



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

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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. The contained use or deliberate release of GMOs requires notification and/or consent from the Environmental Protection Agency ("EPA") under laws implementing Directive 2001/18/EC.

As for genetically modified plant varieties/seeds, authorisation from the EPA is required under laws implementing Directive 98/95/EC.

The export of GMOs requires consent from the authority of the import country prior to the export.

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

Yes, within the European Community.

When marketing a GMO product, part of the information to be provided is the full name and address of the person established in the Community who is responsible for seeking the necessary authorisation, whether importer, manufacturer or distributor.

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

The EPA is responsible for contained use, deliberate release and transboundary movement. The Food Safety Authority of Ireland (“FSAI”) is responsible for GMO foods. The Irish Medicines Board is responsible for GMOs in medicinal and veterinary products. The Department of Enterprise, Trade & Employment is responsible for biological agents at work and the transport of certain GMOs. The Department of Agriculture, Fisheries and Food (“DAFF”) is responsible for marketing of GMO plant varieties.

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?**

Studies from the country of origin may be relied upon. A person who submits a notification for consent pursuant to SI 500/2003, implemented by Directive 2001/18/EC to market a GMO shall, carry out an environmental risk assessment pursuant to the legislation. Part of this assessment is an analysis of the cumulative long-term effects relevant to the release and the placing on the market. Cumulative long-term effects means the accumulated impact of consents on human health and the environment.

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?**

To market a GMO food and make it available for consumption, the applicant will undergo a procedure outlined in EC Regulation 1829/2003. The application is sent to the FSAI. The FSAI informs the European Food Safety Authority (“Authority”). The application includes a technical dossier and monitoring plan. The Authority will then form a reasoned opinion on whether or not to authorise the food.

GMO foods must also comply with labelling and traceability requirements.

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

Yes. The consent of the Pesticide Control Service (“PCS”) of the DAFF is required for the placing on the market of any biocide or plant protection product under laws implementing Directives 98/8/EC and 91/414/EC. Biocides include pest control products. Plant protection products include substances used to influence the life process of plants, other than as a nutrient.

Exporters (and importers) of biocides shall provide annual returns to the PCS. Exporters of pesticides shall also notify the PCS.

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?**

Yes, within the European Community.

An applicant for authorisation of a plant protection product shall be established in a Member State.

An applicant for authorisation or registration of a biocidal product shall have a business premises in a Member State.

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

The PCS is responsible for both plant protection products and biocidal products.

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?

Studies from the country of origin may be relied upon. For biocides, a risk assessment of the active substances present is required, as per Directive 98/8/EC, implemented by SI 625/2001. Where a quantitative risk assessment cannot be made a qualitative assessment is produced.

Plant protection products require tests to be conducted for the purposes of compiling the necessary dossiers to be submitted as part of the authorisation procedure, as per Directive 91/414/EC , implemented SI 83/2003.

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?

No. There is no specific prescription required by a qualified professional in the commercialisation of herbicides.

Herbicides are plant protection products. The same authorisation process as pesticides applies.

Chemists, toxicologists, eco-toxicologists etc are employed by the PCS as part of the commercialisation and authorisation process.