

Summary report on the experiences of Member States with Directive 90/219/EEC as amended by Directive 98/81/EC

Reporting period from 01/01/2006 to 31/12/2008

- **An overview of activities and installations, particularly new ones and those involving GMOs (animals, fish and plants) as well as GMMs**

The Ministry of Environment of the Republic of Lithuania is the Competent Authority responsible for implementation of the Council Directive 98/81/EC of 26 October amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

Currently there are 7 notifications submitted to the Ministry of Environment to carry out contained uses of Class 1 GMMs. The majority of activities are for research and development purposes.

- **Risk assessment and classification of contained uses (including effectiveness of the risk assessment guidelines)**

Before the submission of notification to the Ministry of Environment the user is required to carry out risk assessment of the contained use of GMMs for determination of GMMs classification. The national *Order on Criteria for GMMs Classification* describes the requirements for classification's level determination by the risk assessment of GMMs. The risk assessment requirements lead to more effective and explicit evaluation of potential harmful effects of the GMMs to the environment and human health. Having identified the risks involved it is necessary to assign the appropriate containment level (i.e. Containment Level 1, 2, 3, or 4) and other protective measures, which must be applied in order to control that risk. Containment level corresponds directly to Class.

The classification is determined by consideration of the recipient organism, the donor organism, the insert, the vector and the resulting GMMs. All GMMs activities must be classified into one of four classes: Class 1, Class 2, Class 3, or Class 4:

Class 1 covers activities of no or negligible risk;

Class 2 covers activities of low risk;

Class 3 covers activities of moderate risk;

Class 4 covers those activities of high risk to the environment and human health.

Lithuania has considered the requirements for the risk assessment along the lines of Directive 98/81/EC and Commission Decision 2000/608/EC concerning the guidance notes for risk assessment outlined in Annex III of Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

- **Notification and approval systems (and relevant changes)**

Notification and approval systems are determined in *the Order on Regulation on Contained Use of Genetically Modified Micro-organisms*.

According to the adopted detailed procedures, the notifier (natural or legal person), having intention to carry out the contained use of GMMs, is obligated to receive consent from the Ministry of Environment to execute contained use of GMMs.

The user has to submit the notification to the Ministry of Environment along with the completely filled-in special form of notification both in written and digital formats,

according to the provisions of the above-mentioned order. The notification should include the dossier supplying the name of the person responsible for supervision and safety, information on the training and qualification, the class and purpose of the contained use, the risk assessment, the description of the containment and other protective measures, the emergency plan, the waste management, etc.

The Ministry of Environment upon receipt of the notification for authorization for contained use of GMMs, scrutinizes the completeness of documents presented whether they fully confirm with the requirements stated in the above-mentioned order and, in case of discrepancies, reasonably asks the user to submit lacking information or to modify the conditions of the proposed contained use, to suspend or terminate the use of GMMs.

The Ministry of Environment acknowledges the date of receipt of the notification and dispatches the notification for authorization to the Steering Committee on GMOs and relevant institutions (Ministry of Agriculture, Ministry of Health, State Food and Veterinary service) for submission of draft decision (during the subsequent 10 days period). The Steering Committee on GMOs is a political advisory body, which consists of members appointed by the relevant state authorities, the subordinated organizations, non-governmental organizations, universities, scientific institutes.

The Ministry of Environment having considered and analyzed any observations and recommendations received from the Steering Committee on GMOs and responsible national institutions, takes the final decision for the first time use of Class 1 and Class 2 within the period of 45 days from the submission of the notification, and for Class 3 and Class 4 contained uses within period of 90 days.

Subsequently contained use of Class 1 GMMs may proceed after written notice to the Ministry of Environment. Subsequently contained use of Class 2 GMMs may proceed immediately after submission of new notification to the Ministry of Environment, which prolongs the consent. For subsequent Class 3 and Class 4 contained uses the user has to submit the notification to the Ministry of Environment and the contained use may not proceed without the prior consent of the Ministry of Environment. The decision to proceed the contained uses of Class 3 and Class 4 is made at the latest 45 days after submission of the new notification.

- **Accidents**

There have not been any accidents in Lithuania.

- **Inspection and enforcement issues (including requests by competent authorities for assessments of class 1 contained uses)**

According to *the Order on Regulation on Contained Use of Genetically Modified Micro-organisms*, the Ministry of Environment controls and examines the containment and other applied safety measures, not rare than once per 3 years for Class 1, not rare than once per 2 years for Class 2, not rare than once per 1 year for Class 3 and Class 4. The Ministry of Environment as the Competent Authority is responsible for the monitoring and inspection of installations working with GMMs.

The major objective for inspection is to confirm the effectiveness of containment level and to evaluate the compliance with relevant approval conditions concerning the protection of the environment and human health.

The administrative penalty according *the Code on Administrative Right's Violation* can be imposed on users who carry out activities with GMMs without the approval from

the Ministry of Environment or evades the requirements set out in national law. Approvals can be suspended or revoked where deficiencies with safety measures are discovered.

- **Problems with interpretation of the provisions (possibly with conflict in defining work use with respect to Directive 2001/18/EC)**

There were no occurred specific problems with interpretation of the provisions of Directive 98/81/EC.

- **Clinical trials using the provisions of the Directive**

There were no notifications for clinical trials in Lithuania till December 31, 2005.

The consent from the Ministry of Environment is required before GMOs trials may be carried out according to *the Order on Regulation on Contained Use of Genetically Modified Micro-organisms*.

The clinical trials with GMO's for human medical and veterinary purposes are regulated according to the Council Regulation No. 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products and the Regulation No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

The notifier must receive the consent from the Ministry of Health for clinical trials for human use and in the case of clinical trials involving the GMOs, additionally the consent of the Ministry of Environment for the deliberate release into the environment of GMOs for research and development purposes, according to the order of the Minister of Environment *Regulation on GMOs Deliberate Release into the Environment, Placing on the Market* (Official Gazette 2004, No. 71-2487, in force since 1 May 2004).

The notifier must receive the consent from the State Food and Veterinary Service for clinical trials for veterinary purposes and in the case of clinical trials involving the GMOs, additionally the consent of the Ministry of Environment for the deliberate release into the environment of GMOs for research and development purposes.

- **Public consultation and information**

Lithuanian legislation on GMOs promotes public awareness and participation in decision making as an integral part of its regulatory framework. *The Order on Regulation on Public Information and Participation in Authorization of Consents for Use of GMOs* was drafted taking into consideration Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of GMOs, and Council Directive 90/219/EEC on the contained use of GMMs in conjunction with Council Directive 98/81/EC amending Directive 90/219/EEC.

The order applies for the parties (natural and legal persons, public institutions) involved in the process of information and participation in decision making during the notification and permitting to use GMOs. It declares the rights and duties of the notifier

to inform public announcing the intention to use GMOs, inviting to express and deliver comments on the notification and preliminary decision taken on each specific case. According to *the Order on Regulation on Public Information and Participation in Authorization of Consents for the Use of GMOs* the public has full right to receive freely announced information about the usage of GMOs enquiring what information would like to be given.

According to Article 4 of *the Order on Regulation on Public Information and Participation in Authorization of Consents for Use of GMOs* the Ministry of Environment has to organize use, storage and availability of information about GMOs to the public through the national GMOs database (it could be found via Internet address: <http://gmo.am.lt>), undamaged the rights of confidential and intellectual information. Notifications and information on contained use of GMMs are presented in this database. In the GMOs database there is the section for the direct public opinion presentation.

The Ministry of Environment during the period of 10 days after the acceptance of decision concerning GMOs handling, publicizes via GMOs database and the Official Gazette (supplement of publication “Information announcements”) the information on the consent issued for the contained use of GMMs.

According to *the Order on Regulation on Public Information and Participation in Authorization of Consents for Use of GMOs*, the user has an obligation to inform public during the period of 10 days via different mass media about the fact of receiving of the consent for contained use of GMMs and information on emergency plans for contained use of Classes 2, 3 and 4, including the relevant safety measures.

- **Accident and emergency plans**

No accidents concerning contained use activities were reported in Lithuania till December 31, 2005.

According to *the Order on Regulation on Contained Use of Genetically Modified Micro-organisms*, an emergency plan must be prepared by the notifier and included in the notification as a result of a reasonably foreseeable accident the health and safety of people outside the premises is liable to be affected seriously or there is a risk of serious damage to the environment. For all classess emergency plans are required and these plans must be available at each location where activities are conducted.

An emergency plan should to ensure that in the case of an accident Civil Security, Environmental Protection and other relevant insitutions will be informed.

The following information is required to receive in the case of accident:

- exactly circumstances of the accident;
- the amount of released GMMs;
- potential harmful effect to human health and to the environment;
- emergency response measures, which were implemented in order to protect human health and the environment.

According the above-mentioned order the Ministry of Environment should inform the Commission and Member States, which could be affected by the accident, about the details of the circumstances of the accident, the identity and quantities of the GMMs released, and the response measures taken in order to eliminate the consequences of the accident and their impact.

- **Protection of confidential information**

Lithuania has adopted procedures to protect confidential information in accordance with *the Law on State and Public Service Confidence* (Official Gazette 1999, No. 105-3019). The Ministry of Environment is responsible for confidential information protection and for administrative, technical and other measures, which enable to protect the information from illegal destroy, alteration and usage. The confidential information cannot be disclosed and used for a commercial purpose.

The notifier has to indicate the information in the notification that should be treated as confidential, provided that verifiable justification is given in such cases. Decision, on which information will be kept confidential, is taken by the Ministry of Environment after consultation with the notifier.

Exemptions from the confidentiality clause include:

- name and address of the notifier;
- general description of the GMMs and location of intended use;
- class of contained use and suitability of the containment and other protective measures;
- risk assessment of any potentially harmful effect to human health and the environment.

According to *the Order on Regulation on Public Information and Participation in Issuing of Consents for the Use of GMOs* the public has full right to receive freely announced information about the usage of GMOs enquiring what information would like to be given. The information cannot be given in case the disclosure of it would offend its confidentiality and intellectual property rights. The Ministry of Environment nominated responsible person, who has the permission to receive and work with the confidential information.

- **Waste disposal**

According to *the Order on Regulation on Contained Use of Genetically Modified Micro-organisms*, notifier has to provide information concerning the waste management in the notification.

The following information is required:

- amount and type of waste;
- methods of inactivation;
- final form and destination.

In all cases, including activities at risk Class 1, all types of GMMs must be inactivated prior to discharge.

Currently the Ministry of Environment is not aware of any failure on behalf of the user to decontaminate waste prior to disposal.

- **Transposition of Directive 98/81/EC into national legislation**

Lithuania has constructed the national legislation along the lines of Directive 98/81/EC, amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms. The requirements of Directive 98/81/EC was transposed into *Law on GMOs* and in the orders under this Law.

Lithuanian legislation related to contained use of GMMs are following:

– **Law on GMOs** adopted on June 12, 2001, (No. IX-375, amended on March 20, 2003 by the order No. IX-1384, on June 22, 2006 by the order Nr. X-720) legally came into force since 31 of December 2002.

– **Order on Regulation on Contained Use of Genetically Modified Micro-organisms** adopted by the order No. 413 of the Minister of Environment on August 4, 2003 (amended on April 29, 2004 by the order No. D1-233 and on March 4, 2005 by the order No. D1-130). The overall objective of this legal act is to ensure safe use of GMMs in contained use, thus protecting human health and the environment from possible negative harmful effects posed by GMMs.

– **Order on Criteria for GMMs Classification** was adopted by the trilateral agreement No. D1-693/V-954/B1-1107 of the Minister of Environment, the Minister of Health and the Director of State Food and Veterinary Service on December 28, 2004. The aim of this order is to set up the regulation on the requirements for the classification of GMMs in the Republic of Lithuania.

– **Order on Regulation on Public Information and Participation in Authorization of Consents for Use of GMOs** was adopted by the Minister of Environment on June 11, 2003 (amended on December 30, 2005 by the order No. D1-660, 2006 by the order 2006, Nr. 4-127).