

Guidelines for the Registration of New Products with MAPA

Registration with Brazil's Ministry of Agriculture and Livestock (MAPA) is mandatory for fertilizers, inoculants, soil amendments, biofertilizers and plant substrates intended for manufacture, import or commercialization, as well as for individuals or legal entities that manufacture, import or commercialize these products.

Product registration requests are submitted through the SIPEAGRO system by manufacturing or importing establishments. Applicants must provide the product classification, characterization and manufacturing process, list the raw materials used in its formulation and indicate the guarantees to be offered, in accordance with the standards established under current legislation.

Products that do not meet the minimum quality standards established by legislation but nevertheless demonstrate viability of use and agronomic efficiency are classified as "new products" and may be registered provided that the requirements of Article 15 of the Annex to Decree No. 4,954/2004 are met:

"Article 15. Any new product, whether manufactured domestically or imported, with no previous history of use in Brazil in any of its technical aspects, shall only be granted registration after the issuance of a conclusive technical-scientific report by an official or accredited Brazilian research institution attesting to the viability and efficiency of its agricultural use. When research with the product is required, such research shall not extend beyond three agricultural seasons, unless subsequent technical circumstances require an extension.

§ 1. When research is required, the registration request for a new product must be accompanied by a conclusive technical-scientific report issued by an official or accredited Brazilian research institution attesting to the viability and efficiency of its agricultural use.

§ 2. Research conducted with the product must comply with the requirements established in the research protocols for evaluation of the product's viability and agronomic efficiency, as provided for in a specific regulation issued by the Ministry of Agriculture, Livestock and Food Supply.

§ 3. The unit responsible for analyzing the technical-scientific report may determine that the research work must also be evaluated by specialists in the relevant field.

§§ 4 and 5. (Revoked by Decree No. 12,858/2026)

§ 6. An imported product intended exclusively for research and experimentation is exempt from registration. Authorization for its importation shall be granted by the inspection service of the Federal Superintendence of Agriculture of the Ministry of Agriculture, Livestock and Food Supply in the state where the applicant's establishment is headquartered, based on a research project prepared by an official or accredited Brazilian research institution and submitted by the applicant."

Without prejudice to Article 15 of the Annex to Decree No. 4,954/2004, when official analytical methods are not suitable for the analysis of new products, the applicant must submit a detailed description of the proposed alternative method for recognition by the competent MAPA authority, under penalty of cancellation of the product registration.

Therefore, to register this type of product, the company must electronically file a process through SEI with the Agricultural Inputs Inspection Service of the Federal Superintendence of Agriculture (SFA) in the relevant state. In addition to the Product

Registration Request, the process must include laboratory analyses characterizing the product and a research report submitted through the Scientific Work Submission Form.

The list of research institutions accredited for this purpose is available on MAPA's website. Official public research institutions, such as Embrapa, federal, state or municipal universities and state research centers, are accepted regardless of formal accreditation.

Documents in foreign languages may be added to the process provided that they are accompanied by a translation signed by a sworn translator.

Registration of Remineralizers

For the registration of remineralizers, pursuant to Article 9 of Normative Instruction No. 05/2016, agronomic tests or research studies conducted by official institutions or institutions accredited by MAPA may be submitted.

The studies must involve plants and must be conducted in a greenhouse or under field conditions. They may be supplemented by incubation tests or leaching-column tests that conclusively demonstrate that the product is suitable for its intended purpose.

The agronomic tests referred to in item I of Article 9 of Normative Instruction No. 05/2016 do not necessarily need to have followed the parameters established in the minimum protocols required for research trials under Normative Instruction No. 53/2013, since they were conducted before publication of those minimum protocols.

Research studies referred to in item II of Article 9 of Normative Instruction No. 05/2016 must comply with the minimum protocols, subject to Article 42 of Normative Instruction No. 53/2013. Publication of the studies in a scientific journal is not required, provided that the remineralizers evaluated in the trials comply with the parameters and guarantees required for registration under Normative Instruction No. 05/2016.

Under Article 15 of the Annex to Decree No. 4,954/2004, only remineralizers that fail to comply with one or more parameters established under Normative Instruction No. 05/2016 will be considered new products.

Research Report for Registration of a New Product

The research report must be issued by an official or accredited research institution and signed by the researcher or researchers responsible for conducting the project.

The report must describe a structured research study designed to evaluate the viability of use and agronomic efficiency of the new product.

If the product performs the same function as an input already available on the market, it is recommended that the existing input be included among the treatments as a standard control or positive control.

If the product represents the introduction of a new technology for the crop concerned, the research must have at least two objectives:

- a) evaluate the product's ability to positively affect one or more crop-performance variables;
- b) demonstrate that the product acts directly or indirectly on plant nutrition and/or plant development.

At the end of the report, the researcher responsible for conducting the research project must provide a conclusion regarding the product's efficiency and viability of use and state whether or not the product is recommended for registration with MAPA, taking the above provisions into consideration.

These guidelines apply only to fertilizers, inoculants and soil amendments. They do not apply to products intended for phytosanitary control or plant growth stimulation through hormonal action.

These products are regulated under specific legislation applicable to pesticides and related products and follow a separate registration procedure within MAPA, conducted by the General Coordination of Pesticides and Related Products (CGAA).

Processing of Registration Requests for New Products

Administrative proceedings for registration requests for new products begin at the Federal Superintendence of Agriculture (SFA), where the documentary requirements and technical merits of the request are evaluated.

If an analytical method not included in MAPA's approved Manual of Analytical Methods is submitted, after the technical evaluation the process must be forwarded to the General Coordination of Fertilizers, Inoculants and Soil Amendments of the Department of Agricultural Inputs (CGFIC/DSV) in Brasília.

Product registration will only be granted after MAPA's General Coordination of Laboratories (CGAL) evaluates the feasibility of applying the proposed analytical method.

Registration of Imported New Products

Registration of imported new products follows the same procedure as registration of domestically manufactured products.

Only research studies conducted in Brazilian territory are considered.

The importation of product samples for trials conducted in Brazil follows a specific procedure.

The company or research institution must request import authorization from the Inspection Service of the relevant Federal Superintendence of Agriculture (SFA), accompanied by a summarized research project.

The research project must specify the quantity of samples required, consistent with the application rates and areas in which the product will be tested.

The request is evaluated directly by the SFA Inspection Service.

Whenever the product contains an organic component or a living organism, the process will also be evaluated by the SFA Plant Health Service and/or by the Department of Plant Health (DSV/SDA) in Brasília.

Specific Requirements for the Registration of New Products

The physical, chemical or microbiological characterization of the product to be registered must be conducted using the official methods established by MAPA.

Only when the official method is unsuitable may an amendment to the official method or an alternative method be proposed.

Applicants must comply with the method of expressing results established for each product standard. In the case of nutrients, for example, the applicable standard may require results to be expressed as total content, water-soluble content or content extracted using a specified extractant.

Research studies involving new inoculant products must follow the specific protocols available on MAPA's website.

Experimental conditions must be designed to minimize interference from other variables in the final results.

For example, in a trial designed to evaluate an alternative source of a specific nutrient, all other nutrients must be supplied according to the requirements of the crop.

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