



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")?

Under Spanish GMO regulations, the deliberate release and the commercialisation of GMOs (which would comprise the planting, the commercialisation and the import, as applicable) are subject to prior authorisation. For food and feed containing GMOs, EU law establishes a single authorisation procedure valid throughout the Community. In Spain, in practice, most GMOs applications are submitted under this procedure. Exports to third countries are generally subject to the importer's consent.

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

Placing of GMOs on the market must be made under the responsibility of a person established in the Community, whether it be the manufacturer, the importer or the distributor. Also, the applicant for an authorisation of GMOs to be used as food or feed, the authorisation-holder, or his representative shall be established in the Community. Certain entities or products are subject to specific prior registration or authorisation obligations (e.g. food, feed or biocides operators).

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

Generally, GMO related matters are the responsibility of central government bodies ascribed to the Ministry of the Environment, Agriculture, Fisheries and Livestock. Where applicable, these bodies include representatives from other Ministries such as Health, Finance, Science and Technology, scientific institutions, or the autonomous regions. Autonomous regions also exercise certain powers, among others, regarding surveillance, control, inspection and penalty proceedings.

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 performed in the country of origin of the product would not per se be considered sufficient. The risk assessment must be carried out on a case-by-case basis, so that the information required may vary depending on the nature of the GMOs, their intended uses, whether any other GMOs have already been released in such environment, and, generally, the prevailing conditions in the receiving territory. This is without prejudice to existing GMO mutual recognition mechanisms.

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?

Food and feed containing GMOs must be authorised under a specific authorisation procedure before EU authorities. The authorisation granted valid throughout the EU. These products are subject to specific traceability obligations, labelling requirements (except for those foods containing GMOs in proportions no higher than 0.9 per cent, provided that this presence is adventitious or technically unavoidable), and, finally, to applicable EU and Spanish regulations regarding food products generally.

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

Both biocides (for use in non-agricultural sectors) and plant protection products must be authorised and registered in Spain prior to their placing on the market (certain low-risk biocides are subject only to prior notification). Authorisations granted by another EU Member State should be automatically recognised in Spain, unless authorisation conditions are not equivalent. Exports of certain hazardous chemicals and pesticides are subject to the importer's prior informed consent.

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?

Applicants of authorisations for placing plant protection products on the market must have a permanent address within the EU. As regards biocides, current regulations require that the applicant has a permanent office in an EU Member State (but not necessarily in Spain). However, in practice, Spanish authorities still require that the company responsible for placing the product on the market has a local address or representation office in Spain.



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

Generally, the Ministry of Health is responsible for all matters related to biocides, and the Ministry of the Environment for matters related to plant protection products. In any case, the competent bodies will be assisted as necessary by representatives of other Ministries or of the autonomous regions. The autonomous regions are responsible for the registration of the premises located in their respective territory, and, generally, surveillance, inspection, control and penalty proceedings.

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 performed in the country of origin are not per se considered sufficient. As regards plant protection products, it is expressly foreseen that, where the product is authorised in another EU Member State, there is no need to carry out new studies if the plant health, agricultural and environmental conditions are equivalent. In principle, although no express provision exists, a similar conclusion would apply to biocides. This is without prejudice to applicable mutual recognition procedures.

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?

Prescription by a qualified professional is not required. However, distributors, sellers and other market operators of herbicides must have the proper University degree, or employ someone who has such qualification, in order to commercialize herbicides. On the other hand, any personnel who handles herbicides or applies herbicides treatment must be in possession of a particular license (“carnet de aplicador”), with different levels depending on the nature of the herbicide concerned.