

Sharing Best Practices in Biotech Stewardship: Field Trial Compliance Training in Africa

SUMMARY: The manual on “Compliance Management of Confined Field Trials of Biotech-derived Plants” contains best practices and guidelines developed by industry to organise, manage and complete field trials – a critically important stage of biotechnology research and development – in compliance with regulations. Educational workshops based on the manual have been given around the world to share this information with regulators, researchers and members of the biotech industry who are conducting trials, monitoring research or even drafting new regulations. The training has been especially useful in Africa where agriculture biotech research is blossoming.

Since agriculture biotechnology research began in earnest in the early 1990s, stewardship strategies, tools and protocols have been developed to encourage the safe and responsible use of biotech products at every step of research, development and commercialisation. The member companies of CropLife International pool their collective experience in biotechnology stewardship, and share it broadly with the agriculture community through resource materials and training. As part of this commitment, they published a manual entitled “Compliance Management of Confined Field Trials of Genetically Engineered Plants” which is used in educational workshops worldwide and adapted for local conditions and needs.

Why field trials?

Safety assessments for biotech crops begin in the lab, but field trials are the only way to gain real-world information on the agronomic potential and environmental safety of plants. Stewardship practices that enable farmers to grow the product safely and effectively in open fields are developed during field trials, and the trials produce material for food and feed safety tests. For these reasons, field trials are a critical step in developing biotechnology crops.

“Confined” field trials represent the first time experimental plants are grown outside of the lab or greenhouse, and they are authorised by regulatory authorities to take place under strict conditions in order to minimise exposure to the environment. Standard Operating Procedures (SOPs) have been developed by researchers to help them comply with those strict regulatory conditions by using detailed methods for performing routine tasks associated with field trials in ways that reduce possible risks.

The manual

CropLife International’s “Compliance Management of Confined Field Trials” manual is a practical guide designed to help those conducting field trials to comply with regulatory requirements. Its chapters describe industry best practices for every stage of conducting field trials:

- **Transport and storage** of plant materials, including obtaining necessary permits for shipping, labelling materials appropriately and securing storage areas.
- **Site management** of areas where field trials will be conducted, including site selection, marking and mapping, cleaning field equipment and isolating the field trial plants.
- **Harvest and disposition** of materials from field trials, including monitoring the trial site harvest and disposing of, keeping and transporting harvested material.
- **Post-harvest management** of the trial site, including restrictions on land use to monitor for removal of residual experimental plants.

The Manual provides sample SOPs and reporting forms for each stage of field trial management as well as case studies describing field trial requirements and processes around the world, including in developing countries.

The workshops

More than 25 training workshops based on the manual have been given since 2005, primarily in developing countries. In addition to explaining best practices for each stage of conducting field trials, the two-day training sessions typically include site visits to see stewardship measures in field trials first-hand and real-life scenarios to work through.



For example, if your field trial of maize is about to flower and you discover that your neighbour has also planted maize within 400 meters of your trial, are you out of compliance with field trial regulations? If so, must you notify the authorities? What can you do to get back into compliance? These scenarios are regularly rated as the participants' favourite part of the training because they are able to apply everything they've learned to real-life situations.

The impact

The "Compliance Management of Confined Field Trials" manual has become an important educational resource for two types of organisations: regulatory agencies that are developing field trial guidelines for their countries and research institutions that are conducting field trials.

In Africa, at least four countries have borrowed ideas from the manual to develop their own regulatory systems for field trials. The first two countries to receive training were Kenya and Tanzania, both then in the process of developing regulatory requirements for field trials. Impressed with the stringent yet practical management tools in the manual, they adopted many of the requirements and reporting forms, while adapting them to conditions in their own countries. Regulators from Kenya and Tanzania trained their counterparts in Uganda, and regulators in Burkina Faso also made use of the material. Because they drew on the same source, these four countries have similar requirements for field trials. Ongoing training ensures that regulators, scientific advisors and risk assessors all interpret requirements and monitor field trials consistently. This enables researchers to more easily plan field trials to assess the regional benefits of biotech crops.

Research organisations in Africa have used the manual in slightly different ways to establish field trial management protocols within their institutions. Africa Harvest is a non-profit agriculture biotechnology research organisation working with sweet potatoes and sorghum and running field trials of these crops in several countries. Following a workshop on the CLI manual, they are developing their own version of the manual that will provide detailed protocols to meet compliance requirements in all of the countries where they are active. Similarly, the African Agricultural Technology Foundation (AATF) has used the CLI manual to develop their own SOPs for field trials of the Water Efficient Maize for Africa (WEMA) project to comply with requirements in each of the five countries where those trials will take place. They have also trained all of their field trial managers and staff working on the project.

Many of the educational workshops have brought diverse audiences together, enabling regulators and researchers to learn about each other's needs and concerns. This further aids the development of practical and appropriate field trial management systems in Africa, good stewardship and compliance with science-based regulations.

Conclusion

Whether serving as "refresher" courses in countries that have already commercialised biotech crops, as educational opportunities for those working with plant biotechnology, or as a model for regulating field trials for policy makers in countries just beginning to adopt the technology, the "Compliance Management of Confined Field Trials" manual is having an impact. In Africa and elsewhere around the world, industry best practices for managing field trials are enabling new biotech crops to be tested responsibly according to international standards and local requirements.