbicide/Weed Resistance Management or Fungicide/Disease Resistance Management).

Development of plans for incident response, resistance monitoring, and resistance mitigation are also included. Because resistance decreases the utility and sustainability of the trait, IRM plans should have a global framework with the flexibility for regional and local considerations and implementation.

Abbreviations/Acronyms

BMP	Best Management Practices
ETS	Excellence Through Stewardship
IPM	Integrated Pest Management
IRM	Insect Resistance Management
PIP	Plant Insecticidal Protein
PUG	Product Use Guide
TUA	Technology Use Agreement

Definitions[2]

Dose: The level of control of a target insect pest provided by an insect protected product.

Insect Resistance Management (IRM): A program, including actions, taken to delay the development of insect resistance to pest control measures in target pest populations.

Integrated Pest Management (IPM): A strategy that includes "the careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of resistant pest populations and keep pesticides and other interventions to levels that are economically justified and reduce or minimize risks to human health and the environment. IPM emphasizes the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms."[3] IRM is a component of IPM.

[2] For the purposes of this guide insect traits and proteins are the ones expressed by biotechnology-derived plant products.

[3] International Code of Conduct on the Distribution and Use of Pesticides, FAO, November 2002.

Plant Insecticidal Protein (PIP): An insecticidal protein expressed in a biotechnology-derived trait/event.

Natural Control Mechanisms: Management of pest populations using natural predators, parasites or pathogens.

Pyramiding: A breeding or molecular stack of genes where two or more genes produce different proteins that provide at least two modes of action against the same target pest(s).

Refuge: Host plants that do not contain any biotechnology-derived insect protection traits, allowing a portion of a targeted insect pest population to escape exposure so that susceptibility to the trait/protein produced may be better maintained in an insect pest population.

Resistance: A genetically heritable change in a target insect pest population that arises from exposure of the insect pest population to the insect protection trait in the field and reduces the sensitivity of the insect pest population to the trait.

Stacking Genes: Inserting two or more transgenes which may express different proteins into one crop species.

Target Pest(s): Pest(s) in a cropping system that are economically damaging and are targeted by a PIP.

Trait: A genetically determined characteristic. In the context of this guide means biotechnology-derived trait or event.

Format of this Guide

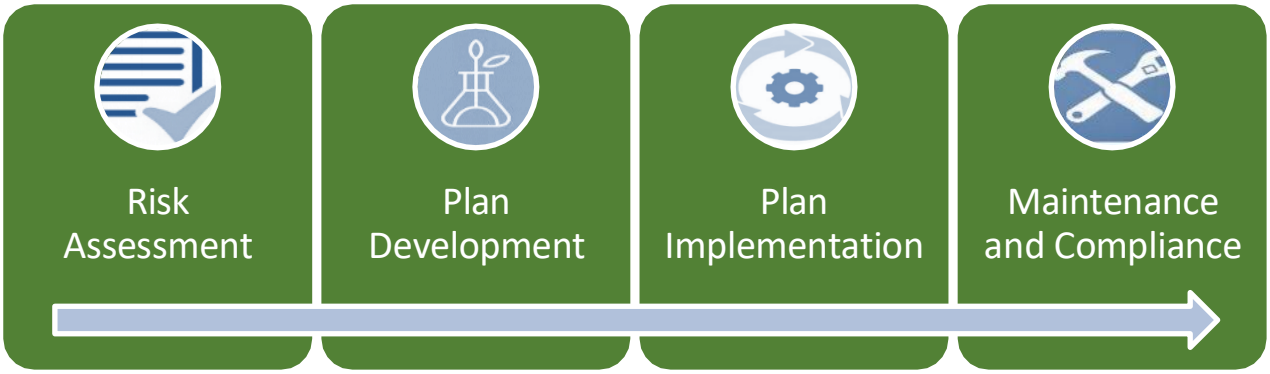
An organization may be involved in one or more activities associated with the development and commercialization of a biotechnology-derived trait for insect control where there is potential for development of resistance. For example, an organization may limit its activities to construct development, whereas another organization may have multiple integrated functions bridging from the laboratory to commercial production and sales. To accommodate these different business activities, this Guide has been developed as a series of informative educational modules that can be adapted to the specific activities pertinent to the organization's own operations and regulatory requirements. There is an emphasis on product sustainability through incorporation of IRM strategies in product development and commercialization. The organization can adopt the modules that are applicable to its own individual circumstance (e.g. licensees or technology developers). Each module covers activities with shared operational and regulatory considerations.

The guidance in this document is intended to be flexible and its application may differ according to an organization's policy, industry initiatives, regulatory requirements, geographical scope, and type of product involved.

IRM STEWARDSHIP ACTIVITIES

There are several activities that an organization should consider in developing an IRM plan. Not all the activities outlined in the modules below may be applicable or necessary for all organizations or products in each geographic area. Appropriate functions within an organization should be consulted in the process of designing an IRM plan that includes activities to meet the specific needs of its products, intended use, and geography. Those functions may include stewardship, biology, marketing, legal, licensing, production, regulatory, research, supply chain, and/or communications.

The Guide includes activities in four modules related to IRM Stewardship Activities:



Risk Assessment: This module involves activities related to a resistance risk assessment of the particular crop/insect control trait(s) combination regarding the intended agricultural geography where it is to be produced and commercialized.

IRM Plan Development: During IRM plan development, activities related to defining and exploring IRM options should be organized using the information gathered during the Risk Assessment.

IRM Plan Implementation: During this phase, the IRM plan should be integrated into the business activities. Key activities conducted during this phase include identifying sufficient resources (e.g., budget, employees), communicating the IRM plan, training stakeholders including growers, and ensuring the availability of appropriate refuge seed.

Maintenance of IRM Plan and Compliance with Requirements: The activities that are conducted at this phase support ongoing stewardship to ensure continuing compliance to the IRM plan and to monitor for issues which may require action, including adjustments to the plan.

KEY CONSIDERATIONS ACROSS MODULES

Establish an IRM Team

The IRM Team is responsible for each phase of the IRM plan and should include individuals that have sufficient knowledge and experience to be subject matter experts regarding insect pest resistance. This team could include subject matter experts from stewardship, biology, marketing, legal, licensing, production, regulatory, research, supply chain, and/or communications. Responsibilities of individuals should be defined.

The primary role of the IRM team is to effectively coordinate the following:

- Develop and ensure implementation of an IRM program.
- Be points of contact and subject matter experts for internal and external stakeholders.
- Handle changes to the IRM plan throughout the product life cycle.

Suggested Timing

Each module includes suggested timing for those activities. However, the timelines may differ considerably depending on several key factors including if it is a new trait or one already being utilized, the type of trait and target insect pest, and initial product launch and future commercialization plans. In addition, various activities may be applicable to the technology provider, licensee, or both. For purposes of the ETS audit program, the audit scope and checklist questions are identified as applicable to the technology provider, licensee, or both.

Documentation and Record Keeping

IRM plan documentation and record keeping linked to the IRM stewardship activities should be fully integrated into your Quality Management System and Stewardship Program. Policies and procedures for records and documentation are critical components of an IRM program. This documentation and record keeping should be managed according to an organization's own global documentation management policy. ETS members can access additional information in Records Management and Document Control on the Members Only webpage: https://www.excellencethroughstewardship.org/qmsbasics.

Third-Party Collaborations

Due to the nature of IRM, some of the outlined procedures, data, and documentation will be performed or provided by a third party. This may be done by local/regional seed associations, regulatory working groups, or other external stakeholders that have locally organized this activity. This information may be used to revise the IRM plan in case changes or failures are detected.

Developers, Providers and Licensees

Developers, technology providers, licensees, and those responsible for commercialization of biotechnology-derived PIPs may have different responsibilities for each phase of the IRM requirements. Some examples include but are not limited to:

- A single organization may be responsible for all phases of a product life cycle including development through commercialization and therefore all phases described for IRM.
- An organization may also license commercial PIPs to others who may need to implement and monitor what the organization already has in place for IRM.
- Other organizations may only manage transformation and early research and development activities but license mid to late development and commercialization activities to others. In this case the licensee may have sole responsibility for all phases described for an IRM plan.

Responsibilities for each phase of IRM described within this Guide must be identified by those involved.

MODULE 1: RISK ASSESSMENT

Module 1 of the IRM plan involves risk assessment. This first phase includes 4 components to develop and consider:

- ✓ Identify the intended geography and existing insect pest management programs.
- ✓ Identify biology and ecology of major insect pests to be controlled by insect resistant trait.
- ✓ Identify key stakeholders.
- ✓ Record keeping and documentation procedures.

Suggested Timing for a New Trait/Protein: Product concept through three or more years prior to proposed product launch.

The product concept for a new insect-protected product will guide the organization in defining product attributes based on the IRM strategy. This initial phase involves activities related to a resistance risk assessment of the particular crop/insect control trait(s) combination regarding the intended agricultural geography where it is to be produced and commercialized.

Identify Geography and Existing Management Programs

During the development of an IRM plan, identify the geography in which production and commercialization of the product is proposed and assess the local agronomic practices. The assessment will guide the organization in determining the components of an appropriate IRM plan. Considerations include:

- Geographic distribution of farm sizes
- Intercropping, monocultures and/or crop rotation
- Projected product adoption levels
- Expected level of adherence with refuge requirements and configuration
- Local agricultural economic drivers (e.g., spectrum from subsistence to industrialized)
- Local growers' current experience or history with insect protected crops
- Ability to influence and monitor grower behavior with respect to IRM
- Products offered and volumes, including products or crops with similar traits or offered by competitors
- Existing insect protected crops with similar or different modes of action
- Availability and current recommendations being used for insect control prior to trait use
- Expected shift from effective chemistry to biotechnology-derived insect protected product(s)
- Cultural (e.g., crop rotation) and biological control tools

Identify Biology and Ecology of Controlled Insects

Defining the intended use of an insect protected product will help an organization assess appropriate IRM requirements. With the identification of the target insect pest(s), the organization can determine the appropriate scope of IRM requirements and plan through consideration of items such as:

- Number of insect generations/growing season
- Stage(s) of insect life cycle responsible for damage
- Alternate crop and non-crop host utilization and distribution
- Adult movement and mating behavior
- History of resistance in target insect pest(s) and related insect pests
- Genetics of resistance and exposure to existing insect resistant crops, if any
- Cross-crop IRM requirements

Identify Key Stakeholders

It is important to develop a communication plan to engage with various stakeholders and key influencers who are directly affected by, and/or can influence the IRM plan development and implementation. Different stakeholders may need to be consulted and/or provided different types/levels of information at different times. Key stakeholders may include licensees, governmental regulators, grower associations, trade associations, academic/scientific experts, crop consultants, and food and feed value chains.

Record Keeping and Documentation Procedures

Specific examples of documentation in this module may include:

- Literature reviews on agricultural systems and biology of key target insect pest(s).
- Results of the risk assessment.
- Records of communication and collaboration with key stakeholders and key influencers.

MODULE 2: IRM PLAN DEVELOPMENT

Module 2 of the IRM plan involves plan development. IRM plan development includes 8 components to consider. These components include:

Suggested Timing for a New Trait/Protein: Two or more years prior to proposed product launch.

- ✓ Evaluate the product performance of the trait
- ✓ Establish baseline susceptibility for key target insect pest(s)
- ✓ Develop IRM requirements based on product characteristics and prior insect pest management practices
- ✓ Evaluate refuge options
- ✓ Develop strategies to evaluate effectiveness of the IRM plan
- ✓ Identify Regulatory Requirements and Industry Guidance
- ✓ Communicate with key stakeholders
- ✓ Record keeping and documentation procedures

Key considerations for each component of IRM plan development are summarized below.

Evaluate Product Performance

Key considerations in evaluating the product performance of a trait to be utilized in the development of an IRM plan include:

- Level of control at the economically important life stages of each target insect pest.
- Expression levels (in terms of insect control) within the target plant or plant parts during different crop development stages when target insect feeding occurs e.g., within leaves, buds, flowers, stems/stalks, roots, etc.
- Reliance on scouting, thresholds and possible/probable use of supplemental insect management measures when insect pest populations are excessive and control of target insect pest by PIPs may be incomplete e.g. use of insecticides for supplemental insect pest management when target pest populations are excessive.

If conducting field trials to evaluate the product performance of the trait during R&D phases, there may be additional regulatory requirements pertaining to the trials, depending on the geography and the regulatory status of the product (see Module 3 of the ETS Guide for Maintaining Plant Product Integrity).

Establish Baseline Susceptibility

To monitor the changes in susceptibility to PIPs, organizations should measure the baseline susceptibility of key target insect pest(s) populations to the trait across the growing region and this should be completed prior to widespread planting of insect protected crops. Considerations include:

- Frequency of monitoring
- Sampling methods
- Testing protocol

Develop IRM Plan Requirements

An IRM plan should be developed considering the available science as well as any other constraints that were identified, including:

- Pyramiding (stacking) multiple insecticidal traits (with different modes of action) versus single insecticidal traits
- Refuge management
  - Planning
  - Planting
  - Recording
  - Refuge dynamics: ratios allowed for PIP acreage vs. refuge acreage e.g. 80:20 or 95:5; potential for using integrated refuge products based on target pest biology
- Maximum acreage allowances

Additional IRM tools:

- BMP's that complement refuge effectiveness may include:
  - Scouting and applying insecticides appropriately (consideration for both insect protected and refuge acres)
  - Use products with multiple modes of action to reduce the likelihood of resistance development
  - Cultivation
  - Destruction of crop residues
  - Crop rotation
  - Seed treatment
- Regulatory submissions: in some countries the IRM plan must be provided to the regulators for review.
- Consider value of aligning IRM approaches for products with similar attributes for ease of farmer implementation and management

Evaluate Refuge Options

Factors to be considered include:

- Attributes and characteristics of refuge relative to the product such as compatible agronomic characteristics, plant size, bloom, fruiting, maturity group, and crop cycle
- Relative size of refuge
- Ratios of crop: refuge
- Placement of refuge
- Allowances for insecticide usage within the refuge
- Agronomic management of refuge (fertilizer, irrigation, pesticide applications)
  - Compatibility with current pest management and agronomic practices
  - Harmonize refuge options within a comprehensive IPM plan
- Contribution of alternate host crops or natural vegetation
- Industry guidance and examples on refuge options
- Regulatory requirements for refuge
- Deployment options for refuge (e.g., blended seed products; co-packaging of seed)
- Likelihood that growers will comply with IRM requirements
  - Ways to enhance compliance
  - Practicality of refuge
- Planning for refuge seed availability and distribution, by the organization developing the trait or by agreement with another organization

Develop Strategies to Evaluate Plan Effectiveness

This strategy should consider evaluation of the effectiveness of program and plan components such as:

- Product performance
- Insect resistance monitoring
- Strategies for monitoring grower compliance (with refuge and BMP guidelines)
- Education and training

The strategy should consider both regulatory and industry requirements and recommendations and address how changes will be incorporated into the plans, when required. Alignment with all other applicable industry members (trait providers and chemistry providers) when developing the strategy should be considered.

Identify Regulatory Requirements and Industry Guidance

During the development of an IRM plan, identify and address the regulatory requirements of the geography for which production and commercialization is planned. In addition to regulatory requirements for an IRM plan, industry initiatives and regional or local IRM initiatives should also be considered when determining an appropriate IRM plan.

Examples of Local and Regional IRM Initiatives and Regulatory Requirements include:

Brazil – Boas Prácticas Agronômicas – The Good Agricultural Practices program was developed in Brazil to facilitate a dialogue with producers and scientists on the benefits of these practices intended to preserve the effectiveness of Bt technology.
https://boaspraticasagronomicas.com.br/

Colombia – Programa MARI – MARI is a local IRM program that outlines the best tools for insect resistance management in Colombia.
https://www.programamari.com/

USA – Environmental Protection Agency - https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/insect-resistance-management-bt-plant-incorporated

Communicate with Key Stakeholders

The development and implementation of a communication plan for IRM is recommended to ensure the program supports product sustainability. The communication plan provides an opportunity to receive input from various stakeholders as well as communicate resistance management plans for the new product. Different stakeholders may need different types/levels of information at different stages. Communication and outreach to stakeholder groups often begins during the pre-commercial scale-up of the product and can continue throughout the remainder of the product life cycle. Examples of relevant stakeholders include licensees, government regulators, grower associations, trade associations, local academic/scientific experts, crop consultants, employees, and food and feed value chains).

Record Keeping and Documentation Procedures

Specific examples of documentation in this module may include:

- Refuge seed availability plan
- Product-specific IRM needs
- Communications with stakeholders

MODULE 3: IRM PLAN IMPLEMENTATION

Module 3 of the IRM plan involves plan implementation. This third phase includes 5 components to develop and consider. These components include:

Suggested Timing for a New Trait/Protein (Where Practical): Two years prior to launch. For licensees this timing may differ depending on circumstances.

- ✓ Develop and implement market deployment strategy by region/geography
- ✓ Develop and implement literature, education, and training programs
- ✓ Communicate broadly and transparently regarding IRM plans and implementation requirements, including tools specific to the product
- ✓ Early Assessment of IRM implementation efforts
- ✓ Record keeping and documentation procedures

Key considerations for each component of IRM plan implementation are summarized below.

Develop and Implement Market Deployment Strategy

IRM stewardship activities, including education, monitoring for technology adoption and compliance with refuge requirements, and promotion of BMPs should be integrated into the local commercial business model and activities. Specific consideration should be given to activities that would help to enhance and promote compliance with the IRM plan such as:

- Delivery of refuge
  - Blended products (e.g., seed mix) where biotechnology-derived insect protected seed and refuge seed are combined within a single bag for the purposes of IRM when allowed by local law and when appropriate regarding the biology of the insect pest.
  - Co-packaging (e.g., bag in bag) where the refuge seed is provided in a smaller package along with the biotechnology-derived insect protected seed when allowed by local law and when appropriate regarding the biology of the insect pest
  - Refuge sold separately.
- Availability of Refuge Seed
  - Refuge seed is included in supply chain plan and is available to growers in the geography and market where the trait is being sold.
  - Organization selling the seed and PIP traits ensures that sufficient and appropriate refuge seed is available from their organization or other organization(s) in the geography.
- Local commercialization plan, website, brochures, and customer care:
  - May consider additional activities or programs to enhance compliance with IRM requirements with seed dealers and retail sales representatives, and growers to promote proper planting and management of refuges.

- Farm visits or similar survey activities to measure and understand grower adoption of IRM requirements

Develop and Implement Educational Materials and Training Programs

Education/training programs should be developed and implemented for key stakeholders specific to their role in the IRM plan. Education/training tools may include:

- Product Use Guides (PUG)
- Technology User Agreements (TUA)
- Development of tools to promote and manage IRM
  - Website (e.g., http://www.irac-online.org/)

Examples of key stakeholders that may require education/training include:

- Growers
- Internal employees
- Licensees
- Sales Agents/Distributors/ Retailers

Communications

Organizations should develop adequate educational materials and communication tools as necessary to communicate broadly and transparently regarding IRM plans requirements that are specific to the PIP product.

Employees: An internal communication plan for personnel involved in implementation of the IRM plan should be developed that provides information regarding the importance of IRM, the key requirements of the product-specific IRM plan, regulatory implications (if applicable) and consequences of non-compliance with refuge requirements.

Distributors, retailers, growers and licensees: The development and implementation of a communication plan that includes training for growers, distributors, retailers and licensees for IRM stewardship is crucial for guiding and informing these stakeholders of requirements associated with the product that they must fulfill. Communication and training may be accomplished through various formats such as grower meetings, product literature, messaging at retailers, customer mailings, product labeling, Technology Use Agreement (TUA), Product Use Guide (PUG), and/or website.

Other stakeholders: The implementation of a communication plan for IRM stewardship is recommended for guiding and informing stakeholders. Different stakeholders may need different

types/levels of information at different stages. These might include governmental authorities and regulators, grower associations, trade associations, chemistry providers, local academic/scientific experts, crop consultants, and food and feed organizations and value chains. Communication/outreach to stakeholder groups often begins during the pre-commercial scale-up of the product and can continue throughout the marketing phase.

Early Assessment of IRM Implementation

The organization should have systems in place in order to assess IRM plan implementation and effectiveness of the education activities during this early phase. A more comprehensive assessment is expected during Module 4 – IRM Plan Maintenance and Compliance with IRM Requirements. However, during implementation it may be useful to assess and respond to early feedback from growers, employees, regulators and other key stakeholders. This implementation phase assessment should be evaluated and may suggest appropriate modifications to the IRM plan.

Record keeping and documentation procedures

Specific examples of documentation in this module may include:

- Training, training records, and communications materials
- Product and IRM educational materials
- Plans for refuge seed supply
- Early Assessment of IRM implementation efforts (change management)

MODULE 4: MAINTENANCE AND COMPLIANCE

Module 4 of the IRM plan involves plan maintenance and compliance with IRM requirements.

This fourth phase of the IRM plan includes 8 components to develop and consider. These include establishing and implementing procedures for:

Suggested Timing for a New Trait/Protein: During product launch, use, and sale through product discontinuation.

- ✓ Adoption rates and agronomic use patterns in relevant geographies
- ✓ Compliance with refuge and other IRM requirements (including BMPs)
- ✓ Resistance monitoring
- ✓ Collaborating with applicable industry representatives
- ✓ Complaint handling or non-compliance with refuge requirements
- ✓ Mitigation plan development
- ✓ Compliance with regulatory requirements
- ✓ Record keeping and documentation

Key considerations for each component of IRM plan maintenance and compliance with IRM requirements are summarized below.

Adoption Rates and Agronomic Use Patterns

One of the key components of the risk assessment used to develop the IRM plan was the assessment of current agronomic practices (Module 1). As the agronomic practices/patterns change, the effectiveness of the IRM plan can be affected. Therefore, it is important for an organization to monitor the technology adoption levels and changes in agronomic use patterns and practices (e.g., alternate hosts) and make necessary changes to the IRM plan to improve effectiveness.

Compliance with Refuge and Other Requirements

For an organization to assess compliance with the IRM plan, programs should be in place to monitor compliance with refuge and other IRM requirements, particularly if a structured refuge is part of the plan. Monitoring activities to assess compliance with IRM requirements may include grower surveys and/or in-field inspections. Depending on the regulatory requirements, this monitoring may be mandatory or voluntary. Considerations include:

- Developing a plan to identify and manage customers who have not complied with the IRM requirements. This plan may include additional education and assistance or denied access to the technology in subsequent seasons.

- Refining educational programs based on compliance with refuge requirements.
- Reviewing the IRM requirements to determine if they can be made more flexible or practical without compromising their effectiveness.

Complaint Handling or Non-Compliance

The organization should have procedures in place to address grower complaints as well as any concerns that are identified through the course of the various monitoring procedures as described above. Key considerations to include are:

- Tracking complaints and non-compliance with refuge requirements
- Communication plan for:
  - Follow-up with growers/ customers
  - Changes made to the IRM plan

Resistance Monitoring

It is important for an organization to implement procedures to monitor for changes in target insect pest susceptibility to the product. This type of monitoring will inform the organization of any changes in product efficacy that may require changes to the IRM plan. Considerations include:

- Baseline studies
- Insect pest susceptibility studies which may include:
  - Insect pest populations collected annually across the production area
  - Insect pest populations collected following control complaints
  - Laboratory feeding tests with purified or semi-purified proteins
  - Standardized lab or greenhouse testing of insects against plants expressing the trait
- Assessment of technology's performance in the field including evaluation in response to reduced efficacy or performance complaints
- Process for investigating performance inquiries including collection and bioassay of target insects when appropriate and possible
- Monitoring secondary/minor insect pests as their population can increase because of the decrease in the target insect pest(s) population(s)

Collaboration

If there is more than one trait provider, collaboration with the other applicable industry members to conduct monitoring should be considered.

Mitigation Plans

- Process for investigating performance inquiries
- Update the IRM plan to manage any potential insect resistance development and align with industry initiatives when applicable
- Refine educational programs

Regulatory Reporting Requirements

Depending on the geography and regulatory authority requirements, there may be reporting requirements that must be fulfilled. A process should be established to handle the reporting requirements. Examples of reporting requirements may include: refuge adherence monitoring results, baseline susceptibility, resistance monitoring activities and results, product performance complaints, etc.

Record keeping and documentation

Specific examples of documentation in this module may include:

- Insect resistance baseline and monitoring for resistance
- Compliance with refuge requirements
- Reports of potential resistance
  - Include the final status of the potential resistance follow-up (e.g., not resistant, confirmed resistance)
- Product adoption and use data

RESOURCES

- CropLife International (http://croplife.org/plant-biotechnology/stewardship-2/resistance-management/)

- CropLife International - Practical Approaches to Insect Resistance Management for Biotech-Derived Crops (http://croplife.org/wp-content/uploads/2014/04/Practical-Approaches-to-Insect-Resistance-Management-for-Biotech-Derived-Crops.pdf)

- Graham P. Head and John Greenplate. 2012. *The Design and Implementation of Insect Resistance Management Programs for Bt Crops* https://www.tandfonline.com/doi/full/10.4161/gmcr.20743

- Insect Resistance Action Committee (http://www.irac-online.org/)

- IRAC Biotechnology Web Page (http://www.irac-online.org/teams/biotechnology/)

For Information on Herbicide/Weed Resistance Management, please refer to the following:

Global Herbicide Resistance Action Committee **-** https://hracglobal.com/

"The global Herbicide Resistance Action Committee (HRAC) is an international body founded by the agrochemical industry, helps to protect crop yields and quality worldwide by supporting efforts in the fight against herbicide-resistant weeds. HRAC is dedicated to a cooperative approach to the management of herbicide-resistant weeds. By collecting, assessing and sharing information on weed resistance, HRAC acts as a comprehensive and reliable source for the people who feed our growing world."

- *Best Management Practices (HRAC)* - https://hracglobal.com/prevention-management/best-management-practices
- *Guideline to the Management of Herbicide Resistance* - https://hracglobal.com/files/Management-of-Herbicide-Resistance.pdf
- *Regional HRACs* - https://hracglobal.com/who-we-are/regional-hracs

Croplife International

- *Implementing Integrated Weed management for Herbicide Tolerant Crops* - https://croplife.org/wp-content/uploads/2014/04/Implementing-Integrated-Weed-Management-for-Herbicide-Tolerant-Crops.pdf