



**Requirements to Sell, Manufacture or Commercialize Transgenics,
Insecticides, Pesticides, Herbicides and Rodenticides**

BRAZIL
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- 1. Is permission required from the government in order to plant, commercialize, import or export products that have been genetically modified or engineered ("GMOs")?**

Yes, a permission from the National Technical Commission on Biosafety, CTNBio, is required for any activities involving GMOs. In Brazil Law no. 11.105/2005 provides for safety rules and mechanisms of inspection of the engineering, growing, production, handling, transportation, transfer, importation, exportation, storage, research, marketing, consumption, release to the environment and disposal of genetically modified organisms, GMOs, and its by products.

- 2. Is local presence required in order to be considered a duly registered distributor where the GMO is going to be imported and sold?**

It is necessary that the company interested in conducting activities and projects involving GMOs and its by products be established and organized in Brazil; therefore, the company is required to have a local presence to take part in any activity involving GMOs.

3. Which governmental authorities are involved in the determination of the regulations involving GMOs (for example, food and agriculture, environmental, health, safety)?

The National Biosafety Council, CNBS, and the National Technical Commission on Biosafety, CTNBio. CNBS is an agency in charge of providing high-level advice to the President of the Republic for the formulation and implementation of the National Biosafety Policy.

4. Are local performance and/or environmental safety studies required to obtain the permit to plant, commercialize, import or export GMOs, or are studies carried out in the country of origin of the GMO where it has already been certified, valid or accepted?

The entity intending to carry out lab research, field or contention regime, as part of the process to attain a GMO or a GMO biosafety assessment must apply for the issuance of the Biosafety Quality Certificate, CQB, with CTNBio. The application requires (among others) summary of research projects or further activities that will be conducted with the GMOs and their byproducts.

5. Does the permission granted by the Government authorize the consumption of GMOs by human beings? Are there specific rules for the consumption of GMOs?

No, it is also necessary to obtain a commercial release authorization from CTNBio. The commercial release of GMOs and their by products, that is, external activities (marketing, consumption, etc) requires compliance with the provisions in CTNBio's Normative Ruling no. 05/2008, as well as with the preconditions established in the authorization issued by CTNBio.

6. Is governmental permission required for foreign companies to commercialize, import or export pesticides, insecticides, rodenticides and/or their consumables?

The performance of the abovementioned activities requires the Products Registration with, and the Companies' Operating Authorization and License from, the Ministry of Health and public agencies in charge of controlling chemical products, under the sanitation legislation and the specific technique applicable to each individual product.

7. Is local presence required in order to be a registered or authorized distributor where the pesticides, insecticides, rodenticides and/or their consumables are going to be imported and sold?

In view of the fact that the products at issue are subject to the sanitation surveillance system and the control of chemical products (if applicable), such products can be distributed only upon prior authorization and licensing of the establishments by the applicable public agencies in charge of controlling chemical products (see question 8). Therefore, such establishments shall require a local presence by means of formation of a local entity in accordance with the applicable Brazilian Laws.

8. Which governmental authorities are involved in the determination of the environmental health and safety of pesticides, insecticides, rodenticides?

Ministry of Health (Federal); ANVISA - National Sanitation Surveillance Agency (Federal); Health Departments of the Cities, States, and the Federal District; Federal Police / Chemical Products (if applicable); and Ministry of Defence - Controlled Products (if applicable).

9. Are local performance and/or environmental safety studies required to obtain the authorization to market pesticides, plaguicides, rodenticides, insecticides, or are studies carried out in the country of origin of the products, valid or accepted?

The party applying for the marketing of the products in question must present: (i) Proof of payment of the corresponding fees; (ii) Technical reports and data required under the specific rules; (iii) Stability data; (iv) Package design and label model; (v) liability Instrument, signed by the Legal Representative and the Responsible Technician. Technical reports and certificates issued in the country of origin allowing better evaluation of the products may be requested as well.

10. Is a prescription by a qualified professional required in the herbicides commercialization? If the answer is "YES", what is the professional that grants such prescription?

Yes, in specific cases, such as when the product is used for agronomic purposes, an Agronomic Prescription is required. Agrotoxic and similar products are sold upon a proper prescription, issued by a professional, legally qualified by the Regional Engineering, Architecture and Agronomy Council in compliance with the legislation that regulates the use and commercialization of agrotoxic products, their components, and similar products.