

> Regulation of Law No. 21,349 on fertilizers and biostimulants is published

On August 28, 2023, Supreme Decree No. 61 (the "Regulation") was published in the Official Gazette, which approves the regulation of Law No. 21,349 on "Composition, Labeling and Marketing of Fertilizers and Biostimulants" (the "Law").

I. Content of the Regulation

In general terms, the Regulation covers the following matters:

- 1 Classification of fertilizers, biostimulants and blends, establishing requirements by class.
- 2 Composition, quality parameters and labeling.
- 3 Sampling and analysis.
- 4 Importation of raw materials and finished products.
- 5 Requirements and conditions for fertilizers and biostimulants intended for export.
- 6 Procedure for the issuance of certificates of free sale.
- 7 Inspection, control or sampling actions by the Agriculture and Livestock Service ("SAG").
- 8 Applicable responsibilities.
- 9 Single National Registry for manufacturers, formulators, producers, traders or distributors, packers, importers, and exporters of fertilizers and biostimulants (the "Registry").

II. National Register

Among the aforementioned matters, the provisions relating to registration stand out as one of the main aspects of the Regulation, which establishes the following obligations for registrants:

- 1 Report once a year the volumes produced, manufactured, marketed, or distributed, packaged, imported and exported by product, and the destination of the product.
- 2 Declare the catalog of products for agricultural use that they manufacture, formulate, produce, commercialize, package, import or export, including the following information: (1) labeling and/or brochure; (2) safety data sheet, if it is a hazardous substance; (3) purpose or destination; (4) scientific document or technical publication that supports the function indicated on the label or brochures of biostimulants. This information must be declared within three months of registration in the Register and be updated every six months.

Although the provisions of the Regulation are mainly aimed at fertilizers and biostimulants used for agricultural purposes - which would include agricultural, gardening and/or soil restoration purposes - those who use them for other purposes must also be registered in the Register.

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The obligation of registration entails responsibility for the veracity of the information provided and to report the cessation of activities in order to be removed from the Register. Failure to comply with these obligations will be sanctioned with the imposition of a fine of between 5 to 500 *Unidades Tributarias Mensuales* (Monthly Tax Units)^[1].

III. Enforcement

Inspection will be carried out by the SAG. In this regard, the Regulation establishes, among other things, that the SAG may carry out inspections, audits, and sampling at any stage of the life cycle of the products, for which an annual monitoring program will be implemented.

It is also established that products for agricultural use that do not comply with the labeling requirements or with the tolerance established by SAG itself, **must replace the labeling** of the products, in accordance with the Regulations, applicable resolutions and/or laboratory results. **Imported fertilizers and biostimulants** must replace the labeling of the products, in case they do not comply with the provisions of the Regulation and any complementary resolutions that may be issued, prior to their marketing or distribution in the national territory.

Products that do not comply with the minimum nutritional content and/or that exceed the maximum content of contaminants, impurities, copper, and zinc **may not be distributed or marketed in the country**.

In any case, the conditions for the final disposal of these products will be established by means of a SAG resolution, after a case-by-case evaluation; the manufacturer, formulator, producer, or importer will be responsible for the recovery and final disposal actions.

IV. Entry into force

The obligations imposed by the Regulation will become effective three years after its publication in the Official Gazette, that is, on August 28, 2026.

On the other hand, those producers, manufacturers, formulators, marketers, packers, importers, and exporters of fertilizers and biostimulants that, at the date of entry into force of the Regulation - August 28, 2026 - have initiated activities before the Internal Revenue Service, must request their registration in the Register within nine months from the date of entry into force of the Regulation.

[1] Between USD 360 to USD 36,000 approximately.