



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, all "releases" of GMOs require prior authorisation. The authorising body and extent of authorisation depends on the purpose and territory of the release:

- Releases into the environment for marketing (including importation) require authorisation from a territorial competent authority (TCA - see question 3) under Part C of Directive 2001/18/EC (the Directive)
- Releases into the environment for purposes other than marketing require authorisation from a TCA under Part B of the Directive
- Exports of GMOs require prior authorisation from the first country of import

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

The obligations in EC Regulation 1946/2003 fall on the exporter. The local presence requirements are that there must be a person established in the EC who is responsible for placing the GMO on the market, whether it be the manufacturer, importer or distributor.

3. **Which governmental authorities are involved in the determination of the regulations involving GMOs (for example, food and agriculture, environmental, health, safety)?**
- 4 TCAs authorise UK GMO releases; Defra in England, Scottish Executive in Scotland, National Assembly of Wales in Wales and Department of Environment in Northern Ireland
 - Northern Ireland, England, Wales and Scotland GM Unit administers applications for the TCAs
 - Advisory Committee on Release to the Environment provides scientific advice to TCAs
 - Health & Safety Executive (HSE) regulates contained uses of GMOs
 - Food Standards Agency (FSA) regulates marketing of GMOs for consumption
 - European Food Safety Authority (EFSA) regulates releases for marketing of GMOs for consumption
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?**

Applications for consent to release GMOs must include an environmental risk assessment and data from any previous release by the applicant.

Authorizations to market a GMO from the UK are valid throughout the EU.

A TCA may prohibit a previously authorized release in the EU only on the basis of new evidence found after that consent; which affects the environmental risk assessment on which the consent was based, or where the existing information is reassessed in light of additional scientific information.

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?**

The authorisations detailed above do not authorize release of GMOs for consumption. Such consents are assessed and authorised by EFSA in accordance with EC Regulation 1829/2003 following application to the FSA. Consents are valid throughout the EU for 10 years.

To be authorised, the GMO must not:

- Present a risk to health,
- Mislead consumers,
- Be of less nutritional value than the food(s) it is intended to replace.

Food products containing GMOs must also comply with additional labelling and traceability requirements.

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

Pesticides Safety Directorate (PSD) must approve a pesticide (ie any substance used to control pests) prior to sale or supply in UK.

Authorisation is regulated by Plant Protection Product Regulations 2005 (PPPR) for products containing an existing EU authorised active substance, included in Annex I of Directive 91/414/EEC ('the Directive') or products containing new active substances (marketed in EEA since 26/07/93).

Authorisation is regulated by Control of Pesticides Regulations 1986 (COPR) for products containing existing active substances not included in Annex I.

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?

Under PPPR, the applicant must have a permanent office in an EEA state to import and commercialize a pesticide into the UK. Separate regulations govern the applications in England and Wales and Scotland, dependent upon the location of the principal place of business of the applicant within the UK.

There are no local presence requirements for applicants under COPR.

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

Under COPR:

- HSE authorises non-agricultural pesticides
- PSD authorises agricultural pesticides
- Advisory Committee on Pesticides (ACP) evaluates scientific risk assessments and advises HSE and PSD whether to authorise.

Under PPPR:

- PSD administers all UK applications and represents the UK in the EC process for authorisation
- EFSA evaluates the scientific risk assessment and reports to the European Commission
- Standing Committee on the Food Chain and Animal Health gives its opinion to the European Commission
- European Commission makes the final decision on authorization.

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?**

Under COPR:

- Applications must include environmental and mammalian toxicity risk assessments
- No risk assessment is required for new products containing UK approved active ingredients.

Under PPPR:

- Applications must include a dossier of the data listed in Annex II and III of the Directive.
- Approvals are mutually recognised throughout EEA, therefore products containing Annex I active substances only, do not need repeat risk assessments.

Under COPR and PPPR, imported products identical to a UK approved product, authorised in the export country do not require a risk assessment.

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?**

A prescription is not required for herbicide commercialization. The Code of Practice for Using Plant Protection Products, (produced by Defra) provides guidance on best practice in the use of pesticides.

Suppliers and sellers of pesticides and users of professional pesticide products must hold a certificate of competence or be supervised by someone who holds a certificate. Certificates of competence are issued by the National Proficiency Tests Council and the Scottish Skills Testing Service.