

**Voluntary Report** – Voluntary - Public Distribution

**Date:** February 27, 2024

**Report Number:** CS2024-0004

**Report Name:** Costa Rica Opens Door to Innovative Biotechnologies

**Country:** Costa Rica

**Post:** San Jose

**Report Category:** Agricultural Situation, Biotechnology - Plants and Animals

**Prepared By:** Victor Gonzalez, Agricultural Specialist

**Approved By:** Evan Mangino

**Report Highlights:**

Industry experts expect a November 11, 2023, update to the Costa Rican biotechnology regulatory framework will facilitate utilization of innovative biotechnologies and reduce barriers to common applications of modern biotechnology. FAS/San José expects a genome edited banana variety resistant to yield-reducing fungal diseases sigatoka and fusarium wilt could be the first genome edited product commercialized in Costa Rica later in 2024. Costa Rica was the world's 5th largest exporter of bananas in 2023, shipping more than \$430 million to the United States.

The Costa Rican Government published modifications to its agricultural biotechnology regulations on November 10, 2023. The updated regulations were published in the Official Diary “La Gaceta” as Executive Decree 44244 - MAG – a copy of the regulation can be found (Spanish language only) as an attachment to this report and at the following link under the sub-section labeled “Decretos” within the section labeled “Poder Ejecutivo”.

[https://www.imprentanacional.go.cr/Gaceta/ViewAlcance.aspx?url=/pub/2023/11/10/ALCA222\\_10\\_11\\_2023.html](https://www.imprentanacional.go.cr/Gaceta/ViewAlcance.aspx?url=/pub/2023/11/10/ALCA222_10_11_2023.html)

The most relevant changes in the regulation are related to genome editing, which was not addressed in the earlier regulatory framework. Under the new regulation, Costa Rica would treat a wide range of products created with innovative biotechnologies as equivalent to conventional products.

Among the new or revised definitions in the regulation, FAS/San José has translated and would highlight the following:

**Novel combination of genetic material:** a stable insertion in the genome, of one or more genes or DNA sequences encoding double stranded DNA, RNA, proteins or regulatory sequences that could not be obtained by conventional breeding. (p. 25)

**Organisms equivalent to those obtained through conventional improvement techniques:** Any organism for agricultural use developed with new genetic improvement techniques and which does not have a new combination of genetic material. This includes, but is not limited to:

1. Organisms with a demonstrated absence of a new combination of genetic material, obtained with a technique that uses parents that are living modified organisms (LMO).
2. Organisms obtained by a technique that uses DNA or RNA that will not multiply in a living cell.
3. Organisms obtained through a technique that introduces mutations directed to the site of interest, which produce loss or gain of gene function, but with demonstrated absence of a novel combination of genetic material.
4. Organisms obtained through techniques in which there is temporary expression of DNA or recombinant RNA molecules, but without the presence or introgression of these molecules in the final organism.
5. Organisms obtained through techniques that use DNA or RNA molecules that do not permanently modify the plant's genome when they come into contact with the genome, and which are subsequently absorbed or degraded, whether systemically or not.
6. Organisms with deletions, insertions, and rearrangements that could occur by spontaneous, natural, or induced mutation. (p. 32)

**Products of modern biotechnology:** Living organism for agricultural use obtained from modern biotechnology techniques including genome editing, which could result in a modified living organism or, on the contrary, be equivalent, according to its phenotypic and genetic characteristics, to an organism produced by conventional breeding techniques. (p. 33)

**Living modified organism:** Any living organism that has a novel combination of genetic material that has been obtained through the application of modern biotechnology. It includes what is known as “altered or manipulated organism”, “transgenic organism”, “transgenic material”, “transgenic plants”, or “manipulated or transgenic product”. (p. 33)

The updated regulatory language also includes the following important changes related to the approval of stacked events and individual events that have a previous history of use in the country.

**Simplified procedure for requests to use individual transformation events that have a history of previous use in the country. (p. 40)**

Once the technical assessment process for a potential planting site has been completed, the Genetically Modified Organisms Unit (UOGM by its Spanish acronym) will identify requests to use individual transformation events that have previously received a Certificate of Release into the Environment (CLA by its Spanish acronym). In these cases, the UOGM will resolve the request in a maximum of 45 calendar days based on the previous opinion(s), as well as the technical assessment of the conditions of the potential planting site and will establish the most restrictive biosafety measures according to the available criteria. The result of the request must be communicated to the interested party, through an administrative resolution through the means of communication that was indicated in the request.

For cases in which the objective or intended purpose for the use of the LMO involved in the request is different from those previously authorized, the UOGM may request a review by the National Technical Biosafety Commission (NTBC) and, in this case, obtain its favorable opinion to grant the respective CLA.

**Simplified procedure for stack approval requests for individual events that have a history of previous use in the country. (p. 40-41)**

Once the technical assessment process of the possible planting site has been completed, the UOGM will identify the stacked approval requests for which its individual component events have a respective CLA. Likewise, it will determine with reasonable certainty, based on science and technology, that there are no significant interactions between the new combinations of genetic material contained in the stack to require changes to the biosafety measures established in the previously approved individual CLAs. In these cases, the UOGM will resolve the request within a maximum period of 45 calendar days based on the previous determination(s), the

available scientific literature, as well as the technical assessment of the conditions of the possible planting site and will establish the most restrictive biosafety measures of protection, according to the available criteria. The result of the request must be communicated to the interested party through administrative resolution, through the means of communication indicated in the request.

If the UOGM determines that there is insufficient evidence to guarantee with reasonable safety that there are no significant interactions between the new combinations of genetic material contained in the stack and, therefore, it might be necessary to establish additional biosafety measures or expand existing ones, the UOGM may request a review by the NTBC for the stack to be evaluated as a new LMO and, in this case would require a favorable opinion from the NTBC for the new stack to receive a CLA.

**Article 118 – Regarding applications for the use of products of modern biotechnology, including genome editing, used in agriculture. (p. 55)**

**Presentation of the application.**

To request the use of organisms resulting from new genetic breeding techniques, including genome editing, the interested party must submit the application to the UOGM digitally, in the BIO-07 format available on the official SFE website and in Annex 1 of the regulation, as a sworn statement, providing information on the qualities, legal representation and contact information of the interested party, technical and scientific information of the organism, information related to the genetic modification or improvement process, and information related to authorization in other countries, if applicable.

**Attachments:**

[2023\\_11\\_10 La Gaceta de Costa Rica.pdf](#)