EVALUATION OF IMPACT OF IMPLEMENTATION OF THE DIRECTIVE 2001/18/EC ON THE DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS

Summary

The purpose of this study was to perform integrated evaluation of implementation of the EU directive 2001/18/EB on the deliberate release to the environment of genetically modified organisms in Lithuania, to identify possible financial and social impacts of implementation, and to investigate possible and real timeframe of implementation of the directive.

Legal regulation on GMOs in the European Union

The first legal acts regulating biotechnology on the EU level were adopted in 1990. Since then, the regulatory system was continuously revised and amended. The new intensive stage of development of legal and institutional framework in GMO sector started in 2001 with efforts to establish integrated and systematic approach to any kind of GMO use.

In general terms, use of GMOs may be divided into two categories: contained use and deliberate release into the environment. These two types of use are regulated by corresponding horizontal (framework) directives:

- directive 90/219/EC on contained use of genetically modified micro-organisms, and
- directive 2001/18/EC on deliberate release into the environment of genetically modified organisms (repealing directive 90/220/EEC).

The directive 2001/18/EC establishes legal procedures for deliberate release of GMOs into the environment. The directive 2001/18/EC replaced the directive 90/220/EEC with the same name which is repealed from October 17, 2002. By this date, the Member States were obliged to transpose the requirements of the new directive into national regulatory systems.

In 2001-2002 the Commission has published the proposals for three new regulations:

- Proposal for a Regulation concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (COM (2001) 182 final);
- Proposal for a Regulation on the transboundary movement of genetically modified organisms (COM(2002) 85 final);
- Proposal for a Regulation on genetically modified food and feed (COM (2001) 425 – final).

Together with these legal acts, the use of genetically modified organisms in the EU is regulated by sectoral legislation defining use and marketing of products which may contain GMOs. The main sectoral acts related to GMOs are the following:

- Regulation (EEC) No 2309/93 on medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products;
- Regulation (EC) No 258/97 concerning novel foods and novel food ingredients
- Directive 94/40/EC fixing guidelines for the assessment of additives in animal nutrition;
- Directive 98/95/EC amending seed directives.

The objective of the Directive 2001/18/EC is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment. The directive defines two types of deliberate release:

- placing on the market genetically modified organisms as or in products
- carrying out the deliberate release into the environment for any other purposes than placing on the market.

Directive 2001/18/EC requires to carry out environmental risk assessment before releasing GMOs to the environment. Detailed procedures must be followed in order to obtain consent to release of GMOs to the environment. Notification should be submitted to the competent authority of the Member State in which first release is planned. The competent authority prepares evaluation report which is sent to the Commission and the competent authorities of other Member States. In case of objections either from the Commission or from the competent authorities, opinion of the scientific committee is required and the decision on release may need consent of the Council.

Transposition of the Directive 2001/18/EB to Lithuanian Legislation

Lithuanian Law on Genetically Modifies Organisms (*Žin., 2001 Nr.56-1976)* was adopted in 2001. The Law is applied to any activity related to genetically modified organisms but is rather short and general. The first section of the Law contains definitions of terms, the second section defines functions and responsibilities of governmental institutions. Further (Art. 9-12) the Law requires that any person intending to use GMOs must obtain a permit, the Ministry of Environment must establish database of GMOs, and the public must be provided with the information concerning use of GMOs.

The definitions provided in the Law6 except the definition of "organism" do not transpose the definitions of the directive 2001/18/EC. The term "placing on the market" in the Law is wider than used in the directive and includes, for example, making available genetically modified micro organisms for contained use which is excluded from the definition in the directive.

The Law gives the right to the Ministry of Environment to issue permits for activities involving use of genetically modified organisms. According to the definition of "use" provided in the Law, it includes deliberate release of genetically modified organisms to the environment including placing on the market. According to the directive 2001/18/EC the competent authority should issue only consent for the release to the environment while final decision on placing on the market should be taken according to the requirements of the sectoral legislation.

The goals of the Regulation on issuing permits for use of genetically modified organisms and their products in the Republic of Lithuania, approved by the Order of the Minister of Environment No. 601 from December 18, 2001 *(Žin., 2001 Nr.111-4052)* include monitoring and control of GMOs imported to and exported from Lithuania.

The Directive 2001/18/EC includes provisions on which a traceability system for GMOs could be founded, it neither provides for a definition of traceability for GMOs, the objectives of traceability or a complete approach for its implementation. The principles of tracebility will be set in the new regulations which are already proposed (proposal for regulation on GMO tracebility and labelling COM (2001) 182 final, and proposal on transboundary movement of GMOs COM (2002) 85 final).

It is indicated in the evaluation of consequences of proposed regulation on transboundary movement of GMOs prepared by the Commission that differences and overlap between national laws, regulations and administrative provisions concerning traceability of GMOs and food and feed products produced from GMOs may hinder the free movement of products, creating conditions of unequal and unfair competition. It is likely that the system of control established by

the Order of the Minister of Environment will not satisfy the requirements of the EU regulations and its change in order to comply with the new EU legislation will require additional costs.

Regulation on submitting notifications and issuing permits for placing on the market, deliberate release to the environment and contained use of genetically modified organisms in the Republic of Lithuania approved by the Order of the Minister of Environment No. 467 from September 2, 2002 sets unified procedure for issuing permits for both contained use and deliberate release though the procedures defined in the corresponding directives are different.

In general, the requirements for contained use and deliberate release to the environment in the Law on Genetically Modifies Organisms and regulations of the MoE are mixed together which means that certain requirements for contained use are not implementable in practice and the requirements for deliberate release are not clear and complete.

Lithuanian legislation does not define principles, purpose and methodology of environmental risk assessment and monitoring of GMOs though they are essential requirements of the directive 2001/18/EC.

The Law on Genetically Modified Organisms and the regulations under the law do not transpose the requirements of the directive 2001/18/EC to the Lithuanian legislation.

Institutional Set-up

Various EU countries have established different institutional structures for regulating deliberate release of genetically modified organisms to the environment. In most countries the decision on consent for deliberate release is taken by the institution responsible for environmental protection or subordinated environmental protection agency. However, there are some exceptions. For example, in Sweden responsibility is divided between several governmental institutions which, before taking the decision, are obliged to consult the Environmental Protection Agency.

In most EU countries decisions on deliberate release are coordinated by established advisory councils, however, Gene Technology Board established in accordance with the Gene Technology Act in Finland is performing the functions of the competent authority and its decisions are legally binding.

In Lithuania, the functions and responsibilities of the governmental institutions related to control and monitoring of genetically modified organisms are defined by the Law on Genetically modified Organisms. Separate articles of the Law define functions of the Ministry of Environment, Ministry of Health, Ministry of Agriculture and National Food and Veterinary Service. However, division of responsibilities is not strict and clear as the same functions are given to several institutions (e.g. “The Ministry of Environment together with the Ministry of Health, Ministry of Agriculture, National Food and Veterinary Service establish ...”, etc.).

On the other hand, responsibilities for control of specific products which may contain GMOs are defined by other Lithuanian laws such as Law on medicines, Food Law, Law on Protection of Plant Species and Seeds.

To make the procedures of deliberate release of genetically modified organisms to the environment clear and transparent, collective responsibility should be avoided. Functions of the institutions (except the Ministry of Environment) related to deliberate release of

GMOs to the environment are defined in specific laws regulating specific products and should not be repeated in the Law on Genetically Modified Organisms.

Competent authority in the meaning of the directive 2001/18/EC should be the Ministry of Environment which should be responsible for implementation of all requirements of the directive. However, as environmental risk assessment is related to various aspects of environment and health, it may need assistance from other ministries and institutions. Such assistance should be provided by the Supervision Committee of the Genetically Modified Organisms which should include representatives of all related governmental institutions and NGOs.

Current status of deliberate release of GMOs to the environment

Since 1990, consents have been granted in the EU to the release to the environment of 18 products containing GMOs. In 1998, processing of applications was suspended and currently there are 14 pending applications for deliberate release of GMOs to the environment.

There are several enterprises and research institutions working with genetically modified organisms in Lithuania. However, the products manufactured by these enterprises and placed on the market do not contain GMOs. The directive 2001/18/EC does not apply to such products and its implementation will have no consequences to the biotechnology sector in Lithuania.

One veterinary preparation - vaccine against Aujeszky disease - have been registered in the Lithuanian register of veterinary preparations in 2001. In 2000-2001 two field trials were conducted with genetically modified sugar beets resistant to herbicides (randap). The trials were ordered and financed by Swedish and German companies producing herbicides and genetically modified seeds. Permit from the Ministry of Environment was obtained or the trials.

Both trials were successful producing positive results, however, no further actions were taken and the companies had made no attempts to register the seeds in the Lithuanian register. Abstention from registration most probably is related to small Lithuanian market - registration in the EU could ensure much bigger market which quite soon will include Lithuania.

Currently, no research related to manufacturing of products containing GMOs intended for placing on the market are conducted in Lithuania because of the lack of funding. Lithuanian institutions may be involved in such research only in case if large foreign companies will give orders and corresponding financing.

Evaluation of Consequences of Implementation of the Directive 2001/18/EC

Implementation of the directive will have positive influence on environmental and health protection as well as on GMO producers and users. Detailed environmental risk assessment including evaluation of risks to human health will be implemented. In addition, both short-term and long-term delayed impact on human health and environment will be carefully monitored after release of GMOs. More information will be provided to the public on various aspects of deliberate release of GMOs. The public will have the

opportunity to take part in adopting decisions on deliberate release of GMOs to the environment.

The products manufactured and placed on the market by the Lithuanian biotechnology industries do not contain GMOs and implementation of the directive 2001/18/EC will have no impact on the biotechnology sector in Lithuania.

Currently there are no companies in Lithuania possessing, producing or planning to produce products containing GMOs intended for placing on the market. Potentially notifications on placing on the market of products containing GMOs can be submitted by Lithuanian importers, however, if the product intended for the Lithuanian market already has been approved in the EU, this approval will be valid in Lithuania a year and a half later. Therefore, starting of notification procedure makes no sense.

When Lithuania becomes a member of the EU, there will be no need for submitting separate notifications on release to the Lithuanian market as consent is issued on the EU level and is valid in all Member States.

It means that implementation of the directive 2001/18/EC will cause no additional costs to the Lithuanian business sector.

Implementation of the directive 2001/18/EC will require additional administrative costs for transposition to the Lithuanian legislation, establishment and running of relevant monitoring and enforcement institutions as well as training of required specialists.

The project "*Strengthening of institutional capacities in implementation of EU requirements related to management of chemicals, genetically modified organisms, IPPC and climate change*" funded by PHARE will start in the beginning of 2003. Funding allocated for the project is 560 thousand Euros, additionally 1.97 million Euros is allocate for investments (hardware, software and laboratory equipment). Activities under the project will include transposition and implementation of both current and planned EU legislation including proposed regulation on GMO tracebility and labelling (COM(2001) 182 final) and transboundary movement of GMOs (COM(2002) 85 final).

According to the ToR, the following status is expected after completion of the project:

- structures capable of management, implementation and enforcement of requirements set to genetically modified organisms established;
- conditions for further development of GMO management in Lithuania including required databases are in place
- competent authorities are provided with required hardware, software and laboratory equipment.

The functions of the Lithuanian competent authority (Ministry of Environment) will include coordination and approval of notifications submitted in other Member States. Consents for deliberate release already issued in the EU should also be approved by the Lithuanian competent authority after accession to the EU. Additionally, the competent authority will issue consents for field trials of GMOs in accordance with the Part B of the directive 2001/18/EC, and establish registers of the locations of the release of the GMOs under part B and GMOs grown under part C of the directive.

It is expected that the Ministry of Environment will need one additional position to perform these functions. The costs required for one additional position including taxes, social security, etc., as well as maintenance of the work place are estimated at approximately 40 thousand Litas per year.

Conclusions and Recommendations

1. The requirements of the directive 2001/18/EC are not transposed to the Lithuanian legislation, certain statements in the Law on Genetically Modified Organisms and Orders of the Ministry of Environment are inconsistent with the directive and current Lithuanian legislation. The Law and the Orders of the MoE should be reviewed and reformulated.

2. The requirements for deliberate release of products containing GMOs should be clearly separated in the Lithuanian legislation from the requirements concerning contained use of the GMOs, requirements for environmental risk assessment and monitoring should be clearly defined.

3. The functions of various institutions related to deliberate release of products, which may contain GMOs, (except the Ministry of Environment) are clearly defined in the legislation regulating specific products. Competent authority in the meaning of the directive 2001/18/EC should be the Ministry of Environment, which should take responsibility for implementation of all requirements of the directive 2001/18/EC. As environmental risk assessment is related to various aspects of environmental and health protection, the Ministry of Environment needs assistance which should be provided by the Steering Committee of the Genetically Modified Organisms.

4. Responsibilities for control of import and export of products, which may contain genetically modified organisms are placed on institutions controlling corresponding products (National Plant Protection Service, National Food and Veterinary Service) which have regional departments and boarder posts.

5. Lithuanian biotechnology industries are manufacturing products from GMOs but not containing GMOs. The directive 2001/18/EC has no relation and will have no impact on the Lithuanian biotechnology industry.

6. Certain Lithuanian research institutions are planning development of the genetically modified plants, however, even if required funding will be available, their release to the environment could be expected in the best case after 10 years.

7. As the release of GMOs to the environment is regulated on the Community scale, Lithuanian importers will also have no additional costs.

8. Implementation of the directive 2001/18/EC in the long-time perspective will give substantial benefit to the development of agriculture in general and to competitiveness of its products in the world market in particular.

9. Implementation of the directive 2001/18/EC will provide possibilities to the public to participate in decision taking on proposed releases of products containing genetically modified organisms to the environment and to obtain more confidence in products supplied to the market.

10. The project "*Strengthening of institutional capacities in implementation of EU requirements related to management of chemicals, genetically modified organisms, IPPC*

and climate change" funded by PHARE expected to start in the beginning of 2003 will establish required legal, institutional and material base for implementation of the directive 2001/18/EC. Funding allocated for the project is 560 thousand Euros, additionally 1.97 million Euros is allocate for investments (hardware, software and laboratory equipment).

11. The directive will be implemented with the completion of the project by the end on 2003. No additional funding from the state budget will be required.

12. It is expected that one additional position in the Ministry of Environment will be needed for control and enforcement of the directive 2001/18/EC. The costs required for one additional position including taxes, social security, etc., as well as maintenance of the work place are estimated at approximately 40 thousand Litas per year.

13. Additional costs will be required for implementation of the proposed regulation on GMO tracebility and labelling, however, the costs cannot be evaluated until preparation of the proposal on unique codes and analytical procedures is finished by the Commission.