GUIDELINES

Preliminary note: Where the applicant is unable to determine with certainty whether the resulting organism should be regulated as a Genetically Modified Organism (GMO), the use of the tool “Should my product be regulated?”, available on the website of the Innovation and Biotechnology Coordination Unit, is recommended:

https://www.magyp.gob.ar/conabia/

For any inquiries regarding how to submit the information, please contact:

nbt.biotecnologia@magyp.gob.ar

1. DEFINITIONS

Genetically Modified Organism (GMO): any biological entity capable of transferring or replicating genetic material that possesses a novel combination of genetic material obtained through the application of modern biotechnology.

Species: a group of organisms with similar genetic and phenotypic characteristics that are capable of reproducing among themselves and producing fertile offspring, sharing a common gene pool.

Genome: chromosomal and extrachromosomal nucleic acid, including, but not limited to, plasmids, artificial chromosomes, episomes, and viral genomes.

Insertion: incorporation of genetic material into the genome of an organism, whether in nuclear chromosomal DNA or in extrachromosomal elements such as plasmids, plastomes, and others.

Genomic intervention: a procedure applied to the genome of an organism that may generate genetic variability, whether novel or previously characterized.

Line/Product/Development: organism obtained after the application of a modern biotechnology technique.

Hypothetical Line/Product/Development: organism that is at the design or research stage, or that is planned to be obtained.

Technical officer: person responsible for the biosafe handling of the material until its regulatory status is determined by the National Advisory Commission on Agricultural Biotechnology (CONABIA).

Applicant: natural or legal person submitting an application to the competent authority.

2. SUBMISSION OF THE PRIOR CONSULTATION (PC)

The applicant shall submit a Prior Consultation (PC) to the Innovation and Biotechnology Coordination Unit of the National Directorate of Bioeconomy under the SECRETARIAT OF AGRICULTURE, LIVESTOCK AND FISHERIES of the MINISTRY OF ECONOMY.

The applicant shall complete the required form (see Annexes) and submit it to the aforementioned Coordination Unit, which serves as the Executive Secretariat of CONABIA.

The form shall be submitted in Spanish. Where technical documentation in another language is attached, the competent authority may require an official translation thereof, in whole or in part, where deemed necessary for the relevant analysis.

The submission shall be processed through the TAD platform, under the option “Prior Consultation (PC)” so that CONABIA may determine whether products derived from New Breeding Techniques (NBTs) may or may not be regulated.

For submission, complete the mandatory form by selecting the “Procedure Details” option and entering “Note to the Innovation and Biotechnology Coordination Unit” in the reference field. Then select MINISTRY OF ECONOMY. Any additional documentation to be attached must be signed and scanned and shall be submitted through the “Other Documentation” option.

Where the genomic intervention has given rise to multiple products or lines, it is recommended that a single PC be submitted, grouping the common information in the General Molecular Module, as appropriate in each case, in order to avoid repetition.

During the evaluation, both the aforementioned Coordination Unit and CONABIA may require the applicant to submit additional information and studies in order to complete their analysis.

The applicant shall submit this consultation before the product is tested outside the laboratory.

Until a determination is made that the product is not a GMO, the applicant shall follow CONABIA’s instructions for handling it.

3. NOTIFICATION OF THE CONSULTATION RESPONSE

Once the evaluation is complete, the aforementioned Coordination Unit shall inform the applicant whether the product is considered a GMO.

The response to the submitted PC shall be provided within no more than EIGHTY (80) business days from the date of submission. This period shall not include any time taken by the applicant to provide any additional information that may be required.

4. CONFIDENTIAL INFORMATION

The applicant shall request instructions from the Coordination Unit on how to submit a consultation containing Confidential Information (CI), that is, the full form in which the information intended to remain confidential appears highlighted.

In addition, the applicant shall submit the form with the Confidential Information removed and shall indicate this at the beginning of the documentation submitted. In the body of the text, any omitted data shall be replaced with the phrase “Confidential Information Removed.”

The following information shall not be submitted as Confidential Information:

- Name and address of the entity submitting the consultation, of the entity developing the product, and of the legal representative.
- Taxonomic description of the organism.
- Description of the objective of the intervention carried out or to be carried out.
- Detailed description of the technique used or to be used, and of all steps applied in the case presented.
- Changes in the target sequences following application of the technique.
- Description of the expected/obtained changes in sequence function and phenotype following application of the technique.
- Experimental evidence that the product obtained contains no residual genetic constructs or nucleic acid fragments used in the genome intervention process
- Any information that has been published or disclosed in any format, medium, or channel.

4.1 HANDLING OF CONFIDENTIAL INFORMATION

With CONABIA's approval, the aforementioned Coordination Unit shall provide a list of potential technical specialists and experts authorized to examine the Confidential Information. That list shall be subject to the approval of the applicant entity before access to the documentation is granted. The applicant entity shall be entitled to grant partial approval, provided that any exclusions from the list are based on reasonable grounds.

The evaluators shall sign a confidentiality agreement before access to the CI is granted.

The Confidential Information shall be retained by the Coordination Unit for the duration of the consultation analysis, after which it shall be returned to the applicant entity and may be requested again if necessary.

Notwithstanding the foregoing, CONABIA may determine that information identified as Confidential Information must be submitted in non-confidential form in order to allow the analysis of the case. The applicant shall, in such case, have the option to submit such information in non-confidential form or to withdraw the consultation.

4.2 METHOD OF SUBMISSION

The applicant shall agree with the designated evaluator on how the CI is to be submitted.

5. ANALYSIS CRITERIA

An analysis shall be conducted to determine whether the product submitted contains a novel combination of genetic material. If so, it shall be considered a GMO and, therefore, an application shall be submitted in accordance with Resolution No. 763 dated August 17, 2011 of the former

MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES, its supplementary regulations, or any regulation that may replace it in the future.

A novel combination of genetic material shall be deemed to exist where the intervention in the genome generates a stable insertion, and the following criteria are also met:

- The genotype cannot be obtained through conventional breeding or arise spontaneously in nature.
- The intervention in the genome generates an expression product that is novel to the species' gene pool.

6. HYPOTHETICAL PRODUCTS

In the case of projects to obtain products still at the design or preliminary development stage, the applicant may submit a PC following the same procedures set forth in the preceding sections, in order to anticipate whether the expected products may fall within the scope of Resolution No. 763/11 and its supplementary regulations, or any regulation that may replace it in the future.

In such cases, CONABIA shall conduct a preliminary analysis and provide guidance, which shall be communicated to the applicant through the Coordination Unit. Once such products have been obtained, they shall be subject to the provisions of the preceding sections in order to confirm that they contain the genomic intervention proposed in the preliminary consultation.

Argentine Republic - National Executive Branch
Year of Argentine Greatness

Additional Signature Page
Annex

Number: IF-2026-25410686-APN-DNB#MEC

CITY OF BUENOS AIRES
Wednesday, March 11, 2026

Reference: EX-2025-114026709- -APN-DGDAGYP#MEC_ANEXO

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