



agrolegal

4 Questions and Answers about

Judicial intervention for the approval of pesticide registrations

By Glauco Alves Martins and Martyna Bolgar
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01

What is the procedure for registering pesticides with MAPA, ANVISA, and IBAMA?

Pesticides can only be produced, handled, imported, exported, commercialized, and used in Brazilian territory if they are previously registered with the competent regulatory agency (Ministry of Agriculture – “MAPA”, National Health Surveillance Agency – “ANVISA”, and Brazilian Institute for the Environment and Renewable Natural Resources – “IBAMA”), in compliance with their guidelines and their own requirements.

Those interested in obtaining the registration certificate must submit applications to the registering bodies, accompanied by the respective reports and the data and information required by those bodies in complementary rules. Several reports are required for registering a new technical product. The most common are. e.g., the certificate of physical-chemical analysis of the product, the analyses of five batches, and the report of studies of physical-chemical properties.

01

The analysis of registrations will go through the regulatory agencies in the following order: ANVISA, IBAMA, and MAPA. Upon approval by all of them, MAPA is responsible for publicizing the registration in the Federal Official Gazette, containing the main information about the new approved registration.

02

What is the deadline for approving pesticide registrations?

According to the new text of article 15 of Decree 4.074/02, updated in 2021, these are the deadlines stipulated for the final decision in agrochemical registration processes:

Priority registrations:

Deadline	Type	Initial term
12 months	New technical products	Date of publication of the prioritization, from the date of publication of the prioritization
	Equivalent technical products	
6 months	Equivalent technical products whose technical product is already registered	Date of formulated product filing
	Formulated products whose technical product is already registered	Date of publication of priority list

02

Ordinary registrations:

Deadline	Type	Initial term
36 months	New technical products	Date of application filing
24 months	Equivalent technical products	Date of application filing
	Equivalent technical products whose technical product is already registered	Date of application filing of the formulated product
	Formulated products whose technical product is not registered	Date of application filing of technical product
12 months	New formulated products Date of registration	Date of registration of the respective new technical products
	Technical product registration update	Date of application filing
	Formulated product registration update	Date of application filing

03

Why has judicial intervention been necessary for the approval of these registrations?

The previous text of article 15 of Decree 4.074/02 imposed a deadline of up to one hundred and twenty days on the registering agencies for a technical-scientific assessment for the purposes of registration or re-evaluation of registration. Due to the repeated non-compliance with this deadline by the registering agencies, it became common for injunctions to be filed to force the agencies to conclude the analysis of registrations within the deadline set by the decree.

However, even after the extension of the deadlines with the new text of article 15, there is still considerable sluggishness by the registering agencies, a fact that urges the filing of lawsuits aimed at speeding up the analysis by one or all the registering agencies and the issuance of the registration certificate.

04

How important are the lawsuits filed to speed up the approval of registrations?

The registration of agrochemicals is currently the main barrier to companies interested in marketing agrochemicals in Brazil. It is estimated that, on average, the approval of technical products takes between 5 and 10 years. In view of this, the judicial intervention of this procedure aims to speed up the registration of agrochemicals so that they are approved within the regulatory timeframe, thus enabling the companies to start operating in Brazil within a reasonable and non-exorbitant timeframe. In addition, filing lawsuits of this nature aims to reduce operating costs - such as purchasing registration rights of use.

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