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Questionnaire to MS to report on their experience with Directive 2009/41/EC

Fields marked with * are mandatory.

Introduction

Directive 2009/41/EC (hereinafter referred to as "the Directive") provides that every three years Member States must send to the Commission a summary report on their experience with the Directive (Article 17 (2)) and that the Commission must publish a summary based on these reports (Article 17(3)).
In accordance with such articles, the Commission has already published four reports for the periods 1999-2003, 2003-2006, 2006-2009 and 2009-2014 (reports are available on this European Commission webpage).

QUESTIONNAIRE

The Commission invites Competent Authorities of Member States under Directive 2009/41/EC on the contained use of genetically modified micro-organisms ("GMMs")* to complete this questionnaire for **the period ranging from 6 June 2014 to 31 December 2017** and to submit it to the Commission by **28 February 2018** in order to fulfil the obligations set out in Article 17(2) of the Directive.
This questionnaire is divided into five parts:

- Part I focuses on your experience with the general implementation of the Directive.
- Part II aims at getting an overview of contained uses and premises for GMMs. It also contains additional questions on GM animals/GM plants if also covered under your contained use legislation**.
- Part III focuses on investigational medicinal products that contain or consist of GMOs.
- Part IV concerns gene drive modified organisms.
- Part V allows for additional comments.

A glossary list with definitions of terms used in the questionnaire has been included in **Annex**.

DEADLINE FOR COMPLETION: 28 February 2018

* For the definition of "contained use", "micro-organism" and "GMM" see the Annex.
** For the notion of "contained use legislation" see the Annex.

Annex - Glossary of terms (for the purposes of this questionnaire)

Download this document to check the definitions of terms or the purposes of this questionnaire
Annex.pdf

Contact details

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PART I: GENERAL IMPLEMENTATION OF THE DIRECTIVE

***1. Notification and approval systems (and relevant changes)**

Which is the Competent Authority (CA) for Directive 2009/41/EC on the contained use of GMMs in your Member State (Article 10(1) of the Directive)? (Provide details where other authorities, ministries or scientific institutions are involved or where authorities are established at national/regional level)

Ministry of Environment

*Is the CA for Directive 2009/41/EC in your Member State also CA for Directive 2001/18/EC on deliberate release into the environment of GMO?

- (●) Yes
- ( ) No

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

- (●) Yes
- ( ) No

*Provide rationale:

Additional specific requirements for the contained use of GM plants and GM animals are planned to be prepared in the future.

* Is there any change in the notification and approval system with respect to the last reporting period (2009-2014) in your Member State?

- ○ Yes
- ◉ No

* In your Member State, what is the percentage of notifications* which were not processed within the statutory timeframe in this reporting period?

* *For the definition of "notification" see the Annex.*

- ◉ 0%
- ○ > 0%

* What difficulties specific to the **notification process**, if any, did you encounter during the reporting period?

Please note that clinical trials and gene drive modified organisms are addressed in dedicated sections of the questionnaire and that any difficulties related to those types of contained uses should be reported in the respective sections.

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* What in your opinion should be done or is done already to alleviate these difficulties?

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*** 2. Waste disposal**

What are the means by which waste containing GMMs is inactivated and disposed of, with particular reference to large volumes of waste material (including large GM plants/animals or large quantities of plants /animals inoculated with GMMs)?

There was no change since previous reporting.

* Are there waste treatment facilities in your Member State which are authorised to inactivate waste arising from contained use premises?

- ◉ Yes
- ○ No

Specify how many per class of contained use

	Waste treatment facilities	*comments if any*
Class 1	1	JSC "Rietavo veterinarine sanitarija"
Class 2	1	JSC "Rietavo veterinarine sanitarija"
Class 3	1	JSC "Rietavo veterinarine sanitarija"

Class 4	1	JSC "Rietavo veterinarine sanitarija"
Total	1	JSC "Rietavo veterinarine sanitarija"

How is the transfer of waste from the contained use premises to the authorised waste facility arranged /organised?

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

* Is waste from contained use activities recycled after inactivation?

- ○ Yes
- ◉ No

*** 3. Inspection and enforcement issues**

Outline the procedure undertaken for the inspection of contained use premises (Article 16 of the Directive) during the reporting period, under your contained use legislation, providing details of the number and the overall percentage of premises/contained uses inspected.

There was no change of requirements for inspection of contained use premises since previous reporting. 13 premises were inspected.

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

There were no specific issues.

* What were the corresponding enforcement actions taken?

During carry out of inspections there were fulfilled questionnaires according to the 2009/41/EC directive IV Annex.

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

There were no specific issues.

What type of corrective and/or preventive actions taken, if any, did you apply in order to minimise the occurrence of these issues in the future?

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			
2			
3			
4			
5			

*** 4. Accidents**

Provide information reported by the users on accidents* (as required in Article 14(1) of the Directive) to the CA during the reporting period.

* *For the definition of "accident" see the Annex.*

No accidents were reported.

* Provide information on the measures taken by you, as a CA, on the basis of Articles 14(2) and 15(1) of the Directive.

No accidents were reported.

Comment on a possible improvement regarding the occurrence of similar accidents, as a result of the measures taken by the user(s) and/or by the CA.

No accidents were reported.

*** 5. Public consultation**

Do you carry out any public consultation under your contained use legislation, in accordance with Article 12 of the Directive?

- (●) Yes
- ( ) No

* Provide details of those public consultations and of the information made publicly available as part of the consultations.

The Ministry of Environment has published information about contained use of GMMs and GMOs to the public via Ministry's website http://gmo.am.lt preserving confidentiality rights and intellectual property according to the Order on Public Information and participation and the Order on Genetically Modified Organisms Information System.

Provide details of any public reaction, if received, in response to the consultations.

There were no public reaction received.

6. Interpretation and implementation of Directive 2009/41/EC

Please note that clinical trials and gene drive modified organisms are addressed in dedicated sections of the questionnaire, so answers related to those types of contained uses should be reported in the respective sections.

* What aspects concerning the **interpretation** of the Directive, if any, give you difficulties as CA?

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

* What aspects concerning the **implementation** of the Directive, if any, give you difficulties as CA?

No specific aspects with the implementation of the Directive were reported.

* From the difficulties you have identified in the previous reporting periods, which ones have you solved at national level and how?

There were no specific difficulties identified in the previous reporting periods. 2016-05-04 The Ministry of Environment and Vilnius University organized the Workshop "GMM/GMO CONTAINED USE: NOTIFICATIONS, RISK ASSESSMENT AND CONTROL". LT, IR and NL experts shared their experience and knowledge gained.

* What should be done or is done already to address the difficulties identified?

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PART II: OVERVIEW OF CONTAINED USES AND PREMISES

In this part of the questionnaire you are invited to submit information on the number of notifications and amendments submitted for contained uses of GMMs and on the number of premises for contained use of GMMs, according to the classification of contained use. If also covered under your contained use legislation, similar questions for GMOs (GM animals and GM plants) will be asked.

7. GMMs

How many **notifications of contained uses of GMMs** were submitted in your Member State under the Directive during the reporting period? (from 6 June 2014 to 31 December 2017)

Report all types of notifications and amendments to existing notifications by class; this includes GMMs, combined uses of GMMs and GMOs (to be reported according to the GMM class), clinical trials (where applicable) and gene drive modified organisms (where applicable).

* Classification of contained use (according to Art. 4(3))

	No. of notifications submitted (according to Art. 6, 8 and 9)	**No. of amendments** (according to Art. 11)
* Class 1*	9	2
* Class 2*	2	0
* Class 3*	0	0
* Class 4*	0	0
***Total**	11	2

Number of **premises for contained uses of GMMs** (as referred to in Article 6) with a valid notification* as per December 2017:

* *For a definition of "valid notification" see the Annex.*

	No. of premises	Comments (if any)
* Class 1	15	-
* Class 2	2	The premises according to one of 2 notifications for the 2cnd class are the same as for the 1st class
* Class 3	0	-
* Class 4	0	-
* **Total**	16	-

Number of **contained uses of GMMs** (including combined uses of GMMs and GMOs) with a valid notification* or approval as per December 2017:

* *For a definition of "valid notification" see the Annex.*

	No. of contained uses	Comments (if any)
* Class 2	2	-
* Class 3	0	-
* Class 4	0	-
* **Total**	2	-

8. GM animals and GM plants

How many **notifications** for contained uses of GMOs, i.e. GM animals and GM plants, (excluding combined uses with GMMs) were submitted in your Member State during the reporting period?

* *If you use a different classification system (than classes 1, 2, 3, 4), explain the link between the classification and the category of the risk.*

	Classification of contained use*	**GM animals** - No of **notifications submitted**	**GM animals** - No of amendments	**GM plants** - No of **notifications submitted**	**GM plants** - No of amendments
a					
b					
c					
d					
Total					

* Did you encountered specific challenges related to **notifications** about GM plants or GM animals?

There were no notifications for contained uses of GMOs submitted.

PART III: INVESTIGATIONAL MEDICINAL PRODUCTS THAT CONTAIN OR CONSIST OF GMOs

In this part of the questionnaire you are invited to submit information about the different activities related to the manufacturing and administration of investigational medicinal products for human and veterinary use that contain or consist of GMOs.*

If manufacturing of investigational medicinal products is common for both human and veterinary use, please report this activity under the "Human use" part.

* *This includes but is not limited to Advanced Therapy Medicinal Products ("ATMPs"). For a definition of ATMP see the Annex.*

*** 9. Human use - Manufacturing**

Is the manufacturing of investigational medicinal products for human use that contain or consist of GMOs notified and/or authorised under Directive 2009/41/EC in your Member State?

- ○ Yes
- ◉ No

* What challenges, if any, did you as a CA encounter in implementing the Directive in relation to the manufacturing of investigational medicinal products for human use that contain or consist of GMOs (e.g. notification, risk assessment, authorisation, control, etc.)?

-

* What in your opinion should be done or is done already to address these challenges?

-

*** 10. Human use - Administration (clinical trials)**

Is the administration of investigational medicinal products for human use that contain or consist of GMOs notified and/or authorised under Directive 2009/41/EC in your Member State?

- ○ Yes
- ◉ No

* What challenges, if any, did you as a CA encounter in implementing the Directive in relation to the administration of investigational medicinal products for human use that contain or consist of GMOs (e. g. notification, risk assessment, authorisation, control, etc.)?

-

* What in your opinion should be done or is done already to address these challenges?

-

***11. Veterinary use - Manufacturing**

Is the manufacturing of investigational medicinal products for veterinary use that contain or consist of GMOs notified and/or authorised under Directive 2009/41/EC in your Member State?

- Yes
- No

*What challenges, if any, did you as a CA encounter in implementing the Directive in relation to the manufacturing of investigational medicinal products for veterinary use that contain or consist of GMOs (e.g. notification, risk assessment, authorisation, control, etc.)?

-

*What in your opinion should be done or is done already to address these challenges?

-

***12. Veterinary use - Administration (clinical trials)**

Is the administration of investigational medicinal products for veterinary use that contain or consist of GMOs notified and/or authorised under Directive 2009/41/EC in your Member State?

- Yes
- No

*What challenges, if any, did you as a CA encounter in implementing the Directive in relation to the administration of investigational medicinal products for veterinary use that contain or consist of GMOs (e.g. notification, risk assessment, authorisation, control, etc.)?

-

*What in your opinion should be done or is done already to address these challenges?

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PART IV: GENE DRIVE MODIFIED ORGANISMS

The purpose of this section is to gather information on whether notifications for contained uses of gene drive* modified organisms have been submitted in the Member States and how the Directive is implemented in this respect.

* *For the purpose of this questionnaire, the definition of "gene drive" given in the Annex is applicable.*

*Has your Member State taken any measure regarding gene drive modified organisms under the Directive?

- Yes
- No

* Are there any notifications on gene drive modified organisms submitted under your contained use legislation?

- ○ Yes
- ◉ No

* Are you implementing specific containment measures for gene drive modified organisms?

- ○ Yes
- ◉ No

* Are there any particular challenges, for you as a CA, in implementing the Directive with regard to the contained use of gene drive modified organisms (e.g. notification, risk assessment, authorisation, control, etc.)?

- ○ Yes
- ◉ No

* What in your opinion should be done or is done already to address the challenges identified, with the aim to facilitate the implementation of the Directive?

> As we do not have any experience, however it would be valuable to establish harmonized EU procedure for gene drive modified organisms including notification, risk assessment, authorization and control requirements.

PART V: ADDITIONAL COMMENTS

Thanks for providing comments on any other aspects of the Directive or on other related legislation.

Contact

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