



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

MALTA Ganado & Associates

CONTACT INFORMATION

Jotham Scerri-Diacono
Ganado & Associates
171, Old Bakery Street, Valletta
Malta
356.21.235406
jsdiacono@jmganado.com
www.jmganado.com

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

Indeed, permission is required from the competent authority in Malta in charge with the regulation of GMOs, namely the Malta Environment and Planning Authority (MEPA). In such matters, MEPA consults the Biosafety Co-ordinating Committee (LN290/02) before taking any decisions. The entire regulatory process is underpinned by a detailed environmental risk assessment, prepared by the applicant, who examines and evaluates any possible harmful consequences of releasing a particular GMO.

- 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 a requisite for importation. Transboundary movement of genetically modified organisms is regulated by EU Regulation (EC) No 1946/2003 (Cartagena Protocol).

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

The Biosafety Co-ordinating Committee (BCC) and its Scientific Support and Advisory Subcommittee together with MEPA are involved with Government in the determination of the regulations involving GMOs. The BCC is tasked with ensuring the implementation of an

integrated approach on biosafety, the contained use of GMOs, the deliberate release into the environment and the placing on the market of GMOs.

- 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?**

Consents to release GMOs into the environment for experimental purposes ("Field Studies" or "Part B Releases" under EU Directive 2001/18/EC) are only valid for releases in Malta. Otherwise, consents granted by MEPA for GMOs to be grown, processed or imported for commercial purposes ("Part C Releases" under said Directive) are valid across the EU. In the case of GMOs that are certified, validated or accepted outside the EU, studies carried out outside Malta will not be accepted.

- 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?**

There are no specific rules regulating the consumption of GMOs. However, GMOs are burdened with certain labeling requirements that are intended to inform consumers that those products contain GMOs.

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

Specific authorisation is required in order to deal with or place plant protection products or biocidal products "on the market". The commercialisation, import and export of the products mentioned in the question above will require specific permission (Council Directive 98/8/EEC, Biocides Regulations, 2004-L.N.294/04 and the Pesticides Control Act).

- 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?**

Local Presence is required.

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

With regard to the products mentioned in this question, it is the Plant Health Department (within the Ministry of Resources and Rural Affairs) that acts as the government authority involved in the determination of environmental health and safety - <http://www.planthealth.gov.mt>.

- 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?**

As a rule, local performance and/or environmental safety studies are not required if already obtained in an EU member state. Otherwise, may be required depending on product and authorities' views.

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?

The 'commercialisation' (import/export, sale or manufacturing) of herbicides will require permission as in 6 above). Authorities may require the product's prescription (from qualified personnel) prior to giving permission unless already approved in another EU state (as in prior question).