



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

### POLAND

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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.

According to article 10 of the Polish Act on organisms genetically modified of 22 June 2001 [O.J. RP 2007, no. 36, pos. 233] ("GMO Act"), currently in force, specific permission of the Minister of the Environment is required for:

- 1) placing of GMOs on the Polish market;
- 2) export and transit of GMOs;
- 3) deliberate release of GMO into environment;
- 4) contained use of GMO.

Planting of GMOs does not require any permission. However, article 57 (3) of The Seeds Act of 26 June 2003 [O.J. RP 2007, no. 41, pos. 271 with amendments] establishes a general ban on placing seeds of genetically modified plant species on the market. The compatibility of this provision with the EU legislation has been challenged before courts.

Draft of GMO Act dated 1 August 2008 ("Draft GMO Act") stipulates that placing GMOs on the market as product or as part of product requires a decision of the Minister of Environment or a decision of a competent authority of a EU Member State other than Poland or competent

authority of a member state of EFTA being a party of EEA Agreement [article 131 (1) Draft GMO Act].

Framework Position of Government of Poland dated 18 November 2008 on GMO (“Framework Position”) states that “Polish Government is against placing genetically modified plants on market with planting possibility” and will not approve marketing such plants but declares not to do anything against EU law.

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

Current GMO Act does not include requirement of presence of the distributor on the territory of Poland in order to be considered as duly registered. Thus, EU Directive 2001/18 applies directly establishing a requirement for a motion for placing GMOs on the market (as product or as part of product) to include name and full address of an entity with an registered office in the EU Community responsible for placing GMO on the market, whether it be the manufacturer, the importer or the distributor [EU Directive 2001/18 Appendix IV Additional information section A (2)].

Draft GMO Act requires applicant intending to place on the market the GMOs as a product or as part of a product to have his or his representative domicile or a statutory seat on the territory of a EU Member State or a member state of EFTA being a party of EEA Agreement [article 131 (3) of the Draft GMO Act].

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

Minister of the Environment is the governmental authority competent in all matters regarding determination of the GMO regulations. The Minister of Environment:

- 1) issues orders in cooperation with the Minister of Health and the Minister of Agriculture;
- 2) prepares project of National Strategy of Biological Security and a plan of actions resulting from that Strategy that are both to be approved by the Council of Ministers;
- 3) consults all decisions regarding GMO with the GMO Commission composed of representatives of Ministers of following departments: Environment, Agriculture, Health, National Defense, Transport, Education, Science, and Economy.

Framework Position states that Polish government will adjust to the EU regulations. However, Polish government will take all steps to limit the use of GMOs and prohibit such use to such extend as legal provisions allow.

**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?**

Neither GMO Act, nor Draft GMO Act includes provisions regarding the place of performance or environmental safety studies.

According to article 43 (2) GMO Act, motion for allowing placing of GMOs on the Polish market is required to include following documentation:

- 1) confirming that GMOs that are included in the product or of which the product is made, have been previously used in a closed process (contained use) or have been released into the environment in accordance with relevant regulations,
- 2) confirming that as a result of the contained use or release of GMOs into the environment there has been no threat to human health or the environment; and
- 3) evaluation of possible threat.

In practice, documented studies carried out in the country of origin of the GMO where it has already been certified, valid or accepted should be sufficient for the purpose of the documentation of the motion for placing GMOs of Polish market under GMO Act.

**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?**

Neither GMO Act, nor Draft GMO Act includes provisions regarding consumption of GMOs by human beings.

According to Framework Position GMOs allowed to be placed on market upon Member States and EU Commission decision within the scope of 2001/18 EU Directive Minister of Environment decision can be used in all industrial sectors with an exception of using them as food or feed (fodder).

Therefore, permission granted by the Minister of Environment does not authorize the consumption of GMOs by human beings. Food and Nutrition containing or produced from GMOs are within the scope of Chief Sanitary Inspectorate competency while the Minister of Agriculture is competent in matters regarding feed (fodder) containing or produced from GMOs.

Chief Sanitary Inspector accepts motions for placing on the market of GMOs for food use and food containing, produced from, containing ingredients produced from or consisting of GMOs.

Placing of new food or new ingredients of food on the market requires prior proceedings performed by Chief Sanitary Inspector necessary to determine that it does not misguide consumer or constitute a threat to the health or life of consumers [according to EU Regulation 258/97 and article 92 of Polish Act on Safety of Food and Nutrition of 26 August 2006 (O.J. RP 2006, no. 171, pos. 1225)].

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

The marketing and importing or exporting of pesticides, and consumables from them, in Poland requires a permit under the Plant Protection Act [Plant Protection Act dated 18 December 2003 (O.J. RP 2008, no. 133 pos. 849)] (“PP Act”). Pesticides are grouped as plants protection products, whereas insecticides and rodenticides are biocidal products], which permit is issued by the Minister of Agriculture [art. 37 (1), PP Act]. An applicant that is resident, or has a registered office in Poland, or in another Member State of the European Union, can apply [art. 39 (1), PP Act].

If plant protection products, such as pesticides, have been approved in another Member State, they can be marketed in Poland as well; permission would then be required to parallel import the products [art. 47a (1), PP Act], but an application is then simpler [art. 47a et seq., PP Act].

An applicant who is resident, or who has a registered office in Poland, or in another Member State, can apply to the Minister of Agriculture [art. 47b (1), PP Act]. Additionally, in some circumstances the Voivodship Inspector of Plant Health and Seed Inspection may need to be notified [art. 61 (3), PP Act].

A permit is not required for products that are made in Poland and destined for use in other countries, or for those that are only stored, or in transit, here and which are destined for use in other countries. In all three instances, the product must be authorized by the country of destination to be marketed there [art. 37 (4), PP Act].

The business of making, packaging, and marketing of the products is regulated under the Act on Freedom of Business [Act dated 2 July 2004, (O.J. RP 2007, no. 155, pos. 1095, consolidated version)] and must be registered [art. 64 (1), PP Act], and only those whose business is registered as such can apply for a permit [art. 39 (4.1), PP Act].

The marketing and importing or exporting of insecticides, or rodenticides, is regulated by the Biocidal Products Act [Act dated 13 September 2002, (O.J. RP 2007, no. 39, pos. 252, consolidated version)] (“BP Act”), and the products are categorized as being biocidal products. A permit is required from the Minister of Health [art. 5 (1), BP Act], and an application is filed to the President of Office for Registration of Medicinal Products, Medical Devices and Biocidal Products [art. 7 (1), BP Act]. Registration in the Register of Biocidal Products is also required. Any person that is resident, or who has a registered office in Poland, or in another Member State, can apply for a permit, and for the required registration [art. 7 (1) under art. 3 (6), BP Act].

Biocidal products already marketed in another Member State also require a permit to be marketed in Poland, but an application is then simpler because there is adherence to the EU rules of mutual recognition of permits and registration [art. 50 et seq. BP 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?**

A distributor of plant protection products, which include pesticides, is not required to have a registered office in Poland to be able to become a registered or authorized distributor. It is enough for an importer or seller to be resident, or have a registered office, in another Member State. If that applies, an application for a permit needs to give additional information on who in Poland will be responsible for the importation and distribution of products [Art. 39 (1) and (3); art. 47b, (1) PP Act].

The requirements for insecticides and rodenticides are very similar. The following persons can apply for a permit to market the products: a business person, or the person’s representative, or foreigner’s branch office, or representative, that have a registered office in any other Member State, or EFTA. Those persons are defined as being responsible for marketing [for a legal definition see art. 3 (6) BP Act] a biocidal product [see also answer to question 6].

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

Several administrative and law enforcement agencies control the health, safety, and environmental aspects of pesticides, insecticides, and rodenticides. The Main Inspectorate of Plant Health and Seed Inspection controls environmental aspects [art. 78 et seq. PP Act],



under the supervision of the Minister of Agriculture [art. 82 (1) PP Act]. A Commission for Plant Protection Products reports on the effect the products have on the environment [art. 42 PP Act].

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products is responsible for biocidal products. The Minister of Health is responsible for the effect the products have on the environment and human and animal health and supervises other agencies to guarantee the safety of products [art. 7 BP Act]. The BP Act authorizes other national agencies to control the marketing of them. Those agencies, apart from the National Sanitary Inspection, are: National Labour Inspectorate, State Fire Service, Border Guard and Custom Service, Trade Inspectorate, and Environment Protection Inspectorate [art. 49.5 BP Act].

**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?**

An applicant must provide various information in an application for a permit to market biocidal products, including information on ingredients, physical and chemical properties, results of toxicological and ecotoxicological analyses, and all the documentation needed to be able to assess the product [art. 8, BP Act]. The precise requirements appear in a regulation [Regulation of the Minister of Health dated 28 May 2008 on unified assessment of biocidal products and criteria for assessment of biocidal products (O.J. RP 2008, no. 101, pos. 651)], which provides that results of environmental safety studies and studies of the effect on human and animal health are required. All studies must comply with Good Laboratory Practice [art. 8d (1), BP Act]. If the biocidal product, or the residuum of it, adversely affects the environment, an application will be rejected [art. 9 (1.4), BP Act]. Only authorized research units can undertake the studies [art. 24, Chemical substances and preparations Act, (O.J. RP 2001, no. 11, pos. 84); see also the regulation of the Minister of Health dated 4 June 2003 on the criteria that organizational units must use when studying chemical substances and preparations, and on control of that criteria (O.J. RP 2003, no. 115, pos. 1103)].

There is no requirement that the studies be undertaken in Poland. If not, the foreign research unit must, itself, be authorized to undertake studies that comply with Good Laboratory Practice. The authorization must be evidenced [§ 6, Regulation of the Minister of Health dated 4 June 2003 on the criteria that organizational units must use when studying chemical substances and preparations, and on control of that criteria].

Similar standards apply for pesticides. An applicant for a permit must provide the results of safety studies [art. 39 (4), BP Act]. The precise requirements for studies appear in a regulation [Regulation of the Minister of Agriculture dated 17 May 2005 on the scope of studies, information and details on plant protection products and active substances and on the procedures for assessment (O.J. RP 2005, no. 100, pos. 839)], which provides that results of environmental safety studies and studies on the effect on human and animal health are required [see annexes to the Regulation of the Minister of Agriculture dated 17 May 2005 (O.J. RP 2005, no. 100, pos. 839)]. The Minister of Agriculture authorizes research units to undertake such studies [Regulation of the Minister of Agriculture dated 18 October 2004 on authorization of organizational units to assess and report on plant protection products (O.J. RP 2004, no. 238, pos. 2399) and Regulation of the Minister of Agriculture dated 7 September 2007 on authorization of organizational units to assess and report on plant protection products (O.J. RP 2007, no. 189, pos. 1357)].

**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?**

There are no special requirements for herbicides. They are categorized as being pesticides, which are regulated by the PP Act. The business person that produces, packages, or markets the products must ensure that persons who have direct contact with the product have appropriate training [art. 64 (4.1), PP Act]. The Minister of Agriculture authorizes research units to conduct such training [art. 75 (7), PP Act; a list of the entities see Promulgation of the Minister of Agriculture dated 21 February 2006 on the list of organizational units authorized to train in marketing, packaging, and applying of plants protection products (O.J RP "Monitor Polski" 2006, no. 18, pos. 202) and promulgation of the Minister of Agriculture dated 2 December 2004 on the list of organizational units authorized to train in marketing, packaging, and applying plants protection products (O.J RP "Monitor Polski" 2004, no. 54, pos. 911)].