NO OFICIAL TRANSLATION

NORMATIVE RESOLUTION No. 16, OF JANUARY 15, 2018

Sets forth the technical requirements for submitting an inquiry to the CTNBio concerning Precision Breeding Innovation Techniques.

THE NATIONAL BIOSAFETY TECHNICAL COMMISSION (CTNBio), using its legal and regulatory powers and in observance of sections XV and XVI of article 14 of Law No. 11.105 of March 24, 2005;

Whereas there is a need to assess Precision Breeding Innovation (PBI) techniques, which also comprise the so-called New Breeding Technologies (NBTs) in the light of Law No. 11.105 of March 24, 2005;

Whereas Law No. 11.105, of 2005 defines recombinant DNA/RNA molecules, genetic engineering, and genetically modified organism (GMO) in Article 3, sections III, IV and V, respectively;

Whereas these PBI techniques are based on a set of new methodologies and approaches–that differ from the transgenic genetic engineering strategy that results in the absence of recombinant DNA/RNA in the final product;

Whereas the PBI techniques can introduce innovative uses of molecular biology tools, which can result in:

1. Precise edition of genomes, by the induction of specific mutations, generating or modifying wild and/or mutated alleles without insertion of transgene(s);

2. Genetic transformation and/or control of gene expression (activation/inactivation);

3. Epigenetic regulation of gene expression by natural mechanisms with no genetic modification in the individual;

4. Genetic transformation and/or control of gene expression with genes of sexually compatible species;

5. Temporary and non-inheritable genetic transformation of cells and tissues;

6. Permanent or non-host infection of genetically modified viral elements;

7. The creation of alleles with autonomous inheritance, and recombination potential with the possibility of altering a whole population (gene drive);

8. The construction of heterologous genes or new copies of homologous genes.

Resolves:

Article 1. The techniques described in Annex I hereto are examples, though not limited, of Precision Breeding Innovation (PBI) techniques that could originate a product that is not considered as a Genetically Modified Organism (GMO) and its derivatives, as per definitions of Law 11.105, of March 24, 2005.

Paragraph 1 The product referred to in the main section of this article is defined as the descent, lineage or final product of a process that uses Precision Breeding Innovation Techniques in one of its phases of development.

Paragraph 2. The cases to be classified are not restricted to the technologies described in Annex I, since the ongoing and fast progress of different technologies will lead to new products, to which the provisions of this Normative Resolution shall also apply.

Paragraph 3. The products referred to in the main section of this article show at least one of the following characteristics:

I – Product with proved lack of recombinant DNA/RNA, obtained with a technique using parental GMO;

II – Product obtained through a technique using DNA/RNA which will not multiply in a living cell;

III – Product obtained by a technique which introduces site-directed mutations producing genic function gain or loss, but proved absence of recombinant DNA/RNA in the product;

IV - Product obtained by a technique in which there is temporary or permanent expression of recombinant DNA/RNA molecules, but no presence or introgression of these molecules in the product; and

V - Product which uses techniques employing DNA/RNA molecules that do not modify permanently a plant's genome when in contact, or systemically or non-systemically absorbed by it.

Sole paragraph: In case of a product obtained from a GMO with favorable opinion of CTNBio for commercial release, the conditions described will apply only to the characteristic introduced by PBI.

Article 2. In order to determine whether a product obtained by PBI would or not be considered a GMO and its derivatives, under article 3 of Law 11.105, 2005, the applicant must submit a letter of inquiry to CTNBio.

Paragraph 1. The inquiry must include the details listed in Annex II hereto.

Paragraph 2. After the inquiry has been filed with CTNBio, an extract will be published in the Federal Gazette and sent to the one of the members, full or alternates, for reporting and drafting a final opinion;

Paragraph 3. The final opinion shall be based on a case-by-case analysis of evidence of compliance with at least one of the conditions described in Paragraph 3 of article 1 hereof.

Paragraph 4. For products and technologies obtained through the use of one of the techniques listed in Annex I, the decision of CTNBio shall comply with at least one of the conditions described in Paragraph 3 of art. 1 of this Normative Resolution, and shall be conclusive as to the application of the definitions in arts. 3 and 4 of Law No. 11.105 of 2005.

Article 3. The final opinion referred to in Paragraph 2 of article 2 of this Normative Resolution shall be submitted to at least one of the Permanent Sectoral Subcommittees, according to the parental organism and proposed use of the technique under inquiry, and its approval shall be submitted to a CTNBio plenary session for decision.

Sole Paragraph. The Subcommittees shall have up to ninety days to analyze the submission and draft opinions; this period may be extended for another period of the same length if so decided by a CTNBio plenary session.

Article 4. CTNBio may, as a result of the inquiry or proposal, and with the appropriate scientific reasons, request additional information or studies.

Article 5. Any situations not foreseen herein will be assessed and decided on a case by case basis by CTNBio.

Article 6. This Normative Resolution shall come into effect on the date it is published.

EDIVALDO DOMINGUES VELINI

CTNBio PRESIDENT

ANNEX I

"New Precision Breeding Innovation (PBI) Techniques" - Examples

TECHNIQUE	SUMMARY
1. Precocious flowering	1.1 Silencing and / or super-expression of genes related to flowering by inserting genetic modification into the genome and subsequent separation or through transient expression by viral vector.
2. Seed Producing Technology	2.1 Inserting fertility-restoring genetic modification in naturally male-sterile lines in order to multiply these lines maintaining the male-sterile condition but not transmitting the genetic modification to descendants.
3. Reverse breeding	3.1 Inhibiting meiotic recombination in heterozygous plants selected for the trait of interest in order to produce homozygous parental lines.
4. RNA-dependent DNA methylation	4.1 Methylation driven by RNA interference ("RNAi") in RNAi homologous promoter regions in order to inhibit target gene transcription in live beings.
5. Site-Directed Mutagenesis	5.1. Protein or riboprotein complexes capable of causing site directed mutagenesis in microorganisms, plants, animals, and human cells.
6. Oligonucleotide Directed Mutagenesis	6.1 A synthesized oligonucleotide containing one or a few nucleotide alterations complementary to the targeted sequence, on being introduced into the cell, may cause substitution, insertion or deletion in the target sequence through the cellular repair mechanism (microorganisms, plants, animals, and human cells).
7. Agroinfiltration / agroinfection	7.1 Foliage (or other somatic tissue) infiltrated with Agrobacterium sp. or gene constructs containing the gene of interest to obtain a temporary expression at high levels located in the infiltrated area or with viral vector for systemic expression without the modification being transmitted to subsequent generations
8. Topical/systemic use RNAi	8.1 Use of double-stranded RNA ("dsRNA") with targeted-gene homologous sequence specifically silencing this gene or genes. Engineered dsRNA molecules may be introduced/absorbed into the cell from the environment.
9. Viral vector	9.1 Inoculation of live beings with recombinant viruses (DNA or RNA) expressing the genetic modification and amplification of the gene of interest through viral replication mechanisms without host genome modification.

ANNEX II:

I. In relation to original organism (Parentals), indicate:

1.1. identification of the genetic technology, purpose and intended use of the resultant organism and its derivatives;

1.2. taxonomic classification, from family to the most detailed level of the organism to be released, including when appropriate, subspecies, cultivar, pathovar, strain and serotype;

1.3. the classification of risk of genetically modified organism, according to the Normative Resolution No. 2, of November 27, 2006;

1.4. the gene(s) and/or manipulated genetic element(s), organism(s) of origin and their specific functions, where applicable;

1.5. the genetic strategy(ies) used to produce the modification(ions) desired; the genetic map(s) of the constructs used in the process, indicating all the genetic elements present;

1.6. molecular characterization of the result of the manipulation in the recipient organism (parental and final product), where applicable, providing information related to:

(a) number of copies manipulated (e.g. number of genomic sequences, number of alleles, etc.);

(b) location of the manipulated region in the genome, when possible; and

(c) identification of the presence of off-target genetic modifications, if any;

1.7. the product of expression of the genomic region(s) manipulated, described in detail, when applicable.

II. In relation to the product (descent, line or final product), state:

2.1. evidence of the absence of recombinant DNA/RNA molecules through the use of molecular methods;

2.2. if the product containing DNA/RNA molecules for topical/systemic use has recombinant ability to insert into the target species and/or into non-target species;

2.3. whether the product referred to in the submission has been commercially approved in other countries;

2.4. if the product uses the principle of gene drive that may enable the phenotypic change conferred to be potentially disseminated throughout the recipient organism's population. In this case, explain the care to monitor the organism, using at least two different strategies; e

2.5. how the possibility of any off-target effects of the technology that may be present in the product was evaluated.