What are the rules governing genetically modified organisms?

REGERINGSKANSLIET

FACT SHEET
Ministry of Agriculture, Food and Consumer Affairs, Sweden
August 2005

Operators in the agricultural sector have always been trying to improve the properties of their crops. This has normally been achieved through selection or by cross-pollinating closely related plants. Pollen contains genes that determine the properties of a plant. Traditional cross-pollination is a time-consuming process and the results often only become apparent after years of experimental work. Another drawback when using this technique is that it normally leads to more genes than desired being transferred.

Using genetic engineering, however, it is possible to transfer properties between living organisms with much greater precision. The technique therefore creates new opportunities but there are also potential risks involved. For example, biological diversity can be affected if the properties of genetically modified crops are spread via pollen to wild crops of the same species. Genetic engineering is hence the subject of comprehensive legislation stretching from the field to the fork.

The point of departure: human and animal health and the environment

Genetically modified organisms (GMO) are regulated by common European legislation that all Member States must follow. The main aim of the legislation is to protect human health, animal health and the environment. Another aim is to safeguard consumer freedom of choice and to ensure ethical issues are taken into consideration when using GMO. Under the legislation, any possible

Area of responsibility	Competent authority in Sweden
Processes applications for trial cultivation, market release and contained use of genetically modified plants, animals and feed	Swedish Board of Agriculture
Examines cases of accidental GMO in conventional seed	Swedish Seed Testing and Certification Institute
Processes applications for trial cultivation, market release and contained use of genetically modified aquatic organisms	National Board of Fisheries
Processes market release applications for food that consists of or contains genetically modified organisms. Enforces labelling regulations	National Food Administration
Processes market release applications for genetically modified forest trees intended for timber production	National Board of Forestry
Processes applications for trials and market release of genetically modified micro-organisms, nematodes, insects and arachnids	Swedish Chemicals Inspectorate
Supervises the contained use of genetically modified micro-organisms	Swedish Work Environment Authority
Processes applications for the use and clinical trials of pharmaceutical products containing genetically modified organisms	Medical Products Agency

environmental and health risks must be analysed and the consequences of potential damage evaluated. The risk scenario is mainly influenced by factors such as plant biology, the nature of the genes introduced, where the plant is cultivated and how it is used.

All GMO-related activities require a permit from an authority. The requirements laid down in the permit application differ depending on the organism and the area of use. Generally speaking, however, a considerable amount of information must be reported so that the authority can determine whether the genetically modified organism in question is as safe as its unmodified equivalent. Compulsory information to be submitted includes the origin of the organism and its potential environmental impact and harmful effects. Further information is often required to facilitate assessment.

GMO-related activities are divided into three areas:

- Market release, i.e. the sale of GMO or their use in various products
- Trial cultivation in the field
- Contained use, e.g. in greenhouses and laboratories

The authorities are responsible for enforcement and inspection as regards the regulations in their respective areas. The Swedish Environmental Protection Agency and the Swedish Gene Technology Advisory Board act as advisory bodies.

Market release

In the EU, there are two ways of applying for GMO market release approval. One application procedure applies to GMO that are to be used as food or animal feed and the other is for other uses. The difference between the two procedures is that the former is mainly dealt with at the EU level whereas the latter is of a more national nature. In both cases, a decision to approve the GMO means that the product may be sold anywhere within the EU. The decision is valid for ten years, with the possibility of an extension for a further ten years.

Application for use as food or animal feed

A party wishing to gain approval for the cultivation or import and use of GMO as food or animal feed must submit an application to the competent authority in the relevant Member State. This authority then examines the application to ensure all the formal requirements have been fulfilled. The next step is for the authority to pass the application on to the European Food Safety Agency (EFSA) for scientific risk assessment. The EFSA may delegate the environmental risk assessment to the competent authority in a Member State. The scientific background data is forwarded to the Commission. Based on this data, the Commission then puts forward a draft decision to the Standing Committee on the Food Chain and Animal Health, on which all Member States have representation.

The Commission must gain the support of a qualified majority on the Committee in order for the decision to be approved. If the proposal does not receive enough votes in the Committee, the matter is passed to the Council of Ministers for a decision. If the Council of Ministers cannot gain the majority needed to decide, it is up to the Commission to take the final decision.

Applications for other uses

In order to gain approval for the cultivation or use of a GMO for some purpose other than for food or animal feed, e.g. as technical starch and other industrial products, the application must be submitted to the competent authority in the Member State. In these cases, the authority makes the preliminary scientific risk assessment. If it considers the application can be approved, other Member States and the Commission are given the opportunity to comment. If there are no objections, the authority issues an approval that is valid throughout the EU.

If, on the other hand, a Member State or the Commission raises an objection and agreement cannot be reached, the matter is decided at the EU level. The same procedure as for the approval of GMO as food or animal feed then applies. This means that the EFSA participates in the scientific risk assessment process and that either the Commission or the Council of Ministers decides on the matter.

Trial cultivation

The EU also has regulations governing the trial cultivation of genetically modified organisms. These cover inter alia the assessment of the environmental and health impact and include a monitoring requirement to check compliance with the regulations. It is normally the national authority that decides whether to grant a permit for trial cultivation after a risk assessment has been carried out.

Contained use

A permit is also required to work with GMO in laboratories, greenhouses and animal facilities. The authority examines the handling of the GMO to ensure it does not constitute a risk to the facility personnel, the general public and the natural environment. The activities must also be ethically acceptable. The decision on contained use is made at the national level.

Compulsory labelling to guarantee traceability

All GMO or products that come from GMO must be labelled and be traceable back down the produc-

tion chain. The EU has common regulations on how products are to be labelled and how the information is to be transferred at every step from the producer to the shop. The product must also be accompanied by the appropriate documentation.

Even food and animal feed that do not contain anything that can be analysed as a GMO must be labelled and have documentation. For example, an oil made from GMO rapeseed must be labelled even if, upon analysis, it cannot be distinguished from 'normal' rapeseed oil. If a product contains an accidental or technically unavoidable GMO constituent that has been approved in the EU for the use in question, it must be labelled as a GMO product if the constituent exceeds 0.9 per cent of the product. The reasoning behind the labelling regulations is not because there might be a risk associated with using the product, but in order to allow the consumer to make an active choice.

Every GMO has a unique code, consisting of number and letters. This code can be used to obtain more information about the product's properties. The code must accompany the GMO product all the way along the marketing chain, but need not be on the end consumer packaging. The consumer must be able to see whether the product contains GMO by reading the packaging or an adjacent sign. Not only does this give the consumer freedom of choice but also makes it possible to trace a product. The documentation must be kept for five years by all those involved in the marketing chain.

International provisions

The Cartagena Protocol on Biosafety comes under the UN Convention on Biological Diversity (CBD), to which over one hundred nations are signatories. The Protocol regulates transboundary movement of living genetically modified organisms. The aim is to ensure consideration of both the environment and human health is taken when moving GMO between different countries.

The provisions of the Protocol have been incorporated into EU legislation. It contains provisions on, inter alia, notification and information exchange prior to proposed transboundary movements of GMO. A party wishing to transport a GMO must send in a written notification to the competent authority in the country of import prior to the transboundary movement taking place. The recipient country should only need to receive products that it has already approved.

The parties to the Cartagena Protocol on Biosafety have also decided that the products are to be labelled and be accompanied by other documentation so that it is possible to identify type of GMO it is and for what purposes it may be used.

Other international provisions that may be applicable to trade in GMO are certain agreements adopted by the World Trade Organization (WTO). There is one agreement on Technical Barriers to Trade (TBT) and one on Sanitary and Phytosanitary Measures (SPS). Under these agreements, WTO member countries may take action to protect legitimate societal interests, including the health, life and safety of human beings, animals and plants as well as to protect the environment. In accordance with the SPS agreement, action of this type must be preceded by a risk assessment.

Related provisions

Seed

Before seed from most agricultural and horticultural crops may be sold, the variety must be approved and put on a list of approved seed-types. This is also true for genetically modified varieties. Approval involves examining several different aspects, such as the variety's value for cultivation as an agricultural crop. Before the new variety can be sold throughout the EU, it must first be listed in the EU Common Catalogue.

Environmental damage

The EU has provisions on environmental liability in order to prevent and remedy environmental damage. These also cover GMO-related activities. Under the provisions, a party causing environmental damage or constituting an imminent threat shall take the necessary actions to remedy or prevent such damage. The party causing the damage shall pay for the costs. Regardless of whether it has been caused intentionally or is the result of negligence, damage to the natural environment must be restored.

The operator's liability for costs may be reduced if it is a question of so-called 'development damage'. This means emissions or events that were not considered harmful according to the state of scientific knowledge at the time they occurred. The cost liability can also be reduced if the harmful activity took place in accordance with permit conditions.

Organic production

According to EU rules, GMO may not be used in organic production with the exception of veterinary pharmaceutical products. The EU has yet to adopt a special threshold for accidental GMO in organic products.

Co-existence

Co-existence allows farmers to be able to choose between cultivating conventional, organic and genetically modified crops. It should be possible to use these cultivation methods in parallel, without them having any harmful effects on each other.

If pollen from a cultivation of genetically modified crops spreads to organic or conventional crops, it may render the latter unsellable on the market for organically

or conventionally farmed products. This is likely to have an adverse effect on the farmer's financial situation.

The EU Commission has recommended that the Member States develop their own co-existence strategies and have issued certain guidelines to facilitate the work in this area. The Swedish Government is currently looking into whether Sweden should introduce provisions on precautionary measures when cultivating GMO.

Further reading

An overview of the responsibility for genetic engineering activities under the Swedish Environmental Code can be found on-line at www.gmo.nu. This website informs the reader about existing legislation, the appropriate requirements and permits that apply to the various types of activities. The website also says which authorities are responsible for a particular area.

The Joint Research Centre of the European Commission also has a website at http://gmoinfo.jrc.it, which includes summaries of current applications for market release and information on ongoing field trials in different EU countries. The general public also has the opportunity to comment on the applications.

Overview of GMO legislation

European legislation

Council Directive 90/219/EEC on the contained use of genetically modified organisms

Council Directive 98/81/EC amending directive 90/219/EEC on the contained use of genetically modified micro-organisms

Directive 2001/18/EC of the European Parliament and the Council on the deliberate release into the environment of genetically modified organisms and repealing Directive 90/220/EC

Directive 2004/35/EC of the European Parliament and the Council on environmental liability with regard to the prevention and remedying of environmental damage

Regulation 1829/2003 of the European Parliament and the Council on genetically modified food and feed

Regulation 1830/2003/EC of the European Parliament and the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

Regulation of the European Parliament and the Council 1946/2003/EC on transboundary movements of genetically modified organisms

Council Regulation 2092/91/EC on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs

National legislation

The Swedish Environmental Code (1998:808)

Government Ordinance (2002:1086) on the release of genetically modified organisms into the environment

Government Ordinance (2000:271) on the contained use of genetically modified organisms

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Fact sheet produced by the Ministry of Agriculture, Food and Consumer Affairs. Printing by the Printing Works of the Government Offices, Stockholm Sweden, August 2005. Article No Jo 05.016.