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The Chairman of the National Technical Biosafety Committee - CTNBio, in the use of legal attributions vested in her, and in compliance with the request formulated with base in Paragraph 1, of Article 8, Law 8,974/95 of Ministry of Agriculture and Supply (MA), makes public that the cited Committee, in the Extraordinary Meeting held on June 28-30, 2000, assessed and stated the decision, as a Preliminary Conclusive Technical Approach, for the following administrative process:

**I - Process: 01200.001874/2000-07.**

Species: Official Letter/DPC 33/2000.

Interested Institution: Ministry of Agriculture and Supply, Secretariat of Agricultural Defense.

Subject: Application Conclusive Technical Approach on food safety of genetically modified corn.

Summary: The Ministry of Agriculture and Supply has requested, by the process in question, that CTNBio, as urgent matter, due to the break of the corn harvest in the Country, issues Conclusive Technical Approach on animal food safety of the events/hybrid of genetically modified corn grains available in worldwide market for commercialization. This Conclusive Technical Approach will make possible the Ministry of Agriculture and Supply to decide about the import of genetically modified corn grains for use in animal feed. It is a legal attribution of the surveillance agencies of Ministry of Agriculture and Supply, in the field of their competence, in compliance with the Conclusive Technical Approach of CTNBio, according to Article 7, Law 8,974/95, "the issue of an authorization for the entry in the Country of any product containing GMO or derivative from GMO". Moreover, the Paragraph 1, Article 8, of the cited Law, establishes that "the products containing GMO destined to the marketing or industrialization, originating from other countries, will only can be introduced into Brazil after a Preliminary Conclusive Approach of CTNBio and the authorization of the competent surveillance agency, taking into account the technical approaches from another countries, when available".

Decision: The genetically modified corn events, subject of this Conclusive Technical Approach, were grouped by their phenotypic characteristics as a result of the genetic modifications listed below:

Resistance to bugs:

- anti-lepidopterous toxin – gene encoding *cry1a(b)*.
- anti-lepidopterous toxin – gene encoding *cry1a(c)*.
- anti-lepidopterous toxin – gene encoding *cry 9(c)*.

Resistance to herbicides:

- enzyme that inactivates ammonium glufosinate - genes encoding phosphinotricin acetyl transferase (*pat/bar*).
- enzyme that inactivates glufosate - gene encoding the 5-enolpyruvyl shikimate-3phosphate-synthase (mEPSPS) enzyme.

The analysis has included the assessment of food safety events accumulated in the corn grain, alone or in combination, the products of expression for the mentioned genes. The analyses are based on the Regulatory Instruction No. 3 (Guidelines for the Planned Release of Genetically Modified Organisms in the Environment), concerning exclusively to the food safety features established in Section L on genetically modified organisms consumed as food. That Section establishes the necessary and sufficient requirements for supporting this Conclusive Technical Approach.

The scientific analyses, also based on technical approaches from countries that have authorized the marketing use of these products in their territories, allow to conclude:

1) phosphinotricin acetyl transferase: genetically modified corns that accumulate the product from *pat/bar*-gene expression in their grains are equivalent, for their chemical composition, to the non-engineered corns. All the assessed events expressing for phosphinotricin acetyl transferase have shown non-allergenic properties. The enzyme amino acid sequences do not have similarity or identity with known allergenic products and toxins. The enzyme is highly labile to the thermal treatment and with acids, as well as it is labile in human and animal digestive fluids. Regardless the accumulated protein level in the genetically modified corn grains, there is no evidence that the protein produces acute or allergenic toxic effect.

2) 5-enolpyruvyl shikimate-3phosphate-synthase (mEPSPS): genetically modified corns that accumulate the product from *mepsps*-gene expression in their grains are equivalent, for their chemical composition, to the non-engineered corns. The protein mEPSPS was subjected to the analysis of CTNBio as for its allergenic and digestive properties. There is no evidence that the protein produces acute or allergenic toxic effect.

3) Bt - *cry1a(b)*, *cry1a(c)*, and *cry9(c)* toxins: genetically modified corns that accumulate the product from *cry1a(b)*-, *cry1a(c)*-, and *cry9(c)*-gene expression in their grains are equivalent, for their chemical composition, to the non-engineered corns. The *cry1a(b)*, *cry1a(c)*, and *cry9(c)* proteins were subjected to the analysis of CTNBio as for its allergenic and toxic properties. There is no evidence that the cited proteins produce acute or allergenic toxic effects. In addition, the Administrative Order 134, of June of 1995, of the General Secretariat of Sanitary Surveillance, Ministry of Health, that disposes on the Monograph B-01 *Bacillus thuringiensis* as a biological insecticide, Class IV, for agricultural use in different cultures, including the corn, classifying it without restrictions, for upper limit of residues and safety interval, for formulations containing the maximum concentration of *B. thuringiensis* with 1,200 international toxic units/mg.

Before these evidences, the CTNBio's Conclusive Technical Approach is:

1. There are no indications that the genetically modified corn grains, worldwide marketed, subject of the present approach, have harmful effects when used as animal feed.

2. The unloading of genetically modified corn grains, subject of the present approach, should be performed in units located in ports or frontier stations with Services of International Agricultural Surveillance of the Ministry of the Agriculture and Supply, being adopted practices of careful restraint, including in case of eventual and temporary storage in these places. The transportation should be made using in-bulk corn containers, or bulk-like containers, and/or in other units that assure careful restraint, in order to avoid environmental dispersion of genetically modified corn grains.
3. The unload, storage, and transportation as well as the processing of genetically modified corn grains, in the units of feed processing and production, should be performed under careful restraint, as provided for in the Brazilian biosafety law and in the specific regulatory instructions of CTNBio.
4. Only derived products free from viable forms of genetically modified corn grains obtained after the processing can be used as feed in the livestock.
5. The discard of genetically modified corn grains should be performed according to the established in the Regulatory Instruction No.17.
6. Accidental releases of genetically modified corn grains in the environment should be communicated immediately to CTNBio and to the authorities responsible for agricultural, environmental and sanitary surveillance.
7. Importers, transporters, and processors of genetically modified corn grains, subject of the present Conclusive Technical Approach, are responsible for assuring the safety of the product transportation and discard, in order to prevent its inadvertent release in the environment, as established in Article 13, Law 8,974/95.

**Leila Macedo Oda**

**Committee President**