**MINISTRY OF AGRICULTURE, LIVESTOCK, AND FISHERIES**

**SECRETARIAT FOR FOOD, BIOECONOMICS, AND REGIONAL   
DEVELOPMENT**

**Ruling 45/2022**

**RESOL-2022-45-APN-SABYDR#MAGYP**

Rosario, Santa Fe, 06/30/2022

HAVING SEEN File No. EX-2021-122417671- -APN-DGD#MAGYP of the Registry of the MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES, and

WHEREAS:

In virtue of that stated by the Decree No. 50 dated December 19, 2019 and its amendments, it is the responsibility of the SECRETARIAT FOR FOOD, BIOECONOMICS AND REGIONAL DEVELOPMENT of the MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES to “(...) Understand in the approval of biotechnological events and the application of the regulatory framework and policies related to biotechnological products, and in particular the granting of the authorizations to release the biotechnological products into the environment for agricultural use (...)”.

That Ruling No. 763 dated August 17, 2011 of the then MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES in its Article 3rd, establishes that the risk assessment, the design of the biosafety measures and the risk management, in different assessment stages will be the responsibility of the NATIONAL ADVISORY COMMISSION ON AGRICULTURAL BIOTECHNOLOGY (CONABIA), with its Executive Secretary exercising the Coordination of Innovation and Biotechnology of the National Directorate of Bioeconomy of the SECRETARIAT FOR FOOD, BIOECONOMICS AND REGIONAL DEVELOPMENT of the MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES.

That Ruling No. RESOL-2019-44-APN-SAYBI#MPYT dated July 1, 2019, of the then SECRETARIAT FOR FOODS AND BIOECONOMICS of the former GORVENRMENT SECRETARIAT OF AGROINDUSTRY of the then MINISTRY OF PRODUCTION AND LABOR, establishes that the application, assessment and granting procedures for authorizations for contained and confined activities with regulated PLANT GENETICALLY MODIFIED ORGANISMS (Plant GMOs) in the REPUBLIC OF ARGENTINA.

That, in virtue of the knowledge gathered in the risk assessment of the Plant GMOs, as well as other scientific and technological breakthroughs verified in the subject, it is considered necessary to establish a groundbreaking regulation of the aforementioned Ruling No. RESOL-2019-44-APN-SAYBI#MPYT with the purpose of clarifying the requirements to be met when applying for an authorization and a for a higher management efficiency.

That it is convenient to establish a simple and direct regulatory and procedural framework to address the amendment of the regulation.

That the SECRETARIAT FOR FOOD, BIOECONOMICS AND REGIONAL DEVELOPMENT of the MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES, promotes a regulatory update process to be applied to the assessment and approval of contained and confined activities with PLANT GENETICALLY MODIFIED ORGANISMS (Plant GMOs) in the REPUBLIC OF ARGENTINA.

That the NATIONAL ADVISORY COMMISSION ON AGRICULTURAL BIOTECHNOLOGY (CONABIA) has expressed its agreement it the meeting from December 16, 2021.

That the rising criterion of this measure is shared between the Innovation and Biotechnology Coordination of the National Directorate of Bioeconomy and the SECRETARIAT FOR FOODS, BIECONOCICS AND REGIONAL DEVELOPMENT of THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES.

That the INTERNAL AUDIT UNIT of the MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES has acted according to its authority.

The Bureau of Legal Affairs of the MINISTRY OF AGRICULTURE, LIVESTOCK, AND FISHERIES has acted in accordance with its authority.

That the undersigned is competent to pronounce this action in virtue of the provisions in Decree No. 50 dated December 19, 2019, and its amendments, and by Ruling No. 763 dated August 17, 2011, of the then MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES.

Therefore,

THE SECRETARY OF FOOD, BIOECONOMICS, AND REGIONAL DEVELOPMENT

FINDS AS FOLLOWS:

ARTICLE 1°. - The procedures for the assessment and authorization of contained and confined activities with regulated PLANT GENETICALLY MODIFIED ORGANISMS (Plant GMOs) are established hereby.

ARTICLE 2°. - The approval of the “GUIDELINES FOR THE ASSESSMENT AND AUTHORIZATION OF CONTAINED AND CONFINED ACTIVITIES WITH REGULATED PLANT GMOs” that, as Annex I with the File No. IF-2022-29295456-APN-DNB#MAGYP, are an integral part of this ruling.

ARTICLE 3°. - The “FORM FR THE ASSESSMENT OF ACTIVITIES WITH REGULATED PLAN GMOs CONTAINED IN BIOSAFETY GREENHOUSES FOR THE RESEARCH OF LOCAL DEVELOPMENTS (QUALIFIED GREENHOUSES)” has been approved and that, as Annex II with the File No. IF-2022-18664686-APN-DNB#MAGYP, is an integral part of this measure.

ARTICLE 4°. - The “FORM FOR THE ASSESSMENT OF CONTAINED AND CONFINED ACTIVITIES WITH REGULATED PLANT GMOs - OVERVIEW” has been approved and, as Annex III registered with the File No. IF-2022-18664902-APN-DNB#MAGYP, is an integral part of this ruling.

ARTICLE 5°. - The “FORM FOR THE ASSESSMENT OF CONTAINED AND CONFINED ACTIVITIES WITH REGULATED PLANT GMOs - MOLECULAR INFORMATION MODULE (MOL)” has been approved and, as Annex IV registered with the File No. IF-2022-18665054-APN-DNB#MAGYP, is an integral part of this ruling.

ARTICLE 6°. - The “FORM FOR THE ASSESSMENT OF EXPERIMENTAL CONTAINED AND CONFINED ACTIVITIES WITH REGULATED PLANT GMOs - ACTIVITY MANAGEMENT MODULE (MAN)” has been approved, and as Annex V registered with the File No. IF-2022-18665307-APN-DNB#MAGYP, is an integral part of this ruling.

ARTICLE 7°. - The “FORM FOR THE ASSESSMENT OF SEED REPLICATION AND/OR BIOMASS PRODUCTION CONFINED ACTIVITIES WITH REGULATED PLANT GMOs” has been approved and, as Annex VI registered with the File No. IF-2022-18665515-APN-DNB#MAGYP, is an integral part of this ruling.

ARTICLE 8°. - The form “RELEASE ESTABLISHMENT MODULE (EST)” has been approved and, as Annex VII registered with the File No. IF-2022-18665766-APN-DNB#MAGYP, is an integral part of this ruling.

ARTICLE 9°.- The forms “ACTIVITY MATRICES”, “PLANTING REPORT”, “HARVEST REPORT” and “POST-HARVEST REPORT” have been approved and included in Annex VIII, registered with the File No. IF-2022-18665924-APN-DNB#MAGYP, as an integral part of this ruling.

ARTICLE 10.- The non-compliance with this resolution will generate the adoption of the measures contemplated in Articles 7° and 8° of Ruling No. 763 dated August 17, 2011, of the then MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES.

ARTICLE 11 .- The authorizations granted under this measure are related to the preservation of the biosafety of the activities during which Plant GMOs are released into the agroecosystem, notwithstanding other regulations, and competences of bodies of the MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES or other application authorities related to this type of activities or related activities. This includes, but is not limited to, general legal systems regarding aspects such as healthcare and plant quality, the regulation of international production, marketing, and exchange of seeds, as well as environmental and industrial safety regulations applicable to the industrialization of biomass, which are under the scope of their respective competences.

ARTICLE 12. - Ruling No. RESOL-2019-44-APN-SAYBI#MPYT of July 1, 2019, of the then SECRETARIAT FOR FOOD AND BIOECONOMICS of the former AGROINDUSTRY GOVERNMENT SECRETARIAT of the then MINISTRY OF PRODUCTION AND LABOR has been repealed.

ARTICLE 13. - This ruling will enter into effect SIXTY (60) consecutive days after its publication in the Official Bulletin.

ARTICLE 14. - Be it hereby communicated, issued, and given to the NATIONAL BUREAU OF OFFICIAL REGISTRY, and archived.

Luis Gustavo Contigiani

NOTE: The Attachment/s comprising this Ruling are not published. These can be consulted at: www.magyp.gob.ar/normativa/

e. 04/07/2022 No. 49675/22 v. 07/04/2022

**Issuing date** 07/04/2022