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THREE-YEAR MEMBER STATES REPORTS TO THE COMMISSION ACCORDING TO ARTICLE 17(2) OF DIRECTIVE 2009/41/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 6 MAY 2009 ON THE CONTAINED USE OF GENETICALLY MODIFIED MICRO-ORGANISMS

Fields marked with * are mandatory.

INTRODUCTION

Directive 2009/41/EC on the contained use of genetically modified micro-organisms ("GMMs") *[1]* (hereinafter referred to as "the Directive") provides that every three years Member States shall send to the Commission a summary report on their experience with the Directive (Article 17(2)) and that the Commission shall publish a summary based on these reports (Article 17(3)).

In accordance with those provisions, the Commission has published five reports for the periods 1999-2003, 2003-2006, 2006-2009, 2009-2014 and 2014-2018 *[2]*.

The Commission invites Competent Authorities of Member States under Directive 2009/41/EC to complete this questionnaire for the period from 1 January 2019 to 31 December 2021 and to submit it to the Commission by **28 February 2022**, in order to fulfil the obligations set out in Article 17(2) of the Directive.

The Directive does not regulate the contained use of GMOs other than GMMs, i.e. GM plants and GM animals. A number of Member States have however laid down national legislation to regulate them as well. The Commission would like to use this questionnaire to allow Member States to share their experience, good practices and challenges encountered in regulating those organisms at national level.

This questionnaire is divided into 3 parts:

- Part I: Member States' experience with the general implementation of the Directive, including an overview of contained uses and premises for GMMs. This part contains additional questions on GM animals and/or GM plants, where contained use legislation *[3]* also covers them.
- Part II: Member States' experience on investigational medicinal products for human and veterinary uses that contain or consist of GMMs.
- Part III: Member States' experience with gene drive modified organisms.

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[1] For the definition of "contained use", "micro-organism" and "GMM", see the Annex.

[2] The reports are available on this European Commission webpage.

[3] For the notion of "contained use legislation" please see the Annex.

PRELIMINARY QUESTIONS

* Member State/Country

Slovakia

* Competent authority

Ministry of Environment of Slovak Republic

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PART I: GENERAL IMPLEMENTATION OF THE DIRECTIVE

Notification and approval systems

Are there changes regarding the Competent Authority (CA) for Directive 2009/41/EC and other authorities involved since the previous reporting period (provide the details, if any, including other authorities, ministries or scientific bodies involved and explain their role)?

Without changes.

Have you enacted national legislation on contained use of GM plants and/or GM animals that are not GMMs?

- (●) Yes
- ( ) No

If yes, does your national legislation contain rules similar to those laid down in the Directive as regards those GM plants and/or GM animals?

Yes

Is there any change in the notification [1] and approval system of the contained use of GMMs with respect to the previous reporting period in your Member State?

[1] For the definition of “notification” see the Annex.

- ○ Yes
- ◉ No

In your Member State, have you faced any challenges in processing notifications within the statutory timeframe in this reporting period?

- ○ Yes
- ◉ No

Waste disposal

Is there any change in the waste disposal management since the previous reporting?

- ○ Yes
- ◉ No

Were there any challenges in the waste disposal management identified during this reporting period?

- ○ Yes
- ◉ No

Inspection and enforcement issues

Are there any changes in the enforcement/inspection procedures established by the CA to examine the conformity with the requirements set by this Directive since the previous reporting?

- ○ Yes
- ◉ No

Have you developed any new measures within your Member State in order to prevent issues previously reported?

- ○ Yes
- ◉ No

Have any changes been made to the procedures relating to the implementation of the Directive due to the COVID-19 emergency situation (e.g. remote inspections using information and communication technologies)? Have you encountered any challenges to apply the Directive in this COVID-19 emergency situation, and would you share any good practice in addressing them?

Inspections were NOT performed during lockdown. The activities of users of genetic technologies were monitored through NCBI databases and the websites of the relevant institutions as well. Consequently, thanks to the preferential vaccination of state administration employees, the inspections were performed without restrictions.

Please provide details of the number and the overall percentage of premises/contained uses inspected during this reporting period.

Number of checked premises: 97
The overall percentage: 18%

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

The most frequent breaches concerned shortcomings in meeting the requirements for the level of protection corresponding to the risk class and shortcomings in meeting the requirements for documentation of premises.

What type of corrective and/or preventive actions were taken, if any, in order to prevent the occurrence of issues reported in the previous question in the future?

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	Deficiencies in meeting the requirements for contained use	Fine to the user.	Publication on the Inspectorate's website and on the Enviroportal website
2	Shortcomings in the documentation.	Corrective measure to the user.	Publication on the Inspectorate's website and on the Enviroportal website
3			
4			
5			

In case you would need more space to provide information on corrective and/or preventive actions under the previous question, please do so here.

Accidents

Please provide information reported by the users on accidents *[2]* (as required in Article 14(1) of the Directive) to the CA during the reporting period.

[2] For the definition of "user" and "accident" see the Annex.

Accidents were NOT reported.

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

Notifications of accidents related to contained use did NOT occure during the reporting period in Slovakia. The notified contained uses did not foresee any transboundary impacts in case of accident.

Public consultation

Are there any changes in your contained use legislation with respect to providing information to the public on aspects of the proposed contained use?

- ○ Yes
- ◉ No

Please provide information on the outcome of the public consultations, if any, undertaken during the reporting period.

Any issues didn't arise from the public consultations which are performed in a written manner.

Interpretation

What aspects concerning the interpretation of the Directive, if any, pose you difficulties as a CA?

Without difficulties.

What could be done to address the interpretation challenges of the Directive, if any, in the future?

Overview of contained uses and premises

In this section 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) are asked.

GMMs

How many **notifications** of contained uses of GMMs were submitted in your Member State under the Directive during the reporting period?

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) and clinical trials (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	80	---
Class 2	21	---
Class 3	---	---
Class 4	---	---
Total	101	---

Number of premises for contained uses of GMMs (as referred to in Article 6) with a valid notification *[3]* as per December 2021:

[3] The definition of "valid notification" is given in the Annex.

	No. of premises
Class 1	11
Class 2	22
Class 3	1
Class 4	---
Total	34

Number of contained uses of GMMs (including combined uses of GMMs and GMOs) with a valid notification or approval as per December 2021:

	No. of contained uses
Class 2	284
Class 3	---
Class 4	---
Total	284

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).

The overall number of notifications received compared to the previous reporting period did not increase neither decrease,

Number of contained uses of GMMs with a valid notification or approval as per December 2021:

Class	Commercial	Research	Other (Education)	Unspecified	**Total**
Class 1	15	2800	---	---	2815
Class 2	---	220	---	---	220
Class 3	---	---	---	---	---
Class 4	---	---	---	---	---
Total	15	3020	---	---	3035

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?

	Classification of contained use*	**No. of notifications submitted for *GM animals***	**No. of amendments for *GM animals***	**No. of notifications submitted for *GM plants***	**No. of amendments for *GM plants***
1		7	--	18	--
2		4	--	--	--
3		--	--	--	--
4		--	--	--	--
5					
Total		11		18	

* 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.

PART II: INVESTIGATIONAL MEDICINAL PRODUCTS THAT CONTAIN OR CONSIST OF GMMs

In this part of the questionnaire Member States are invited to provide information on activities related to the manufacturing and administration of investigational medicinal products for human and veterinary use that contain or consist of GMMs? *[1]*

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

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

Human use

Manufacturing

Are there any changes in the national legislation as regards the manufacturing of investigational medicinal products for human use that contain or consist of GMMs during this reporting period?

- ○ Yes
- ◉ No

Is the manufacturing of the products described in the previous question notified under Directive 2009/41/EC in your Member State?

- ◉ Yes
- ○ No

If yes, please provide information on notifications and/or authorisations granted in your Member State during the reporting period.

Classification of contained use	Total no. of notifications *[2]**	No. of authorisations *[3]**	No. of notifications concerning ATMPs	No. of authorisations concerning ATMPs
Class 1	---	---	---	---
Class 2	---	---	---	---
Class 3	---	---	---	---
Class 4	---	---	---	---
Total	---	---	---	---

*If relevant, specify how many notifications/authorisations were for human and veterinary use (e.g: 4, out of which 1 for human and veterinary use; or 4 for human and veterinary use).

[2] Report all notifications/authorisations, including those related to ATMPs.

[3] For the definition of “notification” see the Annex.

How did you address the challenges, if any, that CAs encounter in implementing the Directive in relation to the manufacturing of investigational medicinal products for human use that contain or consist of GMMs (e.g. notification, risk assessment, authorisation, control, etc.)?

Administration (clinical trials)

Are there any changes in the national legislation as regards the administration of investigational medicinal products for human use that contain or consist of GMMs during this reporting period?

- ○ Yes
- ◉ No

Is the administration of those products described in the previous question notified under Directive 2009/41/EC in your Member State?

- ○ Yes
- ◉ No

How did you address the challenges, if any, that CAs encounter in implementing the Directive in relation to the administration of investigational medicinal products for human use that contain or consist of GMMs (e.g. notification, risk assessment, authorisation, control, etc.)?

What aspects concerning the interpretation of the Directive as regards the manufacturing and administration of investigational medicinal products for human use that contain or consist of GMMs, if any, pose you difficulties as a CA?

What could be done to address the interpretation challenges of the Directive, if any, in the future?

Veterinary use

Manufacturing

Are there any changes in the national legislation on the manufacturing of investigational medicinal products for veterinary use that contain or consist of GMMs during this reporting period?

- Yes
- No

Is the manufacturing of those products described in the previous question notified under Directive 2009/41/EC in your Member State?

- Yes
- No

How did you address the challenges, if any, that CAs encounter in implementing the Directive in relation to the manufacturing of investigational medicinal products for veterinary use that contain or consist of GMMs (e.g. notification, risk assessment, authorisation, control, etc.)?

Administration (clinical trials)

Are there any changes in the national legislation on the administration of investigational medicinal products for veterinary use that contain or consist of GMMs during this reporting period?

- Yes
- No

Is the administration of those products described in the previous question notified under Directive 2009/41/EC in your Member State?

- Yes
- No

How did you address the challenges, if any, that CAs encounter in implementing the Directive in relation to the administration of investigational medicinal products for veterinary use that contain or consist of GMMs (e.g. notification, risk assessment, authorisation, control, etc.)?

What aspects concerning the interpretation of the Directive as regards to the manufacturing and administration of investigational medicinal products for veterinary use that contain or consist of GMMs, if any, pose you difficulties as a CA?

What could be done to address the interpretation challenges of the Directive, if any, in the future?

PART III: GENE DRIVE MODIFIED ORGANISMS

Gene drive modified organisms [1] are not covered by Directive 2009/41/EC. The purpose of this section is to allow Member States to provide information, if any, on experience with regulating the contained use of gene drive modified organisms and how the national legislation, if any, is applied in this respect.

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

Has your Member State taken any measure or changed existing measures regarding gene drive modified organisms under the contained use legislation since the previous reporting?

- ○ Yes
- ◉ No

Have there been any new notifications on gene drive modified organisms submitted under your contained use legislation during this reporting period?

- ○ Yes
- ◉ No

Please explain the measures for the evaluation and reduction of the potential risks which might arise from the activities with gene drive organisms and appropriate containment/or conditions of use that are applied under your contained use legislation.

Is the risk classification system applied at national level to gene drive organisms the same as the one Directive provides for GMMs?

YES

Are the containment and other protective measures for activities with gene drive organisms different from the measures the Directive provides for the contained use of GMMs?

NO

Are there emergency plans foreseen in your contained use legislation in case of accidents involving gene drive organisms?

NO

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

- ○ Yes
- ◉ No

ADDITIONAL COMMENTS

Thank you for providing your comments on any other aspects of the implementation of the Directive, if applicable.

We would like to use this space for notes to the answers provided in questionnaire.

Notes to part I:

The legal provisions on contained use have applied to GMM and GMO since the enforcement of the Act no. 151/2002.

In 2021, an amendment to the Act was adopted, it contained only amendments of technical character and the notification system and approval procedure have stayed the same.

The Inspectorate obtains the most information/documents for proving the decision merits in administrative proceedings from published scientific works.

Notes to part II. (investigational medicinal products for human and veterinary use that contain or consist of GMMs):

In the previous report that covered the period of years 2014-2018 it was reported that the manufacturing of investigational medicinal products for human and veterinary use is not notified under Directive 2009/41. We would like to explain that this referred to authorization of manufacturing of medicines where the State Institute for Drug Control and the State Institute for Control of Veterinary Medicines and Veterinary Medical Products is the Competent Authority that authorizes the manufacturing of investigational medicinal products for human use or veterinary use (under the Act No. 362/2011 on Medicines and Medical Products).
At the same time applies that if an investigational medicinal product contains GMM, the activity (creation /production of this product) has to be notified under the Directive 2009/41.

Although the national legislation related to clinical trials with investigational medicinal products for human use that contain or consist of GMMs was not changed during this reporting period, when such products were intended to treat or prevent coronavirus disease (COVID-19) then was applied an exemption laid down by the REGULATION (EU) 2020/1043 on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19).

Background Documents

Annex to the Questionnaire

Contact

Contact Form