

GMO regulation in Estonia

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General policy context

In 1999, the Estonian first Act on Deliberate Release into the Environment of Genetically Modified Organisms came into force. This act was replaced by a new version in 2004. However, it is important to mention here that although there was no legal framework for the release, production and marketing of GMOs in Estonia until the adoption of the first GMO act (1999), the Seed and Vegetative Propagation Material Act required the labelling of the retail packaging of certified genetically modified seed and vegetative propagation and cultivation material with the letters "GMO".

Estonian GMO law is based on the principle that genetically modified organisms shall be released into the environment and genetically modified organisms in or as products may be placed on the market only based on the written authorisation of the Minister of the Environment. Estonian regulatory approach seems to be based in general on precautionary principle. However, the implementation of the principle is somewhat confusing.

One may state that Estonia has established almost sufficient legal framework and institutions to implement precautionary principle in GMO policy. But at the same time lack of practice of implementation of these provisions is obvious - major Estonian permitting body (the Minister of Environment) hasn't issued any GMO permits to date. Lack of relevant legal practice makes it difficult to analyze Estonian approach of implementation of precautionary principle in GMO related decision-making and to draw any solid and far-reaching conclusions.

1) National regulatory approach to GMO

Estonia has adopted horizontal act on GMOs - Deliberate Release Into the Environment of Genetically Modified Organisms Act, which was passed on 14 April 2004 and entered into force 1 May 2004. This Act aims at transposing of Directive 2001/18/EC on deliberate release of GMOs into the environment. The objective of this Act is to protect persons and the environment against the potential negative effect caused by the release into the environment of genetically modified organisms and to guarantee the safe application of genetic engineering and development thereof in a ethically responsible manner. The Act regulates both - the release into the environment of genetically modified organisms, and placing on the market of genetically modified organisms, and products containing or composed of such organisms. The Act does not apply to modification of genes of human beings by means of genetic engineering; organisms produced by mutagenesis or plant cell fusion, medicinal products prescribed for use by humans containing or composed of genetically modified organisms, the use of which is regulated by other legislation; and contained use of genetically modified organisms, including contained use of micro-organisms.

Estonia hasn't intended to introduce more stringent standards than EC law and has not made use of paragraphs 4 and 5 of article 95 of EC Treaty.

2) Executive competencies in the Member States

GMO permits, both for release and placing on the market, are issued by the Minister of Environment. The Commission for Gene Technology, an advisory body, has been established within the area of government of the Ministry of Environment. The function of the Commission for Gene Technology is to:

- provide consultations to governmental authorities in issues of gene technology and environmental risks arising from genetically modified organisms in or as products;
- provide consultations to notifiers for authorisation for release into the environment of genetically modified organisms,
- review notifications for authorisation for release into the environment of genetically modified organisms,
- provide assessment of the deliberate release into the environment of genetically modified organisms, indicated in the notifications;
- provide consultations to the Labour Inspectorate in issues related to the contained use of genetically modified micro-organisms;
- provide consultations to the Ministry of Agriculture in issues related to the conduct of animal experiment involving genetically modified animals.

GM food and feed are the responsibility of the Ministry of Agriculture. The Ministry of Agriculture is responsible for the implementation of "Regulation 1829/2003/EC on genetically modified food and feed" and "Regulation 1831/2003/EC concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms. The Committee was established by law to advise the ministry during the novel food notification process and for the risk assessment.

3) Implementation and enforcement of Directive 2001/18/CE on the deliberate release into environment of GMO:

- a) The precautionary principle is not *expressis verbis* expressed in Estonian GMO law but Estonian legislation attempts to implement the concept. Under Deliberate Release into the Environment of Genetically Modified Organisms Act a person wishing to release genetically modified organisms into the environment or to import genetically modified organisms shall submit a notification for a corresponding authorisation to the Ministry of the Environment. The notification must contain a description of the potential impact on human health and the environment. An environmental risk assessment concerning the release into the environment of genetically modified organisms must be appended to the notification containing an evaluation of the **potential** negative effects of the release into the environment of genetically modified organisms. The risk assessment concerning the release into the environment of

genetically modified organisms must deal with the direct, **indirect**, immediate, **delayed**, cumulative and **long-term impact** on human health and the environment. One can say that Estonian approach to risk assessment indeed seems to be based on precaution. Risk assessment should not ignore impact of GMOs which is covered by scientific uncertainty. Estonian approach to precaution on the stage of permitting is different. GMO Act prescribes that the Minister of the Environment shall not grant authorisation if the genetically modified organisms are **dangerous** to human health or the environment. It seems that here only the potential risk is not sufficient argument to refuse to issue a permit. As said above, Estonian permitting authority hasn't issued any GMO permits, consequently it is hard to predict how the above mentioned provisions will "work" in practice and how concept of "danger" will be interpreted. As a conclusion it can be stated that on the stage of risk assessment Estonia implements (at least in theory) precautionary principle, but on the stage of risk management (authorisation of release) rather "sound science" approach predominates.

- b) The Commission for Gene Technology is an advisory body established within the area of government of the Ministry of Environment. Main part of the Commission for Gene Technology is formed by gene scientists from various Estonian scientific institutions. In theory Commission plays an important role in the process of assessment of the results of the risk analysis. Under Estonian GMO Law after receiving a notification for release into the environment of genetically modified organisms, the Commission for Gene Technology shall make its' written conclusions and a **proposal** to the Minister of the Environment to grant authorisation, to refuse to grant authorisation or grant an authorisation by which additional conditions are set for prevention of risks. This proposal is not legally binding for the minister. However, as already mentioned, the Commission hasn't performed its functions in permitting procedure and this how the Commission will deal with the situations covered by scientific uncertainty is not known as yet. It still seems that the Commission's prevailing attitude will be based on "sound science" approach.
- c) Supervision over compliance with the requirements of GMO act and legislation established on the basis of this Act is exercised pursuant to the procedure provided by the Environmental Supervision Act. The major supervisory body is Environmental Inspectorate but other institutions are also involved in specific cases - like The Plant Production Inspectorate and the Centre of Forest Protection and Silviculture, Veterinary and Food Board, Health Protection Inspectorate and Customer Protection Board and Customs Board. Consequently the supervisory institutional are fragmented in Estonia and this poses serious problems in implementation and coordination. NGOs don't have authority to supervise. But NGOs still play important role in implementation of precautionary GMO policy. NGOs have initiated public debates and campaigns on these issues. NGOs have also been invited to participate in GMO law drafting committees.
- d) The procedure of issuing of the GMO permits is open procedure. It means that the Ministry of the Environment must publish, at the expense of the notifier, a notice concerning the commencement of processing of a notification and of the grant of authorisation in the official publication *Ametlikud Teadaanded* within seven days after the date of receipt of the

notification or grant of authorisation. The notice must contain a summary of the notification or authorisation (including risk analysis and conclusions of Commission for Gene Technology), a notation as to where the notification can be reviewed and the term within which an opinion can be presented or proposals can be made concerning the release into the environment of the genetically modified organisms. The Minister of the Environment must provide a written response to the proposal within two weeks after receipt of the proposal, informing the person whether the proposal has been accepted or rejected and providing the reasons underlying acceptance or rejection. There are no restrictive standing standards for participation. All persons can participate. Personal connection with the matter must not be demonstrated. The data submitted in notifications for release into the environment of genetically modified organisms or for placing on the market of genetically modified organisms is stored in the environmental register. Data from the register is public. However, the notifier may make a reasoned request in a notification for classification of a part of the data as business secret. The following data must not be classified as business secret by the Minister of the Environment:

- the general description of genetically modified organisms, the name and address of the notifier, the purpose, place and time of releasing the organisms into the environment, and the planned manner of use thereof;
- the method for monitoring genetically modified organisms and the monitoring plan, and remedial action to be taken in the event of accident;
- the result of risk assessment.

e) Court review and standing. In Estonia like in all other jurisdictions, access to court has certain limits. Estonian law is based on the protection of subjective rights. Under this system the right to action is granted to “competent” persons: to certain public authorities and to individuals whose subjective rights have been violated. Under Estonian law the subjective right consists in the legal entitlement of a person to demand from another person certain behaviour, omission or tolerance of the first subjects interests. In the administrative courts only the subjective rights under public law – subjective public rights - can be protected. The notion of the subjective public right is understood in the light of the so called protective norm theory. According to the theory, a violation of a public law provision results in a violation of person’s subjective right only when the violated provision aims, inter alia, to protect the person’s interest. Estonian court practice has been significantly influenced by Aarhus Convention. The early interpretation of the subjective right criterion appeared to be restrictive. The Estonian Supreme Court ruled twice in 1999 that a violation of environmental protection norm does not give standing to individuals and that only competent public authorities may bring a case on these grounds. However, in 2002 two administrative courts of first instance reasoned that individuals may have broader standing to challenge actions of public authorities having negative impact on the environment. In 2004 an appellate administrative court took a step further by stating that the right to a clean environment is a subjective right. Due to this right and right to health protection and privacy a dispute on an excavation permit, may, in principle concern everyone. According to the court, it is not possible to draw a clear distinction between persons concerned and not concerned, although the likelihood diminishes with distance from the excavation site. The court also pointed out

that the opinion of the person whether his or her rights have been violated is important in determining whether this person's rights have been violated. It appears from these cases that the courts have become considerably more liberal in granting standing to individuals in environmental matters (including GMOs release) through more relaxed interpretation of the standing standards.

- f) Estonian law prescribes administrative, criminal and civil sanctions. GMO Act sets up administrative sanctions. Violation of requirements for release into environment of GMOs or placing on market of GMOs as well as violation of requirements for packaging and labelling of GMOs are punishable by a fine. Criminal Code does not stipulate specifically GMO related sanctions, but general sanctions for unauthorized pollution are applicable. GMO Act prescribes also civil sanctions. Any damage caused by the illegal release into the environment of GMOs or unlawful placing on the market of GMOs must be compensated pursuant to the procedure provided by the Law of Obligations Act. Upon failure to remove, as required, the genetically modified organisms released into the environment or failure to eliminate the environmental pollution caused, the Environmental Inspectorate may apply a coercive measure. The Minister of the Environment shall evaluate, at the expense of the polluter, whether or not environmental pollution has been successfully eliminated.

4) Authorisation of the placing on the market of GMOs

- a) The basic principles and procedure of authorization and risk assessment and management were described above. Substantive and procedural rules of authorisation of placing on the market of GMO are similar to those used for authorization of deliberate release. According to multilevel EC law authorization procedure no marketing authorisation is required for the placing on the market, within Estonia, of genetically modified organisms which have been placed on the market or released into the environment based on a marketing authorisation issued in a Member State of the European Union. Authorisation is required only in these cases if the genetically modified organisms in or as products are planned to be placed on the market for a purpose different than that indicated in the marketing authorisation issued in a Member State of the European Union. According to Estonian GMO law in the procedure of authorization economic and social benefits of GMO could not be considered. However it is hard to believe that this provision could work in reality. Risk assessment should take into account the geographic region of placing the product on the market, if necessary. Consequently, at least in theory, specific environmental conditions could be taken into account. The authorisation procedure is open procedure and no personal connection with the matter must be demonstrated for participation. Access to court was described above. Estonian courts are ready to grant broad access to justice.
- b) Authorisations for GM Food and Feed under Regulation 1829/03: GM food and feed are the responsibility of the Ministry of Agriculture. The Ministry of Agriculture is responsible for the implementation of "Regulation 1829/2003/EC on genetically modified food and feed" and "Regulation 1830/2003/EC concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms. The Committee was established by law to advise the ministry during the

novel food notification process and for the risk assessment. If food consists of living organisms, a permit is required from both the Environmental and Agricultural Ministry. The procedure of authorization is open procedure

5) Coexistence

Co-existence is not yet regulated under Estonian law. However, there exists an early draft of respective amendment of Estonian GMO Act. Ministry of Agriculture is responsible for the co-existence strategy. To achieve mutual understanding between different parts in the GM-crops co-existence issue the Minister of Agriculture establishes advisory committee of the different stakeholders. Estonian co-existence strategy prescribes the following basic principles.

- Information sharing between farmers growing GM crops and farmers not growing genetically modified crops;
- Farmers who intend to grow GM crops will have to attend a special course;
- Crop-specific measures should include cropping intervals and cropping distances defined in GMO Act
- GM farmers will have to give detailed information to the Ministry of Agriculture on the type of GM crop(s) they plan to grow.
- All information will be made available to the public;
- GM farmers should be obliged to compensate the damage

Discussions are still ongoing and the Estonia Ministry of Agriculture has planned to force the co-existence legislation in 2007 before the growing seasons

The Estonian Council of Environmental NGOs, the Estonian Farmers' Federation, the Fund of Organic Agriculture, the Centre for Ecological Technologies and Consumers' Organisations from four cities have launched a campaign to establish GMO-free zones, helping farmers to express their determination to remain GMO-free. As there are many unsolved questions about GMOs concerning environment, food safety, socio-economical and legal aspects, the mentioned organisations urge landowners and local authorities to be cautious about use of GM-plants and declare themselves GMO-free. These organisations believe, that it is very reasonable for Estonian farmers and consumers to refrain from cultivation and use of GMOs, as long-term consequences are far from being clear, criteria for safety assessments inadequate and very little independent research on GMOs has been carried out. The campaign for a GMO-free Estonia is collecting information about landowners who are aware of the risks connected to GMOs and do not want to grow them. To declare your land GMO-free one has to fill in the declaration. This is strictly voluntary commitment. No local government has declared itself GMO free as yet.

6) Traceability and labelling

Under Estonian GMO Act after the deliberate release into the environment of genetically modified organisms, the authorisation holder must regularly submit to the Ministry of the

Environment an environmental monitoring report. The information of the report is public information and under the Aarhus convention must be made public upon request.

Products which are sold must be packaged and labelled. The labelling must be clearly visible and understandable. A product must be placed on the market together with accompanying documents which shall set out the unique identification code of the genetically modified organisms. The labelling on the packaging of a product shall set out: the text " this product contains genetically modified organisms" or " This product is composed of genetically modified organisms"; the name of the genetically modified organisms contained in the product; the name and address of the producer; and also a description of the characteristics and appropriate conditions of use of the product. Violation of labelling requirements is a administrative offense and is punishable by a fine.

7) Implementing Directive 2004/35/EC on Environmental Liability with specific reference to GMOs?

Estonia has established a working group to draft new Environmental Liability Act which aims at transposing the liability directive. An early draft has been elaborated and is presently discussed within the government, industry and NGOs. The present draft does not deal specifically with GMO issues. Some provision of compensation and removal are regulated under GMO Act as described above.