

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

* Member State

Czech Republic

* Competent Authority

Ministry of the Environment

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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)

The Ministry of the Environment is the CA for contained use of GMMs in the Czech Republic. The Ministry of the Environment cooperates closely with the Ministry of Health and Ministry of Agriculture regarding the health and agricultural aspects of the use of GMOs.

An expert advisory body to the Ministry of the Environment, the Czech Commission for the Use of GMOs and Genetic Products (CzC GMO), deals with the environmental risk assessment. Members of the CzC GMO are experts from administrative authorities, scientists and representatives of environmental NGOs.

* 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:

Some GM plants and GM animals could pose risk for the environment if accidentally released. Therefore contained use of all GMOs should be regulated. Besides, GMMs and other GMOs are often used in the same premises so the risk assessment of the contained use must consider GM plants and animals as well.

* 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

* Provide explanations

Czech Act No. 78/2004 Coll., on the Use of Genetically Modified Organisms and Genetic Products, as amended, transposes Directives 2001/18/EC and 2009/41/EC. It covers contained use of all GMOs, deliberate release into the environment (Part B of Directive 2001/18/EC) and placing on the market of GMOs as such or in products, including their export and import.

Formats of notifications, procedures of risk assessment etc. are laid down by the implementing Decree No. 209/2004, on Detailed Conditions for the Use of Genetically Modified Organisms and Genetic Products, as amended.

The Czech legislation is stricter than Directive 2009/41/EC as regards Class 1 contained use. Until the end of 2016, a new notification was required in every case a new activity was to be carried out in previously notified Class 1 premises.

According to the amendment to the Act No. 78/2004 Coll., which came into force on 1st January 2017, if a new contained use is to be carried out in previously notified Class 1 premises, the user is required to submit a document on the risk assessment of the intended activity to the Ministry of the Environment. Although the Class 1 contained use may commence immediately after the submission of the assessment, experts from the Ministry's GMO advisory body review the assessment at the same time. If they find the classification of the activity incomplete or incorrect, the Ministry is empowered to require additional information from the notifier and/or decide that the contained use be suspended.

In conclusion, the requirements of the Czech Act on GMOs go beyond Article 7 of the Directive even after the amendment.

The implementing Decree 209/2004 was amended as well, especially as regards new notifications formats for various GMOs uses. Harmonised tables for the risk assessment of contained uses have been annexed to the Decree. These changes, in force since 1 January 2017, have enhanced clarity of notifications both for notifiers and for the competent authority.

* 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.

Before the amendment of the notification formats (set by the implementing Decree as mentioned in 1.3), some notifications and risk assessment documents were not well arranged, therefore they were difficult to review.

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

The Ministry with its experts have developed appropriate formats and tables for notifications and for the risk assessment to be used by notifiers.

* 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)?

GMMs are inactivated and disposed of in the same way and by the same means as infectious waste containing pathogenic microorganisms (by autoclaving, chemical disinfectants etc.)
Likewise, GM laboratory animals and animals inoculated with GMMs are disposed of as other investigational animals.
GM plants are either autoclaved or in large volumes chopped, seeds are ground and the resulting material composted in the area of the user's facility.

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

- Yes
 No

* Is waste from contained use activities recycled after inactivation?

- Yes
 No

Specify for which purpose(s)

The compost where material from GM plants has been deposited is used in the premises.

* 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.

The Authority responsible for the state supervision of the use of GMOs is the Czech Environmental Inspectorate (hereinafter "CEI"). It co-operates with other state supervision bodies in fulfilling this task. CEI undertakes inspections of premises authorised for contained use of GMOs, in accordance with the yearly schedule based on:

- information from the Ministry of Environment on notifications and authorisations,
- results and findings of the previous inspections,
- information from other sources.

The inspections are targeted on compliance with the requirements for the appropriate risk class, documentation, waste treatment, labelling and transport of GMOs within the premises, training of the personnel etc.

Over 100 inspections of contained uses were carried out within the reported period; some of them covered several premises operated by one user (e.g. various laboratories of a university). All authorised premises were checked, some of them repeatedly.

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

Most frequent deficiencies found by the Inspection were of an administrative character: omission to update some part of the documentation, missing signature of the biosafety officer etc. These imperfections did not pose any risk to the environment.

* What were the corresponding enforcement actions taken?

The deficiencies in the documentation were corrected either right at the time of the inspection or immediately afterwards. The CEI requirements were met within the set time limits and without problems.

* 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?

Users consult the requirements in advance with the CA.

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	Administrative deficiencies		Preventive actions: Notifiers can consult the CA in advance of the submission of the notification and during the contained use. Various guidelines, formats and checklists are available for the notifiers / users on the CA's GMO website.
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 accident happened in the Czech Republic during the reporting period.

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

Not applicable

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.

* 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

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?

Sub-cellular elements: whether a specific element falls under the definition of "micro-organism" or not. Consequently, whether certain activities and premises (e.g. trade in life sciences products that includes their storage and distribution) have to be notified.
New gene techniques: whether a specific technique and the resulting organism fall within the scope of the Directive.

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

The same problems as mentioned in the previous point.

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

Sub-cellular elements: we do not consider plasmids as GMOs.

DNA vaccines: according to our experts, a DNA vaccine does not fall under the scope of the Directive. However, during the phase of development of the vaccine, the vaccinated animals should be treated as GMOs until appropriate studies prove that the plasmid DNA has not been integrated into the host genome.

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

General issues, like what sub-cellular elements are covered by the definition of GMM and the legislative status of organisms developed by new gene techniques, should be resolved at EU level.

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*	201** ** Note: According to the Czech Act on GMOs, a new notification or (since 1/1/2017) a submission of the written risk assessment was required in every case a new activity was to be carried out in previously notified Class 1 premises (see Q 1.3). The number summarizes these notifications and submissions of risk assessments during the reporting period.	5*** *** Note: In these cases the notifiers had assessed their activities as Class 1 but the CA's expert advisory body, after the review of the risk assessment, required the contained uses to be classified as Class 2, mostly due to the presence of viral particles.
* Class 2*	47	0
* Class 3*	2	0
* Class 4*	0	0
* Total	250	5

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	68	no comments
* Class 2	91	no comments
* Class 3	2	no comments
* Class 4	0	no comments
* Total	161	no comments

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	205	no comments
* Class 3	2	no comments
* Class 4	0	no comments
* Total	207	no comments

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	Class 1	115** see the note at point 7	0	9** see the note at point 7	0
b	Class 2	2	0	2	0
c	Class 3	0	0	0	0
d	Class 4	0	0	0	0
Total		117	0	11	0

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

No

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

* Were there any notifications and/or authorisations for manufacturing investigational medicinal products for human use that contain or consist of GMOs submitted in your Member State during the reporting period?

- 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.)?

Not applicable

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

Not applicable

*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.)?

Not applicable

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

Not applicable

*** 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

*Were there any notifications and/or authorisations for manufacturing investigational medicinal products for veterinary use that contain or consist of GMOs submitted in your Member State during the reporting period?

- 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.)?

Not applicable

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

Not applicable

*** 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.)?

Not applicable

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

Not applicable

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?

Not applicable

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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