# DIRECTIVE 2009/41/EC

# THREE-YEAR MEMBER STATE REPORTS TO THE COMMISSION ACCORDING TO ARTICLE 17.2 OF THE DIRECTIVE 2009/41/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 6 May 2009 ON THE CONTAINED USE OF GENTICALLY MODIFIED MICRO-ORGANISMS

# QUESTIONNAIRE

# INTRODUCTION

Article 17.2 of Directive 2009/41/EC[1] states that "**Every three years, and for the first time on 5 June 2003, Member States shall send the Commission a summary report on their experience with this Directive"**

Article 17.3 of Directive 2009/41/EC states that "**Every three years, and for the first time on 5 June 2004, the Commission shall publish a summary report on the reports referred to in [Article 17.2]"**

In accordance with these aforementioned articles, the Commission has already published the following two reports:

1. Summary report from the Commission based on the reports of Member States concerning their experiences with Directive 90/219/EEC, as amended by Directive 98/81/EC, on the contained use of genetically modified micro-organisms for the period 1999 – 2003 and Commission staff working paper (Annex to the summary report from the Commission)

2. Summary report on the experience of Member States with Directive 90/219/EEC, as amended by Directive 98/81/EC, on the Contained Use of Genetically Modified Micro-organisms for the period 2003 - 2006.

# QUESTIONNAIRE

The Commission invites Member State Competent Authorities under Directive 2009/41/EC to complete this questionnaire for **the period between 6 June 2006 and 5 June 2009** and to submit it to the Commission by 15 May 2010, in order to fulfil the obligations set out in Article 17.2 of Directive 2009/41/EC.

**DEADLINE FOR COMPLETION: 15 May 2010**


| Contact Details | |
|---|---|
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## 1 Overview of activities and installations

**1.1** How many notifications were submitted in your Member State under Directive 2009/41/EC on the contained use of GMMs during the **reporting period 6 June 2006 and 5 June 2009**?

[1] Directive 90/219/EEC on the contained use of genetically modified micro-organisms has been amended several times (most recently by Directive 98/81/EC), therefore, Directive 2009/41/EC repeals the aforementioned Directives, consolidates their provisions and includes the new Comitology procedure of Regulatory Procedure with Scrutiny (RPS, Article 20).

| **GMMs** | **No. of notifications** |
|---|---|
| Class 1 | **2** |
| Class 2 | - |
| Class 3 | - |
| Class 4 | - |
| Amendments to earlier notifications | - |
| **Total** | **2** |

| **GMMs and GMOs combined** | **No. of notifications** | **Class of GMM** |
|---|---|---|
| GMM + GM plant | - | |
| GMM + GM animal | - | |
| Amendments to earlier notifications | - | |
| **Total no. of notifications received** | - | |

Please provide as annex at your report, a table with all the information required by art 18(2) for each of the notification received, under Directive 2009/41/EC.

**1.2** Of the aforementioned notifications how many were notified for:

- Research purposes **2**
- Commercial purposes -
- Other (please specify) -

**1.3** Please comment on the overall trend compared to the previous reporting period (e.g. has the overall number of notifications received increased or decreased, has there been an increase/decrease in respect of certain classes, commercial or research sectors etc)

**Two notifications relating to class 1 of activities were submitted to the Ministry of Environment during the reporting period. The activities were for research purposes.**

**1.4** Number of installations approved to date:

| Research | Commercial | Other (please specify) |
|---|---|---|
| - | - | - |

**1.5** Number of activities approved to date:

| Class 1 | Class 2 | Class 3 | Class 4 | GMO |
|---|---|---|---|---|
| **2** | - | - | - | - |

**1.6** Were there any particular difficulties you encountered in the notification process during the reporting period and what in your opinion could be done at EU or national level to alleviate these difficulties?

**There were no difficulties**.

## 2 Notification and approval systems (and relevant changes)

**2.1** Who is the Competent Authority (CA) for Directive 2009/41/EC on the contained use of GMMs in your Member State? (Please expand where other authorities or ministries are involved or where authorities are established at national/regional level)

**The Ministry of Environment of the Republic of Lithuania is the Competent Authority responsible for implementation of the Council Directive 2009/41/EC on the contained use of genetically modified micro-organisms.**
**Notification and approval systems are determined in the Order on Regulation on Contained Use of Genetically Modified Micro-organisms.**

**2.2** Has the scope of the transposing legislation been extended to the contained use GM plants and GM animals in your Member State?
Yes __+___ No _____
If not, why not.
_____
_____

| **GMOs** | **No. of notifications** |
|---|---|
| GM animals | |
| GM plants | |
| Amendments to earlier notifications | |
| | |
| | |
| **Total** | |

**2.3** What % of notifications were not processed within the statutory timeframe __O___

**2.4** What gave rise to such delays in the notification process and what efforts are being made to lessen or prevent such delays in the future?

**There were no delays in the notification process.**

**3. Inspection and enforcement issues**

**3.1** Outline the procedure undertaken for the inspection of contained use installations/activities during the reporting period providing details of the number and the overall percentage of installations/activities inspected. Please mention the number of specialised inspectors available for inspections under Directive 2009/41/EC.

**According to the Order on Regulation on Contained Use of Genetically Modified Micro-organisms, the Ministry of Environment obligated to control 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 one specialised inspectors available for inspections under Directive 2009/41/EC.**
**The major objective for inspection is to confirm the effectiveness of containment level and to evaluate the compliance with relevant approved conditions concerning the protection of the environment and human health.**

**The administrative penalties according to the Administrative Law Offence Code can be imposed on users, who carry out activities related to GMMs without the approval of the Ministry of Environment or evade the requirements set out in thenational law. Approvals can be suspended or revoked where deficiencies with safety measures are discovered.**

**3.2** What were the problems most frequently encountered during the course of inspections carried out during the reporting period?

**There were no specific problems.**

**3.3** What were the corresponding enforcement actions taken?

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**3.4** How many enforcement actions were taken during the reporting period? _

**3.5** What actions were taken by the user (and/or advised by the CA) in order to minimise the occurrence of these problems in the future?

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**4. Problems with interpretation of the provisions**

**4.1** What aspects of implementation of Directive 2009/41/EC on the contained use of GMMs place the greatest burden on you as a Competent Authority?

**There were no occurred specific problems with interpretation of the provisions of Directive 2010/41/EC.**

**4.2** What could be done to improve the process at EU and/or national level?

**Lithuania has not so much practice in this activity.**

**5. Accidents**

Provide details of accidents (including the identity of the GMM, the class of activity involved and quantities of GMMs concerned where the accident has involved a spillage) as defined under Article 2(d) of Directive 12009/41/EC, reported to the CA during the reporting period. In addition provide details of the measures taken by the user (and/or advised by the CA) to prevent the occurrence of similar accidents.

**There have not been any accidents in Lithuania.**

**6. Clinical Trials using the provisions of the Directive**

**6.1** How many gene therapy clinical trial applications were carried out under Directive 2009/41/EC on the contained use of GMMs during the reporting period?

**No information given.**

**6.2** Please comment on the overall trend compared to the last reporting period (e.g. has the overall number of gene therapy clinical trial applications carried out under Directive 2009/41/EC increased or decreased etc)

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**7. Public consultation and information**

**7.1** Provide details of public consultations and/or information made publicly available under Directive 2009/41/EC during the reporting period.

**According to the Order on Regulation on Public Information and Participation in Authorization of Consent 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 (Internet address: http://gmo.am.lt), undamaging the rights of confidential and intellectual information. Notification 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.**

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**7.2** Provide details of public reaction (if any) received in response to consultations and/or information made publicly available under Directive 2009/41/EC during the reporting period.

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**8. Waste disposal**

**8.1** What are the means by which GM waste is inactivated and disposed of with particular reference to large volumes of waste material - (including large or large quantities of GM plants and/or GM animals, in particular where those plants and animals have been inoculated with GMMs)?

**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.**

**8.2** **A**re there waste treatment facilities in your Member State which are authorised to inactivate waste arising from GM installations and for what classes of activity? How is the transfer of waste from the GM installation to the authorised waste facility arranged/organised?
**There were no cases of contained use GMMs of class 2 to 4.**
**According to national legal acts GMMs of class 2 to 4 which are capable of reproduction under environmental conditions have to be inactivated prior to disposal. Waste should by mainly inactivate through thermal or chemical means. Inactivated waste should be mainly disposed of through thermal means.**

**9. Other issues**

Please provide comments on any other aspects of the Directive or on other related legislation.

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