LIETUVOS RESPUBLIKOS APLINKOS MINISTERIJA

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Lietuvos nuolatinei atstovybei
Europos Sąjungoje

2014-10-01 Nr. (45-1)-A8-7260

Į Nr.

DĖL ATASKAITOS PERDAVIMO EUROPOS KOMISIJOS SVEIKATOS IR VARTOTOJŲ REIKALŲ GENERALINIAM DIREKTORATUI

Aplinkos ministerija parengė penkerių metų ataskaitą dėl genetiškai modifikuotų mikroorganizmų riboto naudojimo veiklos Lietuvoje pagal Europos Parlamento ir Tarybos direktyvos 2009/41/EB 17.2 straipsnį ir prašo perduoti šį dokumentą Europos Komisijos Sveikatos ir vartotojų reikalų generaliniam direktoratui.

PRIDEDAMA.

1. Raštas Europos Komisijos Sveikatos ir vartotojų reikalų generaliniam direktoratui, 1 lapas.
2. Ataskaita, 6 lapai.
3. Ataskaitos priedas, 1 lapas.

Aplinkos viceministras Linas Jonauskas

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LIETUVOS RESPUBLIKOS APLINKOS MINISTERIJA
THE MINISTRY OF ENVIRONMENT OF THE REPUBLIC OF LITHUANIA

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EUROPEAN COMMISSION
DG SANCO
Unit. E.1-Biotechnology
B232 04/108
B-1049 Brussels/Belgium

2014-10-01 No (45-1)-D8-7259

REPORT UNDER THE DIRECTIVE 2009/41/EC FOR THE PERIOD 2009–2014

The Ministry of Environment has completed the National Report according to the Article 17.2 of Directive 2009/41/EC on contained use of genetically modified micro-organisms for the period 6 June 2009–5 June 2014.

Please find enclosed the Lithuanian Report.

Yours sincerely,

Linas Jonauskas
Vice-minister of Environment

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DIRECTIVE 2009/41/EC

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 three reports.

The Commission invites Member State Competent Authorities under Directive 2009/41/EC to complete this questionnaire for **the period between 6 June 2009 and 5 June 2014** and to submit it to the Commission by 30 September 2014, in order to fulfil the obligations set out in Article 17.2 of Directive 2009/41/EC.

QUESTIONNAIRE

DEADLINE FOR COMPLETION: **30 September 2014**

Contact Details

Competent Authority *The Ministry of Environment of Lithuania*

Contact person *Odeta Pivorienė*

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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 2009 and 5 June 2014**?

GMMs	No. of notifications
Class 1	6
Class 2	
Class 3	

[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).

Class 4	
Amendments to earlier notifications	
Total	6

GMMs and GMOs combined	**No. of notifications**	**Class of GMM**
GMM + GM plant	1	1
GMM + GM animal	2	1
Amendments to earlier notifications	2	1
Total no. of notifications received	5	

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

1.2 Of the aforementioned notifications how many were notified for:

- Research purposes 11
- 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.)

Compared to the previous reporting period 2006 - 2009, the overall number of notifications increased by 9 notifications 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
11	-	-	-	-

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 particular difficulties during the reporting period.

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)

There were no relevant changes since the last report in 2009.

According to the Law on Genetically Modified Organisms the Ministry of Environment is a Competent Authority for Directive 2009/41/EC on the contained use of GMMs. The GMO Experts Committee was established by the Order on Genetically Modified Organisms Experts Committee and consists of 9 scientists with different scientific background. They analyze the report of risk assessment prepared by the notifier and makes scientific proposals and conclusions to the Competent Authority. The GMO Steering Committee was established by the Order on Genetically Modified Organisms Steering Committee and is a political advisory body for the development and enforcement of national regulatory system with respect to biosafety issues including contained use of GMMs and GMOs. This Committee consists of 21 members appointed by relevant state authorities (e.g., The Ministry of Health, The Ministry of Agriculture, State Food and Veterinary Service), the subordinated organizations, national biotech industry, non-governmental organizations and scientific institutions. The State Environment Protection Service is responsible for inspection of contained use of GMMs and GMOs.

Notification and approval systems are determined in the Order on Regulation on Contained Use of Genetically Modified Micro-organisms and the Order on Criteria for Genetically Modified Micro-organisms Classification in conformity to Directive 2009/41/EC.

2.2 Has the scope of the transposing legislation been extended to the contained use of GM plants and GM animals in your Member State?
Yes X 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 -

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?
-

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.

There were no relevant changes with regard to control procedure requirements since the last report in 2009.
In the period 2009 – 2014 about 15 inspections were conducted by one specialised inspector.

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 carried out during reporting period.

3.3 What were the corresponding enforcement actions taken?

-

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?

-

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?

No specific problems with the interpretation of the provisions were reported.

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

Organization of meetings for competent authorities and inspectors to share the experience gained under the Directive 2009/41/EC on contained use of GMMs and GMOs. Better explanation of gene therapy, Synthetic biology and other new techniques, their terminology would be valuable.

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 2009/41/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.

No accidents were reported.

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 clinical trials were notified.

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.)

-

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.

During the reporting period The Ministry of Environment has published information about contained use of GMMs and GMOs to the public through the Competent Authority's Web Site ***http://gmo.am.lt****, preserving confidentiality rights and intellectual property according the Order on Public Information and Participation and the Order on Genetically Modified Organisms Information System. The main tasks of the national GMO information system are to store, process and guarantee access to any available data about GMM and GMO, excluding confidential information.*

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.

No specific reactions were received.

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 Microorganisms, the notifier has to provide information concerning the waste management, including the amount and type of waste, the methods of inactivation and the final form of the waste and destination. In all cases, all types of GMMs had to be inactivated prior to disposal. Waste was mainly inactivated through thermal (autoclaving) or chemical means (e.g. sodium hypochlorite). In case of GM-vertebrates, their remains were transported to waste treatment facility for inactivation under the EU and national legislation.

8.2 Are 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 is facility authorized under the EU and national legislation to handle veterinary and environmental waste including GM-vertebrates. Transportation was arranged by the waste treatment company. There were no cases of contained use of GMMs or GMOs of class 2-4.

9. Other issues

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

The information is provided in the item 4.2.

Annex 1. New notifications received under Directive 2009/41/EC for 2009-2014 period

No.	Institution	Place	No of Notification	Data of submitting	Class	Purpose/GMM, GMO	Containment and other protective measures for laboratory activities	The evaluation of foreseeable effects
1.	JSC Biocentras V. A. Graiciuno str., No 10, LT-02241, Vilnius, Lithuania	Lab	RN-14	2013-03-21	1	Scientific/GMM	Containment level 1	Negligible
2.	JSC Nomads V. A. Graiciuno str., No 8, Vilnius, Lithuania	Lab	RN-1	2011-08-18	I	Scientific/GMM and GM-plants	Containment level 1	Negligible
3.	JSC Baltymas V. A. Graiciuno str., No 8, LT-02241, Vilnius, Lithuania	Lab	RN-11	2011-12-20	1	Scientific/GMM	Containment level 1	Negligible
4.	VU Institute of Biochemistry Mokslininku str., No 12, LT-08412, Vilnius, Lithuania	Vivarium	RN-12 RN-15	2012-06-08 2013-05-31	1	Scientific/GM-mouse	Containment level 1	Negligible
5.	JSC Biotechpharm Mokslininku str. No 4 LT-08412 ,Vilnius, Lithuania	Lab	RN-13	2013-03-21	1	Scientific/GMM	Containment level 1	Negligible
6.	NISR The Centre for Innovative Medicine Zygimantu str., No 9 LT-01102 Vilnius Lithuania	Vivarium	RN-16	2014-02-07	1	Scientific/GM-mouse	Containment level 1	Negligible
7.	JSC Profarma V.A. Graiciuno 8, LT-02241, Vilnius, Lithuania	Lab	RN-17	2014-03-26	1	Scientific/GMM	Containment level 1	Negligible
8.	SSTI Center for Physical Sciences and Technology A.Gostauto str., No 11, LT-01108, Vilnius, Lithuania	Lab	RN-18	2014-05-27	1	Scientific/GMM	Containment level 1	Negligible

During reporting period two other notifications were renewed and one activity for contained use of GMMs was finished in 2010.