

NATIONAL SERVICE FOR HEALTH AND FOOD QUALITY

Resolution No. 694/2024

Buenos Aires - June 26th, 2024

AFTER THE ANALYSIS OF:

File No. EX-2024-63136548- -APN-DGTYA#SENASA; Law No. 27233; Decree-Law No. 3489 of March 24th, 1958; Regulatory Decree No. DECTO-2019-776-APN-PTE of November 19th, 2019; Decree No. 5769 of May 12th, 1959; Resolution No. 350 of August 30th, 1999 of the then SECRETARIAT OF AGRICULTURE, LIVESTOCK, FISHERIES AND FOOD and its amendments; and

CONSIDERING:

That through Decree Law No. 3489 of March 24th, 1958, it is established that the sale in Argentina of chemical or biological products, intended for the treatment and destruction of animal and plant pests that can harm cultivated or useful plants, as well as the sale of adjuvants for such products, is subject to the control of the former MINISTRY OF AGRICULTURE AND LIVESTOCK.

That by Decree No. 5769 of May 12th, 1959, the National Registry System of Plant Therapeutics was created, where the phytosanitary products that are used and sold in the country for the control of pests in the agricultural sector must be registered, as well as the natural or legal persons that sell, import or export pesticide products, and the establishments that synthesize, formulate, or manufacture these products.

That by Law No. 27233, the health of animals and plants, as well as the prevention, control and eradication of diseases and pests that affect the national forestry and agricultural production, flora and fauna, the quality of raw materials resulting from forestry, agricultural, livestock and fishing activities, the production, safety and quality of agricultural products, specific agricultural inputs and the control of chemical residues and chemical and microbiological contaminants in food and the national and international trade of those products and their by-products, are declared to be of national interest, with the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE - SENASA being the responsible authority and the agency in charge of planning, executing and controlling the development of the actions provided for by law.

It also establishes the primary and unavoidable responsibility of every natural or legal person linked to the production, obtaining or industrialization of products, by-products and derivatives of forestry and agricultural origin, whose activity is subject to the control of SENASA, to ensure and respond for the health, safety, hygiene and quality of production, in accordance with current regulations and with those established in the future.

To this end, it determines that such responsibility extends to those who manufacture, process, divide, preserve, store, concentrate, transport, market, sell, import or export animals, plants, food, raw materials, food additives, reproductive material, animal feed and

its raw materials, fishing products and other products of animal and/or plant origin who act individually, jointly or successively in the agricultural chain.

That, in such a context, it establishes that the intervention of the competent health agencies, insofar as it corresponds to their control activity, does not exempt the direct or joint responsibility of the different players in the agribusiness chain with respect to risks, dangers or damages to third parties that might derive from the activity carried out by them.

That through Resolution No. 350 of August 30th, 1999 of the then SECRETARIAT OF AGRICULTURE, LIVESTOCK, FISHING AND FOOD, the Manual of Procedures, Criteria and Scope for the Registration of Phytosanitary Products in Argentina is approved.

That, currently, the Directorate of Agrochemicals and Biologicals, dependent on the National Directorate of Plant Protection of the National Service, administers the National Registry System of Plant Therapeutics.

That Argentina has incorporated into its current regulations the determination of equivalency between technical grade active ingredients based on the "MANUAL ON THE PREPARATION AND USE OF FAO AND WHO SPECIFICATIONS FOR PESTICIDES" of 1999.

That at present, said criteria and procedures have been adopted by the Competent Authorities of countries or groups of countries considered to be of high grade sanitary and phytosanitary surveillance by Argentina.

That the reports and opinions issued by said authorities/agencies are based on procedures and scientific knowledge, as established by the WORLD TRADE ORGANIZATION (WTO) and the Agreement on the Application of Sanitary and Phytosanitary Measures of said Organization, as well as those issued by Argentina.

That, likewise, the agencies and organizations that make up the Competent Authorities of the USA, MEXICO, the EU, the UK, AUSTRALIA, NEW ZEALAND and BRAZIL are considered a reference as an observatory of the decisions that may be adopted for the risk analysis of phytosanitary products.

That, by virtue of this, it is advisable to recognize the evaluation and authorization of leading countries or regions in the regulatory field of phytosanitary products and, particularly, their agencies, among which are the ENVIRONMENTAL PROTECTION AGENCY of the UNITED STATES OF AMERICA, the EUROPEAN FOOD SAFETY AUTHORITY of the EUROPEAN UNION and the AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY from AUSTRALIA.

That, in this regard, it is appropriate to establish a scheme for the recognition of the authorization or registration that the USA MEXICO, the EU, the UK, AUSTRALIA, NEW ZEALAND and BRAZIL grant the active ingredient technical grade, in the case of satisfactory results in terms of equivalency of the active ingredients.

That, in this sense, it becomes necessary to formalize this recognition scheme as a special authorization and specify the requirements and documentation required for its compliance.

That the recognition scheme that is being promoted maintains the conditions of demanding requirements provided for in the Resolution No. 350/99, as well as the standards agreed upon by the Common Market Group of the COMMON MARKET OF THE SOUTH (MERCOSUR) and the WTO.

That the National Directorate of Plant Protection and its dependent directorates with jurisdiction in the matter have taken the appropriate intervention.

That the Directorate of Legal Affairs has taken the intervention that corresponds to it.

That this measure is issued in accordance with the powers conferred by Article No. 8, paragraph f), of Decree No. 1585 of December 19th, 1996 and its amendments.

Thus,

THE PRESIDENT OF THE NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE – SENASA RESOLVES:

ARTICLE 1. - Recognition of equivalency of technical grade active ingredients of pesticides.

The conditions and requirements are established to request the recognition of equivalency of technical grade active ingredients, approved by the Competent Authorities of the countries or groups of countries that make up the list that, as *ANNEX (IF-2024-66957000-APN-DAYB# SENASA)*, forms an integral part of this resolution.

To this end, it is established that equivalence will only be recognized in those cases in which the technical grade active ingredient to be registered comes from the same manufacturing establishment and has the same minimum or higher purity than that registered in the countries that make up the ANNEX.

ARTICLE 2. - Requirements to request recognition of equivalency.

To request the recognition of equivalency established in this rule, within the framework of the application for registration of an equivalent technical grade active ingredient on the “SIG – Trámites” platform of the NATIONAL AGRI-FOOD HEALTH AND QUALITY SERVICE - SENASA, the registrant company must:

Section a) Submit all the information required in Chapter No. 7 “REGISTRATION OF EQUIVALENT CHEMICAL OR BIOCHEMICAL ACTIVE INGREDIENTS” of the ANNEX of Resolution No. 350 of August 30th, 1999 of the then SECRETARIAT OF AGRICULTURE, LIVESTOCK, FISHERIES AND FOOD and its amendments.

Section b) Present the official document issued by the Responsible Agency / Competent Authority of one of the countries or groups of countries mentioned in the ANNEX, stating the name of the technical grade active ingredient, the minimum purity expressed in PERCENTAGE WEIGHT BY WEIGHT (% w/w), the name and address of the synthesizing establishment.

Subsection c) Manage, as an Affidavit, the presentation of the documentation required in the preceding subsections, through the “SIG – Trámites” platform.

ARTICLE 3. - Post-registration control of the equivalent technical grade active ingredient.

SENASA may carry out post-registration inspections of the equivalent technical grade active ingredient. In the event that the inspection demonstrates inconsistencies between the declared information and the analyzes carried out on the official samples, the National Service will cancel the registration in accordance with the procedures established in the current regulations, without prejudice to the sanctions that may apply in accordance with the provisions of Chapter V of Law No. 27233 and its Regulatory Decree No. DECTO-2019-776-APN-PTE of November 19th, 2019, and the eventual application of the relevant preventive measures.

ARTICLE 4. - Post-registration inspection of documents of the equivalent technical grade active ingredient.

SENASA may carry out post-registration inspections of documents of the equivalent technical grade active ingredient. In the event that the inspection demonstrates inconsistencies between the information declared and that presented when requesting registration by equivalency of the active ingredient for the plant in question, the National Service will request the corresponding correction, without prejudice to the sanctions that may apply in accordance with the provisions of Chapter V of the Law No. 27233 and its regulatory decree.

ARTICLE 5. - Official equivalency.

SENASA may decide on the equivalence ex officio if the information required in Article 2 of this standard/rule is public and available.

ARTICLE 6. - Recognition of equivalency. List of recognized countries or groups of countries. Exhibit. Approval.

The List “RECOGNIZATION OF EQUIVALENCE” is approved. LIST OF RECOGNIZED COUNTRIES OR GROUPS OF COUNTRIES” which, as an ANNEX (*IF-2024-66957000-APN-DAYB#SENASA*), forms an integral part of this measure.

ARTICLE 7. - Power.

The National Directorate of Plant Protection of the NATIONAL SERVICE FOR AGRO-FOOD HEALTH AND QUALITY is empowered to modify the list in the ANNEX.

ARTICLE 8. - Non-compliance. Sanctions.

Non-compliance or violations of this rule will be subject to the sanctions established in Chapter V of Law No. 27,233 and its Regulatory Decree No. DECTO-2019-776-APN-PTE of November 19, 2019, without prejudice to the preventive actions that could be adopted by virtue of the provisions of Resolution No. 38 of February 3, 2012 of the then MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES and its amendment, or the one that replaces it in the future.

ARTICLE 9. - Incorporation.

This resolution is incorporated into Book Three, Part Four, Title I, Chapter II, of the Subject Index of the Regulatory Digest of the NATIONAL SERVICE FOR AGRO-FOOD HEALTH AND QUALITY, approved by Resolution No. 401 of June 14th, 2010 and its complementary No. 913 of December 22nd, 2010, both by the National Service.

ARTICLE 10. - Validity.

This rule comes into force upon its publication in the Official Gazette.

ARTICLE 11. - Communicate, publish, send to the NATIONAL DIRECTORATE OF THE OFFICIAL REGISTRY and archive.

Pablo Cortese

Publication date 06/28/2024

ANNEX (IF-2024-66957000-APN-DAYB# SENASA):

RECOGNITION OF EQUIVALENCY.

LIST OF RECOGNIZED COUNTRIES OR GROUPS OF COUNTRIES:

AUSTRALIA

UNITED STATES OF AMERICA

UNITED STATES OF MEXICO

NEW ZEALAND

UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND

FEDERAL REPUBLIC OF BRAZIL

EUROPEAN UNION