HAVING REGARD TO File No. 2020-72811589- -APN-DGD#MAGYP of the Register of the MINISTRY OF AGRICULTURE, LIVESTOCK, AND FISHERIES, and

CONSIDERING:

That Resolution No. 763, dated August 17, 2011, of the then MINISTRY OF AGRICULTURE, LIVESTOCK, AND FISHERIES establishes the regulatory guidelines with which activities with GENETICALLY MODIFIED ORGANISMS (GMOs) must comply in the ARGENTINE REPUBLIC.

That, under Section 2 of Resolution No. 763/11, any release of GMOs to the agro-ecosystem with no commercial approval shall, in all cases, require prior authorization from the SECRETARIAT OF AGRICULTURE, LIVESTOCK, AND FISHERIES of the then MINISTRY OF AGRICULTURE, LIVESTOCK, AND FISHERIES.

That, under Section 3, subsection a) of Resolution No. 763/11, "the risk assessment, the design of biosecurity measures and the risk management, in the different phases of the assessment shall be under the responsibility of the NATIONAL ADVISORY COMMISSION ON AGRICULTURAL BIOTECHNOLOGY OF ARGENTINA (CONABIA)."

That the Coordinating Unit of Innovation and Biotechnology of the National Directorate of Bioeconomy of the SECRETARIAT OF FOOD, BIOECONOMY, AND REGIONAL DEVELOPMENT of the MINISTRY OF AGRICULTURE, LIVESTOCK, AND FISHERIES, acts as the Executive Secretariat of this National Commission.

That Section 6, subsection b) of Resolution No. 112 of December 6, 2016, of the SECRETARIAT OF VALUE ADDITION of the former MINISTRY OF AGROINDUSTRY, includes within the functions of CONABIA those of advising the former Secretariat "on all issues related to agricultural biotechnology that this Secretariat submits to its scientific and technical assessment, and collaborate, when expressly indicated, with other official or private agencies or bodies under the current regulations."

That, under this resolution, a GENETICALLY MODIFIED ORGANISM means any living organism with a new combination of genetic material obtained by the application of modern biotechnology.

That the development of agricultural biotechnology is an essential tool for value addition in the agro-industrial chain in the ARGENTINE REPUBLIC.

That the ARGENTINE REPUBLIC and the rest of the world have significant advances in the development of the commonly named New Breeding Techniques (NBT) applicable to living organisms, also called New Precision or Genomic Intervention Techniques.

That the characteristics of the New Breeding Techniques require a prior case-by-case scientific analysis of the organisms obtained or to be obtained to determine whether the regulation applicable to GMOs covers

them.

That this measure establishes the procedures for determining when an organism obtained from new breeding techniques applying modern biotechnology falls within this measure and it does not alter the scope of the regulatory framework applicable to GMOs.

That the General Directorate of the MINISTRY OF AGRICULTURE, LIVESTOCK, AND FISHERIES has duly intervened.

That the undersigned is competent to issue this act under Decree No. 50 of December 19, 2019 as amended and Resolution No. 763/11.

Therefore,

THE SECRETARY OF FOOD, BIOECONOMY, AND REGIONAL DEVELOPMENT

RESOLVES:

SECTION 1.- The following procedures are the requirements to determine when an organism, obtained by applying the New Breeding Techniques (NBT), falls within Resolution No. 763 of August 17, 2011, of the then MINISTRY OF AGRICULTURE, LIVESTOCK, and FISHERIES and its complementary regulations.

SECTION 2.- The case-by-case analysis shall be based on the following definitions:

"New combination of genetic material": change produced in the genome of the organism by incorporating, stably and jointly, ONE (1) or more genes or nucleic acid sequences that are part of a defined genetic construct.

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

"Genetic construct" or "construct": a nucleic acid sequence consisting of TWO (2) or more contiguous fragments of nucleotides that have been combined by in-vitro techniques.

"Product": biological entity treated with an NBT to obtain a new phenotype.

"Hypothetical product": biological entity in the design stage treated with an NBT to obtain the desired phenotype.

SECTION 3.- The interested party shall carry out a PRIOR CONSULTATION INSTANCE (PCI) before the Coordinating Unit of Innovation and Biotechnology of the National Directorate of Bioeconomy of the SECRETARIAT OF FOOD, BIOECONOMY, AND REGIONAL DEVELOPMENT of the MINISTRY of AGRICULTURE, LIVESTOCK, AND FISHERIES. In this PCI, the interested party shall request that the NATIONAL ADVISORY COMMISSION OF AGRICULTURAL BIOTECHNOLOGY decide on whether

the result of the breeding process constitutes a new combination of genetic material.

SECTION 4.- Before applying for the PCI, the interested parties shall be registered in the National Register of Operators with Genetically Modified Plant Organisms created by Resolution No. 46 of January 7, 2004, of the former SECRETARIAT OF AGRICULTURE, LIVESTOCK, FISHERIES, AND FOOD of the then MINISTRY OF ECONOMY AND PRODUCTION.

Otherwise, the interested party shall submit equivalent proof before the above Coordinating Unit of Innovation and Biotechnology under its terms, only to be authorized to consult:

a. Natural persons shall present a copy of their ID card, or passport if they do not have it.
b. Legal persons shall submit a copy, certified by the competent authority, of the constituent document duly registered, and the documentation certifying the representation of those acting on their behalf.
c. To declare in a note the legal and actual domicile.
d. The above documentation shall be submitted through the Platform of Distance Procedures (TAD).

SECTION 5.- To apply for the PCI on plants, animals, or microorganisms for CONABIA to decide whether the result of the breeding process constitutes a new combination of genetic material, the interested party shall submit a sworn statement to the Coordinating Unit of Innovation and Biotechnology as CONABIA Executive Secretariat, following these general guidelines:

a. The minimum content of the note: information on the type of organism and the species involved, the breeding technique used, the improved feature, evidence of the genetic changes sought, and, for those cases where the technical method involves a transient plasmid or an intermediate GMO, proof of its absence in the final product.
b. Delivery method: through the TAD platform, select the item "PRESENTACIÓN CIUDADANA ANTE PODER EJECUTIVO" (CITIZEN PRESENTATION BEFORE THE NATIONAL EXECUTIVE BRANCH), or as determined in the future. The mandatory form must be completed in the "Datos del Trámite" (Procedure Data) option, indicating "Nota dirigida a la Coordinación de Innovación y Biotecnología" (Note addressed to the Coordinating Unit of Innovation and Biotechnology) as the reference of the procedure. Subsequently, select MINISTERIO DE AGRICULTURA, GANADERÍA Y PESCA (MINISTRY OF AGRICULTURE, LIVESTOCK, AND FISHERIES).

The additional documentation to be attached must be signed, scanned, and sent through the option "Otra Documentación" (Other Documentation).

SECTION 6.- CONFIDENTIAL INFORMATION. If applicants wish some data or information requested in the application to be treated as confidential, they shall specify so on the cover of the submitted documentation and in the body text, where these data were omitted, by marking "Información Confidencial Eliminada" (Confidential Information Deleted).

The interested party must submit to the Coordinating Unit of Innovation and Biotechnology, in a sealed and signed envelope, a complete application form with the information they wish to keep confidential highlighted

("Confidential Information", hereinafter referred to as "CI"). This document shall present in the upper right margin of each of its pages the inscription "Copia con IC" (Copy with CI).

Exclusions: The following information may not be presented as CI:

a. New phenotypic features.
b. Name and address of the applicant, legal representative, or attorney-in-fact.
c. Any information published or communicated in any format, means, or place.

Notwithstanding the above, CONABIA may require that any information identified as CI must be submitted in a non-confidential format to allow an analysis of the case. In this case, the interested party may submit this information on a non-confidential basis or withdraw from the consultation.

TREATMENT OF CONFIDENTIAL INFORMATION. The Coordinating Unit of Innovation and Biotechnology shall propose, with the consent of CONABIA, technicians and experts authorized to examine the CI. Before any such examination, this proposal shall be approved by the interested party, entitled to grant partial consent, justifying the exclusions from the list.

The interested party or its designee may be present at the CI opening and examination hearing.

Assessors shall sign a confidentiality agreement before examining the CI. The persons present at the CI examination hearing shall sign as many identical copies of the minutes recording the experts' opinion as appropriate. ONE (1) copy shall be delivered to the interested party, and another shall be included in the corresponding file.

The Coordinating Unit of Innovation and Biotechnology shall withhold the CI during the consultation analysis. Then, it shall be returned to the consulting party and may be requested again if necessary.

SECTION 7.- The Coordinating Unit of Innovation and Biotechnology shall conduct a pre-assessment of the information received within a period not exceeding EIGHTY (80) business days from the date of submission and shall include the consultation in the following CONABIA meeting. Based on the information presented in the PCI, CONABIA shall analyze whether a new combination of genetic material has been generated. Likewise, if applicable, CONABIA shall verify if there is strong scientific evidence of the absence of temporary event(s) used in obtaining the product.

The Coordinating Unit and CONABIA may request additional information and studies from the applicants to complete their analysis.

SECTION 8.- If CONABIA concludes that there has not been a new combination of genetic material in the product, it shall issue a technical opinion and notify the SECRETARIAT OF FOOD, BIOECONOMY, AND REGIONAL DEVELOPMENT of the MINISTRY OF AGRICULTURE, LIVESTOCK, AND FISHERIES, which shall duly inform the interested party that its product does not fall within Resolution No. 763/11.

Notwithstanding the above, as the case may be, CONABIA and the Coordinating Unit may recommend that the SECRETARIAT OF FOOD, BIOECONOMICS, AND REGIONAL DEVELOPMENT, based on a

scientific-technical justification, carry out a regular follow-up on a determined product analyzed when its characteristics and/or novelty justify so.

SECTION 9.- HYPOTHETICAL PRODUCTS. Regarding projects aimed at obtaining organisms derived from new breeding techniques still in the design stage, the interested party may carry out a PCI, following the same procedures in the preceding sections to anticipate whether the expected hypothetical product would fall within Resolution No. 763/11 and its complementary regulations.

In this case, CONABIA shall perform a preliminary analysis and provide an indicative response, which shall be notified by the Secretariat to the interested party. If the improved organisms are then obtained, they shall be subjected to the provisions of the preceding sections to confirm that they have the genetic change proposed in the preliminary consultation.

On a case-by-case basis, CONABIA shall define the biosafety procedures applicable during the obtaining of the product.

SECTION 10.- Annexes I, II, and III, which, registered under numbers IF-2020-80790435-APN-SABYDR#MAGYP, IF-2020-80790460-APN-SABYDR#MAGYP, and IF-2020-80790473-APN-SABYDR# MAGYP, respectively, are an integral part of this Resolution, are hereby approved.

SECTION 11.- This Resolution shall become effective on the day following its publication in the Official Journal.

SECTION 12.- This Resolution is notified, published, referred to the National Directorate of the Official Register, and filed.

ANNEX I

ANIMAL

SECTION 1.- The analysis of possibly affected sequences outside the target sequences shall be requested depending on the technique used.

SECTION 2.- The effective demonstration of the resulting phenotype shall be requested depending on the technique used.

ARTICLE 3.- Those hypothetical cases in which it is not possible to anticipate whether the organism to be obtained will not be considered GM and its development in the country is sought shall be covered by current GM animal regulations until the final product is obtained and proved not to contain a new combination of genetic material.

SECTION 4.- The following guide is established to provide the applicant with guidance on the required information to submit in the PCI.

Guidance for the submission of Prior Consultation Instances for animals obtained through New Breeding Techniques

(It is not mandatory to complete all points for hypothetical cases)

I - GENERAL MODULE
Entity making the consultation
Identification of the development/product/line
Legal representative of the interested party making the consultation

Name
Address
Person in charge of the management
Telephone
E-mail
Technical Manager of the interested party making the consultation
Name
Address
Telephone
E-mail

II. ORGANISM MODULE

A. Taxonomic description up to the most possible detailed range including, when applicable, subspecies, race, and lineage.

III. MOLECULAR BIOLOGY MODULE

A. A detailed description of the technique used, and all its steps applied in the submitted case.

B. Molecular description of the target nucleotide sequences of the organism, in their state before applying the technique.

C. Function of the sequences in their state before applying the technique.

D. Molecular characterization of target sequences after applying the technique (genotype expected/obtained).

E. Changes expected/obtained in the sequence function and the phenotype after applying the technique.

F. Map of any genetic construct or nucleic acid fragments used in the process of obtaining the product, detailing the genetic elements (if applicable).

G. Analysis of possibly affected sequences outside the target sequences.

H. Evidence demonstrating that the product obtained does not present new combinations of genetic material.

IV. REFERENCES

In case of submitting publications, please attach a copy.

ANNEX II

MICROORGANISMS

SECTION 1.- The analysis of possibly affected sequences outside the target sequences shall be requested depending on the microorganisms and the technique used.

SECTION 2.- The effective demonstration of the resulting phenotype shall be requested depending on the microorganisms and the technique used.

SECTION 3.- The following guide is established to provide the applicant with guidance on the required information to submit in the PCI.

Guidance for the submission of Prior Consultation Instances for microorganisms obtained through New Breeding Techniques

I - GENERAL MODULE
Entity making the consultation
Identification of the development/product/line
Legal representative of the interested party making the consultation
Name
Address
Person in charge of the management
Telephone

E-mail
Technical Manager of the interested party making the consultation
Name
Address
Telephone
E-mail

II. ORGANISM MODULE

A. A taxonomic description up to the most possible detailed range including, when applicable, subspecies, line, strain, or serotype.

III. MOLECULAR BIOLOGY MODULE

A. A detailed description of the technique used, and all its steps applied.

B. Molecular description of the target nucleotide sequences of the organism, in their state before applying the technique.

C. Function of the sequences in their state before applying the technique.

D. Molecular characterization of target sequences after applying the technique (genotype expected/obtained).

E. Changes in the function of the sequences after applying the technique (please justify).

F. Map of all genetic construct or nucleic acid fragments used in the process of obtaining the product, detailing the genetic elements (if applicable).

G. Analysis of possibly affected sequences outside the target sequences.

H. Evidence demonstrating that the product or microorganism obtained does not present new combinations of genetic material.

IV. PHENOTYPIC MODULE

A. In the case of a product, please report the occurrence of other effects beyond the intended phenotype.

IV. REFERENCES

A. In case of submitting publications, please attach a copy.

B. In the case of animal experimentation, please submit a report by the animal care and use commission endorsing the procedures.

ANNEX III

PLANT

SECTION 1.- The interested parties apply for the PCI before their product is tested outside the laboratory unless it is handled as regulated under Resolution No. 763/11 and its complementary regulations.

SECTION 2.- The following guide is established to provide the applicant with guidance on the required information to submit in the PCI.

Guidance for the submission of Prior Consultation Instances for plant material obtained through New Breeding Techniques

I - GENERAL MODULE
Entity making the consultation
Identification of the development/product/line
Legal representative of the interested party making the consultation
Name
Address
Person in charge of the management
Telephone
E-mail

Technical Manager of the interested party making the consultation
Name
Address
Telephone
E-mail

II. ORGANISM MODULE

A. Taxonomic description up to the most detailed range possible.

B. The name assigned to the genotype obtained.

III. MOLECULAR BIOLOGY MODULE

A. A detailed description of the technique used, and all its steps applied in the submitted case.

B. Molecular description of the target nucleotide sequences of the organism, in their state before applying the technique.

C. Known function of the sequences in their state before applying the technique.

D. Changes expected/obtained in the target sequences after applying the technique.

E. Changes expected/obtained in the function of the sequences and the phenotype after applying the technique.

F. Map of any genetic construct or nucleic acid fragments used in the process of obtaining the product, detailing the genetic elements (if applicable).

G. Evidence demonstrating that the product obtained does not present new combinations of genetic material.

IV. REFERENCES

In case of submitting publications, please attach a copy.