

A. Introduction

In pursuit of their mission, CGIAR Centers continuously evaluate potentially useful breakthroughs in science and technology to responsibly incorporate them in their own work. The range of tools and methods used by CGIAR Centers is therefore constantly increasing. CGIAR's formal policy position on research involving modern biotechnology is as stated in the November 2020 approved [CGIAR Ethics Research Code](#).¹

Whereas many biotechnologies (e.g. molecular markers, tissue culture, molecular diagnostics, genomics) are used ubiquitously in agricultural R&D around the world, others (e.g. Genetic Engineering, Genome Editing) are subject to country specific regulations reflecting the complexity of risk assessment and sometimes diverging views on how to ensure safety to human health and the environment.

This 'Questions and Answers' document focuses on CGIAR Centers' use of Genetic Engineering to insert foreign DNA containing new genes or other DNA sequences into the genome of plants or animals to confer new and useful properties. The products of the application of this technology are genetically engineered organisms, often referred to as "genetically modified organisms". A separate statement focuses on CGIAR Centers' use of genome editing technologies when used to change the DNA sequence in an existing gene in the genome of plants or animals.

B. Questions and Answers

What is Genetic Engineering?

In Genetic Engineering, genes or parts of genes are inserted into the genomes of plants or animals. The most frequently relied upon means of inserting genes in crop plants takes advantage of the natural DNA transfer capacity of a soil bacteria *Agrobacterium tumefaciens*. Other methods have been developed, including methods for inserting genes in animals. The inserted gene(s) can be of any source including the same species as the host organism into which the gene is inserted, and other, more evolutionary-distant species, genera, or kingdoms. Once inserted, the foreign genes are transmitted to the next generation in the same manner as all other genes.

¹ In the event of any inconsistency between this Q&A document and the CGIAR Research Ethics Code, the latter prevails.

When and why would CGIAR Centers use Genetic Engineering?

All CGIAR Centers' plant and animal genetic improvement programs currently depend on conventional breeding techniques, assisted increasingly by a variety of molecular technologies such as molecular markers, and genomics. Genetic Engineering technologies are considered when conventional technologies are either unable to achieve the desirable genetic improvement, or when large efficiencies can be gained in optimizing a high-priority trait, including when existing genetic variation is insufficient to reach the desired impact. The decision to use Genetic Engineering technologies is guided by multiple criteria, including absence of effective and efficient conventional alternatives, safety considerations, priority or value of the attribute to improve, regulatory requirements, intellectual property environment, resource efficiencies, financial costs, and expected benefits. Examples by CGIAR Centers include Golden Rice, bacterial wilt resistant banana, and late blight resistant potato.

CGIAR Centers have a responsibility in pursuit of the respective mandates to ensure that the potential benefits of science, including genetically engineered crops and animals, are equitably available to resource-poor farmers and consumers who may use them within their respective national policies and regulations.

What are the advantages of using Genetic Engineering technologies?

Genetic Engineering technologies offer new possibilities: the introduction of resistance and tolerance genes beyond the reach of conventional breeding tools and methods, the redirection of biochemical pathways to enhance nutritional improvement or reduce allergens and toxins, and increasing rates of genetic gain of crop and animal improvement. After more than two decades of commercialization of genetically engineered crops, global analyses of the impact of genetically engineered crops are reporting a reduction of chemical pesticide use, an increase in crop yields and farmer profits, and positive impacts on the environment.

CGIAR Centers consider that Genetic Engineering applied to crop and animal genetic improvement can have a role in providing integrated solutions for target beneficiaries along with conventional breeding, crop management, post-harvest, and other technologies.

What risks and concerns are associated with Genetic Engineering?

The introduction of foreign genes into the genome of a plant or animal could have additional effects to the ones intended, depending on the genes introduced, the recipient organisms, and the place into the genome where they are inserted. These effects could, at least in theory, have a negative impact on human and animal health when used as food or feed, affect biodiversity and the environment.

Since their introduction, organisms deriving from the application of Genetic Engineering have been extensively assessed for their potential to negatively impact on human health, biodiversity,

and the environment. Biosafety and risk assessment of genetically engineered organisms are now well-established processes with robust protocols and methods in many countries. They undergo extensive performance evaluations to confirm the intended benefits and identify any potential unintended attributes before they are released or commercialized.

CGIAR Centers advocate the use of science-based risk assessment on the final product while considering the weight of evidence of safety to human health and the environment.

To date, numerous national and international research organizations and regulatory institutions have concluded that genetically engineered crops are as safe as their conventional counterparts, finding no reproducible scientific evidence of a negative impact on human or animal health.

CGIAR appreciates that concerns have been raised about the potential of Genetic Engineering (and other advanced technologies) to contribute to market concentration. CGIAR conducts research to monitor these potential effects. In their efforts to maximize impact of these technologies on target beneficiaries, CGIAR Centers will seek partnerships with a wide range of organizations, including small and medium size companies when possible and appropriate.

How does CGIAR ensure it respects country sovereignty and complies with biosafety regulations?

CGIAR Centers recognize and respect the sovereignty of individual nations to determine if, when and how Genetic Engineering technologies will be used in their territory.

CGIAR Centers comply with all applicable biosafety, environmental and food-related regulations and guidelines concerning Genetic Engineering technologies in the countries in which they and their partners operate. CGIAR Centers do not undertake Genetic Engineering research or development in countries that do not have national biosafety policies and regulations, and official agencies to oversee that research.

CGIAR Centers follow national regulatory guidelines in each country and comply with countries' biosafety regulations when transferring or distributing genetically engineered materials to recipients in those countries. Stewardship and liability issues are addressed and resolved by all parties involved in activities using the genetically engineered materials.

CGIAR Centers implement internationally recognized stewardship standards and work closely with a range of actors from national agricultural research and extension services to small seed companies and regulators to ensure best practices in development, application, safe use and deployment of genetically engineered organisms.

CGIAR Centers perform risk assessment following internationally accepted standards to study potential impacts of genetically engineered crops and animals on human health and the environment. When potential negative impact is anticipated, CGIAR Centers will implement mitigation measures, develop appropriate crop management practices, or search for new alternatives.

CGIAR Centers have institutional policies and protocols governing the safe handling of genetically engineered materials. These policies and protocols are always compliant with laws of the countries where the research is conducted and to which the research products are sent, and often go beyond. CGIAR Centers have Institutional Biosafety Committees that review, approve and oversee Genetic Engineering research, stewardship and quality management plans and work in tandem with host country regulatory agencies for their development and deployment.

CGIAR centers operate transparently and regularly publish reports on their research using Genetic Engineering technologies on their respective public websites and other media.

Does CGIAR adopt a public goods approach to technology development and dissemination?

Genetic Engineering technologies often have restrictions on their use due to intellectual property rights. CGIAR Centers seek to maximize global access and impact in accordance with the [CGIAR Principles on the Management of Intellectual Assets](#) ('CGIAR IA Principles'). Whereas CGIAR Centers typically pursue a public goods approach to the R&D it produces, in accordance with the CGIAR IA Principles, they may accept and impose restrictions to access where necessary for the acquisition and stewardship of third party proprietary technologies, the further improvement of the technology, or for enhancing the scale and scope of its impact on target beneficiaries through strategic partnerships.

Does CGIAR provide capacity building to partners?

CGIAR Centers' research and development concerning Genetic Engineering technologies is often conducted with a range of partners from developed and developing countries. CGIAR Centers often provide training and capacity building for these partners concerning the development and use of the technologies and gathering information for risk assessments. Upon request, CGIAR Centers provide technical support to national competent authorities responsible for developing biosafety policies, regulations, and guidelines.

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