CGIAR Questions and Answers on Genome Editing

CGIAR
Science for a food-secure future

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 Genome Editing to change the DNA sequence of an existing gene in the genome of plants or animals to confer new and useful properties. The products of the application of this technology are genome- or gene-edited organisms. A separate statement focuses on CGIAR Centers' use of Genetic Engineering which is a technology to insert foreign DNA containing new genes or other DNA sequences into the genome of plants or animals to confer useful properties.

B. Questions and Answers

What is Genome Editing?

In Genome Editing, an existing DNA sequence is modified in a specific location of the genome by changing the 'letters' of the genetic code thus changing the functionality of a specific gene. Genome Editing depends on the use of sequence-specific nucleases which act as "molecular scissors" to create double-strand DNA breaks in target sequences of the genome, which are then repaired by the cell's own DNA repair mechanism. The resulting organism will have a gene that has lost its function or a gene with a change in its function that is copied from the same gene in a parent organism.

The most recently discovered system (CRISPR-Cas9) occurs naturally as a defense system in bacteria against invading viruses. It has been customized to work in plants and animals where it can change the DNA sequence at a specific targeted location to activate, deactivate or modify genes. The resulting genetic changes are more precise and efficient than those that can be realized through conventional mutagenesis and breeding. Genome Editing can also facilitate the insertion of a new gene at a specific location, in which case the resulting organism is essentially a genetically engineered organism. For the purpose of this statement, Genome Editing is limited to the activation, deactivation or change in an existing gene, and does not include the insertion of foreign genes. CGIAR has a separate statement concerning its use of genetic engineering.

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

What is Genome Editing used for?

An organism's genes can be edited so that it produces less anti-nutritive compounds, allergens, or toxins. Other genes that limit the accumulation of valuable nutrients can be edited so that nutrients accumulate in higher amounts. Genes can be edited to reduce organisms' susceptibility to pathogens that cause diseases. Blocks of genes responsible for undesirable characteristics can be eliminated by Genome Editing tools. Many traits can be modified by Genome Editing provided the organism possesses genes controlling them.

When and why would CGIAR Centers use Genome Editing?

Most CGIAR Centers' work on crop and animal genetic improvement is based on conventional breeding methods. However, in the last 15 years, Genome Editing technologies have been used in various research programs. First as a laboratory tool, CGIAR Centers used Genome Editing for validating genes' function. Various CGIAR Centers now use Genome Editing as part of research projects to develop new lines with improvement on useful traits. Examples of improvements obtained by Genome Editing include resistance to maize lethal necrosis, improved micronutrient content in maize, improved water use efficiency in maize, resistance to bacterial wilt and bacterial blight in rice, *Striga* resistance in sorghum and pearl millet, flour quality in pearl millet, *banana streak virus* resistance in plantains, and resistance to bacterial and fungal diseases in banana. In all cases, Genome Editing technologies are used by CGIAR Centers to activate, deactivate or modify existing genes in the crop.

Does Genome Editing introduce new risks?

After editing the DNA sequence, the change is characterized to select the suitable organism. The loss of function, activation, and editing of the gene will cause changes which are the same as those in existing variants which are known to be safe to human health and the environment. Just like in mutagenesis breeding, Genome Editing could lead to off-target mutations and might confer, at least in theory, an undesirable property. However, the rate of off-target mutations in gene editing is much lower than the rate of background mutations that occur in conventional breeding. These genetic changes however can be minimized by using specially designed tools and methods or can be segregated away from the intended genetic change during the subsequent breeding process. In light of these considerations, the assessment of the impact on human and animal health and the environment of genome edited organisms should be conducted following the same principles of conventional breeding (phenotype, agronomic performance, and essential components); Genome Editing does not introduce new risks other than those associated with mutagenesis breeding.

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

The CGIAR Centers have institutional policies, procedures and committees for appropriate decision-making, stewardship and quality control of research and products involving crop improvement.

The CGIAR Centers consider that plants and animals whose genetic changes resulted from Genome Editing where no foreign DNA is integrated should not be treated differently than those which are modified through conventional breeding methods to achieve similar results.

The CGIAR Centers recognize and respect the sovereign right of all countries to regulate scientific research and development, and the development and release of genome edited crops and animals. CGIAR Centers comply always with applicable laws and regulations in countries where they undertake their research and in which the products of their research are disseminated.

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

Genome Editing technologies often have restrictions on their use due to intellectual property rights. CGIAR Centers seek to maximize global access and impact in accordance the CGIAR Principles on the Management of Intellectual Assets ('CGIAR IA Principles'). Whereas CGIAR Centers typically pursue an international 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 Genome Editing 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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