



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

**U.S.A., OREGON
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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")?**

Depending on the nature of the specific GMO product, permission may be required from the United States Department of Agriculture (USDA), the U.S. Food and Drug Administration (FDA), and/or the U.S. Environmental Protection Agency (EPA).

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

Local presence is not required for exporters of GMO products, however, generally the exporter or applicable government agency in the exporting country must certify that the product meets U.S. standards. See, e.g., 7 C.F.R. § 319.56-28 (concerning importation of tomatoes from certain countries). Furthermore, permits are generally required for import and the importer must submit to inspection of the imported goods by the USDA. See *id.* § 319

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

USDA, FDA, EPA, some local jurisdictions. See response to question 1, *supra*.

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?**

USDA regulations generally require local field tests before a GMO crop can be commercialized. Under some circumstances the USDA will approve the importation and planting of a GMO crop for experimental purposes based on foreign studies. See 7 C.F.R. §§ 340.0 to .8; USDA-APHIS Biotechnology Regulatory Services Notification Guidance (Feb. 5, 2008), available at http://www.aphis.usda.gov/brs/pdf/Notification_Guidance.pdf

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?**

FDA approval is only required before a GMO substance may be offered for human consumption if the agency deems the substance a “food additive.” See 21 U.S.C § 348. Historically, GMO producers have generally not been subject to food additive approval because they have engaged in successful consultation with the FDA.

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

All pesticides, insecticides, and rodenticides must be registered with EPA before they can be marketed as a commercial product in the U.S. Successful registration requires that the producer demonstrate through sufficient data that the product, when used according to widespread and commonly recognized practices, will not cause unreasonable adverse effects to humans or the environment. See 7 U.S.C. § 136a.

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?**

U.S. law does not require a foreign pesticide exporter to have a local presence, however, EPA must approve the importation of pesticides into the U.S. See 7 U.S.C. 136o(c). Those wishing to import pesticides into the U.S. must submit a Notice of Arrival Form and wait for EPA approval before obtaining possession of foreign pesticides. 19 C.F.R. § 12.112.

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

EPA is primarily responsible for regulating pesticides, but state agencies also have some authority. See response to questions 6-7, supra and question 10, infra.

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?**

With certain exceptions, EPA accepts data from foreign laboratory and field studies in determining whether to register a foreign pesticide for use in the U.S. EPA will not accept data from tests which involved test sites or test material that is not characteristic of the U.S. Applicants submitting foreign data must use U.S. materials, or show a lack of relevant differences between the selected material or test site and the U.S. material or test site. See 40 C.F.R. § 158.80(a).



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?

Federal and state laws require pesticide users to possess certain technical expertise, but do not have similar requirements for pesticide marketers. Individual U.S. states have authority to apply training requirements to pesticide users. See *id.* § 136w-5. Moreover, U.S. law requires users of certain restricted pesticides to be certified by either EPA or their local state government. See *id.* § 136a(d)(1)(C); *id.* § 136i(a).

