



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

ESTONIA

Lepik & Luhaäär LAWIN

CONTACT INFORMATION

Holger Tilk

Lepik & Luhaäär LAWIN

Niguliste 4, 10130, Tallinn

372.630.6460

holger.tilk@lawin.ee

www.lawin.ee

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

In case of deliberate release of genetically modified organisms into the environment (applies only, when no measures are taken to avoid its proliferation), import from outside EU and commercialisation of genetically modified organisms written permission of Minister of the Environment is required. However, when permission has been issued in any EU memberstate, no additional permission is required, unless the field of application differs. No permission is required for 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?**

Local presence is not required, when import and selling is onetime activity. However, when distributor constantly carries out economic activity in Estonia, a branch must be established.

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

In Estonia Ministry of Environment, Ministry of Agriculture (food and feeding stuffs) and Ministry of Social Affairs is involved in the determination of the regulations involving GMO. Ministry of Environment, firstly, carried out transposition of EU directive 2001/18 into Estonian law and secondly, it administers in its area of government a commission of genetechnology, which counsels Government authorities in the matters of genetechnology and environmental risks of GM organisms or products.

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?

Current legislature provides that if a permission has been provided in any EU memberstate then no additional permission and therefore no local environmental safety studies or performance have to be executed. However, if the area of application varies, no permission has been granted by any EU memberstate or in case of import from non-EU country permission must be applied for (including environmental risk assessment). Risk assessment must be submitted per each release of GMO product to 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?

Consumption by human beings is being regulated by different procedure and permission for GMO consumption by human beings must be granted under procedure enacted by EC and EP regulation nr 1829/2003. Relevant permission is granted in liaison with Food and Veterinary Board (Estonia), European Food Safety Authority, European Commission, all memberstates, publicity and the Standing Committee on Food Chain and Animal Health. Permission granted by European Commission will be valid for 10 years.

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

Estonian legislation requires person to apply permission of Plant Protection Inspectorate for commercializing plant protection product in Estonia or when importing plant protection products from non-EU state to Estonia. In case plant protection product has been allowed to be commercialized in another EU memberstate, Plant Protection Inspectorate may recognize this decision, when application circumstances are comparable. These requirements apply to foreign companies as well as to local companies.

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?

See answer 2.

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

Plant Protection Inspectorate determines the environmental health and safety concerning plant protection 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?

Usually local performance of environmental safety studies are required. Local performance and environmental safety studies are not required, when applicant submits to Plant Protection Inspectorate documentation providing that given plant protection measure has been allowed to be commercialised in another EU country and from the point of disposal of the measure agricultural-, plant health and environmental conditions ,including climate conditions, in Estonia and in this EU memberstate are comparable

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?

Prior to submitting an application for the permission to commercialize plant production product, this must be tested by professionals of this specific field recognized by Plant Protection Inspectorate.