

TOP 10 INNOVATIONS

NEW AGRICULTURAL PESTICIDE LEGAL FRAMEWORK

DEMAREST



AGRICULTURAL PESTICIDE

After nearly 24 years, the Brazilian Congress finally passed <u>Bill No. 1459/2022</u>. The President of Brazil signed it into law on December 28, 2023 to establish the new legal agricultural pesticide framework (<u>Law No. 14,785/2023</u>).¹

The new law provides for the research, testing, production, packaging, labeling, transport, storage, sale, use, import, export, registration, classification, control, inspection, supervision, and final waste disposal and packaging of pesticides, environmental control products, and related technical products.



The new law repeals:

- Laws No. 7802, issued on July 11, 1989, and No. 9974, issued on June 06, 2000;
- Law no. 9782, Annex II, Item 8, issued on January 26, 1999.
- Renewable Natural Resources and Environment Institute (Ibama)'s Services and Products Price table, part III, Items 2.2.1 to 2.2.5, items 2.3 to 2.7, and items 4.2 to 4.4, part of Law 6938, issued on August 31, 1981; and



The new legal framework overhauls Brazil's agribusiness segment by modernizing the 1989 regulation and tackling the sector's common hurdles, such as red tape, registration delays, unpredictable reassessment procedures, and the applicable precautionary principle (social responsibility to protect the public from potential harm) to approve inputs.

¹ Given that the President of Brazil approved Bill 6299/02 with 14 vetoes, these vetoes must be analyzed by the Brazilian National Congress, the House of Representatives and the Federal Senate in a joint session. At least 257 representatives and 41 senators (separately) must vote to effectively overrule a presidential veto. As such, this document is subject to updates or revisions.



TOP 10 INNOVATIONS

Created by our Life Sciences team, the list below highlights the Top 10 innovations of the new legal framework.



Shorter product analysis deadline

The Ministry of Agriculture and Livestock (MAPA) must complete registration and amendment procedures within the deadlines listed below. These deadlines are valid immediately after MAPA receives the request.



Products used by manufacturers (technical product)

New active ingredient: 2 years.

Equivalent to a registered active ingredient: 1 year.

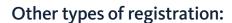


Products used by farmers (formulated products)

New product: 2 years.

Generic ("copies" of registered active ingredients): **1 year.**

Identical (same qualitative and quantitative composition of a registered product): **2 months.**





Organic farming products: 1 year.

Biological pesticides: 1 year.

Atypical product (copper, sulfur, vegetable oil or mineral-based pesticides): **1 year.**

Temporary registration for research and testing: **30 days.**

Premixes: 12 months.

In conclusion, the maximum analysis period is now two years, which the sector has seen as a major improvement, given that product approvals used to take up to eight years.

However, the legislation establishes that these deadlines will stop running if any assessment agents request, in writing, and provide reasoning for submitting additional documents or information. The deadline will resume after the applicant fulfills this requirement.

Amendments

MAPA **must grant or deny the claim** within **180 days** after the applicant requests the amendment. MAPA's technical evaluation criteria are the production process, technical formulated product specifications, raw material changes, other ingredients or additives, manufacturer's inclusions, and update-related adjustments for previously documented crop residue.

2

Ban: only in case of "unacceptable risk."

Agricultural pesticides cannot be registered if their recommended use **poses an unacceptable risk to human health or the environment** despite risk management measures.

The law's new wording disregards the following terms: "teratogenic effects," "carcinogens," "mutagens," or "hormonal disorders" as factors to ban registering agricultural pesticides.

Requirements for registration of agricultural pesticides, environmental control products, and the like must comply with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), and the Codex Alimentarius.





Single registration to enable information sharing

Legal entities providing the services below must file a single registration with MAPA: applying; producing; Importing; Exporting; or Selling agricultural pesticides.

This registration identifies the applicants and their respective activities and shares information with other organizations and municipal and state bodies.





Creation of two information systems



Unified System for Registration and Use of Pesticides and Computerized Environmental Control Products: Registration bodies, within their respective scopes, will implement, continue, and update this system nationwide.

Registration will be mandatory for: Producers, Handlers, Importers and exporters, Research and testing institutions, Distributors, Agronomists or forest engineers, Small-scale farmers, Pesticides and environmental control products application providers.

This registration will ensure agility and transparency in the approval process through a unified electronic system that authorities and agents may use to monitor the process.



Unified Information, Petition, and Electronic Evaluation System (Sispa): MAPA will establish and manage this system within 360 days after the law is published.



Changes in risk reassessment



Shorter deadline: MAPA now **must finish** reassessing pesticides, environmental control products, and the like within **one year. This deadline may be extended for six months** if there are technical reasons for that.



No interference with other proceedings: Reassessing an active ingredient **will not interfere** with analyzing ongoing registration and amendment requests, selling, producing, importing, or using the product made from the active ingredient under reassessment.



No more different treatment: Companies with ongoing registration or amendment claims will have the same treatment as companies with registration or authorization to sell, produce, import, export, and use the product made from the active ingredient under reassessment.



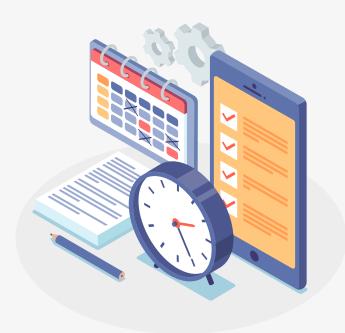
Reassessment documents: Registration reassessment must not be based on **the registration holder's self-reported** data or information.

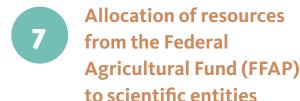


Deadline to start production

Now, after the product is registered, the registration holder must start producing and selling within two years; **otherwise**, **it may lose the registration**.

Companies must notify the registration authority when production and sale start.





Now, FFAP resources for development projects will have to be applied, with priority, in projects developed by public research and technology dissemination organizations. Private non-profit organizations will also be able to receive FFAP subsidies.



Extended deadlines to amend the registration of packaging, labeling, and package inserts wording

The registration holder must amend packaging, labels, and package inserts within 12 months if there are registration amendments that MAPA must evaluate technically (e.g., trademarks, corporate names, ownership transfers, address changes, manufacturer inclusions, etc.).

The previous deadline was 6 months.

Unamended packaging, labels, and package inserts can still be used within these 12 months.



Exclusion of crimes under the previous legislation, and definition of a new crime

Under the new law, there are only two crimes:



1) Producing, storing, transporting, importing, using, or selling pesticides, environmental control products, or the like **without registration or authorization** (new crime): three to nine years in prison and a fine.



2) Failure to comply with the new law when producing, importing, selling, or disposing of waste and empty packages of pesticides, environmental control products, or the like: two to four years in prison and a fine.

The new law excludes crimes regarding employers, respective professionals, or service providers transporting, providing packaging-related services, or employing health protection measures.



Increased fine amounts and a fine for continuing offense

Fines are now capped at BRL 2,000 to BRL 2 million and will be applied proportionately to how serious the offense is (the previous cap was BRL 20,000).

In case of a continuing offense, the fine will be applied **daily** until the offender stops the offense. Meanwhile, the company or laboratory must shut down and suspend operations.

MAIN CONTACTS

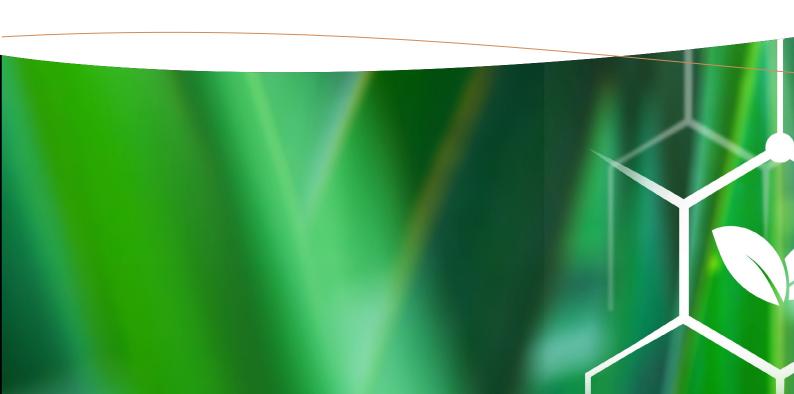
Demarest's **Life Sciences** team is available to provide any further clarifications that may be necessary.



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