EUROPEAN
COMMISSION

Brussels, 31.5.2021
SWD(2021) 114 final

COMMISSION STAFF WORKING DOCUMENT
Accompanying the document

Report from the Commission

Experience of Member States with 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 for the period 2014 – 2018

{COM(2021) 266 final}

COMMISSION STAFF WORKING DOCUMENT

PART I: GENERAL IMPLEMENTATION OF THE DIRECTIVE

1. Notification and approval systems (and relevant changes)

1.1 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)

2014 -2017	
AT	The Federal Ministry of Education, Science and Research is CA for contained uses in Universities and scientific institutions; the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection is CA for all other contained uses.
BE	The EU regulatory framework concerning the contained use of GMMs is implemented and enforced in Belgium at the regional level. Three different regional decrees therefore exist. The scope of the Belgian regional legislation is broader than the scope of the EU Directive since it includes, in addition to genetically modified microorganisms (GMMs), genetically modified organisms (GMOs) and pathogenic organisms. A Cooperation agreement concerning biosafety was set up in 1997 to ensure that the transposition and practical implementation of the "contained use" Directive are done in a harmonised way between the three Regions at the administrative and scientific level. The competent authorities in charge of the regional decree on contained use of GMMs (and pathogens) application are: - For Wallonia: Service Public de Wallonie, Direction Générale Opérationnelle 3 "Agriculture, Ressources naturelles et de l'Environnement (DGARNE), Department of Permits and Authorisations – External directions. - For the Flemish Region: Departement Omgeving, Afdeling Gebiedsontwikkeling, omgevingsplanning en –projecten (GOP), Environmental permit service. - For the Brussels-Capital Region: Institut Bruxellois pour la Gestion de l'Environnement (IBGE) / Brussels Instituut voor Milieubeheer (BIM), Authorisation Service At the federal level, the competent authority in charge of emergency planning for the contained use of GMMs is the Federal Public Service Home Affairs.
BG	Bulgarian Ministry of Environment and Water is the Competent Authority for Directive 2009/41/EC on the contained use of GMMs and for contained use of other GMOs. Control activities are performed by the regional inspectorates of the Ministry and laboratory analysis by Environmental Executive Agency.
CY	Ministry of Labour, Welfare and Social Insurance
CZ	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.
DE	The CAs for Directive 2009/41/EC in Germany are the Federal state (Bundesländer) authorities (n=16); The coordinating Competent Authority is the Federal Office of Consumer Protection and Food Safety (BVL)
DK	The working environment authority and the environmental protection agency
EE	Labour Inspectorate
EL	Directorate of Natural Environment Management and Biodiveristy
ES	In Spain, Directive 2009/41/EC has been transposed in the domestic legislation through the Law 9/2003 and Royal Degree 178/2004 and the subsequent modifications. For the implementation in our country of this legislation there are two different CAs: 1) At national level, the Inter-ministerial Council for GMOs (CIOMG) and the National Commission on Biosafety (CNB) at the Ministry of Agriculture,Fisheries, Food and Environment (Madrid, Spain). They are CAs for the activities of contained use carried out by Government Public Research Institutes or for activities with GMOs focused on medical purposes (clinical trials, human and animal medicines/vaccines, etc). The first one (CIOMG) is the CA for grating permits at national level and the CNB is the scientific body dealing with the risk assessment of activities and installations, which report to the CIOMG and also to the CAs of the Spanish regions. 2) At regional level, the Autonomous Communities (Spanish regions) are the CAs for granting permits for most of the activities carried out with GMOs (except in the cases mentioned above)
FI	Geenitekniikan lautakunta (Board for Gene Technology) is the licencing authority. The Board has members of several ministries. The Board uses governmental institutions as expert institutions at need and it has nominated external experts as its presenting officials. The supervisory authority for contained use is Sosiaali- ja terveysalan lupa- ja valvontavirasto Valvira (National Supervisory Authority for Welfare and Health).
FR	Ministère de l'Enseignement Supérieur, de la Recherche et de l'Innovation pour l'utilisation confinée des OGM Autres: Ministère de la défense pour les établissements relevant de son autorité; Haut Conseil des biotechnologies (HCB) pour l'évaluation des projets
HR	Ministry of Health and Ministry of Science and Education
HU	Ministry of Agriculture and National Institute of Pharmacy and Nutrition
IE	The Environmental Protection Agency is responsible for implementation of the legislation including enforcement. The Department of Communications, Climate Action and the Environment is responsible for policy.
IT	Ministry of Health (MoH) In compliance with the Italian Legislative Decree 206/2001, CA authorizes GMMs installations and activities in accordance with the opinions of the Biotechnology Health Technical Committee (BHTC) of the Ministry of Health (MoH).

The BHTC was established on 20th May 2015 and it has replaced, with the same functions, the previous "Inter-ministerial Commission for the GMM Evaluations" that had been laid down by Legislative Decree 206/2001.

Regions, autonomous Provinces, Prefect and Mayor

The premises holder that intends to carry out a GMM contained use (CU) has to keep informed the concerned Region and autonomous Province where the installation is located.

The Region and the autonomous Province are informed of each authorized premise by MoH.

When a CU of class 3 or 4 is authorized, the MoH informs the Region and the autonomous Province.

The MoH informs the Prefect, the Mayor and the Presidents of the Region and Province in which a CU is carried out; if the MoH considers, on the basis of the Biotechnology Health Technical Committee (BHTC) assessment, that failure of the containment measures can lead to serious danger, whether immediate or delayed, to humans outside the premise and/or to the environment, the Prefect, the Mayor and the Presidents of the concerned Region and Province draw up the emergency plans promptly, and in any case, within 60 days, on the basis of information included in the notification submitted to the MoH.

The Mayor is responsible to assure that the population at risk is informed about the relevant safety measures and about the correct behavior to be taken based on the emergency plans.

The MoH with the support of the Civil Protection Department (Presidency of the Council of Ministers) ensures the appropriate consultations and the exchange of information with the Competent Authorities of the Member States concerned and makes available the same information as that which is disseminated to Italian nationals.

When an accident occurs the user must inform MoH and the premises holder and, if the accident can lead to serious danger, whether immediate or delayed, to humans outside the premise and/or to the environment, the Ministry for the Environment, Land and Sea Protection and the Presidents of the concerned Region and Province, the Prefects and the Mayors responsible of the territory that, on the basis of their competences, activate the emergency plan.

The Ministry for Environment, Land and Sea Protection, Via Cristoforo Colombo, 44, 00147, Rome - Directorate General for Environmental Assessments and Permits Unit IV - Assessment and reduction of risks arising from chemicals and genetically modified organisms is the Competent Authority for Directive 2001/18/EC.

The Italian Medicines Agency (AIFA), Via del Tritone, 181, 00187, Rome, is the National Competent Authority (NCA) for medicinal products (human use) and for assessment and authorization of clinical trials. Among the tasks of AIFA is to co-ordinate the inspections at manufacturing sites of finished medicinal products in order to ensure compliance with EU Good Manufacturing Practice and the related guidelines. All sites on the Italian territory are regularly inspected, in order to guarantee consistency in the manufacturing process of medicinal products and an adequate pharmaceutical quality of the finished dosage form.

	The Ministry of Health, Directorate General for Animal Health and Veterinary Medicines – Offices 4 and 5 represents the NCA for veterinary medical products which is in charge for the marketing authorizations included the clinical trials on the animals. Among the tasks of NCA there are the inspections at manufacturing sites of finished medicinal products and active substances in order to ensure compliance with EU Good Manufacturing Practice and related guidelines. All sites on the Italian territory are regularly inspected, both for the GMP and Pharmacovigilance compliance in order to guarantee consistency in the manufacturing process of medicinal products and an adequate pharmaceutical quality of the finished dosage form. The Ministry of Health, Directorate General for Animal Health and Veterinary Medicines – Office 6 is the NCA for controls related to the protection of animals used for scientific purposes. The Italian National Labor Inspectorate for the protection of the workers exerts and coordinates the vigilance on the national territory in the field of work, contribution, compulsory insurance and social legislation, including vigilance on the protection of health and safety in the workplace, within the limits of the competences attributed to the Inspection staff of the Ministry of Labor and Social Policies, as established by Legislative Decree 9 April 2008, n. 81.
LT	Ministry of Environment
LU	Ministry of Health - Division of food security (SECUALIM)
LV	Institute of Food Safety, Animal Health and Environment "BIOR"
MT	The Environment and Resources Authority
NL	Ministry of Infrastructure and Water Management (policy), National Institute for Public Health and the Environment (licensing), COGEM (advisory board), Human Environment and Transport Inspectorate (Inspection)
PL	Ministry of Environment
PT	The Competent Authority for Directive 2009/41/EC is the Portuguese Environment Agency (APA). We belong to the Ministry of the Environment, Spatial Planning and Energy. The national legislation – Decree Law n.º 55/2015, establishes that the final approval of a notification for contained use of GMMs and GMOs is granted by the Portuguese Environment Agency, after receiving a favourable opinion from the Directorate General of Health (DGS) and National Health Institute Doutor Ricardo Jorge (INSA). In case of contained use of GMOs (higher plants and animals) the Directorate General for Food and Veterinary (DGAV) is also consulted.
RO	- The Romanian legislation provides for a procedure at the national level for notification and authorization in accordance with the provisions of this Directive, established through the Emergency Government Ordinance No 44/2007 on the contained use of genetically modified microorganisms (GMMs) as amended by Law No 3/2008. Under these legal acts, the institutional framework for the implementation of the GMMs contained use legislation is ensured by the National Environmental Protection Agency, as competent authority, and the following authorities with responsibilities in the field of GMMs: - The national authority for scientific research, which assesses and analyses the notification

	dossier of contained use activities in research and development domain and issues a notice; - The central public health authority, which assess and analyses the notification dossier of GMMs that may have adverse effects on human health, issues a notice, develops and implements plans for inspection and control; - The central public authority for labor and social justice, which assess and analyses all the notification dossiers with GMMs activities, issues a notice, develops and implements plans for inspection and control; - The central public authority for agriculture, which evaluates and analyses notification dossiers of contained use activities in the agriculture, forestry, live-stock domain and issues a notice; - The Biosafety Commission - interdisciplinary scientific body, with an advisory role in the decisions making process by NEPA, independent in carrying out its scientific activity, which issues a scientific notice; - The National Sanitary Veterinary and Food Safety Authority, which ensures the inspection and control of the facilities where contained use activities with GMMs are developed; - National Environmental Guard, as the control body, subordinated to the central public authority for the environmental protection, ensures the inspection and the control of the contained use GMMs activities; National Environmental Protection Agency, as the competent authority, after the acceptance of the notification and subsequent to the achievement of the public information and public consultation procedure, based on the notices issued by the responsible authorities and by the Biosafety Commission, issues the authorization on the GMMs contained use activities.
SE	Swedish Work Environment Authority; SWEA (Arbetsmiljöverket)
SI	The CA for the Directive 2009/41/EC is MINISTRY OF THE ENVIRONMENT AND SPATIAL PLANNING (MESP) of REPUBLIC OF SLOVENIA. Registration of the installations for GM animals requires a consensus of the Veterinary authority which operates under the Ministry of agriculture, food and forestry.
SK	The Ministry of Environment of the Slovak Republic, Department of environmental hazards and biosafety
UK	In England and Wales, the Health and Safety Executive (HSE) and the Secretary of State for the Department for Environment, Food and Rural Affairs (DEFRA) form the CA. The functions are delegated to HSE and DEFRA officials. In Scotland, the CA comprises Scottish Ministers and HSE and similarly these functions are delegated to HSE and Scottish Government officials. n Northern Ireland, the CA is the Health and Safety Executive for Northern Ireland (HSENI) and Department of Agriculture, Environment and Rural Affairs (DAERA), acting jointly. HSENI officials are provided with technical support from HSE, under an Agency Agreement.

2018	
AT	Federal Ministry of Labour, Social Affairs, Health and Consumer Protection Federal Ministry of Education, Science and Research
BE	Service Biosafety and Biotechnology (SBB) of Sciensano Technical expert for the regional competent authorities
BG	Ministry of Environment and Water
CY	Department of Labour Inspection
CZ	Ministry of the Environment
DE	The CAs for Directive 2009/41/EC in Germany are the Federal state (Bundesländer) authorities Coordinating Competent Authority: Federal Office of Consumer Protection and Food Safety (BVL)
DK	The Working Environment Authority (WEA) and the Environmental Protection Agency (EPA)
EE	Labour Inspectorate
EL	Hellenic Ministry of Environment & Energy General Directorate of Environmental Policy Directorate of Natural Environment Management and Biodiversity Biodiversity Department
ES	Interministerial Council of GMO
FI	Board for Gene Technology
FR	Ministère de l'enseignement supérieur, de la recherche et de l'innovation
HR	
HU	Ministry of Agricuture, Department of Biodiversity and Gene Conservation
IE	Environmental Protection Agency
IT	
LT	Ministry of Environment
LU	Division of food safety (SECUALIM)
LV	Institute of Food Safety, Animal Health and Environment “Bior”
MT	The Environment and Resources Authority
NL	Ministry of Infrastructure and Water Management
PL	
PT	Portuguese Environment Agency
RO	NATIONAL ENVIRONMENTAL PROTECTION AGENCY
SE	Swedish Work Environment Authority
SI	REPUBLIC OF SLOVENIA MINISTRY OF THE ENVIRONMENT AND SPATIAL PLANNING (MESP)
SK	Ministry of Environment of the Slovak Republic
UK	United Kingdom

1.1bis 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?

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

2014-2017			
	1.1 bis 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?	**1.2 Has the scope of the transposing legislation been extended to the contained use of GM plants and GM animals in your Member State?**	**Provide rationale:**
AT	Yes	Yes	The Austrian Gene Technology Act covers all aspects of genetically modified organisms
BE	No	Yes	The regional authorities corrected the limitation of the scope (to micro-organisms) by also guaranteeing a risk assessment of GM plants and GM animals used in laboratories, greenhouses or animal housing. This allows appropriate containment measures to be adopted if necessary to protect human health and the environment during activities involving all types of GMOs.
BG	Yes	Yes	Bulgarian GMO Law covers all GMO as it will be complicated and confusing to have separate legislation for different groups of organisms. Activities with GM plants and animals are classified either as class A – no or negligible risk for the human or animal health and for the environment and class B – all other cases.
CY	No	No	There was no need because there were no activities and/or installations involving GMOs
CZ	Yes	Yes	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.
DE	No	Yes	The German GenTG has also implemented Directive 2001/18/EC and extended the scope of 2009/41/EC to the contained use of GM plants and GM animals.
DK	Yes	Yes	In 1986 Denmark implemented the first Act of Parliament regarding regulation of GMO by which both genetically modified microorganism, plants and animals should be regulated. Regarding the implementation of the directive in 1991, Denmark

			kept the legislation on genetically modified animals and plants together with the microorganisms mentioned in the directive. This regulation has been and still is based upon the political attitude toward the subject.
EE	No	No	Ministry of Environment
EL	No	No	Strict interpretation
ES	Yes	Yes	Contained used activities with GMO are regulated under National Law 9/2004
FI	Yes	Yes	Coverage in legislation for all types of GM organisms.
FR	No	Yes	Pour raisons sociétales
HR	No	Yes	In accordance to the Ordinance on the content, scope and methodology for the preparation of risk assessment in relation to contained use of genetically modified organisms ("Official Gazette" No. 84/2006)
HU	Yes	Yes	The same documentation is required in case of GM plants and GM animals as in case of GMMs.
IE	Yes	Yes	Transposing legislation has been extended to require notification, risk assessment and enforcement of contained use activities for GM plants and GM animals.
IT	No	No	According to 2001/18/EC directive, the contained use of GMOs (e.g. for testing/research purposes) should be carried out by implementing containment measures based on the same principles as laid down in 90/219/EEC: it is not expected any notification to CAs. Contained uses of GMOs are non-regulated activities, both toat EC and national levels. Italian CA for Directive 2009/41/EC did not receive any notification of contained use of GMOs. With the exclusion of combined uses of animals and plants with GMMs, Italy has not extended the Directive 2009/41/EC to the use of GM animals and GM plants therefore, if notifications will be submitted, the assessment will be focused on the risks for the operators and the environment that could occur during the GMM manipulation. The GMM CA is evaluating how such type of activities, from a legislative point of view, can be regulated and the different measures and type of authorizations that should be applied. An harmonized approach at European level could support the decisions of Member States to adopt measures based on the same safety criteria for the humans and environment.
LT	Yes	Yes	Additional specific requirements for the contained use of GM plants and GM animals are planned to be prepared in the future.
LU	Yes	No	Directive 2009/41 is not yet transposed in national law.
LV	Yes	No	In Directive there is clear definition of GMM.
MT	Yes	Yes	Not applicable.

NL	Yes	Yes	the scope of the Dutch GMO Decree covers directive 2009/41 and directive 2001/18 and covers both GMM's and GMO's.
PL	Yes	Yes	The reason was the biosecurity of such products which in case of GM plants and animals risk might be higher
PT	Yes	Yes	The Decree Law n. º 55/2015 that transposes to national law the Directive 2009/41/EC stipulates in the scope that it applies to the contained uses of GMMs and GMOs (higher plants and animals).
RO	Yes	No	Not for the time being. Romania limited the scope of the transposition legal act to the scope of the Directive on the contained use of GMMs.
SE	No	Yes	Responsibilities concerning GMOs are divided between authorities that has responsibilities concerning non-GMO: Swedish Agency for Marine and Water Management (Havs- och vattenmyndigheten) is responsible for contained use of water living GMO, SWEA is responsible for contained use of GMMs, Swedish Board of Agriculture is responsible for contained use of GMOs not regulated elsewhere. On this link you can find a representation over the responsibilities and authorities (in Swedish): https://genteknik.nu/hitta-ratt-myndighet/ Earlier website about gene technology in Sweden is no longer up.
SI	Yes	Yes	The biosafety framework in Slovenia is covered by horizontal legislation based on Management of Genetically Modified Organisms (MGMO) Act (OJ RS 23/2005 and amended OJ RS 21/2010). The Act implements the provisions of the Directive 2009/41/EC and beside GMMs regulates also GM plants and animals
SK	Yes	Yes	When a plant and/or animal is the final recipient of the genetic modification/techniques used, it may become a GMO (or a paratransgenic organism which keeps the GMM, though the genome of the plant/animal isn't changed). The Directive 2009/41/EC already set measures for glasshouses and animal units in Annex I B and Annex I C.
UK	No	Yes	The legislation has been extended to require notification, risk assessment and application of control measures for contained use of GM plants or GM animals (referred to as larger GMOs in the UK legislation) that present a risk to human health greater than the unmodified parental organism. Such work is rare, and there has only been one such contained use notified in the reporting period. There is also complementary domestic legislation (Environmental Protection Act 1990, associated regulations and the Genetically Modified Organisms (Northern Ireland) Order 1991) that requires risk assessment and application of containment for the contained use of larger GMOs to ensure protection of the environment. HSE inspects premises working with larger GMOs on behalf of DEFRA, Scottish and Welsh Governments under separate Agency Agreements and Memorandums of Understanding.

2018			
	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?	**In 2018, has the scope of the transposing legislation been changed in your Member State?**	**Provide rationale, in particular if the transposing legislation has been extended to the contained use of GM plants and GM animals:**
AT		No	
BE		No	
BG		No	
CY		No	
CZ		No	
DE		No	
DK		No	
EE		No	
EL		No	
ES		No	
FI		No	
FR	No	No	Le législateur français a considéré que le champ d'application de la réglementation sur les OGM doit être le même, qu'il s'agisse de micro-organismes, de plantes ou d'animaux.
HR			
HU		No	
IE		No	
IT			
LT		No	
LU		No	
LV		No	
MT	Yes	No	N/A
NL		No	
PL			
PT		No	
RO		No	
SE		No	
SI		No	
SK		No	

UK		No	

1.3 Is there any change in the notification and approval system with respect to the last reporting period (2009-2014) in your Member State? If yes, elaborate.

2014-2017		
AT	No	
BE	No	
BG	No	
CY	No	
CZ	Yes	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.
DE	No	
DK	No	
EE	No	
EL	No	
ES	No	
FI	No	

FR	No	
HR	No	
HU	No	
IE	No	
IT	No	
LT	No	
LU	No	
LV	Yes	The CA is changed.
MT	No	No changes were applied in the notification and approval system from the last reporting period
NL	Yes	on 1 March 2015 the revised GMO Decree and GMO Order came into force. These new rules also resulted in different notification and reporting systems and thus also in the way data are presented in this report. Another consequence is that care should be taken when analysing and comparing these data with those in earlier reports. There were no changes in the scope of the Decree.
PL	No	
PT	Yes	In 2015 the Decree Law n.º 2/2001 was revoked by Decree Law n.º 55/2015. Regarding to the approval system and notification, the new Law does not introduce significant changes, foreseeing, namely to: - clarify the legal framework for the contained use of GMOs (higher plants and animals); - for the purposes of the analysis of the notifications and giving opinion, this Law extend the consultation in the context of the evaluation of notifications to the Directorate General of Health (DGS) and the Directorate General for Food and Veterinary (DGAV), in addition to consulting the National Health Institute Doutor Ricardo Jorge (INSA); - set a deadline to the consulted entities for issuing opinions, thus allowing the APA to decide on the authorisations of notifications within the time limit; - introduce the obligation for notifiers to annually report on activities of contained use GMM/GMO.
RO	No	
SE	No	
SI	Yes	The change considers the administrative procedures. In the cases the notifier specifically requires the issue of a permit for work with GMOs, the notifier is due to cover the costs of a scientific opinion.
SK	No	
UK	No	

2018		
	In 2018, did you have any change in the notification and approval system in your Member State?	**Provide explanations**

AT	No	
BE	No	
BG	No	
CY	No	
CZ	No	
DE	No	
DK	No	
EE	No	
EL	No	
ES	No	
FI	No	
FR	No	
HR		
HU	No	
IE	No	
IT		
LT	No	
LU	No	
LV	No	
MT	No	
NL	No	
PL		
PT	No	
RO	No	
SE	No	
SI	No	
SK	No	
UK	No	

1.4 In your Member State, what is the percentage of notifications[1] which were **not** processed within the statutory timeframe in this reporting period?

1.5 *(to appear if reply to 1.4 > 0%)* 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?
Has this figure increased or decreased since the last reporting period?

2014-2017

[1] For the definition of "notification" see the Annex.

	1.4 In your Member State, what is the percentage of notifications which were not processed within the statutory timeframe in this reporting period?	Percentage of notifications which were not processed within the statutory timeframe in this reporting period?	1.5 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?
AT	0%		
BE	> 0%	1	In Wallonia, any project for the contained use of GMO class 2, 3 or 4 must be the subject of an application for an environmental permit. The Walloon legislation imposes strict deadlines for the processing of permit applications. If the decision is not sent within the legal deadline, the permit is supposed to be refused and the project cannot be implemented.) In the Flemish Region, the competent authorities can only respect the time frame to deliver the authorization if the user has already obtained an environmental permit. Often the user chooses to start the procedure to obtain the environmental permit when he starts the procedure to obtain an authorization, but the time frames are different: 45 days or 90 days for an authorization, and maximum 6 months for an environmental permit. In the Brussels-Capital Region, notification procedures do not have any legal timeframe as users can implement their activity the day following their notification, the CA doesn't have to notify any decision. Approval / permit procedures have different legal timeframes regarding the biological class of risk of the operation. It leads to the delivery of a permit by the CA based on its external expert's advice. This timeframe can be suspended if the CA or its external expert are waiting for complementary information from the users. Our procedure includes a visit on site, which is an essential step to consider before declaring the dossier as complete. This visit sometimes leads to asking complementary information from the users, suspending and delaying the procedure.
BG	0%		

CY	0%		
CZ	0%		
DE	> 0%	14	Non-compliance with the deadlines varies between 0 and 62% in the individual federal states. This is particularly due to inadaquate staffing in the authorities, to the necessary involvement of other authorities or to increasing numbers of requests at one timepoint.
DK	0%		
EE	0%		
EL	0%		
ES	0%		
FI	0%		
FR	> 0%	5	Nombre de déclarations élevé par rapport aux ressources qui ont été ajustées depuis
HR	> 0%	9	There was a short time gap between the termination of one mandate and the appointment of another Committee for contained use of GMO.
HU	> 0%	5	The following efforts have been made to prevent the delays: consultation between notifiers and the Competent Authority prior to submission or asking for further information after the submission. Also the communication between the CA and Gene Technology Advisory Committee has been improved.
IE	0%		
IT	> 0%	13	The Legislative Decree n. 206/2006 lays down that the CA issues the authorizations of premises and activities according to the written opinions of the BHTC members that, to be considered valid, must be signed by the members. BHTC members evaluate the submitted notifications only the day of the meeting and the documents are not shared among the members before the meeting because of electronic safety reasons of the mail system. Though the BHTC meetings are planned every 30-45 days, their frequency could be not appropriate and it is hard to increase the number of meetings for practical reasons. Furthermore a web platform, with suitable electronic safety measures to share directly with the BHTC members the notifications sent by the users, is not available. The management of the whole Health Technical Committee (HTC) of MoH is entrusted to the MoH Directorate General for Collegial Bodies for Health Protection. The HTC regulation does not allow to appoint substitutes of HTC members with delegation of powers to issue the opinions on the assessed GMM notifications.

			The designation and replacement of BHTC members inevitably increases the difficulty for the GMM CA to plan and hold the BHTC meetings on time. The submission of the notifications to the CA occurs by certified mail through a MoH centralized electronic protocol system. The personnel is not supported by appropriate software to make available the documents that have to be assessed and time to prepare efficiently the meetings cannot be saved. To date the GMM CA has not an effective and functional electronic archiving system or program to retrieve all information provided by the users with the submitted notifications but only for part of them. The only mean through which part of the information are recorded is to enter them manually in an access database. To retrieve specific information reported in the notifications it is consequently necessary more time and, in several cases, to carry out manually the search of the paper documentation with a further unavoidable waste of time. Part of notifications are not processed within the statutory timeframe due to downtimes that occur when further clarifications or integrations are requested by GMM CA; we observe that in several cases the period of time elapsed from sending the GMM CA requests to receiving the user responses can be very long. All the above mentioned reasons sometime imply an increase of timeframe with which the notifications are processed, therefore for several of them the procedures are finalized with timing not aligned with statutory timeframe. Efforts are being made to lessen or prevent such delays in the future To provide a web platform for GMM CA and BHCT members to share electronically the documents of the notifications, to allow that the evaluations can be conducted in any moment and from any location, to obtain valid and signed opinions by each BHTC member. To open a web space on the mentioned platform in which the users can submit the information required with the notifications or to update the contents of notifications previously submitted; to archive such type of information in a suitable database that allows to retrieve any submitted information, to generate with the retrieved information ad hoc reports and keeping track along the time of the changes

			carried out by the users.
LT	0%		
LU	0%		
LV	0%		
MT	0%		Not applicable
NL	> 0%	13	Delays in the notification process were due to the implementation process of the new rules of the revised GMO Decree. The transition from the old to the new practice had a bigger impact than initially anticipated. Both the users and the authorities needed to adjust to the new practices. Furthermore, the overall complexity of the notified activities are steadily increasing resulting in increased processing times.
PL	0%		
PT	0%		
RO	0%		
SE	> 0%	1,4	Only two notifications were delayed. The reason for delay in both cases is a combination of summer vacation, only two officers handling notifications, and several rounds of requiring more information from the notifier. One notifier had several notifications sent from different persons in the organisation and in some instances the same notification sent twice. SWEA now tries to give the notifier an e-mail with our notification number ("diarienummer"), as soon as the notification has reached the officer who is in charge for handling it. In that e-mail, SWEA states that we will read the notification and will be in touch after that. We can not compare to earlier time periods, as it is a very time-consuming process to calculate time "backwards" in time. But we have a feeling that our internal electronic system for GMM activities and the changed regulations 2011 helped to speed up the notification process.
SI	> 0%	50	According to the provisions of the Management of Genetically Modified Organisms (MGMO) Act the Scientific Committee for the GMOs in the contained use has to evaluate and issue a scientific opinion on every notification. Therefore a big workload of the Scientific Committee for the GMOs in the contained use members is a main cause of the delays.
SK	0%		
UK	> 0%	1	The CA requested several pieces of additional information and advice was sought from an independent scientific advisory committee resulting in a failure to meet the statutory deadline. No specific measures were deemed necessary to remedy this issue as it was an unusual scenario that is unlikely to be repeated. Please note the notifications that did not meet the statutory timeframe is less than 0.33%

2018

	In 2018, in your Member State, what was the percentage of notifications which were not processed within the statutory timeframe?	Percentage of notifications which were not processed within the statutory timeframe in 2018?	From your experience in 2018, do you have new information to report about difficulties in relation to the notification process (including causes for delays in the notification process, actions taken to reduce those delays)?
AT	0%		No
BE	> 0%	1	No
BG	0%		No
CY	0%		No
CZ	0%		No
DE	> 0%	15	Yes
DK	0%		No
EE	0%		No
EL	0%		No
ES	0%		No
FI	0%		No
FR	> 0%	50	No
HR			
HU	0%		No
IE	> 0%	5	No
IT			
LT	0%		No
LU	0%		No
LV	0%		No
MT	0	N/A	No
NL	> 0%	11	No
PL			
PT	0%		No
RO	0%		No
SE	> 0%	5	No
SI	> 0%	11	No
SK	0%		Yes
UK	> 0%	1	No

1.6 What difficulties specific to the notification process, if any, did you encounter during the reporting period?[2]

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

2014-2017

[2] 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.

	1.6 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.	**1.7 What in your opinion should be done or is done already to alleviate these difficulties?**
AT	none	not relevant
BE	In the Flemish Region : Some problems are met in the interpretation of the terms 'notification' and 'admission request'. The regional legislation for the Flemish Region defines that a 'notification' or an 'admission request' can be submitted for subsequent activities of risk level 2. Besides a difference in administration fee there is also a difference in the way the competent authority shares its decision (one short letter versus a complete decision including the external expert's advice). This latter point is not clear to all users.	To solve this difficulty, this point could be cleared out by explaining into detail the difference between 'notification' and 'admission request' as a kind of FAQ on the Belgian Biosafety Server (www.biosafety.be)
BG	Requirements for contained use of GMO other than GMM have not been harmonized on EU level and differ between the member states. No list of Generally regarded as safe (GRAS) laboratory strains, laboratory animals and cultivars has been adopted at EU level.	Directive 2009/41/EC provides only for the contained use of GM microorganisms but not for GM plants and animals. It will be helpful if the scope of the Directive is extended to all GMO and unified requirements for contained use of GM plants and animals are established. In addition it will be useful if a list of Generally regarded as safe (GRAS) laboratory strains, laboratory animals and cultivars is adopted at EU level, because they account for most of the activities done at universities and research institutions.
CY	There was no difficulty in the notification process.	No change is required.
CZ	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.	The Ministry with its experts have developed appropriate formats and tables for notifications and for the risk assessment to be used by notifiers.
DE	incomplete application documents, difficult definition issues (GMO status, user assessment of further class 1 uses), concentration effect, questions of fire protection, handling of class 3** organisms,	reliable consulting for users, involvement of the ZKBS (German advisory board) in difficult issues and cases of unclear risk assessment

	procedures of inactivation in class 3 or 4 uses	
DK	See answer 3.2	Better information on the requirements on our webpage and the guide lines.
EE	not difficulties	better knowledge
EL	No notification in that period.	No notification in that period.
ES	Generally statutory timeframe is fulfilled, although in the most of the cases the clock is stopped when additional information is required.The administrative process is quite long taking into account the previous assessment by the National Commission on Biosafety, visits and control at the facilities and the different procedures, opinions or permits granted by the CIOMG and the different CAs (CIOMG or regions). On the other hand, in Spain, clinical trials with GMOs are regulated as deliberate reléase activities, but it is not clear if facilities in which GMOs are handled or stored must be notified as contained used activities. There are also problems in the interpretation if products obtained by new genetic techniques (NBT) and whether they are under the scope of Directive 2009/41/EC or not	The status of clinical trials and NBT needs to be harmonised at EU level
FI	As before, the outdated definitions of the directive 2009/41/EC for GMM have been a major problem in the present research environment with its new molecular biology techniques. This leads to situations where both the operators and authorities are uncertain whether a notification is actually required or not. Classification of viruses and cell cultures has also been problematic in some cases. A special problem has been the classification of pathogens that have been attenuated (= can an attenuated pathogen ever be considered apathogenic according to the directive, and if so, on what conditions?). A constant administrative issue is that research groups move frequently from one institution to another, or their old premises are repaired, or the use of premises changes, leading to a situation where the same operators have to repeatedly send new notifications of their premises.	It would be urgent to revisit the definitions of a GMO in directive 200/41/EC. Perhaps it would be even useful to evaluate the pros and cons of technology-based regulation versus trait-based regulation when dealing with a rapidly developing technology. Also, the Commission could give more specific guidance on the classification of pathogenic organisms in cases where their pathogenicity has been attenuated. Considering the constantly changing premises of individual research groups and organizations as well as SMEs, possibilities to lessen the administrative burden of notification requirements of Article 6 should be examined.

FR	L'application "DUO" (traitement dématérialisé des dossiers) utilisée nécessite des développements pour répondre pleinement aux besoins	Revoir "DUO" pour améliorer et simplifier le traitement des dossiers
HR	We do not have any difficulties in the notification process.	So we suggest that Union make list with of known biological agents in accordance to the hazards and in accordance to certain levels of contained use of GMMs.
HU	None.	None.
IE	Classification of attenuated viral vectors	In February 2018 the CA liaised with other CAs under Directive 2009/41/EC to determine how attenuated viral vectors were classified in respective Member States. The CA also discussed the matter with their Advisory Committee and the advice was that they should continue to be classified as Class 2 GMMs.
IT	See previous answer.	See previous answer.
LT	-	-
LU	Recently the GMO dossier was taken over by SECUALIM. SECUALIM does not have a complete overview of former actions. Luxembourg does not apply the notification process, we still have an authorisation procedure.	Directive 2009/41 is being transposed + more resources have been recruited to perform on field inspections.
LV	We do not have received any notification.	-
MT	No difficulties were encountered during the notification process	Not applicable.
NL	See earlier answer; the overall complexity of the notified activities are steadily increasing resulting in increased processing times.	Both users and authorities are adjusting to the new practices. Authorities and users are involved in stream-lining these practices.
PL	none	better translation of required rules
PT	No particular difficulties were found.	No particular difficulties were found.
RO	Not applicable.	Not applicable.
SE	The risk assessment and notification system and the Directive is somewhat ancient. New methods does not always fit well in notification of "new use Class 2". It is difficult to explain to the notifier that they need to do a case-by-case notification when it is a high-throughput system with very different inserts in the same virus vector in the same "runs". The description of a "GMM use" is often too vauge to comply with the Directive, giving only "gene of interest" or "cDNAs" as identification of insert. Another complication is the limit between Class 1 and Class 2 for GMM uses with a replication deficient virus vector that is very common	The notification procedure could be simplified in the Directive for Class 1 and Class 2 with only notification on information on class, type of activity, organisation involved, contact information for responsible persons and address to the workplace.

	now: on one hand, the vector is not capable of replication in cells, on the other hand, the vector may contain genes that in worst case, if introduced to a worker, could give a single cell unwanted properties (cell death, uncontrolled growth, carcinogenic activity). Our current limit is between GMM uses with or without virion particles: when there is (risk for) particles, it should be handled in Class 2, and when there are no particles present, it can almost always be handled in Class 1. (And there is no need to notify a Class 1 activity where there is a Class 2 activity already.)	
SI	However, most of the delays were short and in all cases the notifiers were approached with the ample explanation. We did not receive any complaint about it. Slightly longer delays are caused by the Veterinary authority which operates under the Ministry of agriculture and forestry.	MESP put a lot of effort to explain the situation to the Veterinary authority in order to acquire their consent sooner.
SK	-----	-------
UK	The notification requirements under the GMO(CU) Regulations (the regulations which implement Directive 2009/41/EC) are well-understood by users and there is believed to be a high level of compliance with these requirements in the UK.	The notification of contained use of GMM in the UK is working well.

2018		
	1.6 What new difficulties specific to the notification process did you encounter in 2018, and in your opinion what should be done or is done already to alleviate these difficulties?	**1.7 Were there new reasons in 2018 for delays in the notification process and what efforts have been made to lessen or prevent such delays in the future?**
AT		
BE		
BG		
CY		
CZ		
DE	High complexity of application documents.	no
DK		
EE		
EL		
ES		
FI		
FR	Insufficient personnel	Réorganisation du processus administratif

HR		
HU		
IE		
IT		
LT		
LU		
LV		
MT	No difficulties were encountered during the notification process.	N/A
NL		
PL		
PT		
RO		
SE		
SI		
SK	Amount of contained uses notified and submitted in one notification on activities under risk class 3. The complexity of the assessment process threatened to cause delays in the statutory timeframe for decision. The recipient was M. tuberculosis; one genome of a GMM can contain about 5000 genes and 18 activities were notified using 11 groups of vectors. The period of time during which the ministry is waiting for the opinion of its advisory body – recommendations from experts and from the Biosafety Committee – falls (is taken) into the statutory timeframe for decision. If the same notifier submits a new notification under risk class 3, the timeframe of 45 days for decision will apply according to Article 9 par. 2, letter a) of the Directive 2009/41/EC. We consider the period insufficient. We think that the period of time during which the ministry is waiting for the opinion of its advisory body should not be taken into account, or, the Competent Authority should have the possibility to influence the extent of the notification. Isolation of the laboratory suite was doubted by some members of the Biosafety Committee as the enclosed facility of containment level 3 was built	No new reasons. To prevent delays in case of the notification desribed above, we had to find some „problem points“ and ask the notifier to submit a new notification related to these points, what reduced (a bit) the number of contained uses considered.

	inside of another laboratory. We would appreciate a guidance on „the laboratory is separated from other areas in the same building“ (Annex IV, table I A, point 1 of the Directive).	
UK		

2. Waste disposal

2.1 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)?

2014 - 2017	
AT	Waste from facilities using GMM/GMO must be treated appropriate to the GMMs/GMOs risk class in order to limit its contact to the environment. GMM/GMO of risk classes 2-4 must be inactivated by appropriate measures. Animals which have been inoculated with GMM in a non-survival project must be killed by an approved humane method and disposed of by incineration.
BE	In the Regional decrees implementing Directive 2009/41/EC, there is an explicit requirement to inactivate all types of GMMs and GMOs - even of risk class 1 - by appropriate and validated means prior to disposal as waste. Inactivation can either be done on site, or after transport in biohazard containers to a waste processing company. In each region, these requirements are completed by specific regulations on waste originating from medical care and dangerous waste in general, including waste from animal experiments, imposing rules for storage, for incineration and for collection by a certified or accredited company. Steam sterilisation (autoclaving of solid waste) and chemical inactivation (fluids) are the predominant means of inactivation of large volumes of GM waste material in situ. Taking into account the broadened scope of the contained use legislation toward the intentional use of pathogenic organisms, waste streams are not limited to GM waste. This explains why other means, like high temperature and high pressure alkaline hydrolysis of animal carcasses, are evaluated on a case-by-case basis and are subject to validation. Smaller amounts of waste material originating from contained use facilities are often treated by steam sterilisation, chemical inactivation or are collected by specialised companies for incineration of hazardous waste in authorised waste-processing firms. Regarding waste management, the Brussels-Capital region notes that it is very complex to apply simultaneously the different existing regulations on animal waste, health care waste and dangerous waste.
BG	The waste must be inactivated and disposed in appropriate manner. The manner of inactivation and disposal is described in notification for approval of the facility as information for waste management and processing. During the approval process is ensured that the relevant European and national requirements are followed. All approved facilities are part of academic institutions and only small to moderate amounts of waste are generated at any given time. The inactivation takes place on the premises and is usually done by

	autoclaving. Inactivated waste is disposed following the general requirements.
CY	There were no large volumes of waste material. For the inactivation of the GM waste, chemical disinfection and autoclave were used. For the final disposal inactivated GM waste was transferred to a facility authorised for treatment of clinical waste.
CZ	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.
DE	Usually, waste is autoclaved for 20 min at 121 °C or 134 °C. There are two genetic engineering facilities in Germany where large animals can be disposed of with the help of a digestor (alkaline lysis). Some facilities are individually equipped with incinerators. Occasionally, chemical inactivation also plays a part in the treatment of waste.
DK	For class 1 the treatment of the waste is based on the risk assessment in each specific case. For class 2 the waste has to be inactivated with validated methods before final discharge. For class 3 the waste has to be inactivated before final discharge with validated chemical or physical methods. For class 4 only a validated physical inactivation is sufficient.
EE	labor clothes, labor animals
EL	Not applicable
ES	The waste material is treated and eliminated following the legal requirements for each type of waste. Usually autoclaves and chemical treatments are used for GMMs and incineration for GM plants and animals. In Spain, we follow the provisions according to Directive 2009/41/EC, so it means that, for laboratory activities the inactivation of GMMs in effluent from hand-washing sinks or drains and showers and similar effluents was not required for containment levels 1 and 2, it was optional for level 3 and obligatory for level 4; however, for laboratory activities the inactivation of GMMs in contaminated material and waste was optional for level 1 and obligatory for levels 2, 3 and 4. Nevertheless, the CNB always recommends the inactivation of all GMOs in the cases of 'not required or optional'. Generally, there are waste treatment certified companies which collect the waste after the treatment is carrying out.
FI	Several methods can be used depending on the GMO, the facility and the methods available. For example heat treatments (autoclaving, incineration, burning, steaming), chemical treatments (disinfectants, acids, alkali, oxygenating agents), UV treatments, freezing (although only for certain plant and animal materials), mechanical treatments (shredding, pressure), and composting. When necessary, two or more methods can be combined or different methods may be used for different tissues of a GM-plant or animal.
FR	Les déchets solides et liquides issus des activités de recherche mettant en œuvre des OGM sont inactivés par des procédures chimiques ou thermiques validées, sur le site de production et sont ensuite collectés comme DASRI pour incinération
HR	In the Republic of Croatia, mostly GM waste was inactivated by chemical liquid (HOCl or other disinfectant) or was inactivated by autoclav depends by class of risk assessment og GMO. If it is large amount GM waste then it is incinerated.

HU	Usually autoclave or burning. Large volume of waste is transported and disposed by specialized companies according to the rules of hazardous waste management. Waste from biotechnological activities (both hazardous and non-hazardous) is treated under the national legislation concerning hazardous waste.
IE	All GMM waste irrespective of Class of the activity, must be inactivated by validated means prior to disposal. Class 1 and Class 2 GMM waste may be sent off site for treatment with the prior agreement of the CA. Class 3 GMM waste must be treated on site. GM animal remains whether inoculated with Class 1/2 GMMs or not must be treated by incineration /rendering. Waste from GM plants is usually autoclaved. By and large waste, emanating from GMO / GMM contained use activities is treated by - autoclaving of solid or liquid waste; - use of disinfectants to treat small volumes of liquid waste or routine spillages.
IT	Basically, two methods are in use: thermal inactivation, by using dedicated equipment for biological waste sterilization (e.g. overkill thermal cycle with temperature > 121 ° C); chemical inactivation, by using sodium hypochlorite and/or soda; after the inactivation, for their disposal. Waste derived from animal treated with GMM are taken by authorized firms to be transported to the incinerator plant according to the Reg. (EC) No 1069/2009. The waste information required in the notification refers to the type of inactivation that is carried out inside the premises and whether a registered firm is used. For laboratory and other activities, the inactivation of GMMs is carried out respectively according to the article 5 of the Directive 2009/41/EC, the specifications provided in Table IA, points 19-20, and Table II, points 22-23 of the Annex IV and in compliance with the current waste legislation. The applied measures have to be based on the risk assessment for the human health and the environment carried out by the user and to be reported in the notification. Waste is transferred to firms authorized in compliance with the Italian Legislative Decree n.152/2006 (ref. chapter IV). Waste treatment takes place on the basis of the assessment of its hazard characteristics, as laid down with in the Annex III of Directive 2008/98/EC, and on the assignment of a European harmonized code in accordance with Commission Decision 2014/955/EU. Based on the codes assigned to the waste, they are collected separately, e.g. solvents, carcinogenic substances, halogenated compounds, and afterwards taken by the mentioned authorized firms that provide for their disposal in chemical-physical treatment plants. The responsibility to comply with the legislation in force on inactivation and disposal of waste is in charge to the waste producer up to final destination of waste and it cannot be delegated to third parties. The users have to ensure and declare in the submitted notifications the compliance to the current waste legislation based on the agreements they stipulate with the authorized firms. The authorized firms that provide such type of service are not directly monitored by the

	GMM CA consequently the means by which large volumes of waste materials are inactivated and/or disposed by these firms are not always reported in the submitted notifications. Comment related to the next question: Italian GMM CA has not authorised any waste treatment facility to inactivate waste arising from GM installations. The authorized firms that provide such type of service are not directly monitored by the GMM CA. As additional information it is to point out that the waste disposal plants must be authorized according to Legislative Decree No. 152 of 03/04/2006. The applications must to be submitted to the Region or, in some circumstances to the Province/Metropolitan City when they are delegated to issue the authorizations. Copy of the application has to be sent to the Municipality and to the Italian National Institute for Environmental Protection and Research ISPRA (Istituto Superiore per la Protezione e la Ricerca Ambientale). The issued authorizations expire after 10 years. More detailed information can be obtained on the following web site: http://www.catasto-rifiuti.isprambiente.it/index.php?pg=comaut. The controls are applied by all the subjects that contribute to the issue of authorizations and to the various police forces that carry out activities on the national territory. The Provinces, the Regional Environmental Protection Agency, the Local Health Authority and other Bodies are responsible for monitoring the operations of the plant operators, which must be carried out in compliance with the regulations in-force and the specific provisions contained in the authorizations (Legislative Decree No 152/2006, articles 208 and 214). With regard the waste recycling of contained use activities, several authorized firms are involved in the waste disposal and to date this information is not required in the notification.
LT	There was no change since previous reporting.
LU	autoclave, incineration
LV	No experience.
MT	The only permitted Class 1 facility inactivates the small volume of waste it generates through autoclaving.
NL	A Ministerial Decision provides that all waste has to be inactivated by validated means. Waste storage must comply with the rules as laid down in an annex to the Ministerial Order. GMO waste of all the classes is inactivated at the premises itself. If this is not possible for waste of class 1 or 2, the waste has to be transported in well-defined and properly labelled containers to dedicated facilities. This transport has to comply with ADR.
PL	Mostly are GM microorganism which don't have high mean.
PT	In all cases, including at risk class 1 and 2, effluents, residues and wastes must be inactivated prior to disposal-autoclave. Although there are no waste treatment facilities authorised specifically to inactivate waste arising from contained use premises, there are several companies dedicated to inactivate biological waste, who operate mainly with hospital contaminated residues, and also with GM biological waste. Usually, the waste treatment company supplies proper collectors to the GM installation and, depending on the quantities of waste produced collects the waste and inactivates it in their facilities.

RO	In national legislation, Emergency Government Ordinance 44/2007 as amended by Law NO 3/ 2008, regulates the necessary measures on waste management: - Inactivation of genetically modified micro-organisms from materials and hazardous waste is optional for the contained use class 1 and binding for the contained use of classes 2, 3 and 4. - Inactivation of genetically modified micro-organisms in effluent from hand washing sinks or drains, showers and similar effluents is not necessary for the contained use classes 1 and 2, is optional for contained use Class 3 and binding for the contained use of class 4. These requirements are completed by specific regulations on waste originating from medical care and dangerous waste in general, imposing rules for storage, for incineration and for collection by an approved company.
SE	In Sweden, there is an absolute requirement of physical containment, why it is necessary to inactivate GMM. Inactivation of GMM is preferably done in-house. But waste from Class 1 and Class 2 activities containing GMMs that are not inactivated can be transported under the Dangerous Goods regulations to a "regular" waste treatment facility and be incinerated without opening the transport boxes. Transportation should be performed under the same conditions as transportation of waste in Class 6.2. Waste containing GMMs from Class 1 or Class 2 can also be moved to a larger, central autoclave unit within the building or "campus" area if it can be safely transported there. If GMMs are inactivated in-house by a validated physical or chemical method, they are considered no longer active and the waste can be treated as any waste. When notifying a GMM activity, the notifier needs to provide information of inactivation methods. If not inactivated, the name of receiver of the waste must be provided to SWEA.
SI	In all cases special attention is given to the waste treatment. In the risk assessment notifiers must elaborate a detailed plan for waste treatment, inactivation procedures and final disposal of the wastes and waste waters in concord with Regulation of risk assessment of work with genetically modified organisms in contained use (OJ RS 45/2004) and Decree of waste management (OJ RS 34/2008 and 103/2011). The waste disposal mode must be included in the risk assessment and is taken into consideration by the Scientific Committee before the premises for contained use of GMOs are registered or approval for work with GMOs in the contained system is issued. For the time being the biggest volume of biosafety class 1 GMMs is limited to semi-industrial reactors of 1000 l.
SK	As for the risk class 1, inactivation of GMMs/GMOs is optional. There is required a minimal inactivation by a disinfectant solution of an adequate concentration and duration of action. In the risk class 2 - 4, there is required a sterilization at temperature 120 °C during 30 minutes. GM plants are being liquidated by crushing and plowing on the land or by sterilization and GM animals by the killing in the installations for the contained use, moving into PVC covers, depositing in the fridge for cadavers and then they are transported to the incinerator. The user of genetic technologies and genetically modified organisms who gathers hazardous waste in annual volumes exceeding 1 tonne of hazardous waste is obliged to have the consent to this activity from Departments of Environmental Protection at District Offices under Article 97 par.1 g) of the Act No 79/2015 on waste and on amendments to certain acts.

	Gathering of waste means the preliminary storage of waste by the waste holder prior to further management thereof that is not storage of waste. A waste producer is a) any original producer whose activities produce waste, or b) anyone who carries out processing, mixing or other operations resulting in a change in the nature or composition of this waste. Waste holder means the producer of the waste or person who is in possession of waste.
UK	The Regulations transpose the requirements of the directive in respect of GM waste. Contained uses will generate contaminated waste, which must be inactivated by a validated means at class 2, 3 and 4. Inactivation at class 1 is only not required where the following criteria are met: a. do not have the potential to cause harm to human health or the environment; b. must be biologically contained (e.g. possess multiple disabling mutations or restrictive nutrient requirements that cannot be met outside the laboratory); c. do not have the capacity to establish and multiply in the environment; and d. do not have capacity to transfer genetic material to other micro-organisms (e.g. non-mobilisable plasmid). The risk assessment should conclude whether inactivation of waste at class 1 is required and the methods for achieving this. For the purposes of the Regulations, any of the following methods, i.e. disinfection, off-site treatment (e.g. rotaclave, incinerator) or autoclave may be considered to be validated means and comply with the Regulations. This is provided appropriate steps are taken to confirm the efficacy of the method, the appropriate control measures are put in place for the safe transport and storage of the waste material and the process is completed in a safe manner. The level of compliance forms an important part of the HSE inspection programme of notified premises. Autoclaving remains the most popular choice of method of inactivation. However, there has been an increase in the number of commercial waste disposal companies inactivating GM waste e.g. incinerators at GM registered sites to deal with waste containing GMMs. These are primarily used for class 1 and class 2 waste, for example, in animal bedding or clinical waste from gene therapy trials.

2018: Do you have changes to report regarding waste disposal for 2018, compared to the information already reported for the period 2014 - 2017?

2018		
	Do you have changes to report regarding waste disposal for 2018, compared to the information already reported for the period 2014 - 2017?	**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)?**
AT	No	
BE	No	
BG	No	

CY	No	
CZ	No	
DE	Yes	Usually, waste is autoclaved for 20 min at 121 °C or 134 °C. There are two genetic engineering facilities in Germany where large animals can be disposed of with the help of a digestor (alkaline lysis). Some facilities are individually equipped with incinerators. Occasionally, chemical inactivation also plays a part in the treatment of waste. In 2018, the inactivation of soil containing GMO-seeds by a validated steam method was authorized.
DK	No	
EE	No	
EL	No	
ES	No	
FI	No	
FR	No	Tous les OGM sont inactivés sur place par traitement chimique et/ou autoclavage puis envoyés pour incinération
HR		
HU	No	
IE	No	
IT		
LT	No	
LU	No	
LV	No	
MT	No	The only permitted Class 1 facility inactivates the small volume of waste it generates through autoclaving.
NL	No	
PL		
PT	No	
RO	No	
SE	No	
SI	No	
SK	No	
UK	No	

2.2 Are there waste treatment facilities in your Member State authorised to inactivate waste arising from contained use premises?
If yes, specify how many per class of contained use.

	2014-2017	2018
AT	No	
BE	Yes	
BG	No	
CY	No	
CZ	No	
DE	Yes	Yes
DK	No	
EE	Yes	
EL	No	
ES	Yes	
FI	Yes	
FR	Yes	Yes
HR	Yes	
HU	Yes	
IE	Yes	
IT	No	
LT	Yes	
LU	Yes	
LV	No	
MT	No	No
NL	Yes	
PL	No	
PT	No	
RO	Yes	
SE	Yes	
SI	No	
SK	Yes	
UK	Yes	

BELGIUM 2014 - 2017

	Waste treatment facilities	*comments if any*
Class 1		Not known
Class 2		Not known
Class 3		Not known
Class 4		Not known
Total		Not known

GERMANY 2014-2017

	Waste treatment facilities	*comments if any*
Class 1	3	
Class 2	1	
Class 3		
Class 4		
Total		

GERMANY 2018

	Waste treatment facilities	*comments if any*
Class 1	3	-
Class 2	1	-
Class 3	0	-
Class 4	0	-
Total	4	-

ESTONIA 2014 - 2017

	Waste treatment facilities	*comments if any*
Class 1	3	
Class 2	3	the same as class 1
Class 3	1	
Class 4	1	the same as class 3
Total	4	

SPAIN 2014 - 2017

	Waste treatment facilities	*comments if any*
Class 1		
Class 2		
Class 3		
Class 4		
Total		

FINLAND 2014 - 2017

	Waste treatment facilities	*comments if any*
Class 1	8 municipal incinerating waste treatment plants + dozens of on site laboratory facilities + 1 biowaste recycling plant	This question is partially irrelevant, as most waste is treated on site and anyway inactivation of class 1 waste is optional. Also, we do not authorise municipal waste facilities for contained use, as they would not be in a position to fulfil the obligations of Articles 4 and 6 of the Directive.
Class 2	1 hazardous waste plant + dozens of on site laboratory facilities	We do not authorise municipal waste facilities for contained use, as they would not be in a position to fulfil the obligations of Articles 4 and 6 of the Directive.
Class 3	7 on site laboratory facilities + 2 for class 2 GM animals (highest GM animal class)	For class 2, inactivation has to take place on site
Class 4	0	No BSL4 laboratories in Finland. The question is irrelevant as Class 4 GMM waste must be managed in the lab.
Total	>100	

FRANCE 2014 - 2017

	Waste treatment facilities	*comments if any*
Class 1	non	oui
Class 2	oui	oui
Class 3	oui	oui
Class 4	oui	oui
Total	Notre système d'information ne nous permet pas de répondre en l'état actuel des choses	

FRANCE 2018

	Waste treatment facilities	*comments if any*
Class 1		Traiement chimique ou autoclavage
Class 2		Traitement chimique et/ou autoclavage et incinération
Class 3		Traitement chimique et autoclavage et incinération
Class 4		Traitement chimique et autoclavage et incinération
Total		

CROATIA 2014 -2017

	Waste treatment facilities	*comments if any*
Class 1	3	
Class 2		
Class 3		
Class 4		
Total		

HUNGARY 2014 -2017

	Waste treatment facilities	*comments if any*
Class 1		
Class 2		
Class 3		
Class 4		
Total		

IRELAND 2014 - 2017

	Waste treatment facilities	*comments if any*
Class 1	2	
Class 2	1	
Class 3	0	
Class 4	0	
Total	3	

LITHUANIA 2014 -2017

	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"

LUXEMBOURG 2014 - 2017

	Waste treatment facilities	*comments if any*
Class 1	1	
Class 2	1	
Class 3	1	
Class 4	0	no level 4 facility in Luxembourg
Total	1	1 facility for all confinment levels

NETHERLANDS 2014 - 2017

	Waste treatment facilities	*comments if any*
Class 1	1	
Class 2	1	
Class 3	1	
Class 4	1	
Total	1	there is only one facility

ROMANIA 2014 -2017

	Waste treatment facilities	*comments if any*
Class 1	autoclaving	
Class 2	autoclaving	
Class 3	autoclaving	
Class 4	autoclaving and incineration	
Total		

SWEDEN 2014 - 2017

	Waste treatment facilities	*comments if any*
Class 1	6	4 regular waste treatment plants; 2 central university hospital autoclave facilities serving both hospital and university.
Class 2		
Class 3		
Class 4		
Total		

SLOVAKIA 2014 - 2017

	Waste treatment facilities	*comments if any*
Class 1	at least 1	
Class 2	at least 1	
Class 3	at least 1	
Class 4	at least 1	
Total	at least 1	The Ministry of Environment of the

		Slovak Republic as the Competent Authority for the use of GMM/GMOs does not have data about waste treatment facilities, neither the Competent Authorities in the field of waste could provide it as no legal obligation on evidence regarding waste arising from this specific kind of activities exists and the existing registers are not designed to retrieve the requested type of data.

UNITED KINGDOM 2014 - 2017

	Waste treatment facilities	*comments if any*
Class 1	5	
Class 2	8	
Class 3	0	
Class 4	0	
Total	13	

If yes, how is the transfer of waste from the contained use premises to the authorised waste facility arranged/organised?

2014 - 2017	
BE	Biologically contaminated waste originating from contained use activities, which is not inactivated in situ, is collected for incineration in installations that are authorised for treatment of hazardous waste (authorised in an environmental permit). Both the specialised transport companies (certified for collection of hazardous waste) and the waste-processing firms have to comply with regional regulations regarding waste treatment, imposing rules for collection and storage prior to incineration. Transport of waste material follows the UN recommendations of dangerous goods.
DE	The internal transport of the GMO-containing waste is carried out in tightly sealed, unbreakable and labeled containers in accordance with the German Genetic Engineering Act (GenTG). Transporting on public roads is beyond the scope of the GenTG according to the regulations on dangerous goods transport. Transport and disposal are recorded.
EE	in special containers.
ES	the transfer of waste from the GM installation to the authorised waste facilities is arranged by the users. These treatment facilities are authorised by the Spanish Regional Competent Authorities for the waste inactivation. They collect the waste which is conducted to their own facility where is inactivated by thermal, chemical or incineration methods.
FI	In closed containers marked with GMO info. Class 2 waste which is not inactivated on site is transferred to the waste facilities by companies specialized in hazardous waste transport.
FR	Par prestataire de service autorisé
HR	In closed containers.
HU	Some waste treatment facilities in Hungary are authorized to pursue such activities; however, they are not specialized solely to the treatment of waste arising from GM installations. The activity of inactivating waste arising from GM installations falls under a separate registration procedure. The transfer from the installation to the waste treatment facility can only be

	commenced possessing an authorization, under controlled conditions and specifying the route of transfer.
IE	In accordance with the Article 3(2) of Directive 2009/41/EC on the contained use of GMMs, the transport of GMMs by road, rail, inland waterway, sea or air is excluded from the scope of the Directive. Transfer of waste from the contained use premises to the authorised waste facility is regulated under the ADR Regulations and the Waste Permit Regulations.
LT	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.
LU	contained transport
NL	in the Netherlands there is one facility authorized for destruction of GMO-waste. This GMO-waste may originate from all classes, where waste of class 3 and 4 has to be inactivated at the premises before transport and destruction. The waste is being transported by authorized waste carriers under ADR.
RO	Emergency Government Ordinance No 44/2007 as amended by Law No 3/ 2008, requires users of contained use of genetically modified micro-organisms, the endowment with equipment of autoclaving for the waste inactivation from such activities
SE	Four waste treatment facilities have notified GMM activities Class 1 dedicated only to destruction of GMMs, as well as two central autoclave facilities at university hospitals. Waste from Class 1 and Class 2 activities containing GMMs that are not inactivated can be transported under the Dangerous Goods regulations. Transport within a university hospital needs to be controlled and safe.
SK	In Slovakia there are specialized facilities for processing of organic waste. The waste arising from GM installations has to be inactivated before the transfer. The inactivation may be done by the user or a specialized facility. The inactivated waste is then transported for a final disposal (some materials may be recycled). Rules for dangerous waste apply to the transfer of waste from the GM installation to the authorised waste facility [Regulation concerning the International Carriage of Dangerous Goods by Rail (RID), European Treaty on International Road Transport of Dangerous Goods (ADR)]. Landfill of waste arising from health care and veterinary care as a way of final disposal is forbidden. Landfill of waste arising from health care and veterinary care after processing/treatment is forbidden as well.
UK	It is the waste producer's responsibility, in all cases, to ensure that the waste is inactivated or correctly packaged in approved containers and labelled appropriately. The waste producer completes a consignment note confirming the waste type and any specific precautions that need to be taken, sending a copy with the waste and retaining a copy for their records. This should all be verified before the driver removes the waste from site. All drivers are required to have the appropriate level of training, which includes the transport of dangerous goods, the correct use of personal protective equipment and an appreciation of standard operating procedures, local rules and risk assessments. Additionally, drivers are trained in the use of waste spillage kits, which contain a surface disinfectant and are located in vehicles.

	On arrival at the plant, the driver informs the plant manager that GM waste has been delivered, hands over the consignment note for verification and it is then passed back to the waste producer to confirm that the waste has been processed. In Northern Ireland, all waste is treated at the site of origin, either by chemical means and/or autoclave. Inactivated waste then goes to land fill. There is no large scale production of GM waste in Northern Ireland.

2018	
DE	The internal transport of the GMO-containing waste is carried out in tightly sealed, unbreakable and labeled containers in accordance with the German Genetic Engineering Act (GenTG). Transporting on public roads is beyond the scope of the GenTG according to the regulations on dangerous goods transport. Transport and disposal are recorded.
FR	Par transporteur agréé
MT	Waste generated by the Class 1 facility is first inactivated by same facility, and it is then transferred to a waste facility by a licensed waste carrier to be disposed of.

2.3 Is waste from contained use activities recycled after inactivation?
If yes, specify for which purposes.

AT	No	
AT 2018	No	
BE	Yes	In some cases, animal by-products (cage bedding and excrements) or plant waste originating from contained use activities are composted. In one contained use activity of GMM, sludge from the sewage treatment plants are spread as fertilizer in field.
BE 2018	Yes	In some cases, animal by-products (cage bedding and excrements) or plant waste originating from contained use activities are composted. In one contained use activity of GMM, sludge from the sewage treatment plants are spread as fertilizer in field.
BG	No	
BG 2018	No	
CY	No	
CY 2018	No	
CZ	Yes	The compost where material from GM plants has been deposited is used in the premises.
CZ 2018	No	
DE	Yes	in one instance: biogas plant
DE 2018	Yes	one case: biogas plant
DK	Yes	Some but not all companies use their waste to produce biogas or fertilizer to be sold to the Danish farmers for the use of nutrition on the fields. This is not true for all produced GM waste, only in certain instances. More and more companies focus on the opportunity of producing biogas from production biomass.
DK 2018	Yes	Some but not all companies use their waste to produce biogas or fertilizer to be sold to the Danish farmers for the use of nutrition on the fields. This is not true

		for all produced GM waste, only in certain instances. More and more companies focus on the opportunity of producing biogas from production biomass.
EE	No	
EE 2018	No	
EL	No	
EL 2018	No	
ES	No	
ES 2018	No	
FI	Yes	In special cases class 1 GMM waste has been accepted to be used as a part of biocomposting process or for biofuel production. Also, composted GM plants can under certain limits be used as part of growth medium (soil) in closed circulation.
FI 2018	Yes	For compost products (only two operators producing large volumes of fermentation waste)
FR	No	
FR 2018	No	
HR	No	
HR 2018		
HU	No	
HU 2018	Yes	After the applied alcaline treatment the waste was placed in a land disposal unit.
IE	No	
IE 2018	No	
IT	No	
IT 2018		
LT	No	
LT 2018	Yes	It depends on recycled content
LU	No	
LU 2018	No	
LV	No	
LV 2018	No	
MT	No	
MT 2018	No	N/A
NL	No	
NL 2018	No	
PL	No	
PL 2018		
PT	No	
PT 2018	No	
RO	No	
RO 2018	No	
SE	No	
SE 2018	No	
SI	Yes	According to the provisions of the Decree of waste management (OJ RS 34/2008 and 103/2011) all wastes should be separated and recycled. After inactivation mostly plastic materials, glass, metals and paper are separated and recycled. Chemicals are also treated as required. Several waste incineration facilities are often used by the notifiers for final disposal of (inactivated for

		biosafety level 2 or higher) GMO waste.
SI 2018	Yes	According to the provisions of the Decree of waste management (OJ RS 34/2008 and 103/2011) all wastes should be separated and recycled. After inactivation mostly plastic materials, glass, metals and paper are separated and recycled. Chemicals are also treated as required. Several waste incineration facilities are often used by the notifiers for final disposal of (inactivated for biosafety level 2 or higher) GMO waste.
SK	Yes	Some materials are recycled in Slovakia. Obligations of waste holders are specified under Article 14 of the Act No. 79/2015 on waste and on amendments to certain acts. 2018: SAME INFO
SK 2018	Yes	Some materials are recycled in Slovakia. Obligations of waste holders are specified under Article 14 of the Act No. 79/2015 on waste and on amendments to certain acts.
UK	No	
UK 2018	No	

3. Inspection and enforcement issues

3.1 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.

2014 - 2017	
AT	Inspections were carried out randomly, based on the characteristics of the activity, e.g. risk class of the GMMs/GMOs, large scale equipment, inoculation of animals, etc. In the reporting period inspections were undertaken in installations working in biosafety level 1 and 2, as well as in all installations working in biosafety level 3.
BE	In Wallonia, no specific control was required. There was only one issue that required the intervention of the inspection: it concerned an accident at a company. Controls were carried out in this company in order to verify the implementation of corrective measures. In the Flemish Region, 53 installations were inspected in the period from June 2014 till the end of 2017. In the Brussels-Capital Region, all the installations concerning a demand of biological class risk 2 (and upper) are inspected before approval /permit. During the reporting period, 7 installations have been controlled in the frame of Inspection after approval /permit.
BG	Inspections are performed by the regional inspectorates of Ministry of Environment and Water. Representatives of Environmental Executive Agency and the Ministry are also present. Facilities to be inspected and the schedule of inspections are approved yearly by the Minister of the Environment and Water based on the list of actual or potential operators that might work with GMOs. Additionally, unscheduled inspections may take place when unauthorised use of GMO is suspected. After receiving notification for initial approval of facilities for contained use of GMO, inspections are performed to verify conformity with the requirements for safe work at given containment class. Approved facilities should be

	inspected at least once every two years but in practice all of them have been inspected annually. Samples can be taken during the inspection if necessary and analysed for presence of GMOs. Currently in each of the sixteen regional inspectorates there is at least one person appointed to undertake inspections for contained use and release into the environment of GMOs. In addition, there is an analytical laboratory (two people) in the Environmental Executive Agency that performs the necessary analytical work and whose staff participates in inspections and collection of samples. The number of inspections during reporting period is as follows: 2014 (whole year) - 16 inspections; 2015 – 9 inspections; 2016 – 8 inspections; 2017(data from 14 out of 16 regional inspectorates) –9 inspections.
CY	The Department of Labour Inspection during the reporting period has carried out inspections in the premises of the installation approved for the use of GMMs and in various premises in order to verify whether GMMs are used. About 20 Labour Inspectors were partially involved under the instructions of a specialised Labour Inspection Officer. 100% of the premises that applied for GMMs use was inspected.
CZ	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.
DE	In Germany, the CAs of the Bundesländer are responsible for the inspection of contained use premises and uses and the resulting enforcement measures. Inspections are conducted on a case-by-case basis or as rule monitoring. Event-related inspections are carried out for instance in - new premises (mostly before commissioning), - significant changes in equipment, - inquiries or incidents. The rule inspections are carried out at predetermined intervals, which are the shorter, the higher the security level and also the more intensive the use of the facility is. In addition, the intervals can be adapted to experience gained from previous inspections. Correspondingly, the following intervals result for rule monitoring:

	- BSL1 facilities: every 3 to 5 years, - BSL2 facilities: every 2 to 3 years, - BSL3 and BSL4 facilities: annually. During the reporting period almost all genetic engineering facilities were inspected at least once.
DK	When a class 2, 3 or 4 GMO location are notified the first time, it will always be visited to be approved. This also applies when changes are made to an already classified location. There are 2 inspectors in Denmark who spend part of their working hours with inspection. The procedure for class 1 GMO was changed in 2015 so that the work start based on the notification. There does not have to be a visit to the locations before they can start. Instead there will be inspections afterwards at selected locations.
EE	5/75%
EL	No authorised premises in the reporting period.
ES	There is not an Official Body for inspection under Directive 2009/41/EC in Spain. Generally, the Spanish regions are the competent for the inspection actions. Nevertheless, after the application of the notification by the users and before giving the consent, specialised member(s) of the National Commission on Biosafety (CNB) accompanied by a representative of the competent region where the installation is placed, regularly carry out visits and controls on the premises. They check the records of activities and the major objective of control is to confirm the effectiveness of the respective containment level and to evaluate compliance with relevant approval conditions. 100% of installations are visited and controlled. There are 5 members from the Biotechnology Unit at the Ministry of the Agriculture, Food and Environment, as part of the National Commission on Biosafety (CNB), who participate at the visits and controls.
FI	An inspector from the National Supervisory Authority for Welfare and Health, Finland (Valvira) contacts the operator before the inspection and prepares an inspection report after the visit. From 2007 it has also been possible to use a written inspection procedure for the inspection of earlier inspected activities and premises, if certain conditions are met. The inspection of the operators which commence Class 2 or 3 use of GMOs for the first time or start using higher class than before is prioritized. The inspection interval is risk based, so that active Class 3 use is inspected more often (at least every second year) than Class 1 or 2 use. During the reporting period 23 notifications or applications were inspected (5 % of all valid notifications and applications). Until June 2016 two full-time inspectors worked in control of GMO use, after that only one full-time inspector has been in charge of supervision.
FR	2 visites sur site ont été effectuées ainsi que 800 contrôles distants

HR	20 inspections without any measures.
HU	Laboratories complying with Class 1 and Class 2 containment level specifications also conform to the requirements of the quality assurance systems of Good Laboratory Practices (GLP). The GLP requirements themselves are stricter than what is needed to execute for Class 1 and Class 2 containment measures for GMOs. The audits are conducted once a year and the compliance with GLP is checked every two years. Every contained use has been verified in these schemes. Each contained use has been verified by 4 inspectors (on average).
IE	Each year a draft site inspection plan for GMO/GMM contained use activities is drawn up. During the site inspection we consult with a competent person on site (usually the biological safety officer). We use a checklist originally adopted by the European Enforcement Project (EEP). We do not charge for site inspections. The CA aims to inspect: - Class 2 GMM, Class 3 GMM, GM Animal / Plant activities once every 3 years; - Class 1 GMM contained use activities once every 6 years (given their history of safe use and negligible risk). During the reporting period 35 facilities were inspected comprising approximately 50%.
IT	According to the Italian Legislative Decree n. 206/2001, the inspection functions are exercised by officers identified by the BHTC on 20 May 2015, and appointed by Health Minister on the basis of designations provided by other institutional Bodies. If needed, inspections to GMM installation/activity are requested by BHTC. No inspections have been requested by during the reporting period. In 2015 the National Centre for Disease Prevention and Control of MoH decided to start a project for a training course for inspectors and to constitute a Directorate permanent inspectorate to conduct inspections to contained use premises. The project ended in 2017 and a ministerial decree with the appointed inspectors has to be issued.
LT	There was no change of requirements for inspection of contained use premises since previous reporting. 13 premises were inspected.
LU	1 inspection carried out in 2017. The facility was 100% compliant. SECUALIM designed a new inspection cheklist and procedure in 2017
LV	No inspection provided due to lack of activities with GMM.
MT	Malta has no specialised inspectors on GMMs. One should note that Malta only received one application to date (before this reporting period).
NL	During the period from 6 June 2014-31 December 2017 the inspectorate carried out 214 inspections involving contained use, mainly audits-on-site with recent addition of audit-on-desk for a small proportion of inspections. Year 2014 2015 2016 2017 Number of inspections 40 78 69 27 Percentage 16% 31% 28% 11% Up to 1 January 2017 the task was carried out by five inspectors (about 4 FTE). From 1 January 2017 onwards three inspectors are responsible for conducting these inspections

	(about 2.3 FTE). The inspectorate has the aim to contact each user at least every five to eight years. Based on risk, compliance and complexity of work this frequency may increase. Inspections generally cover containment, annual audits of the biological safety officer, waste treatment and administrative obligations. With the new legislation effective march 2015, the correctness of class I and II risk assessments is an important topic as well.
PL	The Minister of the Environment responsible for environmental issues issues a permit for running a genetic engineering plant in which the closed use of GMMs or GMOs is to be carried out, after obtaining the opinion relevant to the location: 1) the State Sanitary Inspection the state voivodship sanitary inspector - in terms of occupational hygiene; 2)the Chief Labour Inspection - in the area of meeting occupational safety and health requirements by facilities, premises, positions and work processes. 100 % permises were inspected.
PT	Until the present date, the Inspectorate General for Agriculture, Fisheries, Environment and Spatial Planning (IGAMAOT) hasn´t carried out inspections of contained use instalations/activities.
RO	National Environmental Guard (NEG) is the control and inspection body under the Ministry of Environment and Climate Change. Within the Biodiversity, Biosecurity and Protected Areas of NEG Control Directorate, there are inspectors with responsibility regarding control and inspection activities for the entire domain of activities in the directorate, not strictly specialized in accordance with Directive 2009/41/EC. They also have other inspection and control duties in accordance with Directive 2001/18/EC, as well as on biodiversity and natural protected areas.
SE	SWEA can perform an inspection both if found necessary because of information in a notification, and as a control measure after notification has been processed. Our policy is to give priority to inspections of new installations for Class 3 and Class 4 activities. Class 1 and Class 2 installations may be inspected if necessary. We also can plan more random inspections. We try to develop a mailing system for control of administrative compliance of Class 1 and sometimes Class 2 users, since there are large travel distances to several of our GMM users and the risks by definition are low or neglible. During the reporting time, 6 physical visits were made, all due to notifications. Three of the visits were only information and discussions because of misconceptions or unclear notifications that we deemed could be better explained when discussed person to person than by mail. The other visits also contained discussions but also physical inspection. One was a Class 3 activity that renewed their notification, one was not clear whether it should be a Class 2 or Class 3 activity and one was unclear how many activities they had in Class 1 and Class 2. An inspection is pre-notified, since we often need to travel to the site. Several inspections are then usually performed within 2-3 days in the area, sometimes in the same organisation, sometimes directed to different organisations. The inspection is often performed together with our regional work environment inspector, who can inspect work environment and occupational health aspects of the installation. Also, 22 Class 1 users have been contacted by e-mail and regular mail concerning their GMM activities notified more than five years earlier. We wanted to know the status of their GMM activities. If changed or no longer active, Swedish law obliges the user to notify that to SWEA. Two still remain to leave their answer. Of the 20 that answered our could not be reached, four had changed and made an update notification, four still had the same activity

	and twelve did no longer have GMM activity or the company was proven no longer active.
SI	Installations and activities are inspected according to annual plan of inspections ensuring that each installation is inspected at least every four years, or more often depending on the outcome of the previous inspection. Newly registered installations are inspected as soon as possible. In the reporting period 43 inspections were performed.
SK	The Slovak Environmental Inspectorate organised inspections to ensure that users comply with the Directive. There were 455 enclosed facilities checked during the reporting period, 85% of the overall percentage of authorized contained uses.
UK	In the UK, inspections are undertaken by HSE and HSENI. HSE carries out such inspections across Great Britain and applies the same inspection regime to all contained use work with high-hazard biological agents (including GMMs). Inspection is undertaken by HSE specialist microbiology inspectors. In Northern Ireland HSENI's inspections (mostly class 1 and 2 GMM contained uses) are carried out by a non-specialist inspector, who calls on HSE for specialist support, when required. The inspection programme in Great Britain covers contained uses involving GMMs, larger GMOs, non-genetically-modified human pathogens (under domestic legislation implementing Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work) and specified animal pathogens (derived from domestic legislation but also implements Directive 2003/85/EC on Community measures for the control of foot-and-mouth disease). The inspection programme is prioritised according to a hazard and risk system that focuses on activities in CL3 and CL4 laboratories. Contained uses involving GMMs are not targeted per se but captured as part of this programme. Higher hazard laboratories receive more frequent inspections. CL4 laboratories are inspected at least once per year, most being visited multiple times per year. CL3 laboratories are inspected based on a prioritisation scheme that considers the inherent hazard of the work, the safety performance of the user and time elapsed since last inspection. Those laboratories undertaking class 3 contained uses are generally inspected every 2-5 years. Premises that only work with class 1 and 2 GMMs are not inspected as part of a proactive inspection programme. However, many of the premises will be visited as part of other inspection or engagement visits. For example, HSE's Regulatory Compliance Officer (RCO) may provide advice on compliance with the legislation either through site visits or presentations at industry led events. Similarly, the lower containment laboratories may be scrutinised as part of a CL3 inspection or a larger GMO inspection at that specific premises. Furthermore, an inspection may be instigated should issues be identified from a contained use or premises notification, where in the view of the inspector further enquiries are merited. Inspections are generally topic-based and may cover a range of topics (e.g. containment and control, training and competence, audit and inspection and risk assessment etc.). Preparation for an inspection will include a review of the notified GM contained uses at the site. The topic of risk assessment evaluates the correctness of final classification and considers compliance with the GMO (CU) Regulations.

	HSE undertakes a programme of 16 inspections of laboratories handling larger GMOs (e.g. animals, plants and insects) each year on behalf of DEFRA and the Devolved Administrations. This includes a review of the risk assessments and inspection of the premises used for the contained use work, to check the adequacy of the containment and control measures. HSE has a specific team (Microbiology and Biotechnology Unit – CEMHD8), which implements the inspection regime and reviews the adequacy of notifications of biological agents (including GMMs). Currently the Microbiology and Biotechnology Unit comprises 7 Specialist Inspectors, 3 Principal Specialist Inspectors and 1 Regulatory Compliance Officer.

In 2018, did you implement changes in the procedure undertaken for the inspection of contained use premises (Article 16 of the Directive) under your contained use legislation?

	In 2018, did you implement changes in the procedure undertaken for the inspection of contained use premises (Article 16 of the Directive) under your contained use legislation?	**Provide details:**
AT	No	
BE	No	
BG	No	
CY	No	
CZ	No	
DE	No	
DK	No	
EE	No	
EL	No	
ES	No	
FI	No	
FR	No	
HR		
HU	No	
IE	No	
IT		
LT	No	
LU	No	
LV	No	
MT	No	Malta has no specialised inspectors on GMMs. One should note that Malta only received one application to date (before 6 June 2014).
NL	No	
PL		

PT	Yes	In 2018, the Inspectorate-General for Agriculture, the Sea, Environment and Territorial Planning established a guide to support the inspection of operators using genetically modified organisms / micro-organisms.
RO	No	
SE	Yes	SWEA can perform an inspection both if found necessary because of information in a notification, and as a control measure after notification has been processed. Our policy is to give priority to inspections of new installations for Class 3 and Class 4 activities.
SI	No	
SK	No	
UK	No	

In 2018, how many premises/contained uses have been inspected?

	In 2018, how many premises/contained uses have been inspected?
AT	Inspections were based on the characteristics of the activity, e.g. risk class, large scale, inoculation of animals, etc. In the reporting period 31 inspections have been carried out.
BE	In the Flemish Region: 2 installations were inspected. In the Brussels-Capital Region and in Wallonia: 0
BG	Inspections are performed by the regional inspectorates of Ministry of Environment and Water. In 2018 7 inspections of 7 premises have been carried out.
CY	One premise (there is only one premise approved for contained use in Cyprus) has been inspected in 2018,
CZ	22 premises: all that were notified in the time period and some premises in Class 2 and 3
DE	1613
DK	43 (just premises are inspected)
EE	0
EL	None - there were no premises working within the framework of Directive 2009/41/EC in 2018
ES	80
FI	Five premises / six notifications.
FR	Visites d'inspection ou de conseil : 11 établissements en recherche + 7 en production industrielle
HR	
HU	None.
IE	Four premises

IT	
LT	4
LU	0
LV	0
MT	0
NL	25
PL	
PT	In 2018, 10 premises were been inspected, that held permits for, globally, 15 confined uses.
RO	Not applicable yet
SE	1
SI	8
SK	48 premises
UK	22 inspections

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

2014 - 2017	
AT	The issues most frequently encountered did not affect biosafety but concerned administrative issues only (e.g. documentation, lab journal)
BE	In Wallonia: / In the Flemish Region: following issues (in order of occurrence) were most frequently encountered: - No permit or correct permit for the contained use of GMO's and pathogens - No correct storage of biohazardous waste. - No correct labelling of biohazard materials. - No registration of training staff. - No register of used GMO's/pathogens. - No restricted access to the laboratories in which contained use takes place. - No instructions for the correct use of disinfectants. - No microbial safety cabinet available - No validation of the disinfection method. - No biosafety manual. - No instructions in case of incident (fire). In the Brussels-Capital Region: - The biological risk class notified in the dossier was not correct. - Ancient wood furniture which was not suitable for effective disinfection. - No adequate validations of waste inactivation.
BG	No major issues have been encountered during the reporting period.
CY	No problems have been encountered during the course of inspections.
CZ	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.
DE	- missing or inadequate labelling of the work area,

	- structural defects, deficiencies of basic Equipments, - inadequate protective clothing (lab coat etc.), - lack of regular testing / maintenance of equipment such as safety workbenches and autoclaves, or poor documentation of these tests / maintenances, - missing suitable transport containers - inadequate or delayed instruction of employees or service personnel (cleaning staff, craftsmen etc.), - cramped or untidy laboratories, - unsuitable or dirty surfaces (in the work area), - no clear distinction between writing and laboratory work areas, - insufficient hygiene or disinfection measures, - inaccurate operating instructions and hygiene plans, - inaccurate or incomplete recording of the genetic engineering operations, - inadequate or incorrect user risk assessment, - non-compliance with the notification requirements, - no notification of changing of safety-relevant equipment such as autoclaves or safety cabinets, - carrying out further BSL2 operations without prior notice, - missing or delayed notification of the change of responsible persons (project leader, BBS) or changes of security-relevant institutions, - incomplete recording of persons working in BSL2 (or higher).
DK	When examining the notifications for research projects the risk assessment is often not sufficient. During inspections some times the written material on working procedures does not always correspond to the way things are carried out in practise. Some times it also turns out that the company has forgotten to notify the research project and has just notified the location where the project is going to take place. Companies don't always remember to give the information that a location is no longer being used for work with GMM's. Examples of things that are not in order when inspecting could be a missing sign on the door or on a freezer, disorder in the laboratory, alterations in the room, that have not been notified, lack of maintenance making the laboratory less cleaning friendly.
EE	some issues of choosing of labor gloves, washing of labour clothes
EL	No authorised premises in the reporting period.
ES	Problems most frequently encountered are: 1) Deficiencies in Good Laboratory Practices (GLPs) or SOPs, and to use inadequate equipments, inappropriate contained measures and/or waste disposal procedures for the confined level notified. 2) Lack of Internal Biosafety Committees at the installations. The CNB always recommend establishing this kind of internal committees in order to implement properly the confined and control measures according with the class of risk and to have a Biosafety Officer in charge of these issues.
FI	In general, documents were available but could be outdated or inaccurate. Inadequate book-keeping or risk assessment and taking new premises into use without giving notice were the most frequent problems. Also, persons responsible for the notification had sometimes left for another job without informing the authorities.

	In some cases, training of the staff was not recorded. In several cases, the premises were not properly marked or there were minor problems with waste management. In some cases, protective measures in use needed adjustment or rarely used personal protective equipment was missing. Sometimes it was unclear for operators that it is their responsibility to evaluate whether the waste management practice or equipment maintenance is appropriate considering the GMO use.
FR	Les problèmes rencontrés sont : - Traitement des déchets d'activité de recherche sur les OGM de classe C1 et C2 - Non respect des confinements entre C2 et C3, agents biologiques et OGM des groupe 3*
HR	not applicable
HU	Minor problems have been reported, as regards documentation.
IE	Typical issues that arose during the course of site inspections included: - non notification of research projects involving GMOs / GMMs; - validation labels showing the date on which a piece of equipment was last validated and when next validation was due were not displayed; - incomplete records , lack of signage; Violations are not significant in terms of posing a risk to human health and the environment.
IT	N.A.
LT	There were no specific issues.
LU	The facility was still under construction during the inspection. Signe regarding the confinement level as well as the protective gear to wear were forseen but not yet put in place before entering the rooms.
LV	-
MT	No matters to report.
NL	The compliance is high, > 90%. The issues most frequently encountered were: • waste management was not according to regulation; • use of disinfectants that have not been admitted as biocides; • the biosafety officer did not perform all internal controls; • there were no clear and up to date administrative records of all GMOs held by the institution; • not all internal procedures and instructions for the safe handling of GMOs were drafted. • Details of the laboratory infrastructure was not according to regulations.
PL	Usually facilities don't follow all necessary requirements needed for safety class. But mostly one of the rooms which was subjected as a part of GM facility did not meet all criteria for safety of class.
PT	Not applicable.
RO	Not applicable.
SE	Common errors are the text needed to accompany the biohazard sign (most occupational health), how and where to inactivate GMM and the limits between different GMM activities or GMM uses (both concerning responsibilities, as well as descriptions). Other issues were the class of the notification: Class 3 or Class 2?
SI	In the 3-year reporting period only minor infringements were disclosed such as minor equipment and furnishing inadequacies or insufficient documentation management (e.g. emergency action plans were not sent to the local authorities as required, yearly reports

	were not sent to the ministry, notifier failed to report the closure of the installation, etc.) At the present, containment measures and good laboratory practice are well observed, so the inspection process only encounter minor administrative infringements.
SK	Only minor deficiencies in fulfilling the requirements for enclosed facilities documentation were found.
UK	The most frequently encountered issues (formally raised following inspections/investigations indicating GM activities) were: • Risk assessments not sufficient to cover all the activities being undertaken; • Adequacy of standard control measures (e.g. sealability; HEPA filtrations restricted access) with respect to on-going planned preventative maintenance; • Training provision and training records – insufficient to demonstrate competence of the user

2018	
AT	The issues most frequently encountered did not affect biosafety but concerned administrative issues only (e.g. documentation, lab journal)
BE	No change relative to period 2014-2018
BG	No major issues have been encountered during the reporting period.
CY	No issues.
CZ	Like before, only minor administrative issues.
DE	- missing or inadequate labelling of the working area, - structural defects, deficiencies of basic equipment, - inadequate protective clothing (lab coat etc.), - lack of regular testing / maintenance of equipment such as safety workbenches and autoclaves, or poor documentation of these tests / maintenances, - inadequate transport containers, - inadequate or delayed instruction of employees or service personnel (cleaning staff, craftsmen etc.), - cramped or untidy laboratories, - unsuitable or dirty surfaces (in the work area), - no clear distinction between writing and laboratory work areas, - insufficient hygiene or disinfection measures, - inaccurate operating instructions and hygiene plans, - inaccurate or incomplete recording, - inadequate or incorrect risk assessment by the user, - insufficient labelling of gmo-specimen - violate the notification requirements
DK	When examining the notifications for research projects the risk assessment is often not sufficient. During inspections some times the written material on working procedures does not always correspond to the way things are carried out in practise. Some times it also turns out that the company has forgotten to notify the research project and has just notified the location where the project is going to take place. Companies don't always remember to give the information that a location is no longer being used for work with GMM's. Examples of things that are not in order when inspecting could be a missing sign on the door or on a freezer, disorder in the laboratory, alterations in the room, that have not been notified, lack of maintenance making the laboratory less cleaning friendly.
EE	0
EL	None

ES	Restricted access for type 2, practicable windows for type 2, do not use the corresponding PPE (protective equipment) when working in type 1 and 2
FI	Most frequently encountered issues were missing notices concerning new containment level 1 premises and inadequate or insufficient bookkeeping and/or risk assessment. Some operators had shortcomings in the action plans and in recording staff education. Sometimes changes of responsible persons had not been reported to the authorities. In situations where GM-micro-organisms were used in animal facilities, attention needed to be paid for ensuring proper information flow between the experimental animal facility and the GMM user.
FR	Validation des procédures d'inactivation des déchets liquides
HR	
HU	No issues were encountered.
IE	Typical issues that arose during the course of site inspections included: - non notification of GMMs that were held in storage; - validation certification for autoclave was not available during the course of the inspection.
IT	
LT	-
LU	N.A.
LV	-
MT	N/A
NL	no other than reported last year
PL	
PT	Processes under analysis.
RO	Not applicable
SE	Common errors are the text needed to accompany the biohazard sign
SI	In the reporting period only minor infringements were disclosed such as minor equipment and furnishing inadequacies or insufficient documentation management (e.g. emergency action plans were not sent to the local authorities as required, yearly reports were not sent to the ministry, notifier failed to report the closure of the installation, etc.). At the present, containment measures and good laboratory practice are well observed, so the inspection process only encounter minor administrative infringements.
SK	Contained use without notification (activities classified risk class 1).
UK	The most frequently encountered issues formally raised following inspections were: - Risk assessments not sufficient to cover all the activities being undertaken; - Adequacy of standard control measures (eg sealability; HEPA filtration, restricted access) with respect to on-going planned preventative maintenance; - Training provision and training records – insufficient to demonstrate competence of the user.

3.3 What were the corresponding enforcement actions taken?

2014 - 2017	
AT	improvement measures
BE	In Wallonia: / In the Flemish Region:

	If shortcomings were revealed in the application of containment measures an exhortation was drawn up and the user had to comply with these exhortations within a limited timeframe. Afterwards, follow-up inspections have been carried out and if the user still didn't comply an official report of infringement was written. Also if the shortcomings were that severe that a risk existed that the contained use could be breached a report of infringement was written. In the Brussels-Capital Region: The permit imposes to provide to the CA pictures or documents as a proof that the corrective measures have been taken.
BG	When it is found that GMOs are used or are about to be used in the near future in facilities that have not been approved and registered for such contained use regional inspectorate issues injunction ordering notification for initial approval to be submitted to the Ministry of Environment and Water within 40 days and prescribing that no work with GMOs should be carried out before the approval procedure is completed. Similar measures will be taken if work with Class 2-4 GMM or Class B GM plants and animals that has not been notified takes place. When it is found out that facility for contained use of GMO or the activities taking place in them do not comply fully with relevant requirements, injunction will be issued prescribing measures than need to be taken and the timeframe. If observed issues of non-compliance could result in increased risk for human or animal health or for the environment all activities involving GMOs will be stopped. No injunctions have been issued during the reporting period and no contained use activities have been stopped.
CY	No enforcement action was taken during the reporting period.
CZ	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.
DE	-verbal information and requests for removal of defects during the inspection (in the case of immediately implementable, smaller measures), - revision letter or minutes requesting the rectification of deficiencies and deadlines, - inclusion of conditions in approval decisions (in the case of new annexes or significant changes), - give notice of orders for rectification of defects or of subsequent conditions, - initiation of administrative offense proceedings, - in individual cases, the (temporary) prohibition of genetic engineering works.
DK	When a company has not notified e.g. a research project they are given an order with short notice to get the matter settled. Regarding the other problems experienced it depends on the situation. Sometimes companies are given advice on how to make things right. If the problem is more serious companies may be given an order with notice to get the matter settled.
EE	recommendations
EL	No authorised premises in the reporting period.
ES	Users have to correct the deficiencies before beginning the activities. If they not fulfil the requirements requested by the CNB, the favourable opinion is not released by the National

	Commission on Biosafety (CNB) and the permit is no granted by Competent Authority (the Inter-ministerial Council for GMOs (CIOMG) at national level or the CA of the affected Spanish region).
FI	No changes since the previous report. Most often the inspectors ordered correcting measures already during the inspection visit and discussed them together with the operator. The measures to be taken are always written down in the inspection report, and if necessary, the operator has to confirm in a written statement that the inspector's orders have been followed. In more severe cases a written note of complaint is written to the operator and their superiors, and in very severe cases the issue is presented for the Board of Gene Technology, which has more authority in enforcement actions. Usually, however, the operators are very co-operative, and inspectors' orders and recommendations are followed without problems.
FR	Des instructions ont été données pour corriger les problèmes
HR	not applicable
HU	Providing detailed information on what kind of documentation is required.
IE	By and large violations are quickly rectified. Other than to request resolution within a certain timeframe, more stringent enforcement actions (such as serve notices, prosecutions as specified under the national legislation) have not proved necessary.
IT	N.A.
LT	During carry out of inspections there were fulfilled questionnaires according to the 2009/41/EC directive IV Annex.
LU	Report requiring corrective actions to be taken
LV	-
MT	No actions taken.
NL	Most of the violations are not significant. In those cases the inspectorate sends a letter and requests for remedial actions within a given time frame. For more serious cases a report of the offence is made or a penalty is imposed on a daily basis in case of non-compliance.
PL	We try to informed applicants about frequently mistakes done by other.
PT	Not applicable.
RO	Not applicable.
SE	All errors were corrected within the notification procedure.
SI	Two decisions and 16 written warnings with a time limit were issued and in some cases the enforcing measure was only verbal communication with written minutes. In one case the insitution of the notifier was reorganised into two separate legal entities, none of them intended to carry on work with GMOs and they failed to notify the closure of installation. In this case the GMO inspector issued the decision for a formal deletion of the aforementined installation from the GMO Registry. All of the notifiers were keen to make good a deficiency, therefore we believe they understand the purpose of the biosafety system and want to contribute to adequate biosafety themselves.
SK	There were issued 9 decisions on fines.
UK	Inspectors use a range of enforcement tools to ensure that users of GMMs comply with the legislation. These include: • Verbal instructions to achieve required improvements (used where users are broadly compliant – minor issues); • Providing written direction to achieve compliance e.g. letter (used where there is a material breach of the legislation); • Serving statutory enforcement notices, requiring improvements to achieve the required

	level of compliance (Improvement Notices) within a specific timeframe or the immediate cessation of work where it poses an immediate risk to human health or the environment (Prohibition Notices); • Withdrawal or variation of consent or addition of conditions to carry out the notified GM contained use; and • Prosecution – where it is in the public interest to hold the user accountable for a failure to meet their legal obligations. HSE's Enforcement Policy Statement sets out the factors that inspectors consider when deciding upon the most appropriate enforcement action (www.hse.gov.uk/enforce/enforcepolicy.htm)

2018	
AT	Premises had to take improvement measures
BE	In Wallonia: / In the Flemish Region: If shortcomings were revealed in the application of containment measures an exhortation was drawn up and the user had to comply with these exhortations within a limited timeframe. Afterwards, follow-up inspections have been carried out and if the user still didn't comply an official report of infringement was written. Also if the shortcomings were that severe that a risk existed that the contained use could be breached a report of infringement was written. In the Brussels-Capital Region: The permit imposes to provide to the CA pictures or documents as a proof that the corrective measures have been taken.
BG	When it is found that GMOs are used or are about to be used in the near future in facilities that have not been approved and registered for such contained use regional inspectorate issues injunction ordering notification for initial approval to be submitted to the Ministry of Environment and Water within 40 days and prescribing that no work with GMOs should be carried out before the approval procedure is completed. Similar measures will be taken if work with Class 2-4 GMM or Class B GM plants and animals that has not been notified takes place. When it is found out that facility for contained use of GMO or the activities taking place in them do not comply fully with relevant requirements, injunction will be issued prescribing measures than need to be taken and the timeframe. If observed issues of non-compliance could result in increased risk for human or animal health or for the environment all activities involving GMOs will be stopped. No injunctions have been issued during the reporting period and no contained use activities have been stopped.
CY	No enforcement actions.
CZ	Like before, no penalty was imposed. In few cases, the user just got a notice from the

	Inspection.
DE	- verbal instructions - revision letters requesting the rectification of deficiencies with deadlines, - inclusion of conditions in decision of approval - initiation of administrative offense proceedings, - in individual cases, the (temporary) prohibition of genetic engineering works
DK	When a company has not notified e.g. a research project they are given an order with short notice to get the matter settled. Regarding the other problems experienced it depends on the situation. Sometimes companies are given advice on how to make things right. If the problem is more serious companies may be given an order with notice to get the matter settled.
EE	Nothing
EL	None
ES	No enforcement action were necessary during this period. Inspection visits are always carried out and information is required from the applicants to verify that these deficiencies have been rectified before authorizing the facilities.
FI	No changes since the previous report. Most often the inspectors ordered correcting measures already during the inspection visit and discussed them together with the operator. The measures to be taken are always written down in the inspection report, and if necessary, the operator has to confirm in a written statement that the inspector's orders have been followed. In more severe cases the issue was presented to the Board of Gene Technology, which can decide whether additional measures are needed besides a written complaint and an order to the operator to fulfil the requirements of the Gene Technology Act.
FR	Enforcement measures taken: obligation to provide procedures
HR	
HU	No actions were taken.
IE	By and large violations are quickly rectified. Other than to request resolution within a certain timeframe, more stringent enforcement actions (such as serve notices, prosecutions as specified under the national legislation) did not prove necessary.
IT	
LT	-
LU	None taken
LV	-
MT	N/A
NL	one more warning letter was sent during 2018
PL	
PT	Processes under analysis.
RO	Not applicable
SE	errors were corrected within he notificiation procedure
SI	Four written warnings with a time limit were issued. All of the notifiers complied and remediated the shortcomings within the given time limit. Therefore we believe they understand the purpose of the biosafety system and want to contribute to the adequate biosafety themselves.
SK	A fine to the user.
UK	Inspectors used the following enforcement tools to ensure that users of GMMs comply

	with the legislation: - Verbal instructions to achieve required improvements (used where users are broadly compliant – minor issues); - Providing written direction to achieve compliance e.g. letter (used where there is a material breach of the legislation).

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

	2014-2017	**2018**
AT	Information and regular training of the staff	Information and regular training of the staff
BE	In Wallonia: / In the Flemish Region: Shortcomings had to be corrected case by case and were inspected during a follow-up inspection. In the Brussels-Capital Region: Issues had to be corrected by the user.	In Wallonia: / In the Flemish Region: Shortcomings had to be corrected case by case and were inspected during a follow-up inspection. In the Brussels-Capital Region: Issues had to be corrected by the user.
BG	No specific actions have been undertaken as no major issues have been encountered during the inspections.	No specific actions have been undertaken as no major issues have been encountered during the inspections.
CY	Not applicable.	N.R.
CZ	Users consult the requirements in advance with the CA.	The users may apply various checklist, guidelines and methodology documents published and disseminated by the Ministry.
DE	The identified deficiencies were remedied by the users usually promptly or within the specified deadline. If required, the frequency of official inspections was increased. The authorities usually offer early consultations. The users took different measures to minimise the occurrence of the problems, i.e. nomination of a dedicated person for dealing with legal and safety requirements and keeping in touch with competent authorities, training of biosafety officers and of project leaders etc.	The identified deficiencies were remedied by the users usually promptly or within the specified deadline. If required, the frequency of official inspections was increased. The authorities usually offer early consultations. The users took different measures to minimize the occurrence of the problems, i.e. nomination of a dedicated person for dealing with legal and safety requirements and keeping in touch with competent authorities, training of biosafety officers and of project leaders etc.
DK	If any serious problems we will revisit the company.	If any serious problems we will revisit the company.
EE	better choosing of gloves, better labor clothes washing arrangement	No actions needed
EL	No authorised premises in the reporting period.	No actions
ES	First of all, the main positive action in order to prevent problems is to clarify questions through previous consultations between the users and officials from the Biotechnology Unit before applying the final notifications to the Competent Authority.	Many consultations from the users (notifiers) are received during the authorization procedure to solve doubts about the facilities or equipments. CA informs about specific actions required in each case.

	On the other hand, the CNB makes several recommendations to users in order to improve their installations although the measure to implement wouldn't be compulsory.	
FI	The operators followed the instructions given during inspections, according to their statement to Valvira. Apart from giving specific instructions to correct the observed deficiencies: - Future plans of GMO activities were discussed with operators and inspectors gave instructions about the liabilities of gene technology legislation when starting new types of activities. - Operators were advised to ensure that new or changed information related to GMO use is shared efficiently within the organization and (when needed) across organizational borders. -Importance of in-house control systems was emphasized to operators.	The operators followed the instructions given during inspections, confirmed by their statement to Valvira. The inspector also ensures that the requested documents will arrive to the CA. Whether the operator has actually taken further actions can be ensured at latest during the next inspection, but in many cases they can be observed when inspecting other operators working in the same institute and using common premises and infrastructure, such as waste management. Apart from giving specific instructions to correct the observed deficiencies: - Future plans of GMO activities were discussed with operators. Inspectors gave instructions about the liabilities of gene technology legislation when starting new types of activities. - Operators were advised to ensure that new or changed information related to GMO use is shared efficiently within the organization and (when needed) across organizational borders. -Importance of in-house control systems was emphasized to operators.
FR	Des actions de communication sont menées à destination des publics concernés	écriture et validation des procédures
HR	not applicable	
HU	Notifiers took account of the documentation required by the authorities.	No actions were taken.
IE	The user is requested to respond to the enforcement action in writing within a specified timeframe thereby informing the CA if and how the enforcement action was completed. In addition, multi-user sites (institutions) are required to have Biological Safety Committees (BSC) and Biological Safety Officers (BSO) in place who liaise between the user and the CA and who impress upon the user then need to comply with the legislation.	The user is requested to respond to the enforcement action in writing within a specified timeframe thereby informing the CA if and how the enforcement action was completed. In addition, multi-user sites (institutions) are required to have Biological Safety Committees (BSC) and Biological Safety Officers (BSO) in place who liaise between the user and the CA and who impress upon the user the need to comply with the legislation.
IT	N.A.	

LT	There were no specific issues.	-
LU	/	N.A.
LV	-	-
MT	Not applicable.	N/A
NL	Four warning letters were send. All the violations had ceased within the given time frame.	no other than reported last year
PL	We try to informed applicants about frequently mistakes done by other.	
PT	Not applicable.	Processes under analysis.
RO	Not applicable.	Not applicable
SE	As all errors were corrected, we expect new notifications from the same notifier to be more accurate.	-
SI	During the process we realised some notifiers needed more help and advice, so in the collaboration with The Scientific Committee CA regularly helps with the pre-notification/renovation visits of the premises and on-site discussion of the possible containment measures.	During the 15 years of notification process we realised some notifiers need more help and advice than the others. So in the collaboration with The Scientific Committee CA regularly helps with the pre-notification/renovation visits of the premises and onsite discussion of the possible containment measures.
SK	Designation of responsible person who will take part in the training organised by the Ministry of Environment for the users of genetic technologies and GMMs/GMOs about the legal requirements.	Training of all employees.
UK	The user formally responds to the enforcement action in writing within a given timeframe setting out how the matters have been rectified. The information is used to inform the prioritisation for further inspection. There were 5 specific instances, where issues were raised by inspectors via written direction, specifically referring to failure to comply with the GMO(CU) Regulations.	The user formally responds to the enforcement action in writing within a given timeframe setting out how the matters have been rectified. The information is used to inform the prioritisation for further inspection.

3.5 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?

AUSTRIA 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

AUSTRIA 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

BELGIUM 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	In the Flemish Region: See above	Shortcomings had to be corrected	Follow-up inspection.
2	In the Brussels-Capital Region: The biological risk class notified in the dossier was not correct.	The biological risk class was adapted, so as the information on the door of the laboratory, and the work practices.	The inspectors and direct contacts of users made them aware of biosafety topics before approval/permit.
3	In the Brussels-Capital Region: Ancient wood furniture were present in facilities, not suitable for effective disinfection.	Ancient wood furniture were removed and replaced by modern equipment, suitable for disinfection.	The inspectors and direct contacts of users made them aware of biosafety topics before approval/permit.
4	In the Brussels-Capital Region: No adequate validations of waste inactivation were undertaken.	Adequate validation procedures were set up for waste inactivation.	The inspectors and direct contacts of users made them aware of biosafety topics before approval/permit.

BELGIUM 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	See above	Shortcomings had to be corrected	Follow-up inspection.
2	The biological risk class notified in the dossier was not correct.	The biological risk class was adapted, so as the information on the door of the laboratory, and the work practices.	The inspectors and direct contacts of users made them aware of biosafety topics before approval/permit.
3	Ancient wood furniture were present in facilities, not suitable for effective disinfection.	Ancient wood furniture were removed and replaced by modern equipment, suitable for disinfection.	The inspectors and direct contacts of users made them aware of biosafety topics before approval/permit.
4	No adequate validations of waste inactivation were undertaken.	Adequate validation procedures were set up for waste inactivation.	The inspectors and direct contacts of users made them aware of biosafety topics before approval/permit.

BULGARIA 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive

			measure(s)
1			

BULGARIA 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

CYPRUS 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

CYPRUS 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

CZECH REPUBLIC 2014-2017

	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.

CZECH REPUBLIC 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

GERMANY 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

GERMANY 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

DENMARK 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

DENMARK 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

ESTONIA 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	golves will break very easily	recommentation to change supplier	better choosing of gloves
2	there is not washing mashine in the lab, employees wash their labclothes at home	recommenation to arrange better system for cleaning clothes	buying washing mashine for the laboratory

ESTONIA 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

GREECE 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

GREECE 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

SPAIN 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive

			measure(s)
1			

SPAIN 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

FINLAND 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	Neglect of risk assessment of new type of GMO-activities and submitting notifications to CA when needed.		Future plans of GMO activities were discussed with operators and inspectors gave instructions about the liabilities of gene technology legislation when starting new types of activities.
2	The problems of information flow within the organization and across organizational borders.		Contact with the persons in charge of waste management and infrastructure maintenance in the organization. Education of operators about their responsibility to ensure gaining the information about the changes in conditions affecting to the safety of GMO use.
3	Lack of information among the operators about the liabilities of gene technology legislation		Presentations in biotechnology associations. Visits, lectures and presentations in educational institutes.
4	Lack of knowledge of the legislative boundaries of the authorities		Contacts to occupational health authorities. Information on the legislation on gene technology for occupational safety and health authorities.
5	Commencing the use of GM-influenza virus without making risk assessment and	Valvira informed the Board for Gene Technology about a possible violation of the	The operator was requested to interrupt the use of GM-influenza virus until the CA had

	submitting notification or application to the CA (Board for Gene Technology).	gene technology legislation.	evaluated the risk assessment and handled the notification concerning its use by the operator. The operator sent a new notification on Class 2 use, which was handled by the CA.

FINLAND 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	Taking new premises into class 1 contained use without giving notice or neglect in bookkeeping, risk assessment and making the action plan.		The operators were educated about the requirements of gene technology legislation, and the operator had to confirm in a written statement that the inspector's orders have been followed.
2	The operator had used class 1 GMMs for years/ extended period without giving the notification concerning the premises for contained use.	Valvira informed the Board for Gene Technology about a violation of the gene technology legislation and issue was presented for the Board of Gene Technology. A written note of complaint was written to the operator and it was ordered to obey the duty to give notification to the Board for Gene Technology.	Valvira (the supervisory authority) asked for more information to find out whether the use of class GMMs had caused adverse effects or risk of adverse effects considering the nature of the use.
3	Commencing class 3 activity in premises which were notified as containment level 2+ premises	Valvira informed the Board for Gene Technology about a violation of the gene technology legislation and issue was presented for the Board of Gene Technology. A written note of complaint was written to the operator. As the class 3 use had already ended , the operator was adviced to submit an application of	Supervisory authority asked the operator for more information to find out whether the use of class 3 GMMs had caused adverse effects or risk of adverse effects (considering the nature of the use). It appeared that there had not been adverse effects and the risk for adverse effects was estimated very small considering the nature of

		planned commencing of class 3 use to Board for Gene Technology, when needed.	the GMM activities and the use of containment level 3 measures during the work.

FRANCE 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

FRANCE 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

CROATIA 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

CROATIA 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

HUNGARY 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

HUNGARY 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	0	-	-
2	0	-	-
3	0	-	-
4	0	-	-
5	0	-	-

IRELAND 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)

1	Non-notification of research projects involving GMOs / GMMs	Provide the user with details of notification requirements, forms, timelines and require the submission of an application within a certain period. Provide links to legislation.	Liaise with BSO/BSC. CA provides seminars on the legislative requirements.
2	Validation labels showing the date on which a piece of equipment was last validated and the date of next validation are not displayed.	Clarify if validation is completed or not. If not, require that validation be completed within a certain timeframe. If it has been completed require that a validation label be displayed within a certain timeframe.	Liaise with BSO/BSC
3	Incomplete records / lack of signage	Require that records be completed / erection of signs with confirmation in writing within a certain time period.	Liaise with BSO/BSC

IRELAND 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	non notification of GMMs that were held in storage;	Request the user to submit risk assessments to the CA	Liaise with BSO/BSC.
2	validation certification for autoclave was not available	Clarify if validation was completed. If not, require that validation be completed within a certain timeframe. If it has been completed require that a validation certificate be submitted to the CA within a certain timeframe.	Liaise with BSO/BSC

ITALY 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	N.A.	N.A.	N.A.
2	N.A.	N.A.	N.A.
3	N.A.	N.A.	N.A.
4	N.A.	N.A.	N.A.

5	N.A.	N.A.	N.A.

ITALY 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

LITHUANIA 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

LITHUANIA 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

LUXEMBOURG 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

LUXEMBOURG 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	N.A.	N.A.	N.A.

LATVIA 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	-	-	-

LATVIA 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

MALTA 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

MALTA 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

NETHERLANDS 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

NETHERLANDS 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

POLAND 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

POLAND 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

PORTUGAL 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

PORTUGAL 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

ROMANIA 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

ROMANIA 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

SWEDEN 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

SWEDEN 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1			

SLOVENIA 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	Failure to notify the closure of installation	Decision for a formal deletion	Upon registration CA specifically explains the conditions for a deletion of the installation from the register
2	Minor equipment and furnishing inadequacies	Written warnings	
3	Insufficient documentation management	Written warnings	

SLOVENIA 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	Minor equipment and furnishing inadequacies	Written warnings	
2	Insufficient documentation management	Written warnings	

SLOVAKIA 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	Missing documents	Fine	Completing of documentation Designation of

			responsible person

SLOVAKIA 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	contained use without notification	fine	publication of the decision on the fine on the Inspectorate's website and on the Enviroportal website

UNITED KINGDOM 2014-2017

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	(GMO(CU)) Reg 18(1) Sch 8 - CL3 laboratories must be 'sealable to permit disinfection' or 'sealable for fumigation'	Letter	Formal response required setting out timeframe for corrective measures
2	GMO(CU) Regulation 8(1) risk assessments are reviewed regularly	Letter	Formal response required setting out timeframe for corrective measures
3	GMO(CU) Reg18(1) Schedule 8 requires that written records of training are kept for those staff working at CL3	Letter	Formal response required setting out timeframe for corrective measures
4	GMO(CU) Reg 8 and Reg 26 GMSC not in place to provide competent advice on RA, classification of work	Letter	Formal response required setting out timeframe for corrective measures. Projects stopped until reviewed by GMSC
5	GMO(CU) Reg 18(1) Schedule 8 requires that written records of training are kept for those staff working at CL3	Letter	Formal response required setting out timeframe for corrective measures

UNITED KINGDOM 2018

	Issue	Enforcement action(s)	Corrective/preventive measure(s)
1	(GMO(CU)) Reg 18(1) Sch 8 CL3 laboratories must be 'sealable to	Letter	Formal response required setting out timeframe for corrective measures

	permit disinfection' or 'sealable for fumigation'		
2	GMO(CU) Regulation 8(1) risk assessments are reviewed regularly	Letter	Formal response required setting out timeframe for corrective measures
3	GMO(CU) Reg 18(1) Schedule 8 requires that written records of training are kept for those staff working at CL3	Letter	Formal response required setting out timeframe for corrective measures

4. Accidents

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

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

4.3 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.

	4.1 Provide information reported by the users on accidents (as required in Article 14(1) of the Directive) to the CA during the reporting period.	**4.2 Provide information on the measures taken by you, as a CA, on the basis of Articles 14(2) and 15(1) of the Directive.**	**4.3 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.**
AT 2014-2017	No accidents were reported	not applicable	
AT 2018	No accidents were reported	not applicable	not applicable
BE 2014-2017	In Wallonia one accident occurred due to a technical failure. The competent authority has been informed and corrective measures have been taken.	The external technical expert has been informed and has analysed some documents (with actions undertaken and future actions pointed out) as well as the intern contingency plan. The external technical expert gave advise on the measures that should be taken.	
BE 2018	In Wallonia one accident occurre due to a human error. The competent authority has	The external technical expert has been informed (by phone and by online assessment form)	/

	been informed and corrective measures have been taken.	and has analysed some documents (with actions undertaken and future actions pointed out) as well as the intern contingency plan. The external technical expert gave advise on the measures that should be taken.	
BG 2014-2017	No accidents have been notified to the Ministry of Environment and Water during the reporting period.	No accidents have been notified to the Ministry of Environment and Water during the reporting period.	Not applicable as no accidents have been notified.
BG 2018	No accidents have been notified to the Ministry of Environment and Water during the reporting period.	No accidents have been notified to the Ministry of Environment and Water during the reporting period.	Not applicable as no accidents have been notified.
CY 2014-2017	No accidents were reported during that period.	Not Applicable	Not Applicable
CY 2018	No accident reported.	No measures taken under Articles 14(2) and 15(1) of the Directive.	N.R.
CZ 2014-2017	No accident happened in the Czech Republic during the reporting period.	Not applicable	
CZ 2018	No accident occured during the reporting period.	not applicable	
DE 2014-2017	1. Water damage in a class 3 premise (M. tuberculosis) Due to a sensor failure the automatic lock of a full storage tank of an autoclave did not work. As a consequence, the storage tank, that was used for collecting water from the shower and hand basin of the air lock chamber flowed over and dispended from the airlock chamber into the internal BSL3 corridor of an BSL3 laboratory and also to further premises including the floor below. 2. Malfunction of a fermenter Due to false signalling a fermenter was opened that was still in progress to cultivate a	1. After discovery, the rooms were immediatly blocked. The CA was immediatly informed by the user. During the incident (around midnight) no work took place. The water was absorbed by qualified personnel and inactivated, surfaces were desinfected. Permission to resume work was not given by the CA until some actions were taken by the user (negative testing for M. tuberculosis, restoration of full function of the autoclave as well as the doors of the airlock chamber, training of staff members, regular maintenance of spill barriers). 2. The discharged culture and contaminated material	

	stock of recombinant E. coli W followed by a discharge of a large amount of bacteria culture. 3. Release of virus-active (recombinant FLUAV-vaccine strains) wastewater into the sewage system with possible entry into surrounding waters The floor drains in two cleaning rooms of the premise were - contrary to the blueprints - not connected with the in-house sewage inactivation system but led directly to the public sewage system. Thus, residues of the seed solution from the vaccine containers and residues of allantoic liquid of infected chicken eggs from the harvesting containers arrived without sufficient inactivation in the public sewage system and were released into the environment. 4. Infection with recombinant MRSA The infection of one laboratory staff member was presumably due to a leaky hose connection in biofilm experiments with S. aureus. The laboratory staff member tried to repair the connection when his glove presumably came in direct contact with the face. Approximately one year later he and also his wife developed disease symptoms and surgical removal of the furuncles was neccessary. The microbial analysis identified the recombinant strain.	(personal protective equipment) were inactivated, contaminated surfaces were desinfected. The staff member was examinated by the doctor. The bacteria are apathogenic and are classified as class 1 organisms. The CA was immediatly informed by the user. The staff member as well as the environment were not endangered. 3. The regional CA was immediatly informed by the user. The regional CA has forwarded the information to different regional and national authorities and involved them in the next steps. The user provided his own risk assessment. The public was informed by declarations of the company and of the authorities.The coordinating CA (BVL) was asked for involvement of the ZKBS (Central Committee on Biological Safety). With the participation of further experts the ZKBS concluded that after release of the recombinant FLUAV, a significant dilution of the virus particles occurred in the sewage system and later in the surrounding waters. FLUAV show a low tenacity and resistance to environmental influences. Due to (i) at least short-term exposure to high temperatures in a cleaning process performed by the company and (ii) the presence of detergents and high concentrations of microorganisms and suspended matter in the wastewater, which lead to inactivation, degradation or adsorption of viral particles, the inactivation	

		of the majority of virus particles can be expected. In view of the low concentration of infectious viral particles in the surrounding water, an exceeding of the infectious dose in humans or wildbirds by respiration of aerosols or droplets seems very unlikely. The faulty connection was corrected immediately by the company. The correct connection of all lines in the factory was checked and confirmed. There were several consultations and inspections by the regional CA. 4. Different authorities and Ministries including the CA were involved after determination of the recombinant strain. Examination of surrounding contacts of laboratory staff members, family members and further persons, were instigated and carried out by the competent health authority. Decontamination of the complete premise (H2O2 fumigation) was instigated. The CA inspected the premise. There were consultings and the instigation to adjust the operating instructions.	
DE 2018	none	none	
DK 2014-2017	N/A	N/A	N/A
DK 2018	N/A	N/A	N/A
EE 2014-2017	0	N/A	N/A
EE 2018	0	No measures needed	
EL	No accidents reported.	No accidents reported.	

2014-2017			
EL 2018	No accidents reported in reporting period	No measures were required in reporting period	
ES 2014-2017	Accidents were not reported	Accidents were not reported	
ES 2018	Accidents have not been reported by the users.	Accidents have not been reported by the users.	
FI 2014-2017	A few needle stick accidents concerning the employee working with a GMM. Also, an effluent overflow in the premises of a large scale operator had possibly led to release of live class 1 GM organisms from the contained use.	In the accident report the operators must describe which corrective measures they have already taken and what kind or measures they are going to take in order to prevent similar accidents in the future. A presenting official of the Board examines each case and decides whether these measures are sufficient. Valvira supervises that the corrective measures are actually taken.	Valvira's inspector follows that the corrective and preventive measures were executed by requesting information about the actions taken from the operators. In the effluent overflow case the pumping capacity was increased, automatic monitoring of the liquid level was added to stop pumping at the threshold level, and the staff was educated to foresee, recognize and prevent similar situations.
FI 2018	No accidents reported in 2018.	-	-
FR 2014-2017	None	None	None
FR 2018	None	None	None
HR 2014-2017	not applicable	not applicable	not applicable
HR 2018			
HU 2014-2017	No accidents were reported.	No accidents were reported.	
HU 2018	None.	None.	-
IE 2014-2017	No accidents were reported during the reporting period.	No accidents were reported during the reporting period.	Not applicable
IE 2018	No accidents were reported during the reporting period	No accidents were reported during the reporting period	n/a
IT 2014-2017	No accident has been reported, despite the legislative decree n. 206/2001 lays down the measures referred to Article 14	N.A.	N.A.

	(2) and 15 (1) of the Directive and requires that, in the event of an accident, the user should keep informed the holder of premise and the CA.		
IT 2018			
LT 2014-2017	No accidents were reported.	No accidents were reported.	No accidents were reported.
LT 2018	0	0	
LU 2014-2017	no accidents reported	no accidents reported	no accidents reported
LU 2018	No accident reported	No accident reported	No accident reported
LV 2014-2017	-	No accidents registrated.	-
LV 2018	No, accidents	No, measures taken	
MT 2014-2017	No accidents occurred.	Not applicable.	Not applicable.
MT 2018	No accidents occurred.	N/A	N/A
NL 2014-2017	number of accidents: 0 Number of incidents: 9, details of incidents: - A needle stick injury with a GM tumor cell line in mouse work. - A fire, causing heavy smoke damage in several GMO labs. The containment was not breached by the fire. - During renovation activities in a lab, GMO waste is not properly being disposed of. Instead the waste ends up in an open container with construction waste outside of the building. - A small amount of GMO	In all cases of reported incidents the BSO was contacted and entered into an agreement with the CA. In some cases those directly involved in the incident were interviewed. One case has led to a follow-up extensive audit. No accidents occurred, hence no reporting to MS or EC was necessary.	In the case of the needle stick injury, a safer kind of needle should prevent future incidents. In case of the clarification system, both temporary and technical measures should prevent future incidents. The incident with GMO waste asked for better procedures. Maintenance work will be followed by internal inspection of BSO before units are brought back on line.

	material was discharged onto the local sewers system, because of a release of air from a clarification system that led to an unintentional flow of GMO material to the drain. - possible discharge of small amount of GMO from small bioreactor into sewers due to miscommunication on disinfection status of bioreactor. - A needle stick injury during work with mice to screen for loss of GMO in their blood, following treatment with GMO. Mice turned out to be clean. - Change from under-pressure to over-pressure in DM-III unit that was not yet in use for experiment. Cause: during maintenance valves were operated, but not reconfigured to the proper state at completion of the work. The system malfunctioned a few months after the maintenance work was performed. - A needle stick injury during work with a GMO. Employee was put on curative medication, as a precautionary measure. - A needle stick injury during work with a GMO. Employee was put on antibiotics, as a precautionary measure.		
NL 2018	7 CU incidents in 2018: - DM-II GMO waste was not disposed of in the prescribed manner - ML-I GMO was handled in conventional lab (no discharge) - Company using GMO's	In all cases of reported incidents the BSO was contacted and entered into an agreement with the CA. In some cases those directly involved in the incident were interviewed. One case has led	No other comments than given last time.

	without appointed BSO - During construction works the duct of a vetilation outlet of an ML-I lab got breached - ML-I GMO was accidentally discharged into sewers - Use of ineffective desinfactant in ML-II lab, resulting in a possible small discharge of GMO - Use of combination of host/vectors at containment level ML-II, instead of ML-III. The work was discontinued and GMO's destroyed.	to a follow-up extensive audit. No accidents occurred, hence no reporting to MS or EC was necessary.	
PL 2014-2017	No accidents so far.	Standard procedure	
PL 2018			
PT 2014-2017	No accidents were reported in this period.	Not applicable.	
PT 2018	No accidents were reported in this period.	No accidents were reported in this period.	
RO 2014-2017	Not applicable	Not applicable	Not applicable
RO 2018	Not applicable	Not applicable	Not applicable
SE 2014-2017	No accidents were reported.	No accidents were reported.	
SE 2018	-	-	-
SI 2014-2017	In the reporting period CA in Slovenija did not received any report of an accident involving GMMs, GM animals or GM plants.	No measures were taken since there were no reports. All neccessary requirements for the emergency cases are implemented in the legislative framework.	
SI 2018	No accidents were reported in the reporting period.	The biosafety framework in Slovenia is covered by horizontal legislation based on Management of Genetically Modified Organisms (MGMO) Act (OJ RS 23/2005 and amended OJ RS 21/2010). The Act	

		implements the provisions of the Directive 2009/41/EC and therefore also the provisions of Articles 14(2) and 15(1). Together with the notification documentation the notifier is obliged to propose a plan of actions in the case of an accident. The plan is assessed by the CA and the Scientific Committee	
SK 2014-2017	No accidents were reported during the reporting period.	No accidents related to contained use activities occured during the reporting period in Slovakia. The notified contained uses did not foresee any transboundary impacts in case of an accident.	
SK 2018	No accidents were reported in 2018.	No accidents related to contained use activities occured during the reporting period in Slovakia. The notified contained uses did not foresee any transboundary impacts in case of an accident.	
UK 2014-2017	There have been no accidents notified to the UKCA as required under Article 14(1) during the reporting period.	Not applicable	Not applicable
UK 2018	Injured person (IP) working in Containment Level 2 laboratory preparing GM non-replicative oncogenic Lister vaccinia virus before transferring the virus in loaded syringes to the Biological Services Unit in the animal unit for inoculation into mice. Whilst preparing the syringes a miscalculation of the amount of virus in the cryotubes led to the IP trying to put some of the viral stock back in to the cryotube using the syringe and inadvertently stabbing the needle into their left forefinger.	The CA carried out a full investigation of the cause of the accident. Immediate causes of the accident and consequences of resulting infection of the member of staff concerned were identified as: - Failure to follow acceptable procedures when using sharps with GM viruses. - Failure to carrying out procedures in the designated laboratory. - Failure to notifying relevant	IP was given sharps training when handling GM viruses and other GM biological agents and the mandatory training courses on GM biosafety for all staff involved in GM work. The IP and other relevant laboratory staff were informed of old accident and emergency procedures. Risk assessment – management of risk assessments for GMOs (vaccinia virus and others) have been reviewed. Risk assessments have been given a defined review period of one year for medium to high residual risk and up to three years for low residual risk. High risk procedures and biosafety

		people about the accident in a timely fashion. Underlying causes were identified as: - Inadequate risk assessment for procedures using sharps with GM biological agents. - Inadequate training and competence assessment for the use of sharps with GM biological agents. - Inadequate accident and emergency procedures and OH provision Report sent to the European Commission	issues such as the use of sharps with virus has been prioritised in relevant risk assessments. All reviewed risk assessments are re-issued to researchers and related staff and recorded. Emergency procedures – formal procedures established and implemented for accident and emergencies when working with GM vaccinia virus and other GM biological agents. Clear lines of communication defined in the event of an accident or emergency and staff made aware of procedures through training. Definitive guidance for staff working with GM vaccinia virus and other GM biological agents when pregnant or immunocompromised has been established and training provided and recorded. Occupational health - the role of OH in accident and emergencies formalised. Agreed protocols produced for post-incident actions with occupational health's role clearly defined and systems in place to ensure they are provided with all relevant information. Training – lessons learnt document prepared and issued across the University for compliance via the H&S Management Groups. Appropriate sharps training for handling GM viruses and other GM biological agents and mandatory training courses on GM biosafety established, implemented and recorded for all staff involved in GM work.

5. Public consultation

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

If yes, provide details of those public consultations and of the information made publicly available as part of the consultations.

2014 - 2017		
AT	No	
BE	Yes	Public consultation is performed, when relevant, through the general procedures established under the regional environmental laws. The procedures for public consultation aim at providing general information to the neighbourhood regarding the contained use of GMOs and/or pathogens. In the Flemish and Brussels Capital Regions, this information is given via a "public dossier", which is a short summary of the full notification drafted by the user and containing information written in everyday language and without any reference to confidential information. The consultation also gives the public the possibility to express comments, observations or objections regarding the contained uses. The CA take the comments, observations or objections into account when drafting their final decision. All decisions are made available to the public for a time-limited period. Appeals against decisions may be submitted to the competent authority within that period. A similar procedure of public consultation is established in Wallonia during the course of the environmental permit demand to the competent authority. In Wallonia, requests for environmental permits for this type of activity are rarely subjected to opposition or comments from residents. In case a remark is made by the public, it is taken into account in the summary report which is sent to the CA and, where appropriate, special operating conditions which should be added to the permit are proposed to the competent authority. In the Flemish and Brussels-Capital Regions, public consultation occurs only in the frame of the environmental permit demand. To that purpose, a copy of the public dossier is joined to this demand.
BG	Yes	During the reporting period no public consultations were conducted, as there is no such requirement when initial approval of facilities for contained use of GMO. Such public consultations should take place before permission is granted for work that involves contained use of GMM Class 2, 3 or 4 and GMO Class B. A public registers of the premises for contained use of GMOs and permissions for work were established and are maintained in an electronic form at http://www.moew.government.bg/bg/priroda/gmo/registri-gmo/ (in Bulgarian only). Information contained in notifications can be received from the Ministry of Environment and water upon request with the exception of confidential and personal data.
CY	No	
CZ	No	

DE	Yes	Public consultation is carried out in case of approval procedures (class 3 or 4 activities). Authorizations are usually published in the Federal State Gazette and on the homepages of the CAs of the Federal States. The following information is published: file number, security level, operator, location of the installation, title of the work, period and location of the public display of the approval documents. The public has the possibility to have the documents sent to them, to see them and to file a complaint against the permit.
DK	Yes	All notifications are registered in a common database between the WEA and the EPA. Other authorities can get access to this database when needed. The public can apply for access following the rules laid down in the law concerning Access to Public Records. Before the EPA makes a decision about the application for production are published in a national and a local newspaper. When the approval is published you have 4 weeks to file a complaint against the decision to the Environmental Appeal board.
EE	No	
EL	Yes	Public consultation is required by law and takes place in cooperation with local/decentralised authorities. However no public consultation took place during the reporting period because no notifications were received.
ES	Yes	Only notifications of class 3 and 4 activities are made available to the public through the Ministry Webpage. Information provided by the notifier is published in compliance with the laws regarding the protection of personal details.
FI	No	
FR	Yes	"Dossier d'information au public" transmis au Maire de la commune d'implantation de la structure
HR	Yes	On website Ministry of Health and Ministry of Science and Education
HU	Yes	The Biotechnology Advisory Board ensures that civil society organizations are involved in the authorisation procedure. The Registry Office appointed by the Competent Authority makes information concerning contained use available. Notifications are published on the internet. The notification of an activity has to include a short, easily understandable summary of the risk assessment for public information purposes, which can be consulted at the Secretariat of the Gene Technology Advisory Board.
IE	Yes	Notifiers submitting applications in respect of Class 3/4 GMM contained use activities are required to publish a notice in a newspaper informing the public of submission of the application to the CA, the nature of the proposed activity and inviting members of the public to make representations to the CA within a period of 4 weeks.
IT	Yes	No public consultations have been carried out during the reporting period. The list of GMM authorized installations is publicly available on the Ministry of Health website, at the following address: http://www.salute.gov.it/imgs/C_17_pagineAree_4243_listaFile_itemName_0_file.pdf Additional information regarding the public consultation: Public consultation is mandatory when a notification for a class 4 premise is submitted to the Ministry of Health. In this case the notifier, at the same time of the submission and at his own expense: a) submits a copy of the notification to the municipality where the class 4 premise is planned; b) the same day the notifier shall issue a notice of the filing of the documentation on the

		two most widely disseminated newspapers in the territory concerned, indicating the place where it is possible to view it. Anyone who intends to provide informative and evaluation elements that he or she considers to be negative for the authorization of the class 4 premise, may submit written comments to the Ministry of Health and the local Authorities within 30 days of the publication of the notice referred to the previous paragraph. Public is also informed before a contained use commences when the MoH considers, on the basis of the Biotechnology Health Technical Committee assessment, that failure of the containment measures can lead to serious danger, whether immediate or delayed, to humans outside the premise and/or to the environment. In this case the MoH informs as soon as possible the Prefect, the Mayor and the Presidents of the concerned Region and Province that draw up the emergency plans promptly and, in any case, within 60 days. The emergency plan is drawn up on the basis of information included in the notification submitted to the MoH. The Mayor is responsible to assure that the population at risk is informed about the relevant safety measures and about the correct behavior to be taken based on the emergency plans. The information included in the emergency plan has to be updated at appropriate intervals. Information on such emergency plans, including the relevant safety measures to be applied, has to be made publicly available The MoH with the support of the Civil Protection Department (Presidency of the Council of Ministers) ensures the appropriate consultations and the exchange of information with the Competent Authorities of the Member States concerned and makes available the same information as that which is disseminated to Italian nationals.
LT	Yes	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.
LU	Yes	A notice indicating the purpose of the application for authorization is posted for fifteen days in the municipality where the operation is planned by the care of the college of mayors and aldermen. The posting must take place no later than ten days after the receipt of the file. The display must take place simultaneously at the town hall and, quite clearly, at the location where the operation is planned. From the day of posting, a copy of the application with its annexes, with the exception of information recognized as confidential.
LV	No	
MT	No	Not applicable.
NL	Yes	In the Netherlands licensing of the GMO contained use facilities and the authorization of contained use activities are two distinct legal processes.

		The contained use facilities for GMO's are part of a general environmental permit for the premises. The public is consulted during this licensing procedure. During the consultation process details concerning the number and containment level of the various rooms destined for contained use of GMO's, are made publicly available. Once such a general environmental permit for the facility is obtained users may start their authorized GMO-activities. The GMO-notifications are not subject to public consultation, but the general public may access a public web-based database to obtain general information on the notifications (such as user, title, municipality of the facility and authorization date).
PL	Yes	We have online register lists with all contained use of GMO/GMM
PT	No	
RO	Yes	The national legislation transposing Directive 2009/41/EC includes provisions regarding public consultation and public information in the decision making process regarding the contained use of GMMs. The approval procedure is public, National Environmental Protection Agency, publishes it on the website www.anpm.ro, within 10 days from acceptance of the notification and within 30 days from the display, receives comments from the public. For the contained use classes 3 and 4, National Environmental Protection Agency holds public debates and elaborates a report that is send to the authorities that are involved in the notification procedure. The public information at the national level is made in collaboration with county environmental agencies that are subordinated to the National Environmental Protection Agency. All risk assessments submitted by the notifiers and the summary of all decisions taken by the competent authority are published on the NEPA website: www.anpm.ro and if necessary, public debates are held during the authorization procedure for contained use of genetically modified microorganisms. Confidential information is treated in conformity with Directive 2009/41/EC. The CA ensuring the confidentiality of the information and of the intellectual property rights. In no case the following information shall be kept confidential: - The general characteristics of the genetically modified micro-organisms, name and address of the notifier, and location of the activity; - The class of contained use and measures of containment; - Any harmful effects on human health and the environment; - The emergency plans.
SE	No	
SI	Yes	Management of Genetically Modified Organisms (MGMO) Act provides that the public is to be consulted on aspects of the proposed contained use in the cases of contained use installations for BSL 3 and 4. Since no notification for BSL 3 or 4 facilities has been received in SLOVENIA no public consulatation was carried out so far.
SK	Yes	The Ministry is obliged to inform the public on the substantial part of the application for approval through the Internet (http://www.minzp.sk/postupy-ziadosti/geneticky-

		modifikovane-organizmy/pripomienky-k-ziadostiam-ohlaseniam/), and by any other appropriate means as well if it is necessary to effectively inform the public, with a call for public comments and with the deadline for their submission. Publicly available are made the substantial part of the application, summary of risk assessment and the emergency plan. The Ministry evaluates the comments after the deadline for submission of comments to the application published and will let the party* and the advisory body of the ministry "The Committee for Biological Safety" to comment on them. The Ministry will not give the party and the advisory body such comments which express general questions on the use of GMOs and personal attitude/opinion and are not specifically related to the genetically modified organism or other issue which the application contains, from a technical point of view. *Party to the proceeding is the applicant and also a civic association under certain conditions Generally, the Ministry is obliged to inform the public through the Internet as well as by any other appropriate means, a) on the substantial part of content of the applications for approval , as well as on issued permits (contained use, intentional introduction of GMO into the environment, placing on the market), b) summary report on issued approvals for contained use classified into risk classes 3 and 4, comprising description, purpose and risks, as well as reporting in form of summary announcement information format, c) evaluation report when products are placed on the market, d) a report on monitoring results, e) information about detected unauthorized introduction into the environment or placement on the market and on adopted safety measures, f) decisions on adopted safety measures.
UK	Yes	The Regulations which transpose Directive 2009/41/EC in GB have been reviewed and consolidated and came into force on 1 October 2014. As part of this process, a public consultation was undertaken. The CA maintains a public register of information on all notifications concerning contained use (with the exception of those withheld for reasons of national security). This contains information on premises and individual contained uses including the nature of the work to be carried out at the premises, the purpose of individual contained uses and the characteristics of the GMOs involved. The register can be found on the HSE website [http://www.hse.gov.uk/biosafety/gmo/publicregister.htm]. In Northern Ireland

		the Register is held at HSENI headquarters 83 Ladas Drive, Belfast. The Scientific Advisory Committee on Genetic Modification (Contained Use) (SACGM(CU)), which provides technical and scientific advice to the UK CA on all aspects of the human and environmental risks of the contained use of GMOs publishes minutes of its meetings and annual reports and has in the past held open public meetings although no public meetings were held during this reporting period. The CA in GB has received a number of requests for information relating to GMMs under the Freedom of Information Act/Environmental Information Act, all of which have been answered to deadline.

2018		
AT	No	
BE	No	
BG	No	
CY	No	
CZ	No	
DE	Yes	Public consultation is carried out in case of approval procedures (class 3 or 4 activities). Authorizations are usually published in the Federal State Gazette and on the homepages of the CAs of the Federal States. The following information is published: file number, security level, operator, location of the installation, title of the work, period and location of the public display of the approval documents. The public has the possibility to have the documents sent to them, to see them and to file a complaint against the permit.
DK	Yes	All notifications are registered in a common database between the WEA and the EPA. Other authorities can get access to this database when needed. The public can apply for access following the rules laid down in the law concerning Access to Public Records. Before the EPA makes a decision about the application for production are published in a national and a local newspaper. When the approval is published you have 4 weeks to file a complaint against the decision to the Environmental Appeal board.
EE	No	
EL	No	
ES	No	
FI	No	
FR	No	Néant
HR		
HU	No	
IE	Yes	During 2018, one notification for the contained use of a Class 3 GMM was submitted to the CA, in respect of which, the notifier published a notice in a newspaper circulating in the district of the proposed contained use activity. The notice informed the public of the submission of the notification to the CA, the nature of the proposed activity and invited members of the public to make representations to the CA within a period of 4 weeks.
IT		
LT	No	
LU	No	
LV	No	
MT	No	N/A
NL	Yes	In the Netherlands licensing of the GMO contained use facilities and the authorization of

		contained use activities are two distinct legal processes. The contained use facilities for GMO's are part of a general environmental permit for the premises. The public is consulted during this licensing procedure. During the consultation process details concerning the number and containment level of the various rooms destined for contained use of GMO's, are made publicly available. Once such a general environmental permit for the facility is obtained users may start their authorized GMO-activities. The GMO-notifications are not subject to public consultation, but the general public may access a public web-based database to obtain general information on the notifications (such as user, title, municipality of the facility and authorization date).
PL		
PT	No	
RO	Yes	All the notifications are published on the website of NEPA. Public information at the national level is performed in cooperation with the county environmental agencies, functioning under the National Environmental Protection Agency. All the risk assessments submitted by the notifiers and the summary of all the decisions taken by the competent authority are published on the website of NEPA: http://www.anpm.ro/biosecuritate , http://www.anpm.ro/notificari.
SE	No	
SI	No	
SK	No	
UK	No	

5.2 *(if yes to question 5.1)* Provide details of any public reaction, if received, in response to the consultations.

2014 - 2017	
BE	In Wallonia, there was only one dossier for a permit application concerning the contained use of genetically modified organisms of risk class 2, for which there was an observation during the public inquiry concerning the proximity of the laboratory to the residences and a school. In the Flemish and Brussels Capital Regions, there was no public reaction received in response to consultations and/or information made publicly available under Directive 2009/41/EC.
BG	No public reactions have been received so far about contained use of GMO.
DE	none
DK	None
EL	
ES	No comments were received.
FR	Pas de réactions portées à notre connaissance
HR	not applicable
HU	No public reactions received to date.
IE	No public reaction has been received in response to consultations and/ or information made publicly available to date.
IT	N.A.

LT	There were no public reaction received.
LU	None received
NL	The public consultation concerns the facility in its entirety and not only or specifically the GMO facilities within such a premises. In general, received public comments focus on the overall premises, and very rarely on the aspect of the GMO facilities in particular.
PL	
RO	Not applicable.
SI	Since no consulatations were carried out, no reactions were received.
SK	No reactions from public were received in the reporting period.
UK	A summary of responses to the consultation on the proposed consolidation of the Genetically Modified Organisms (Contained Use) Regulations, which were predominantly supportive of the proposals, has been published at: https://webcommunities.hse.gov.uk/connect.ti/HSEmeetings/view?objectId=618981

2018	
DE	no response
DK	None
IE	No public reaction was received.
NL	The public consultation concerns the facility in its entirety and not only or specifically the GMO facilities within such a premises. In general, received public comments focus on the overall premises, and very rarely on the aspect of the GMO facilities in particular.
RO	Not applicable

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.

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

2014-2017	
AT	none
BE	There are some elements to be considered for the interpretation of the GMO definition in the context of Gene Editing techniques. The CA of the Flemish Region got a request concerning genetic modifications induced in plants and animals by the transient presence of the CRISPR/Cas9 system delivered as purified ribonucleoprotein with or without a homologous repair DNA template. Does this fall under the scope of the legislation of contained use? Based on an advice from the SBB on this request, the CA concluded that the intended uses under containment of animals and plants genetically modified as described before should be considered for exclusion from the scope of the Decree of the Flemish Government of 6 February 2004, according to Annex 15 B of this Decree (Annex II Part A of Directive 2009/41/EC).
BG	There is no clear procedure to distinguish whether a clinical trial of products containing genetically modified organisms (both for human and for veterinary use) should be considered contained use and when release into the environment.

	It is not entirely clear how the provisions of the Directive should be applied in some special cases, e.g. when GMM is administered in hospital during clinical trial or in the case of microorganism collections where the organisms are stored under cryogenic conditions. It is not clear whether in those cases notifications of the premises should be submitted.
CY	None.
CZ	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.
DE	A clear position of Commission is still missing whether new techniques of genetic modification (ODM, using nuclease derived techniques (e. g. CRISPR-Cas)) fall within the scope of Directive 2009/41/EC. Some CAs of the federal states further encountered problems with the interpretation of Annex IV of the Directive 2009/41/EC and suggested a more precise wording of standards.
DK	Scientist in some cases are confused to which class is appropriate for their laboratory work. This is especially true concerning Adeno associated virus vectors.
EE	there is not this field activity in Estonia
EL	No difficulties in interpretation.
ES	In Spain, clinical trials with GMOs are regulated as deliberate reléase activities, but it is not clear if facilities in which GMOs are handled or stored must be notified as contained used activities. There are also problems in the interpretation if products obtained by new genetic techniques, and whether they are under the scope of Directive 2009/41/EC or not.
FI	1) The definition of a GMO is getting increasingly vague because new molecular biology techniques have evolved. It is no longer clear which organisms are actually covered by the directive. 2) The concept of premises is obscure in certain cases, e.g. where rodents are transported in Scantainers or plants in closed growth chambers to another room or building for temporary procedures (such as photographing or scanning). In research, unanticipated needs for moving the GMOs temporarily to new premises for non-repeating procedures may arise quickly, which can cause an administrative problem.
FR	Pas de difficulté
HR	/
HU	New techniques not considered to result in genetic modification can trigger interpretation problems. Another problem is how to distinct between contained use and deliberate release (i.e. which directive to apply: Directive 2009/41/EC or 2001/18/EC) in case of clinical biotechnological applications. We propose to continue the discussions at EU level regarding this important issue.
IE	1. New techniques, 2. Procedure for the notification of Class 1 GMM activities.
IT	GM plants and GM animals

	It should be clarified whether the contained use of GM plants and GM animals have to be covered by Directive 2009/41/EC or Directive 2001/18/EC. The definition of contained use given in Directive 2009/41/EC include GMM and not GMO.
LT	No specific aspects with the interpretation of the provisions were reported.
LU	/
LV	-
MT	None.
NL	Although the directive is relatively recent, technological developments in the GMO field are huge and lead to problems related to (A) definition of GMO's in relation to, among others, synthetic biology and gene editing techniques, and (B) differences in interpretation of the annexes between the Member States. These problems are similar with the problems encountered with directive 2001/18.
PL	None
PT	No difficulties have arisen regarding interpretation of the Directive 2009/41/EC.
RO	Not applicable
SE	There are no definitions of "recombinant nucleic acid" and "mutatgenesis", that sometimes give rise to academic discussion whether a method is included or not within the scope of the Directive. SWEA interprets "mutagenesis" as the well known techniques with chemical or physical mutation methods, common at the time of the first Directive 1990 (90/219/EEC) and not the later methods involving nucleic acids and site specificity. We try to explain this on our website. It is difficult to understand why some "new" methods should be included and why some should not. Of the "new techniques", it is unfortunate that the Crispr-Cas-techniques are interpreted as only one type. We have several GMM uses involving Crispr-Cas and gene editing, where both the Cas-gene and gRNA are provided by vectors in cells (or cells in laboratory animals). The purpose for those experiments are often to explore gene function and the cell cultures or laboratory animals are never going to be anything else than experiments. Hence, there is no commercial aspect for not calling the experiments "contained use of GMM"
SI	None.
SK	-----
UK	The UK has no significant issues with the interpretation of the Directive.

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

2014-2017	
AT	none
BE	/
BG	No major difficulties have been experienced in implementing Directive 2009/41/EC during the reporting period.
CY	None.
CZ	The same problems as mentioned in the previous point.
DE	There is only one waste disposal facility in Germany for the incineration of class 2 waste. This challenges the inactivation of larger elements such as HEPA filters contaminated with cytostatica.

DK	The class 1 notifications.
EE	N/A
EL	No difficulties in implementation.
ES	The difficulties on the implementation of the Directive are related to the difficulties described in the preceding paragraph.
FI	1) As mentioned in the previous point, the outdated definitions of the directive 2009/41/EC for GMMs have been a major problem in the implementation. The legal uncertainty caused by this is getting increasingly difficult for both the operators, CAs and the supervisory authorities, as it is no longer clear which organisms are actually in the scope of the directive. 2) Classification of viruses and cell cultures has also been problematic in some cases. A special problem has been the classification of pathogens that have been attenuated (= can an attenuated pathogen ever be considered apathogenic according to the directive, and if so, on what conditions?). 3) Research groups move frequently from one institution to another, which means they have to repeatedly send new notifications of their new premises. During the reporting period, many of the old premises have also been renovated, meaning that the notifiers sometimes have moved temporarily into other premises and then back to the old building where the facilities have changed. As the research units are typically large and complex, this has caused a great administrative burden. 4) Waste management of Class 1 organisms has been problematic in some cases. Biological waste can no more be dumped and incineration of wet or moist biowaste is not recommendable for environmental reasons, some operators would like to recycle their contained use waste. Rather than a technical issue, this is an administrative problem, as the interplay of GMO, waste, transport and fertilizer legislations is a real challenge. 5) The development of chemicals legislation has led to a situation where users of pathogenic GMMs have few effective disinfectants available. The users in the laboratories are also poorly informed about the suitable products presently available for their particular GMMs.
FR	Pas de difficulté
HR	/
HU	None.
IE	1. How new techniques (those techniques discussed by the new techniques working group (2007 - 2012) and more recently such techniques as CRISPR-Cas and TALEN) will be regulated under Directive 2009/41/EC. 2. The notification of Class 1 GMM activities which present no or negligible risk to the environment. They are usually crippled strains that would not survive in the environment and often they have a long history of safe use. The notification procedure is time consuming.
IT	Waste disposal:The monitoring of waste disposal is carried out at regional and national level by several CAs. To date the information required about waste management, including the type and form of wastes generated, their treatment, final form and destination are assessed on documental basis with the notification. To implement the verification procedures could be difficult to realize.

	Accidents: As no accident were reported to GMM CA at least since June 2009, it is presumable an undereporting of the accidents by the users. The GMM CA considers this aspect difficult to improve. Gene drive modified organisms No explicit reference, definition and measures are given in the Directive 2009/41/EC for gene drive modified organisms.
LT	No specific aspects with the implementation of the Directive were reported.
LU	Directive not yet transposed
LV	-
MT	None.
NL	(1) New apparatus (e.g. large pipetting robot) in relation to the needed containment measures, (2) the use of desinfectants that have not, or not yet been admitted as a biocide for use under laboratory conditions, (3) the Netherlands encounter differences in the (strict) GMO-regulations and the less strict regulation of wild type pathogens. This could partly be explained by the implementation of the legislation in the Netherlands, but seems also caused by a lack of harmonization at EU level.
PL	None
PT	No difficulties have arisen regarding implementing of the Directive 2009/41/EC.
RO	Not applicable
SE	The notification procedure for Class 1 and Class 2 is of limited value. We think that it could be simplified in the Directive for Class 1 and Class 2, only including information on class, type of activity, organisation involved, contact information for responsible persons and address to the workplace.
SI	The greatest burden for the CA are notifications which contain a lot of information, that need to be processed in the notification procedure. Assessing risks of the notified organisms is a very responsible task. On the other hand the notifiers complain that the preparation of the notifications and risk assessments are laborious and time consuming. There is a fine line between necessary and redundant information.
SK	-----
UK	The UK applies a hazard and risk-based approach to its regulation and inspection activities. The UK has recently consolidated the Genetically Modified Organisms (Contained Use) Regulations 2000 and its amending regulations, which transpose the Directive, to make them more risk based and proportionate and more closely reflect the requirements of the Directive. The UK is able to implement a regulatory framework that permits the risks from contained use of genetically modified micro-organisms to be controlled in a risk based and proportionate manner. The greatest burden on the CA in the UK, from the implementation of the Directive, is in the technical assessment of class 2 notifications. Whilst the UK ensures that all notifications are reviewed, and endeavours to ensure statutory timescales are met, the time spent reviewing lower-risk class 2 activities is disproportionate due to the amount of information required and the volume of notifications received (~90% of activity notifications are class 2). Furthermore, a large proportion of these notifications (~50%) involve work with multiply disabled viral vectors, the risks from which are well defined and the control measures established. The consequence of this is that the majority of the CA time spent on reviewing notifications is biased towards the lower risk work. One further aspect of the Directive that places a burden on the CA is the emphasis, within the definitions of genetic modification in the Directive, on the techniques used in the contained use to determine whether or not the Directive applies. Given the rapid nature

	with which techniques are developed and adapted, this can present challenges for interpretation and potential for disproportionate application of the legislation.

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

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

2014-2017		
	6.3 From the difficulties you have identified in the previous reporting periods, which ones have you solved at national level and how?	**6.4 What should be done or is done already to address the difficulties identified?**
AT	not applicable	not applicable
BE	See above for the Gene Editing techniques.	With regards to the regulatory status of organisms genetically modified through the use of Gene Editing techniques, a harmonized legal interpretation at EU level is urgently needed.
BG	One difficulty observed during the previous reporting period was that most academic institutions were not aware that facilities for contained use of GMO should be approved and registered even when they work only with model organisms routinely used in scientific research (e.g. laboratory strains of E.coli, Arabidopsis thaliana, etc.). The awareness of the requirements and obligations when GMO is used under containment has improved significantly. In addition, Ministry of Environment and Water regularly informs the Customs Agency and the government agencies that fund scientific research about the institutions that have premises with valid notifications for contained uses of GMOs. That information should be taken into account when decisions are made for import of GMO for contained use and for funding scientific research.	In application for clinical trials, the applicant is required to provide information as a filled form on the containment measures for each hospital (which should be registered as such under the Bulgarian legislation) where the medicinal product will be administered. That information is not considered formal notification. In all applications examined so far activities were considered Class 1.
CY	Not Applicable.	Not Applicable.
CZ	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	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.

	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.	
DE	With regard to the distinction between genetic engineering activities in containment and approvement of clinical trials with GMOs, an administrative agreement was reached in March 2015 between the relevant federal and competent authorities.	There are many discussions how to interpret the GMO definition. The ZKBS adopted position statements concerning the assignment of new breeding techniques and organisms resulting from the use of modern nuclease technologies.
DK	No problems have been solved at a national level.	The only suggestion is that class 1 notifications are taken out of the Danish legislation.
EE	Not difficulties	N/A
EL	No difficulties.	No difficulties.
ES	We have asked European Commission to advise our CA about the difficulties concerning the interpretation and implementation of the Directive described in preceding paragraphs. CNB periodically updated national guidances regarding contained uses activities. An electronic procedure has been launched to improve our system for processing of notifications.	It would be desirable to have harmonised Guidelines at EU level (from the Commission) regarding: 1) Clinical Trials in order to clarify whether they have to be carried out under the scope of Directive 2009/41/EC or/and the Directive 2001/18 /EC (or both, "case by case"). 2) Problems in the interpretation if GMOs obtained by new genetic techniques, and whether they are under the scope of Directive 2009/41/EC or not.
FI	Only one where a case was solved concerning recycling of Class 1 GMM waste. This required extensive testings by the notifier and their collaborators on different procedures and showing that the composting process chosen really inactivates the GMMs (ie. that there are no live GMMs in the composted material which is to be recycled).	We have tried to communicate the EU-level difficulties to the Commission and the relevant national authorities.
FR	Néant	Néant
HR	/	/
HU	No relevance.	No relevance.
IE	During the last reporting period the regulation of Class 1 GMM contained use activities was identified as being problematic. These activities continue to be	1. Some direction from the Commission on the evaluation of new techniques in terms of whether they fall within the scope of the GMO legislation and that this be done in a

	regulated since it is a legislative requirement however the submission of annual reports by the user is no longer required and Class 1 GMM contained use activities are inspected once every 6 years.	harmonised way. 2. The notification requirements for Class 1 GMM contained use activities could be aligned with Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work which does not require the notification of activities involving risk group 1 biological agents.
IT	N.A.	A better cooperation with the different National Competent Authorities and an harmonized approach throughout Europe could result useful for the CAs and the users
LT	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.	-
LU	The national law is under revision	The national law is under revision
LV	-	-
MT	Not applicable.	Not applicable. However, further training and capacity building would be relevant to pre-empt any future difficulties.
NL	In the last report we signalled issues related to single use bioreactors and cell sorters (FACS). For the latter general measures were developed and included as provisions in the Ministerial Order. For single use bioreactors general information requirements were developed and implemented in the daily practice.	For (1) discussions at EU level might be helpful. For (2) EU-action seems logical. Numbers correspond with answer on second question.
PL	None	Dissemination of actual law and rules for applicants.
PT	No difficulties have been identified in the previous reporting period.	No difficulties have been identified.
RO	Not applicable	Not applicable.
SE	n.a.	The notification procedure for Class 1 and Class 2 is of limited value. We think that it could be simplified in the Directive for Class 1 and Class 2, only including information on class, type of activity, organisation involved, contact information for responsible persons and address to the workplace.
SI	In collaboration with Slovenian Biochemical Society we prepared and published a brochure which gives examples of	Inclusion of safe organisms in Part C of the Annex II of Directive 2009/41/EC could contribute to reduction of the size of the

	notification forms and adequate documentation needed for the notification od BSL 1 an BSL 2 installations and organisms. We have a positive feed back from the notifiers.	notifications.
SK	------	------
UK	The UK CA has streamlined the notification system to spend less time assessing class 2 activities as the risks are likely to be well understood by users with limited consequences in the event of loss of containment or accidental exposure. This involves targeted assessment identifying key biological hazards and foreseeable risks (routes of exposure/loss of containment) which could realise the hazard based on the nature of the activity.	The notification requirements for class 2 contained uses could be aligned with Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work which requires only the first class 2 contained use at a given premises is required to be notified. Subsequent class 2 contained uses could be carried out, following approval by an internal safety committee, without the need to notify the national CA. Alternatively, the information requirements for class 2 notifications could be minimised (e.g. a description of recipient organism, donor material, evaluation of foreseeable effects and an indication of class). This would limit the requirement from users in providing the relevant information and the time spent by the CA in assessing compliance with the legislation. Similarly the EC could populate the Annex II Part C of the Directive with a list of multiply disabled vectors for class 1 contained uses - this would provide greater delineation of class 1 and 2 contained uses and minimise the degree of over classification. This approach would allow the CA to divert more resource to the assessment of high hazard work, including reviewing notifications and inspections. The definitions of genetic modification within the Directive should be reviewed to ensure they take account of technological advances, new fields or disciplines (e.g. synthetic biology) and there should be an effective means of implementing any revisions. Alternatively, consideration should be given to shifting the emphasis from the technique to the final product in determining whether the GMM is encompassed by the legislation.

Questionnaire 2018

6. Interpretation and implementation of Directive 2009/41/EC. Please provide information regarding notifications of contained uses of GMMs (and GMOs when appropriate) produced with new mutagenesis techniques:

AT	1 notification: Use of the commercial do-it-yourself "Bacterial Gene Engineering DIY-CRISPR-Cas9-Kit" (The Odin) with E.coli K12 as recipient organism for educational purposes (school project)
BE	New mutagenesis techniques, particularly the CRISPR/Cas systems are used and notified since around 2015 in research and development by several investigational groups (universities, companies). The system is used to modify genetically animal and human cells (cell lines and primary cells), plant cells and other micro-organisms. Transgenic animals (mice, xenopus) and plants obtained by the CRISPR/Cas systems have also been notified in Belgium.
BG	No notifications of contained uses of GMMs and GMOs produced with new mutagenesis techniques have been received so far in Bulgaria.
CY	There have not been used new mutagenesis techniques.
CZ	Organisms (microorganisms - mostly cell cultures, some plants and laboratory mice) produced by new mutagenesis techniques had been considered as GMOs within the scope of the Czech Act on GMOs (Act No. 78/2004 Coll.) even before ECJ ruling of July 2018. These GMOs were used only in contained space.
DE	Most of these procedures are only recorded by the researcher and not notified to the authorities. The details are not known to the authorities. Nevertheless, new mutagenesis techniques (especially CRISPR-Cas9) are widely used to generate knock out-, knock in-, and point mutations mostly into the genome of human or mammalian cells in culture. There are also approaches to modify the expression of viral proteins (HPV, HIV-1). The CRISPR-Cas9-system is going to be transferred directly as ribonucleoprotein complex, by plasmids, or by viral vector systems.
DK	N/A
EE	N/A
EL	No notifications produced in reporting period
ES	This information has already been sent to the CA in the European Commission.[3]

[3] Spain provided a document "LEGISLATION ON GMOs AND THE IMPACT OF THE JUDGMENT OF THE EU COURT OF JUSTICE ON DIRECTED MUTAGENISIS", which had two sections related to the contained use of organisms obtained by new mutagenesis techniques:
"*The implication of the Court ruling on deliberate release and confined use activities is also analyzed. Seventeen notifications of contained use activities were presented to national competent authorities between 2015 and 2018. All notifications were evaluated according to the case by case principle and the safety of the final products was considered using the same methodology described in current legislation for GMO. The questions arise on whether this methodology will be applicable for new technological developments.*
In terms of research, development and innovation, the wide range of applications derived from the new genetic editing techniques is highlighted. The growing interest in genome editing results in an increase of scientific publication in recent years. More than 20 species have been used in agricultural research studies, analyzing several characteristics such as the impovement of productive yields or the biotic and abiotic stress. The National Research Agency has financed more than 800 projects including genome editing actitivities. This number it is expected to increase in the future. The authorization procedure of these activities (mainly contained use activities) will delay their implementation by EU researchers in comparision to those from other countries. This will reduce their competitiveness in terms of novelty in publications, technological transfer or patents."
"*Between 2015 and 2018, 17 notifications were received of activities involving the contained use of genetically modified organisms with new techniques. The modified organisms were principally cells, but also animals and viruses. These notifications are addressed according to the precautionary principle and on a case-by-case basis.*

FI	Requirement for the notification of this type of information (specific details on the techniques used) is not stipulated in the national GMO regulations, and therefore it cannot be collected comprehensively from individual notifications. Hence, we have currently no statistics on the use of new mutagenesis techniques in contained use. Information on new mutagenesis techniques is sometimes obtained on a voluntary basis e.g. when the operators describe such activities in a notification, report them during inspections, or when the operator asks the CA for clarification of the scope of the Gene Technology Act.
FR	Le nombre de dossiers est stable sur les quatre dernières années (un peu plus de 1000 dossiers de demande d'autorisation par an).
HR[4]	
HU	Up to date there are no new notifications concerning activities on new mutagenesis techniques.
IE	Five notifications for contained use activities involving organisms produced using new directed mutagenesis techniques' were received during 2018. • 4 notifications with cells; and, • 1 notification with a yeast.
IT	
LT	The Competent Authority of Directive 2009/41 has not received any application linked to new mutagenesis techniques yet.
LU	No notifications were received using new mutagenesis techniques.
LV	No notifications
MT	N/A
NL	Please see also the earlier sent document "NL response to questions court ruling 13dec.DOCX"[5]. Regarding contained use: NL has consistently considered applications of NBTs in the Netherlands as GMOs, except for the use of "traditional" mutagenesis techniques (induced by exposure to chemical substances or irradiation). Dutch national authorities have applied the EU GMO legislation to these organisms and their products in accordance with Directive 2009/41 and in conformity with relevant elements of the Court Ruling in this regard.
PL	
PT	None notification was submitted with GMMs produced with new mutagenesis techniques.
RO	NEPA registered a notification under the Directive 2009/41/EC on the contained use of Listeria monocytogenes, in order to obtain a genetically modified strain of Listeria monocytogenes in containment conditions to establish the high pressure stress response

They were therefore submitted and assessed according the procedure laid down in the national legislation for activities involving the contained use of GMOs."

[4] Croatia has not submitted a report for the year 2018 but provided a statement on the "Directive 2009/41/EC and new mutagenesis techniques":
"In accordance with your request, we hereby would like to inform you that Croatian competent authorities for contained use of GMOs have considered applications of NBTs in the Republic of Croatia as GMOs, except for the use of "traditional" mutagenesis techniques (induced by exposure to chemical substances or irradiation).
In the Republic Croatia there were notified 52 closed systems of contained use of GMOs by the end of 2018. According, at last information that only in 14 closed systems of contained use of GMOs were used new mutagenesis techniques such as ODM, CRISPER/ Cas9, cisgenesis, intragenesis and agro infiltration.
Croatian national authorities have applied the EU GMO legislation to these organisms and their products in accordance with Directive 2009/41 and in conformity with relevant elements of the Court Ruling in this regard."

[5] Section of that document related to the contained use of organisms obtained by new mutagenesis techniques:
"*NL has consistently considered applications of NBTs in the Netherlands as GMOs, except for the use of "traditional" mutagenesis techniques (induced by exposure to chemical substances or irradiation). Dutch national authorities have applied the EU GMO legislation to these organisms and their products in accordance with Directive 2009/41 and in conformity with relevant elements of the Court Ruling in this regard.*"

	mechanism. This activity with genetically modified microorganisms that was authorized in 2018, uses classical mutagenesis and CRISPR - Cas 9 (NT) technique.
SE	There are no definitions of "recombinant nucleic acid" and "mutatgenesis", that sometimes give rise to academic discussion whether a method is included or not within the scope of the Directive. SWEA interprets "mutagenesis" as the well known techniques with chemical or physical mutation methods, common at the time of the first Directive 1990 (90/219/EEC) and not the later methods involving nucleic acids and site specificity. We try to explain this on our website. It is difficult to understand why some "new" methods should be included and why some should not.
SI	Several laboratories use new mutagenesis techniques to prepare GMMs for a research purpose in Slovenia, all of the projects were notified to the CA. No gene drive projects were proposed for the time being.
SK	In Slovakia, 4 users are actively working with new mutagenesis techniques and GMMs/GMOs produced thereof. Activities are classified under risk class 1 and class 2. user A GMO organisms: non-pathogenic bacterial Escherichia coli and yeast Saccharomyces cerevisiae and Pichia pastoris strains used for research laboratory work only. Aminoacid exchanges of several selected amino acid residues in yeast and human Ire1 proteins and plant nasturtium Tropaeolum majus xyloglukan endotransglycosylase protein TmXET6.3 were performed by mutagenesis of respective genes in cloning plasmids using QuikChange II Site-Directed Mutagenesis Kit (Agilent Technologies). Mutated variants has been cloned into expressing yeast vectors and tested for changed phenotype in yeast or by in vitro assays. Aim of these works: The amino acid exchanges were made for structure/function analysis of the proteins (enzymes) mentioned above. user B The recipient: XL-1 Blue supercompetent cells The donor: Homo sapiens; Mus musculus Targeted mutagenesis, transformation caused by thermal shock Aim of these works: Plasmid storage and isolation / Scientific purposes, antibody testing user C 1.) bacteria, yeast Targeted mutagenesis techniques have been performed to exchange codon bases, deletion of genes, labeling of genes of interest, or fusions with various DNA fragments. Purpose: basic research 2.) Mycobacteria Standardly used e.g. allele exchange methods that result in interruption or deletion of the genes under study that can be considered as targeted mutagenesis.

	user D silkworms - Bombyx mori (several dozens over several generations) Purpose: suppression of gene expression for neuropeptides and their receptors by CrisprCas9 system (deletion / mutation of genes) - functional analysis of neuropeptides and their receptors
UK	This would be too difficult to answer due to lack of available resource to revisit and interrogate every single notification received as we have received in 2018. This is approximately 220 notifications and we would envisage that around half of these involve some from of new mutagenesis techniques.

Questionnaire 2018
Please provide information and views on the impact of the outcome of the ruling of the Court of Justice of the European Union on new mutagenesis techniques for you as CA for Directive 2009/41/EC. Provide also information on how such impact is or will be addressed in your country:

AT	No impact, as according to the Austrian Gene Technology Act only non-directed mutagenesis is exempted. Therefore all new mutagenesis techniques are fully covered by the Austrian legislation.
BE	There is no impact of the outcome of the ruling of the CJE on new mutagenesis techniques for us in contained uses of GMOs. Risk assessment and management of contained uses of GMMs and GMOs obtained by these new techniques are performed in the same way as other GMOs obtained by techniques already aimed by Directive 2009/41/EC (annex 1, part A).
BG	The following considerations might be relevant to the questions posed: 1. The Court ruling is in the context of Directive 2001/18/EC, and not Directive 2009/41/EC. Directive 2009/41/EC does not refer directly to Directive 2001/18/EC, but at the present stage, we work with the assumption that the Court ruling will be relevant to the contained use of genetically modified microorganisms (GMMs). The exact consequences though remain to be formally established (see our comments below). 2. The definition of GMMs is given in Article 3 in conjuncture with Annex I of Directive 2009/41/EC, while the definition of genetically modified organisms (GMOs) is given in Article 2 in conjuncture with Annex I of Directive 2001/18/EC. The definitions are practically identical, so we consider that any conclusions related to the definition of GMO are likely be relevant with the necessary changes to the definition of GMM. The conditions for exclusion of organisms from the scopes of the Directive 2009/41/EC and Directive 2001/18/EC are given in Annex IIA and Annex IB respectively. They are similar to some extent but there are significant differences. The exclusion criteria in Directive 2009/41/EC are broader and include cell fusion of all types of cells and even more importantly self-cloning. Under some circumstances, application some of the new techniques for genome modification, might be considered to result in self-cloning. Notably Directive 2009/41/EC does not contain recital equivalent to recital 17 of Directive

	2001/18/EC. In the light of the Court ruling it will seem that in order to the exclude a GMM from the scope of the Directive 2009/41/EC is enough to fulfill the criteria in Annex IIA, without necessity to demonstrate that the organisms are obtained by means of techniques/methods which have conventionally been used in a number of applications and have a long safety record. Under this interpretation some of GMMs obtained by gene editing, might be considered result of self-cloning and thus outside the scope of Directive 2009/41/EC. 3. Directive 2009/41/EC does not cover GMOs other than GMMs. It remains unclear whether and to what extent the national legislation regulating the contained use of GMO different from GMM should follow Directive 2001/18/EC or Directive 2009/41/EC, in particular with the respect to the definition of GMO and the exclusion criteria. Thus the relevance of the Court ruling in those cases remains unclear to us. 4. Bulgaria considers the organisms, incl. microorganisms, obtained through the use of gene editing and other similar techniques to be GMO and thus applies the relevant national legislation for contained use. Bulgarian national legislation on contained use of GMO covers not only GMMs but also all other GMOs. 5. We expect that the main difficulty in applying and enforcing the relevant legislation for the contained use of GMOs obtained through gene editing or some other techniques will be their detection and identification. As stated in a number of replies from the MS in the context of Directive 2001/18/EC, detection and identification of such GMOs can be a significant technical and financial challenge when the introduced changes are very small and/or not known in advance and in some cases it might be outright impossible. In the case of microorganisms additional difficulties will arise from the high natural variability of their genomes and the fast rates of evolution. It can be impossible to decide on the basis of sequencing data alone if a certain DNA pattern is result of natural process, chemical or physical mutagenesis, traditional genetic engineering or use of gene editing. 6. The considerations above show that there might be some legal uncertainties about the application of Directive 2009/41/EC in the light the Court ruling on Case Case C-528/16. It will helpful if the European Commission requests an opinion from its Legal Services on that issue and provides it to the member states as a background for further discussions. 7. It should be noted that the European GMO legislation has been developed with agricultural (plants in particular) applications and the traditional genetic engineering techniques in mind. The field of biotechnology is strongly technology driven and modern applied molecular biology has undergone huge progress in the last 15 years. In order to ensure high level of protection of human health and environment, while allowing the citizen to benefit fully from the new technologies European regulatory framework should adequately reflect the recent technical developments. The issues surrounding gene editing and some other topics seem to show that it is increasingly difficult to accommodate the developments of modern biotechnology by non-legislative means. So in future discussions, serious consideration should be given to the possibility to amend or fully update the European GMO legislation.
CY	No views.
CZ	As regards primary research, the ECJ ruling means only administrative burden for scientists. What is more detrimental, is the impact on innovations. Projects aiming at

	developing gene edited crops are not realized because it would be practically impossible to place a new GMO on the market in EU.
DE	In the past, several Federal States have regulated genome-edited organisms as genetically modified organisms on a precautionary basis, since the European legislation has left room for interpretation on this topic. These Federal States do not see major practical problems if the decision of the European Court of Justice (ECJ) is applied also to the field of contained use. Nevertheless, the application of the decision of the ECJ on the area of directive 2009/41/EC (similar to placing on the market as regulated in 2001/18/EC) does not clarify the legislation, but raise additional questions. This regards the following topics: - self-cloning using new molecular techniques (SDN3) – will it continue to be exempt from regulation under directive 2009/41/EC? - who decides on the time point when mutagenesis techniques can be regarded as safe? What are the criteria for this decision? - using CRISPR-Cas9 variants (new molecular techniques, NMT) like dCas9 with non-functional nuclease, gene function can be transiently altered. Will the application of these techniques lead to the creation of GMOs, even if the genomes of the organisms are not altered? - will the use of the dCas13 variant (also a NMT) only modifying RNA also lead to the creation of a GMO? Genetic engineering operations need to be monitored by the responsible competent authorities. The surveillance of organisms which can not be distinguished from organisms arisen from classical mutagenesis rises problems regarding detection methods of GMOs not only for deliberate release but also in the field of contained use. Directive 2009/41/EC does not seem to be well equipped for risk assessment of genome-edited organisms resulting from SDN3 techniques.
DK	N/A
EE	N/A
EL	No noticeable impact currently under the framework of 2009/41/EC due to lack of reported cases of contained use in Greece
ES	This information has already been sent to the CA in the European Commission.
FI	Currently the legal situation is ambiguous as to whether the ECJ Decision applies to contained use or to certain traditional mutagenesis techniques other than chemical or radiation mutagenesis. In this legally uncertain situation, the Board for Gene Technology has made a non-consensus interim decision that contained use is out of scope of ECJ Decision. However, the Board has also asked for Commission Legal Service's clarification on the situation, especially in the context of deletion mutagenesis where no foreign DNA is inserted in the genome. Currently the legal status of new mutagenesis techniques in contained use is evaluated by the Board on a case-by-case basis, as some variations of these techniques (e.g. gene drives) may result in GMOs.
FR	Le nombre de dossiers à traiter pourrait être multiplié par 10 voire 20. L'AC n'a pas les moyens administratifs de traiter un tel flux selon les règles actuellement applicables aux

	OGM
HR	
HU	After the ruling of the Court of Justice of the European Union on new mutagenesis techniques the gene technology authority requested the users to report about all the gene technology activities including the activities on new mutagenesis techniques that are currently carried out in class 1. Furthermore the gene technology authority informed all the stakeholders about the outcome of the ruling and called upon them to submit notifications for authorisations with regard to class 2, 3 and 4, if applicable.
IE	To date the Irish CA has considered organisms produced using 'new directed mutagenesis techniques' to be GMOs, and has applied the GMO legislation accordingly. However as raised by other MS in more recent times, the basis for applying the ECJ ruling to Directive 2009/41/EC needs to be clarified since the ECJ based its decision on Directive 2001/18/EC. In addition Directive 2009/41/EC relates to the contained use of Genetically Modified Micro-organisms (GMMs). The scope of national transposing legislation was expanded to include GMOs other than GMMs (GM plants and GM animals). This makes the connection between the ECJ decision and its application to GMOs even more tenuous. Other difficulties arising from the ECJ ruling include detection and identification of GMMs / GMOs generated using new directed mutagenesis techniques.
IT	
LT	There is no experience how to handle such type of Applications and what criteria to use for risk assessment and how to assess the risk itself. It would be helpful better explanation of the list of New mutagenesis techniques and what risk assessment methodology and safety measures to use for each New mutagenesis technique. Harmonized EU legislation of New mutagenesis techniques would be welcome.
LU	Clarification is needed as Annex II of directive 2009/41 excludes mutagenesis from the techniques generating GMM. No information is available if targeted or random mutagenesis is meant? Do notifications have to be addressed to CA by users when NMT are applied since they are not considered to produce GMM according to Annex II of directive 2009/41? Directive 2009/41 does not have an equivalent to recital 17 of directive 2001/18 which excludes organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record. Clarification is needed how organisms generated through NMT are to be considered GMM or non GMM? Since the ruling of the European Court of Justice now states that all mutagenesis techniques invented after 2001 produce GMOs, does this restriction also apply to Directive 2009/41? However, the ruling was in reference to Directive 2001/18, which does not directly refer to Directive 2009/41. Moreover, the application of several of the new mutagenesis techniques generate organisms that resemble those produced by self-cloning. So, if these GMM are outside the scope of 2009/41 as long as they stay in confined use conditions, do they become GMOs when outside? Do notifications have to be addressed to the CA when techniques are used that do

	not create GMM?
LV	Application of classic mutagenesis methods and release of mutagenic organisms in the environment is not concern in Latvia. It is possible that there are in environment some varieties having traits obtained from chemical mutagenesis used historically (method is not used anymore). CRISPR/Cas method is not widely used at the moment, but it may become more applied in future to obtain new varieties. It is used in limited amount in laboratory experiments.
MT	N/A
NL	In the Netherlands, the EU Court ruling itself has no consequences for national implementation or inspections. The Dutch authorities have always considered organisms produced by any new breeding technique as GMOs, excluding only products resulting from the use of "traditional" mutagenesis techniques (induced by exposure to chemical substances or irradiation) from the application of the GMO legislation. Dutch national authorities have applied the EU GMO legislation to these organisms and their products. The Court has added significant elements to the legal interpretation of the existing GMO-legislation regarding new techniques, directed mutagenesis techniques in particular and the exemption mechanism of directive 2001/18/EC. These elements need to be addressed and are inter alia: - The scope of what is to be understood by mutagenesis, is undefined and must be clarified by authorities or the EU-legislator in order to provide clarity and legal certainty; - The scope of the existing exemption for mutagenesis is limited to products obtained by mutagenesis techniques "that have conventionally been used in a number of applications and have a long safety record" The Court has not explained what constitutes mutagenesis, nor how to determine when mutagenesis techniques or methods have traditionally been used and have proven to be safe. By consequence, the Court's ruling urges the legislator and authorities to keep the directive up-to-date in respect of technical and scientific progress. It is therefore urgent and essential that EU-authorities and the EU-legislator address these issues without undue delay in order to provide clarity and legal certainty. The Netherlands has noted with disappointment the Commission's position that it will not tackle a revision of the GMO legislation any more as its mandate will soon expire. The Netherlands is firmly convinced of the urgent need of a revision of the GMO legislation as appropriate, taking into consideration the consequences of the CJEU ruling for the implementation thereof. To that end, the Netherlands aims to promote that a revision of the EU GMO legislation and addressing the consequences of the CJEU ruling are adequately included in the mandate and Programme of Work of the incoming Commission.
PL	
PT	This matter is still under evaluation.
RO	No impact
SE	-
SI	New mutagenesis techniques to prepare GMMs for a research purpose in Slovenia are used

	in many laboratories that routinely notify the projects to CAs. For the time being we have encountered no difficulties with the above mentioned ruling.
SK	Not known, yet. We rarely get opinions of the scientists, although we have requested them. The users notify all activities.
UK	As far as Directive 2009/41/EC is concerned, little has changed for the UK. Conventional mutagenesis continues to be exempted. Since the CJEU case was announced, there was never a position or statement to say that the use of 'modern' techniques of mutagenesis (e.g. CRISPR/Cas9) constituted 'mutagenesis' in the meaning of the Directive and Regulations and therefore exempt from the requirements. The UK GM (contained use) guidance, which was last updated in 2014, will be updated to remove ambiguity relating to what may be considered as mutagenesis to bring it into line with the ruling. This impacts significantly on Deliberate Release and the appropriate UK Government agencies are working to ensure clarity across the GM regimes. If any changes need to be communicated, this will be done at the earliest opportunity to users.

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.

- GMMs

7.1 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), clinical trials (where applicable) and gene drive modified organisms (where applicable).

AUSTRIA 2014-2017

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	45	--
Class 2	138	--
Class 3	5	--
Class 4	--	--
Total	188	--

AUSTRIA 2018

Classification of contained use	**No. of notifications submitted**	**No. of amendments**

(according to Art. 4(3))	(according to Art. 6, 8 and 9)	(according to Art. 11)
Class 1	26	1
Class 2	31	5
Class 3	1	--
Class 4	--	--
Total	58	6

BELGIUM 2014-2017

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	57	80
Class 2	141	203
Class 3	9	19
Class 4	0	0
Total	207	302

BELGIUM 2018

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	27	43
Class 2	23	49
Class 3	3	5
Class 4	0	0
Total	53	97

BULGARIA 2014-2017

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	1	9
Class 2	0	0
Class 3	0	0
Class 4	0	0
Total	1	9

BULGARIA 2018

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	0	3
Class 2	0	0
Class 3	0	0
Class 4	0	0
Total	0	3

CYPRUS 2014-2017

Classification of contained use	**No. of notifications submitted**	**No. of amendments**

(according to Art. 4(3))	(according to Art. 6, 8 and 9)	(according to Art. 11)
Class 1	1	0
Class 2	1	0
Class 3	0	0
Class 4	0	0
Total	1	0

CYPRUS 2018

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	0	0
Class 2	0	0
Class 3	0	0
Class 4	0	0
Total	0	0

CZECH REPUBLIC 2014-2017

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 **	5 ***
Class 2	47	0
Class 3	2	0
Class 4	0	0
Total	250	5

** 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.

*** 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.

CZECH REPUBLIC 2018

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	25 (see the notes to the report 2014-2017)	2
Class 2	20	0
Class 3	1	0
Class 4	0	0
Total	46	2

GERMANY 2014-2017

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	884	1243

Class 2	2490	392
Class 3	61	52
Class 4	3	0
Total	3438	1687

GERMANY 2018

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	232	150
Class 2	713	66
Class 3	22	2
Class 4	30	0
Total	997	218

DENMARK 2014-2017

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	356	45
Class 2	43	8
Class 3	0	0
Class 4	0	0
Total	399 420 (including animals and plants)	53

DENMARK 2018

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	158	8
Class 2	24	1
Class 3	0	0
Class 4	0	0
Total	182	9

ESTONIA 2014-2017

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	4	4
Class 2	4	4
Class 3	1	1
Class 4	0	0
Total	5	5

ESTONIA 2018

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	0	0
Class 2	0	0
Class 3	0	0
Class 4	0	0
Total	0	0

GREECE 2014-2017

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	0	0
Class 2	0	0
Class 3	0	0
Class 4	0	0
Total	0	0

GREECE 2018

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	0	0
Class 2	0	0
Class 3	0	0
Class 4	0	0
Total	0	0

SPAIN 2014-2017

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	74	0
Class 2	196	0
Class 3	56	0
Class 4	0	0
Total	325	0

SPAIN 2018

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	8	0
Class 2	54	0
Class 3	6	0
Class 4	0	0
Total	68	0

FINLAND 2014-2017

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	120	23
Class 2	64	15
Class 3	0	0
Class 4	0	0
Total	184	38

FINLAND 2018

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	40 (11 of which joint Class 1 and Class 2 GMM notifications)	0
Class 2	21 (5 of which pure Class 2 GMM notifications, not including other GMOs or Classes)	0
Class 3	0	0
Class 4	0	0
Total	45 (including 4 mixed notifications with both GM-animals and Class 1 GMMs)	0

FRANCE 2014-2017

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	1900	1900
Class 2	1900	1900
Class 3	180	180
Class 4	20	20
Total	4000	4000

FRANCE 2018

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		720= 717 (research) + 3 (industrial production)
Class 2		679 = 676 (research) + 3 (industrial production)
Class 3		46 = 45 (research) + 1 (industrial production)
Class 4		2 (research)
Total		1447

CROATIA 2014-2017

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	24	/
Class 2	7	/
Class 3	0	/
Class 4	0	/
Total	31	/

CROATIA 2018

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		
Class 2		
Class 3		
Class 4		
Total		

HUNGARY 2014-2017

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	24	0
Class 2	36	0
Class 3	0	0
Class 4	0	0
Total	60	0

HUNGARY 2018

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	1	0
Class 2	4	2
Class 3	0	0
Class 4	0	0
Total	5	2

IRELAND 2014-2017

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	50	6
Class 2	26	2
Class 3	0	0
Class 4	0	0
Total	76	8

IRELAND 2018

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	8	2
Class 2	6	3
Class 3	1	0
Class 4	0	0
Total	15	5

ITALY 2014-2017

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	38	55
Class 2	370	115
Class 3	14	9
Class 4	0	0
Total	422	179

ITALY 2018

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		
Class 2		
Class 3		
Class 4		
Total		

LITHUANIA 2014-2017

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

LITHUANIA 2018

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	1	0
Class 2	0	0
Class 3	0	0
Class 4	0	0
Total	1	0

LUXEMBOURG 2014-2017

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	0	0
Class 2	13	/
Class 3	0	0
Class 4	0	0
Total	13	1

LUXEMBOURG 2018

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	0	0
Class 2	0	0
Class 3	0	0
Class 4	no level 4 facility in Luxembourg	no level 4 facility in Luxembourg
Total	0	0

LATVIA 2014-2017

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	-	-
Class 2	-	-
Class 3	-	-
Class 4	-	-
Total	-	-

LATVIA 2018

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	1	0
Class 2	0	0
Class 3	0	0
Class 4	0	0
Total	1	0

MALTA 2014-2017

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	0	0
Class 2	0	0
Class 3	0	0
Class 4	0	0
Total	0	0

MALTA 2018

Classification of contained use	**No. of notifications submitted**	**No. of amendments**

(according to Art. 4(3))	(according to Art. 6, 8 and 9)	(according to Art. 11)
Class 1	**0**	**0**
Class 2	**0**	**0**
Class 3	**0**	**0**
Class 4	**0**	**0**
Total	**0**	**0**

NETHERLANDS 2014-2017

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	306	included in previous number
Class 2	680	included in previous number
Class 3	81	included in previous number
Class 4	0	included in previous number
Total	1067	

* counting from 1-3-2015

NETHERLANDS 2018

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	68	Included in previous number
Class 2	368	Included in previous number
Class 3	32	Included in previous number
Class 4	0	Included in previous number
Total	468	Included in previous number

POLAND 2014-2017

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	189	0
Class 2	54	4
Class 3	1	0
Class 4	0	0
Total	244	4

POLAND 2018

Classification of contained use	**No. of notifications submitted**	**No. of amendments**

(according to Art. 4(3))	(according to Art. 6, 8 and 9)	(according to Art. 11)
Class 1		
Class 2		
Class 3		
Class 4		
Total		

PORTUGAL 2014-2017

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	10	0
Class 2	7	0
Class 3	0	0
Class 4	0	0
Total	17	0

PORTUGAL 2018

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	2	0
Class 2	5	0
Class 3	1	0
Class 4	0	0
Total	8	0

ROMANIA 2014-2017

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	0	none
Class 2	1	none
Class 3	0	none
Class 4	0	none
Total	1	none

ROMANIA 2018

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	0	-
Class 2	1	-
Class 3	0	-
Class 4	0	-
Total	1	-

SWEDEN 2014-2017

Classification of contained use	**No. of notifications submitted**	**No. of amendments**

(according to Art. 4(3))	(according to Art. 6, 8 and 9)	(according to Art. 11)
Class 1	49 (only Art. 6) (concernning at least 68 activities, more than 1 can be included in one notification; 3 closed during period)	-
Class 2	201 (51 (Art. 6) + 155 (Art. 8): 48 new activities, 2 closed during period. Includes at least 201 new GMM uses: more than 1 use can be notified in one notification.)	-
Class 3	8 (Art. 6) + 18 (Art. 9)	-
Class 4	1 + 1 (Art. 6, Art. 9)	-
Total	244	135 notifications amending earlier notifications that did not affect risks (NOT art. 11)

SWEDEN 2018

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	Art 6: 55	-
Class 2	Art 6: 55 Art 8: 170	-
Class 3	Art 6: 9 Art 9: 20	-
Class 4	Art 6: 1 Art 9: 1	-
Total	55+55+170+9+20+1+1=311	-

SLOVENIA 2014-2017

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	16	7 amendments and 7 deletions of installations
Class 2	20	1 amendment
Class 3	-	-
Class 4	-	-
Total	36	15

SLOVENIA 2018

Classification of contained use	**No. of notifications submitted**	**No. of amendments**

(according to Art. 4(3))	(according to Art. 6, 8 and 9)	(according to Art. 11)
Class 1	3	0
Class 2	6	0
Class 3	0	-
Class 4	0	-
Total	9	-

SLOVAKIA 2014-2017

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	170	---
Class 2	15	---
Class 3	---	---
Class 4	----	---
Total	185	---

SLOVAKIA 2018

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	37	--
Class 2	4	--
Class 3	1	--
Class 4	---	--
Total	42	--

UNITED KINGDOM 2014-2017

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	123	0
Class 2	430	30
Class 3	34	4
Class 4	2	0
Total	589	34

UNITED KINGDOM 2018

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	46	N/A
Class 2	130	10
Class 3	8	6
Class 4	1	1
Total	185	17

7.2 Number of **premises** for contained uses of GMMs (as referred to in Article 6) with a valid notification as per December 2017 / December 2018:

AUSTRIA 2014-2017

	No. of premises	Comments
Class 1	95	--
Class 2	95	--
Class 3	5	--
Class 4	--	--
Total	195	--

AUSTRIA 2018

	No. of premises	Comments
Class 1	105	--
Class 2	94	--
Class 3	5	--
Class 4	--	--
Total	204	--

BELGIUM 2014-2017

	No. of premises	Comments
Class 1	132	
Class 2	123	
Class 3	24	
Class 4	0	
Total	279	It is impossible to list all premises for all installations; Only the number of installations are taken into account in this table. Because it is not possible to distinguish the installations that have a valid notification from the others, we report the number of approved contained use activities from 2007 to 2017. The period of 10 years correspond to the maximum validity that could be given for a contained use authorisation.

BELGIUM 2018

	No. of premises	Comments
Class 1	122	
Class 2	121	
Class 3	28	
Class 4	0	
Total	271	It is impossible to list all premises for all installations; Only the number of installations are taken into account in this table. Because it is not possible to distinguish the installations that have a valid notification from the others, we report the number of approved contained use activities from 2008 to 2018. The period of 10

		years correspond to the maximum validity that could be given for a contained use authorisation.

BULGARIA 2014-2017

	No. of premises	Comments
Class 1	5	3 of those premises also have valid notification for Class A activities with GM plants.
Class 2	0	N/A
Class 3	0	N/A
Class 4	0	N/A
Total	5	N/A

BULGARIA 2018

	No. of premises	Comments
Class 1	5	3 of those premises also have valid notification for Class A activities with GM plants.
Class 2	0	N/A
Class 3	0	N/A
Class 4	0	N/A
Total	5	N/A

CYPRUS 2014-2017

	No. of premises	Comments
Class 1	1	Please note that only one installation was approved by the Department of Labour Inspection for Class 1 and Class 2 Activities.
Class 2	1	Please note that only one installation was approved by the Department of Labour Inspection for Class 1 and Class 2 Activities.
Class 3	0	NA
Class 4	0	NA
Total	1	Please note that only one installation was approved by the Department of Labour Inspection for Class 1 and Class 2 Activities.

CYPRUS 2018

	No. of premises	Comments
Class 1	1	Please note that only one installation was approved by the Department of Labour

		Inspection for Class 1 and Class 2 Activities.
Class 2	1	0
Class 3	0	0
Class 4	0	0
Total	1	Please note that only one installation was approved by the Department of Labour Inspection for Class 1 and Class 2 Activities.

CZECH REPUBLIC 2014-2017

	No. of premises	**Comments**
Class 1	68	no comments
Class 2	91	no comments
Class 3	2	no comments
Class 4	0	no comments
Total	161	no comments

CZECH REPUBLIC 2018

	No. of premises	**Comments**
Class 1	71	Class 1 only
Class 2	92	some premises are Class 2 and Class 1
Class 3	3	no comments
Class 4	0	no comments
Total	166	no comments

GERMANY 2014-2017

	No. of premises	**Comments**
Class 1	4696	no
Class 2	1708	no
Class 3	101	no
Class 4	4	3x in operation, 1x construction approval
Total	6509	no

GERMANY 2018

	No. of premises	**Comments**
Class 1	4681	-
Class 2	1734	-
Class 3	104	-
Class 4	5	-
Total	6524	-

DENMARK 2014-2017

	No. of premises	**Comments**
Class 1	835	477 Premises with an

		active project
Class 2	125	75 Premises with an active project
Class 3	0	0
Class 4	0	0
Total	960	549

DENMARK 2018

	No. of premises	**Comments**
Class 1	35	x
Class 2	6	x
Class 3	0	x
Class 4	0	x
Total	41	x

ESTONIA 2014-2017

	No. of premises	**Comments**
Class 1	6	No comments
Class 2	6	same as class 1
Class 3	1	one laboratory has classes 1-3
Class 4	0	No comments
Total	6	No comments

ESTONIA 2018

	No. of premises	**Comments**
Class 1	0	0
Class 2	0	0
Class 3	0	0
Class 4	0	0
Total	0	0

GREECE 2014-2017

	No. of premises	**Comments**
Class 1	0	0
Class 2	0	0
Class 3	0	0
Class 4	0	0
Total	0	0

GREECE 2018

	No. of premises	**Comments**
Class 1	0	0
Class 2	0	0

Class 3	0	0
Class 4	0	0
Total	0	0

SPAIN 2014-2017

	No. of premises	**Comments**
Class 1	69	no
Class 2	57	no
Class 3	12	no
Class 4	0	no
Total	138	no

SPAIN 2018

	No. of premises	**Comments**
Class 1	8	No comments
Class 2	9	No comments
Class 3	1	No comments
Class 4	0	No comments
Total	19	No comments

FINLAND 2014-2017

	No. of premises	**Comments**
Class 1	386	= notifications for premises; may contain rooms in different addresses and buildings
Class 2	162	idem
Class 3	4	-
Class 4	0	-
Total	552	Premises are located in 168 different addresses

FINLAND 2018

	No. of premises	**Comments**
Class 1	?	It is currently not possible to combine the information on premises and classification in the gene technology register as the database is not relational.
Class 2	?	It is currently not possible to combine the information on premises and classification in the gene technology register as the database is not relational
Class 3	3	Cumulative number of different addresses in valid notifications until the end of December 2018.This number could be picked by hand from the individual Class 3 applications.
Class 4	0	-
Total	166	Cumulative number of different addresses in the valid notifications until the end of

		December 2018.

FRANCE 2014-2017

	No. of premises	Comments
Class 1	néant	néant
Class 2	néant	néant
Class 3	néant	néant
Class 4	néant	néant
Total	Notre système d'information ne nous permet pas en l'état de répondre à cette question	Notre système d'information ne nous permet pas en l'état de répondre à cette question

FRANCE 2018

	No. of premises	Comments
Class 1		Our IT resources do not allow us to answer this
Class 2	-	Our IT resources do not allow us to answer this
Class 3	-	Our IT resources do not allow us to answer this
Class 4	-	Our IT resources do not allow us to answer this
Total	-	Our IT resources do not allow us to answer this

CROATIA 2014-2017

	No. of premises	Comments
Class 1	23	/
Class 2	7	/
Class 3	0	/
Class 4	0	/
Total	30	/

CROATIA 2018

	No. of premises	Comments
Class 1		
Class 2		
Class 3		
Class 4		
Total		

HUNGARY 2014-2017

	No. of premises	Comments
Class 1	2	no
Class 2	90	no
Class 3	0	no
Class 4	0	no
Total	92	Each seperate institute belonging to one university

		is considered as one seperate premises for contained use. All together 22 notifications contain 92 premises.

HUNGARY 2018

	No. of premises	Comments
Class 1	1	0
Class 2	2	0
Class 3	0	0
Class 4	0	0
Total	3	0

IRELAND 2014-2017

	No. of premises	Comments
Class 1	14	Many of these premises (institutions in particular) are multi-user sites.
Class 2	10	As above
Class 3	0	-
Class 4	0	-
Total	24	-

IRELAND 2018

	No. of premises	Comments
Class 1	5	-
Class 2	6	-
Class 3	1	-
Class 4	0	-
Total	12	-

ITALY 2014-2017

	No. of premises	Comments
Class 1	88	Only 4 out of 88 are authorized for gene therapy clinical trials (see No. reported in Part III section 10).
Class 2	141	Only 16 out of 141 are authorized in gene therapy clinical trials (see No. reported in Part III section 10).
Class 3	9	N.A.
Class 4	0	N.A.
Total	238	N.A.

ITALY 2018

	No. of premises	Comments
Class 1		
Class 2		

Class 3	[redacted]	[redacted]
Class 4	[redacted]	[redacted]
Total	[redacted]	[redacted]

LITHUANIA 2014-2017

	No. of premises	Comments
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	-

LITHUANIA 2018

	No. of premises	Comments
Class 1	14	0
Class 2	1	0
Class 3	0	0
Class 4	0	0
Total	15	To date number of labs according to Valid notification

LUXEMBOURG 2014-2017

	No. of premises	Comments
Class 1	0	0
Class 2	1	0
Class 3	0	0
Class 4	0	0
Total	1	0

LUXEMBOURG 2018

	No. of premises	Comments
Class 1	0	/
Class 2	2	/
Class 3	2	/
Class 4	0	/
Total	2	Transposition of Directive 2009/41 is ongoing. SECUALIM projects to gather information once the directives has ben transposed in national law.

LATVIA 2014-2017

	No. of premises	Comments
Class 1	-	-
Class 2	-	-
Class 3	-	-

Class 4	-	-
Total	-	-

LATVIA 2018

	No. of premises	Comments
Class 1	1	-
Class 2	0	-
Class 3	0	-
Class 4	0	-
Total	1	-

MALTA 2014-2017

	No. of premises	Comments
Class 1	1	
Class 2	0	
Class 3	0	
Class 4	0	
Total	1	

MALTA 2018

	No. of premises	Comments
Class 1	1	
Class 2	0	
Class 3	0	
Class 4	0	
Total	1	

NETHERLANDS 2014-2017

	No. of premises	Comments
Class 1	380	non
Class 2	274	non
Class 3	101	non
Class 4	0	non
Total	415	In the Netherlands premises for contained use may consist of more than one containment level (e.g. 1, 2 and 3).

NETHERLANDS 2018

	No. of premises	Comments
Class 1	393	non
Class 2	283	non
Class 3	103	non
Class 4	0	non
Total	432	In the Netherlands premises for contained use may consist of more than one containment level (e.g. 1, 2

		and 3). The total number of premises is 432.

POLAND 2014-2017

	No. of premises	Comments
Class 1	189	-
Class 2	54	-
Class 3	1	-
Class 4	0	-
Total	244	-

POLAND 2018

	No. of premises	Comments
Class 1		
Class 2		
Class 3		
Class 4		
Total		

PORTUGAL 2014-2017

	No. of premises	Comments
Class 1	12	No comments.
Class 2	7	No comments.
Class 3	0	No comments.
Class 4	0	No comments.
Total	19	No comments.

PORTUGAL 2018

	No. of premises	Comments
Class 1	14	None.
Class 2	8	None.
Class 3	1	None.
Class 4	0	None.
Total	23	None.

ROMANIA 2014-2017

	No. of premises	Comments
Class 1	0	none
Class 2	2	none
Class 3	0	none
Class 4	0	none
Total	2	none

ROMANIA 2018

	No. of premises	Comments

Class 1	0	-
Class 2	1	-
Class 3	0	-
Class 4	0	-
Total	1	-

SWEDEN 2014-2017

	No. of premises	**Comments**
Class 1	414	Premises may overlap.
Class 2	242	Premises may overlap.
Class 3	14	Premises may overlap.
Class 4	1	-
Total	691	-

SWEDEN 2018

	No. of premises	**Comments**
Class 1	470	-
Class 2	297	-
Class 3	23	-
Class 4	2	-
Total	792	-

SLOVENIA 2014-2017

	No. of premises	**Comments**
Class 1	54	including 9 animal facilities and 2 greenhouses
Class 2	16	-
Class 3	-	-
Class 4	-	-
Total	70	11

SLOVENIA 2018

	No. of premises	**Comments**
Class 1	58	including 10 animal facilities and 2 greenhouses4 premises were renovated or changed and the CA was notified
Class 2	17	3 premises were renovated or changed and the CA was notified
Class 3	0	0
Class 4	0	0
Total	75	7

SLOVAKIA 2014-2017

	No. of premises	**Comments**
Class 1	80	---
Class 2	23	---

Class 3	1	---
Class 4	---	---
Total	104	---

SLOVAKIA 2018

	No. of premises	**Comments**
Class 1	3	--
Class 2	15	---
Class 3	---	The notification on risk class 3 was submitted in 2017.
Class 4	---	---
Total	18	--

UNITED KINGDOM 2014-2017

	No. of premises	**Comments**
Class 1	417	N/A
Class 2	235	N/A
Class 3	72	N/A
Class 4	7	N/A
Total	731	N/A

UNITED KINGDOM 2018

	No. of premises	**Comments**
Class 1	446	N/A
Class 2	279	N/A
Class 3	73	N/A
Class 4	7	N/A
Total	805	N/A

7.3 Number of **contained uses of GMMs** (including combined uses of GMMs and GMOs) with a valid notification[4] or approval as per December 2017 / December 2018.

AUSTRIA 2014-2017

	No. of contained uses	**Comments**
Class 2	222	--
Class 3	11	--
Class 4	--	--
Total	233	--

AUSTRIA 2018

	No. of contained uses	**Comments**
Class 2	190	--
Class 3	12	--
Class 4	--	--

Total	202	--

BELGIUM 2014-2017

	No. of contained uses	**Comments**
Class 2	class 1 : 594 class 2 : 883	Class 1 row is missing in this table.
Class 3	96	
Class 4	0	
Total	1573	Because it is not possible to distinguish the installations that have a valid notification from the others, we report the number of approved contained use activities from 2007 to 2017. The period of 10 years correspond to the maximum validity that could be given for a contained use authorisation.

BELGIUM 2018

	No. of contained uses	**Comments**
Class 2	class 1: 451 class 2: 863	line corresponding to Class 1 is missing
Class 3	82	/
Class 4	0	/
Total	1396	Because it is not possible to distinguish the installations that have a valid notification from the others, we report the number of approved contained use activities from 2008 to 2018. The period of 10 years correspond to the maximum validity that could be given for a contained use authorisation.

BULGARIA 2014-2017

	No. of contained uses	**Comments**
Class 2	0	N/A
Class 3	0	N/A
Class 4	0	N/A
Total	0	N/A

BULGARIA 2018

	No. of contained uses	**Comments**
Class 2	0	N/A
Class 3	0	N/A

Class 4	0	N/A
Total	0	N/A

CYPRUS 2014-2017

	No. of contained uses	**Comments**
Class 2	1	Notification of GMM used in the following labs/departments of the Cyprus Institute of Neurology and Genetics: Molecular Virology, Electron Microscope / Molecular Pathology, Molecular Genetics and Thalassemia, Molecular Genetics and Treatment Operation, Neurology E
Class 3	0	NA
Class 4	0	NA
Total	1	Notification of GMM used in the following labs/departments of the Cyprus Institute of Neurology and Genetics: Molecular Virology, Electron Microscope / Molecular Pathology, Molecular Genetics and Thalassemia, Molecular Genetics and Treatment Operation, Neurology E

CYPRUS 2018

	No. of contained uses	**Comments**
Class 2	1	Notification of GMM used in the following labs/departments of the Cyprus Institute of Neurology and Genetics:Molecular Virology, Electron Microscope / Molecular Pathology, Molecular Genetics and Thalassemia, Molecular Genetics and Treatment Operation, Neurology E
Class 3	0	-
Class 4	0	-
Total	1	-

CZECH REPUBLIC 2014-2017

	No. of contained uses	**Comments**
Class 2	205	no comments
Class 3	2	no comments
Class 4	0	no comments
Total	207	no comments

CZECH REPUBLIC 2018

	No. of contained uses	**Comments**
Class 2	235	according to notified

		GMMs
Class 3	3	no comments
Class 4	0	no comments
Total	238	no comments

GERMANY 2014-2017

	No. of contained uses	**Comments**
Class 2	7027	no
Class 3	320	no
Class 4	14	no
Total	7361	no

GERMANY 2018

	No. of contained uses	**Comments**
Class 2	8026	-
Class 3	364	-
Class 4	13	-
Total	8403	-

DENMARK 2014-2017

	No. of contained uses	**Comments**
Class 2	114	-
Class 3	0	-
Class 4	0	-
Total	114	-

DENMARK 2018

	No. of contained uses	**Comments**
Class 2	149	x
Class 3	0	x
Class 4	0	x
Total	149	x

ESTONIA 2014-2017

	No. of contained uses	**Comments**
Class 2	6	No comments
Class 3	1	On laboratory has classes 1-3
Class 4	0	N/A
Total	6	one laboratory has

		classes 1-3

ESTONIA 2018

	No. of contained uses	Comments
Class 2	0	0
Class 3	0	0
Class 4	0	0
Total	0	0

GREECE 2014-2017

	No. of contained uses	Comments
Class 2	0	0
Class 3	0	0
Class 4	0	0
Total	0	0

GREECE 2018

	No. of contained uses	Comments
Class 2	0	0
Class 3	0	0
Class 4	0	0
Total	0	0

SPAIN 2014-2017

	No. of contained uses	Comments
Class 2	137	49 notifications regarding GMMs, class 1, were also notified.
Class 3	55	NO
Class 4	0	NO
Total	192	NO

SPAIN 2018

	No. of contained uses	Comments
Class 2	54	Valid notification
Class 3	6	Valid notification
Class 4	0	Not apply
Total	60	Not apply

FINLAND 2014-2017

	No. of contained uses	Comments
Class 2	210	-
Class 3	5	-
Class 4	0	-
Total	215	-

FINLAND 2018

	No. of contained uses	Comments
Class 2	202	This is a cumulative number of all valid notifications until the end of December 2018. This number may contain several different notifications b ythe same operator if it has later taken new Class 2 GMM:s into use.
Class 3	6	Cumulative number of valid notifications until the end of December 2018.
Class 4	0	-
Total	208	-

FRANCE 2014-2017

	No. of contained uses	Comments
Class 2	néant	néant
Class 3	néant	néant
Class 4	néant	néant
Total	Notre système d'information ne nous permet pas en l'état de répondre à cette question	Notre système d'information ne nous permet pas en l'état de répondre à cette question

FRANCE 2018

	No. of contained uses	Comments
Class 2	-	-
Class 3	-	-
Class 4	-	-
Total	5000	Around 5000 files from all mixed classes

CROATIA 2014-2017

	No. of contained uses	Comments
Class 2	7	/
Class 3	0	/
Class 4	0	/

Total	7	/

CROATIA 2018

	No. of contained uses	Comments
Class 2		
Class 3		
Class 4		
Total		

HUNGARY 2014-2017

	No. of contained uses	Comments
Class 2	36	no
Class 3	0	no
Class 4	0	no
Total	36	no

HUNGARY 2018

	No. of contained uses	Comments
Class 2	4	0
Class 3	0	0
Class 4	0	0
Total	4	0

IRELAND 2014-2017

	No. of contained uses	Comments
Class 2	26	-
Class 3	0	-
Class 4	0	-
Total	26	-

IRELAND 2018

	No. of contained uses	Comments
Class 2	9	-
Class 3	0	-
Class 4	0	-
Total	9	-

ITALY 2014-2017

	No. of contained	Comments

	uses	
Class 2	329	Only 160 out of 329 concern research and development purposes, 68 research and studies in which animals are used and 62 production and control of biological substances or medicines
Class 3	11	Research and development
Class 4	0	N.A.
Total	340	N.A.

ITALY 2018

	No. of contained uses	Comments
Class 2		
Class 3		
Class 4		
Total		

LITHUANIA 2014-2017

	No. of contained uses	Comments
Class 2	2	-
Class 3	0	-
Class 4	0	-
Total	2	-

LITHUANIA 2018

	No. of contained uses	Comments
Class 2	2	0
Class 3	0	0
Class 4	0	0
Total	2	To date number of activities according to valid notifications

LUXEMBOURG 2014-2017

	No. of contained uses	Comments
Class 2	13	0
Class 3	0	0
Class 4	0	0
Total	13	0

LUXEMBOURG 2018

	No. of contained uses	Comments

Class 2	0	/
Class 3	0	/
Class 4	0	/
Total	0	/

LATVIA 2014-2017

	No. of contained uses	**Comments**
Class 2	-	-
Class 3	-	-
Class 4	-	-
Total	-	-

LATVIA 2018

	No. of contained uses	**Comments**
Class 2	0	-
Class 3	0	-
Class 4	0	-
Total	0	-

MALTA 2014-2017

	No. of contained uses	**Comments**
Class 2	0	
Class 3	0	
Class 4	0	
Total	0	

MALTA 2018

	No. of contained uses	**Comments**
Class 2	0	
Class 3	0	
Class 4	0	
Total	0	

NETHERLANDS 2014-2017

	No. of contained uses	**Comments**
Class 2	1053	non
Class 3	251	non
Class 4	0	non
Total	2908	this figure totals the notifications for class 1, 2 and 3.

NETHERLANDS 2018

	No. of contained uses	Comments
Class 2	1053	non
Class 3	251	non
Class 4	0	non
Total	2908	this figure totals the notifications for class 1, 2 and 3.

POLAND 2014-2017

	No. of contained uses	Comments
Class 2	54	-
Class 3	1	-
Class 4	0	-
Total	55	-

POLAND 2018

	No. of contained uses	Comments
Class 2		
Class 3		
Class 4		
Total		

PORTUGAL 2014-2017

	No. of contained uses	Comments
Class 2	14	No comments.
Class 3	0	No comments.
Class 4	0	No comments.
Total	14	No comments.

PORTUGAL 2018

	No. of contained uses	Comments
Class 2	18	None.
Class 3	1	None.
Class 4	0	None.
Total	19	None.

ROMANIA 2014-2017

	No. of contained uses	Comments

Class 2	1	none
Class 3	0	none
Class 4	0	none
Total	1	none

ROMANIA 2018

	No. of contained uses	**Comments**
Class 2	1	-
Class 3	-	-
Class 4	-	-
Total	1	-

SWEDEN 2014-2017

	No. of contained uses	**Comments**
Class 2	1469	-
Class 3	28	-
Class 4	1	-
Total	1498	-

SWEDEN 2018

	No. of contained uses	**Comments**
Class 2	1600	-
Class 3	30	-
Class 4	2	-
Total	1632	-

SLOVENIA 2014-2017

	No. of contained uses	**Comments**
Class 2	26	-
Class 3	-	-
Class 4	-	-
Total	80	-

SLOVENIA 2018

	No. of contained uses	**Comments**
Class 2	32	0
Class 3	0	0
Class 4	0	0
Total	32	0

SLOVAKIA 2014-2017

	No. of contained uses	Comments
Class 2	112	---
Class 3	---	---
Class 4	---	---
Total	112	---

SLOVAKIA 2018

	No. of contained uses	Comments
Class 2	23	--
Class 3	18	All 18 activities were the scope of one notification.
Class 4	---	--
Total	41	--

UNITED KINGDOM 2014-2017

	No. of contained uses	Comments
Class 2	2246	N/A
Class 3	235	N/A
Class 4	14	N/A
Total	2495	N/A

UNITED KINGDOM 2018

	No. of contained uses	Comments
Class 2	2376	N/A
Class 3	243	N/A
Class 4	15	N/A
Total	2634	N/A

- GM animals and GM plants

8.1 How many **notifications** for contained uses of GMOs[6], 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.

[6] This question did not appear in the questionnaire of those Member States which declared that they have not extended the scope of the Directive to GM animals and GM plants in their national legislation.

AUSTRIA 2014-2017

Classification of contained use*	GM animals		GM plants	
	No. of notifications submitted	No. of amendments	No. of notifications submitted	No. of amendments
Class 1	734			
Total	734			

* 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.

AUSTRIA 2018

Classification of contained use*	GM animals		GM plants	
	No. of notifications submitted	No. of amendments	No. of notifications submitted	No. of amendments
Class 1	78	103	1	--
Class 2	4	--	--	--
--	--	--	--	--
--	--	--	--	--
Total	82	103	1	--

BELGIUM 2014-2017

Classification of contained use*	GM animals		GM plants	
	No. of notifications submitted	No. of amendments	No. of notifications submitted	No. of amendments
Class 1	10	7	4	9
Class 2	2	2	0	3
Class 3	0	0	0	0
Class 4	0	0	0	0
Total	12	9	4	12

BELGIUM 2018

Classification of contained use*	GM animals		GM plants	
	No. of notifications submitted	No. of amendments	No. of notifications submitted	No. of amendments
Class 1	2	3	0	0

Class 2	1	2	0	2
Class 3	0	0	0	0
Class 4	0	0	0	0
Total	3	5	0	2

BULGARIA 2014-2017

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
Class A, no or negligible risk for the human or animal health and for the environment - 3 premises	0	0	1	5
Class B, all other cases - 0 premises	0	0	0	0
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
Total[7]	0	0	1	5

BULGARIA 2018

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
Class A, no or negligible risk for the human or animal health and for the environment - 3 premises	0	0	0	3 (check)
Class B, all other cases – 0 premises	0	0	0	0
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
Total[8]	0	0	0	3 (check)

[7] 3 premises, all for Class A activities with GM plants
[8] 3 premises, all for Class A activities with GM plants.

CZECH REPUBLIC 2014-2017

Classification of contained use*	GM animals		GM plants	
	No. of notifications submitted	No. of amendments	No. of notifications submitted	No. of amendments
Class 1	115** see the note at point 7	0	9** see the note at point 7	0
Class 2	2	0	2	0
Class 3	0	0	0	0
Class 4	0	0	0	0
Total	117	0	11	0

CZECH REPUBLIC 2018

Classification of contained use*	GM animals		GM plants	
	No. of notifications submitted	No. of amendments	No. of notifications submitted	No. of amendments
Class 1	18 (see the note on Class 1 notifications in item 7)	0	3	0
Class 2	0	0	0	0
Class 3	0	0	0	0
Class 4	0	0	0	0
Total	18	0	3	0

GERMANY 2014-2017

Classification of contained use*	GM animals		GM plants	
	No. of notifications submitted	No. of amendments	No. of notifications submitted	No. of amendments
Total				

GERMANY 2018

Classification of	GM animals	GM plants

contained use*				
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
-	-	-	-	-
-	-	-	-	-
-	-	-	-	-
-	-	-	-	-
Total	-	-	-	-

DENMARK 2014-2017

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
x	x	x	x	x
x	x	x	x	x
x	x	x	x	x
x	x	x	x	x
Total	21	0	68	x

DENMARK 2018

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
x	x	x	x	x
x	x	x	x	x
x	x	x	x	x
x	x	x	x	x
Total	26	0	5	0

SPAIN 2014-2017

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
1	19	0	5	0
2	8	0	0	0
3	1	0	0	0

4	0	0	0	0
Total	28	0	5	0

SPAIN 2018

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
1	10 Notifications for contained uses of GM animals and their correspondent premises.	0	2 Notifications for contained uses of GM plants and their correspondent premises.	0
2	0	0	0	0
3	0	0	0	0
4	0	0	0	0
Total	10	0	0	0

FINLAND 2014-2017

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
1	17	6	11	2
2	1 (Class 2 of GM animals corrssponds to Classes 3-4 of GMMs and GM plants)	-	8	6
3	-	-	0	-
Total	18	6	19	8

FINLAND 2018

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**

1 animals, 1 plants	8	0	0	0
2 animals, 2 plants	0	0	0	0
3 plants	-	-	0	0
4 plants	-	-	0	0
Total	8	0	0	0

FRANCE 2014-2017

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
	2500	2500	250	250
Total	2500	2500	250	250

FRANCE 2018

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
GMO animals and plants are covered by our legislation. Unable to differentiate records regarding microorganisms, animals and plants	-	-	-	-
-	-	-	-	-
-	-	-	-	-
-	-	-	-	-
Total	-	-	-	-

CROATIA 2014-2017

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**

	3	1	3	
Total	3	1	3	

CROATIA 2018

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
Total				

HUNGARY 2014-2017

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
1	16	0	3	0
2	22	0	5	0
Total	38	0	8	0

HUNGARY 2018

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
class 1	0	0	1	0
class 1	1	0	0	0
class 2	5	0	0	0
0	0	0	0	0
Total	6	0	1	0

IRELAND 2014-2017

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
Class 1	16	-	8	-
Total				

IRELAND 2018

Classification of contained use*	GM animals		GM plants	
	No. of notifications submitted	No. of amendments	No. of notifications submitted	No. of amendments
-	5	1	2	-
-	-	-	-	-
-	-	-	-	-
-	-	-	-	-
Total	5	1	2	-

ITALY 2018

Classification of contained use*	GM animals		GM plants	
	No. of notifications submitted	No. of amendments	No. of notifications submitted	No. of amendments
Total				

LITHUANIA 2014-2017

Classification of contained use*	GM animals		GM plants	
	No. of notifications submitted	No. of amendments	No. of notifications submitted	No. of amendments
Total				

LITHUANIA 2018

Classification of contained use*	GM animals		GM plants	
	No. of notifications submitted	No. of amendments	No. of notifications submitted	No. of amendments
0	1	0	0	0
0	0	0	0	0
0	0	0	0	0
0	0	0	0	0

Total	1	0	0	0

MALTA 2014-2017

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
0	0	0	0	0
Total				

MALTA 2018

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
0	0	0	0	0
Total				

NETHERLANDS 2014-2017

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
--	--	--	--	--
Total				

NETHERLANDS 2018

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
--	--	--	--	--
--	--	--	--	--
--	--	--	--	--
--	--	--	--	--
Total	--	--	--	--

POLAND 2014-2017

Classification of contained use*	GM animals		GM plants	
	No. of notifications submitted	No. of amendments	No. of notifications submitted	No. of amendments
	10	10	2	2
2	30	30	2	2
Total	40	40	2	2

POLAND 2018

Classification of contained use*	GM animals		GM plants	
	No. of notifications submitted	No. of amendments	No. of notifications submitted	No. of amendments
Total				

PORTUGAL 2014-2017

Classification of contained use*	GM animals		GM plants	
	No. of notifications submitted	No. of amendments	No. of notifications submitted	No. of amendments
class 1	4		3	
class 2				
class 3				
class 4				
Total	4		3	

PORTUGAL 2018

Classification of contained use*	GM animals		GM plants	
	No. of notifications submitted	No. of amendments	No. of notifications submitted	No. of amendments
-	-	-	-	-
-	-	-	-	-
-	-	-	-	-
-	-	-	-	-
Total	-	-	-	-

SWEDEN 2014-2017

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
Not water living (Board of Agriculture reporting)	67	0	33	0
Water living (Agency for Marine and Water Management reporting)	9	0		
Total	76		33	

SWEDEN 2018

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
x	x	x	x	x
x	x	x	x	x
x	x	x	x	x
x	x	x	x	x
Total	x	x	x	x

SLOVENIA 2014-2017

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
Class 1	1 installation 1 activity			
-	-			
-	-			
-	-			
Total	2			

SLOVENIA 2018

Classification of	**GM animals**	**GM plants**

contained use*				
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
class 1	1 installation 1 activity	-	-	-
-	-	-	-	-
-	-	-	-	-
-	-	-	-	-
-	-	-	-	-
Total	-	-	-	-

SLOVAKIA 2014-2017

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
risk class 1	15	---	33	----
risk class 2	3	----	-----	----
risk class 3	----	----	-----	----
risk class 4	----	----	-----	-----
Total	18	----	33	-----

SLOVAKIA 2018

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
1	6	---	10	---
2	---	---	---	---
3	---	---	---	---
4	---	---	---	---
Total	6	---	10	---

UNITED KINGDOM 2014-2017

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
Unable to complete this table, see comments below	table, see comments below	table, see comments below	table, see comments below	table, see comments below

Total				

UNITED KINGDOM 2018

Classification of contained use*	**GM animals**		**GM plants**	
	No. of notifications submitted	**No. of amendments**	**No. of notifications submitted**	**No. of amendments**
Unable to complete this table see comments below	Unable to complete this table see	Unable to complete this table see	Unable to complete this table see	Unable to complete this table see
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
Total	N/A	N/A	N/A	N/A

8.2 Did you encounter specific challenges related to notifications for GM plants or GM animals?

2014 - 2017	
AT	no
BE	No specific challenges were encountered with notifications of GM plants or GM animals.
BG	It will be helpful if the scope of the directive is extended to all GMO and unified requirements for contained use of GM plants and animals are established, as the requirements differ significantly between the member states at present.
CZ	No
DE	The German GenTG has also implemented Directive 2001/18/EC and extended the scope of 2009/41/EC to the contained use of GM plants and GM animals.There is no distinction between GMM, GM plants and GM animals in notification procedures. There is no consideration in collection of data, the numbers are included under 7. So our database can not be evaluated concerning those criteria.
DK	-
ES	Challenges regarding notification were described in previous questions.
FI	Yes, about the legal status of the progeny of CRISPR-Cas9 modified plants. Also about the legal status and classification of certain CRISPR-Cas9 insects (no gene drive situation). In general issues about the legal status arise where the genome of an organism has been modified with site specific mutagenesis, especially when an existing mutant organism is reverted to wild type with novel mutagenesis techniques.
FR	Non
HR	No
HU	No
IE	No
LT	There were no notifications for contained uses of GMOs submitted.
MT	Not applicable.
NL	No, except the fact that due to our reporting system it is not possible for the Netherlands

	to differentiate on this and to fill out the above table. The data given in questions 7.1 to 7.3 encompass also activities with GM plants and GM animals.
PL	Environmental Risk Assessment
PT	No particular difficulties were found regarding specif challenges related to notifications about GM plants or GM animals.
SE	There are no classifications sytems. No GMOs should escape regardless of species. Case-by-case. No challenges today, but in future if different classes or differentiate between contained use and deliberate release - how to assess the risks?
SI	No specific challenges were encountered related to notifications of GM animals or GM plants respectively. Members of the Scientific Committee are nominated according to the provisions of the Slovene GMO act. The provisions ensure that the members are nominated in order to cover adequate fields of expertise for GMMs, GM animals and GM plants.
SK	----
UK	Please note, the Directive is only concerned with genetically modified microorganisms (GMM) and does not require collection of information on work with genetically modified organisms (GMOs i.e. animals and plants). Consequently, such information has, historically, not been collected in a form that is amenable for reporting purposes.

2018	
AT	no
BE	No specific challenges were encountered with notifications of GM plants or GM animals.
BG	It will be helpful if the scope of the directive is extended to all GMO and unified requirements for contained use of GM plants and animals are established, as the requirements differ significantly between the member states at present.
CY	GMOs are not covered under the contained use legislation in Cyprus. The Department of Labour Inspection is not the competent authority for GMOs it is the Department of Environment however no notification was submitted to the Department of Environment in 2018.
CZ	No.
DE	No challenge but comment: The German GenTG has also implemented Directive 2001/18/EC and extended the scope of 2009/41/EC to the contained use of GM plants and GM animals. There is no distinction between GMM, GM plants and GM animals in notification procedures. There is no consideration in collection of data, the numbers are included under 7. So our database cannot be evaluated concerning those criteria.
DK	No
EE	N/A
EL	No notifications received
ES	No
FI	(1) The legal status of the progeny of GMO:s that do not inherit the modification. (2) Classification in certain cases, especially when GMMs are used in combination with GM animals or GM plants. (3) Whether the ECJ decision is to be applied also to contained use; (4) Legal status when an existing mutant organism is reverted to wild type using novel mutagenesis techniques.
FR	
HR	
HU	No

IE	No
IT	
LT	The activity is with already genetically modified mice, 1st risk class
LU	No
LV	We did have notifications about GM plants and/or GM animals
MT	N/A
NL	No, except the fact that due to our reporting system it is not possible for the Netherlands to differentiate on this and to fill out the above table. The data given in questions 7.1 to 7.3 encompass also activities with GM plants and GM
PL	
PT	Not applicable.
RO	Not yet
SE	xxxx
SI	The biosafety framework in Slovenia is covered by horizontal legislation based on Management of Genetically Modified Organisms (MGMO) Act (OJ RS 23/2005 and amended OJ RS 21/2010). The Act implements the provisions of the Directive 2009/41/EC and beside GMMs regulates also GM plants and animals. Therefore the legislative and administrative aspect of GM plants and GM animals is well covered.
SK	We did not encounter any specific challenges related to notifications on GM plants or GM animals.
UK	Please note the Directive is only concerned with GMMs and does not require collection of information on work with GMOs (animals and plants) Consequently, such information has, historically, not been collected in a form that is amenable for reporting purposes.

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.[9]

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

III.1 Human use

a. Manufacturing

9.1 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?

9.2 If yes, 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?

	9.1 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	**9.2 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**

[9] This includes but is not limited to Advanced Therapy Medicinal Products ("ATMPs").

	Member State?	reporting period?
AT	Yes	No
AT 2018	Yes	No
BE	Yes	Yes
BE 2018	Yes	Yes
BG	Yes	No
BG 2018	Yes	No
CY	No	
CY 2018	No	
CZ	Yes	No
CZ 2018	Yes	No
DE	Yes	Yes
DE 2018	Yes	Yes
DK	No	
DK 2018	No	
EE	No	
EE 2018	No	
EL	No	
EL 2018	Yes	No
ES	Yes	Yes
ES 2018	No	
FI	Yes	Yes
FI 2018	Yes	No
FR	Yes	Yes
FR 2018	Yes	Yes
HR	No	
HR 2018		
HU	Yes	No
HU 2018	No	
IE	No	
IE 2018	Yes	No
IT	Yes	Yes
IT 2018		
LT	No	
LT 2018	No	
LU	Yes	No
LU 2018	No	
LV	No	
LV 2018	No	
MT	No	No
MT 2018	Yes	No
NL	No	
NL 2018	No	
PL	Yes	No
PL 2018		
PT	Yes	Yes
PT 2018	Yes	Yes

RO	No	
RO 2018	Yes	No
SE	No	
SE 2018	No	
SI	No	
SI 2018	No	
SK	No	
SK 2018	No	
UK	Yes	Yes
UK 2018	Yes	Yes

If yes, provide details:

BELGIUM 2014-2017

Classification contained use	**Total no. of notifications***	**No of authorisations***	**No. of notifications concerning ATMPs**	**No. of authorisations concerning ATMPs**
Class 1	5	5	4	4
Class 2	7 (one for veterinary use)	3 (one for veterinary use)	6 (one for veterinary use)	3 (one for veterinary use)
Class 3	1	1	0	0
Class 4	0	0	0	0
Total	13	9	10	7

* Report all notifications/authorisations, including those related to ATMPs (and if relevant, specify how many notifications/authorisations were for human and veterinary use, e.g: 4, out of which 1 for human and veterinary uses; or 4 for human and veterinary uses)

BELGIUM 2018

Classification contained use	**Total no. of notifications***	**No of authorisations***	**No. of notifications concerning ATMPs**	**No. of authorisations concerning ATMPs**
Class 1	5	5	5	5
Class 2	11 (one for veterinary use)	5	10	5
Class 3	1	0	1	0
Class 4	0	0	0	0
Total	17 This table concerns the period June 2014-December	10	16	10

	2018			

GERMANY 2014-2017

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

GERMANY 2018

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

SPAIN 2014-2017

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

FINLAND 2014-2017

Classification contained use	Total no. of notifications*	No of authorisations*	No. of notifications concerning ATMPs	No. of authorisations concerning ATMPs
Class 1	7 (all for human use)	7	7	7
Class 2	0	0	0	0
Class 3	0	0	0	0
Class 4	0	0	0	0
Total	7	7	7	7

FRANCE 2014-2017

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

FRANCE 2018

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

ITALY 2014-2017

Classification contained use	Total no. of notifications*	No of authorisations*	No. of notifications concerning ATMPs	No. of authorisations concerning ATMPs
Class 1	1	0	1	0
Class 2	13	10	13	10
Class 3	2	1	2	1
Class 4	0	0	0	0
Total	16	11	16	11

PORTUGAL 2014-2017

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

PORTUGAL 2018

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

UNITED KINGDOM 2014-2017

Classification contained use	Total no. of notifications*	No of authorisations*	No. of notifications concerning ATMPs	No. of authorisations concerning ATMPs
Class 1	Unable to provide this information (see below)	Unable to provide this information (see below)	Unable to provide this information (see below)	Unable to provide this information (see below)
Class 2				
Class 3				
Class 4				
Total				

UNITED KINGDOM 2018

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

9.3 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.)?

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

	9.3 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.)?	**9.4 What in your opinion should be done or is done already to address these challenges?**

AT	none	not applicable
AT 2018	none	not applicable
BE	Sometimes, the manufacturing of investigational medicinal products (IMP) has been made in another country. The applicant describes the manufacturing of IMP but does not provide sufficient details (for example: cells transduced with lentiviral vectors, information concerning the absence of residual free functional LV in the final product is often not sufficiently detailed). If the manufacturing of IMP is made in another country, to what extent do we verify all the data? In Wallonia, some dossiers have been notified under contained use but not authorized by the competent authority because the applicant does not introduce his application for an environmental permit.	The applicants need to be aware that different competent authorities should evaluate the same data and they should provide all the information concerning the manufacturing of IMP in their application dossier. It could be interesting to create a network of experts evaluating the different aspects of the medicinal products (safety, biosafety, quality) in order to share information. In Wallonia, in our advices, we remind to the applicant that our advice is not an authorization and that he should introduce an application for an environmental permit.
BE 2018	Sometimes, the manufacturing of investigational medicinal products (IMP) has been made in another country. The applicant describes the manufacturing of IMP but does not provide sufficient details (for example: cells transduced with lentiviral vectors, information concerning the absence of residual free functional LV in the final product is often not sufficiently detailed). If the manufacturing of IMP is made in another country, to what extent do we verify all the data? In Wallonia, some dossiers have been notified under contained use but not authorized by the competent authority because the applicant does not introduce his application for an environmental permit.	The applicants need to be aware that different competent authorities should evaluate the same data and they should provide all the information concerning the manufacturing of IMP in their application dossier. It could be interesting to create a network of experts evaluating the different aspects of the medicinal products (safety, biosafety, quality) in order to share information. In Wallonia, in our advices, we remind to the applicant that our advice is not an authorization and that he should introduce an application for an environmental permit.
BG	Bulgaria has no experience with manufacturing of investigational medicinal products for human use that contain or consist of GMOs. Only applications for clinical trials with such products manufactured elsewhere have been received.	No specific opinion, see reply to Question 10.
BG 2018	Bulgaria has no experience with manufacturing of investigational medicinal products for human use that contain or	No specific opinion, see reply to Question 10.

	consist of GMOs. Only applications for clinical trials with such products manufactured elsewhere have been received.	
CY	Not Applicable.	Not Applicable.
CY 2018	None no investigation of GMOs for human use in Cyprus.	N.R.
CZ	Not applicable	Not applicable
CZ 2018	not applicable	not applicable
DE	In Germany, the manufacturing of an ATMP requires further authorization by the CA responsible for good clinical practices. In relation to the implementation of 2009/41/EC (GenTG) there is no destinction between GMO status and ATMP status. Evaluation of numbers of manufactured ATMPs is not possible with our database. With regard to the distinction between genetic engineering activities in containment and approvement of clinical trials with GMOs, an administrative agreement was reached in March 2015 between the relevant federal and competent authorities.	-
DE 2018	comment (no challenge): In Germany, the manufacturing of an ATMP requires further authorization by the CA responsible for good clinical practices. In relation to the implementation of 2009/41/EC (GenTG) there is no destinction between GMO status and ATMP status. Evaluation of numbers of manufactured ATMPs is not possible with our database.	-
DK	N/A	N/A
DK 2018	N/A	N/A
EE	Labour Inspectorate don't deal with this area	Labour Inspectorate don't deal with this area
EE 2018	N/A	There is not such kind of premises
EL	Not applicable	Not applicable
EL 2018	None	N/A
ES	This question has been addressed in previous section	This question has been addressed in previous section
ES 2018	Differences in procedures between MS (Some MS have considered these activities as contained use and other MS as deliberate	Harmonise procedures between MS.

	release).	
FI	1) Notifying multisite trials; and 2) the concept of "notifier" (whether it is the company developing the product, the CRO, or the hospital/vaccination clinic where the ATMP is administrated); and 3) who should be the individual appointed as the responsible person? (We have tried to be flexible on points 1, 2 and 3.); and 4) supervision of ATMP manufacturing according to GMO legislation is somewhat overlapping with GMP supervision and (in certain cases) also with occupational safety supervision (protection of workers from exposure to biological agents).	Interplay of contained use, GMP, occupational safety, and ABS regulations should be clarified so as to avoid unnecessary regulatory burden for the operators and authorities involved.
FI 2018	No special challenges, when it is question of traditional gene modification techniques.	-
FR	néant	néant
FR 2018	-	-
HR	not applicable	/
HR 2018		
HU	None.	Not relevant.
HU 2018	No challenges were encountered.	-
IE	The CA has not received any applications of this type. Investigational medicinal product is defined as "A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form".	Not applicable
IE 2018	n/a	n/a
IT	The holder of a premise and the user responsible for the manufacturing of investigational medicinal products that contain or consist of GMOs are required to provide a considerable number of information to GMM CA; part of these	Information requested to submit a notification may be improved and simplified. It is desirable that the requested information by every European CA can be harmonized. A better cooperation with the other National

	information could be not held and they have to be provided by the clinical trial sponsor. Sponsor, holder and user could encounter difficulties to cooperate in order to prepare the notification to submit to the CA, especially in case of multicenter clinical trials. The management of the controls to GMM premises and activities should take also into consideration that the same premises and activities are inspected for several crosswise aspects by different CAs. Examples of involved CAs in proceedings controls are: i) Italian National Labor Inspectorate for the protection of the workers; ii) for the GMP: the Italian Medicines Agency and Directorate General for Animal Health and Veterinary Medicines of MoH for the controls on medicines/IMP/ATMPs respectively for human and veterinary use; iii) for controls related to the protection of animals used for scientific purposes: Local Health Authority (at regional level) and Directorate General for Animal Health and Veterinary Medicines of MoH; iv) CAs involved in the control on waste management.	Competent Authorities would allow to get more data and to improve the monitoring system, most of all it would be important to reach an harmonization among the European CAs.
IT 2018		
LT	-	-
LT 2018	-	-
LU	Directive not yet transposed	Transposition of the directive is ongoing
LU 2018	Directive not yet transposed	Transposition of the directive is ongoing
LV	No experience.	No experience.
LV 2018	-	-
MT	Not applicable.	Not applicable.
MT 2018	N/A	N/A
NL	--	--
NL 2018	--	--
PL	risk assessment	sharing procedures across Member States (for example ERA, notification, etc.)

PL 2018		
PT	The CA didn't encounter any challenges in implementing the Directive in relation to this subject.	The CA didn't encounter any challenges in implementing the Directive in relation to this subject.
PT 2018	The CA didn't encounter any challenges in implementing the Directive in relation to this subject.	Not applicable.
RO	Not applicable.	Not applicable.
RO 2018	Not applicable	Not applicable
SE	All GMO that are medicinal products are handled as deliberate release. Only preparations and sample analysis may be notified as any other contained use of GMMs. A challenge is that applicants can be confused what part is contained use and what part is not. But MPA and SWEA cooperates in order to make the process for applicants smooth.	Possible future actions can be implementation of ERA for inspectors of the GMP (good manufacturing practice) qualification.
SE 2018	-	-
SI	No challenges were encountered	-
SI 2018	No experience	-
SK	----	-----
SK 2018	---	---
UK	Unfortunately we cannot provide this information as it is not specifically recorded. There have definitely been broad notifications covering the manufacturing of vectors for use as IMPs (e.g. lentiviral vectors) but sometimes these notifications could cover a range of cargo genes and is not necessarily exhaustive. We would estimate the number of notifications in the reporting period to be between 5-10 class 2. There is no notification requirement for class 1 activities.	Not applicable
UK 2018	We are not aware of any. Only if the activity of manufacturing the IMP was a class 2 (or higher) activity would notification be received. Often this would be a class 1 activity so no activity notification would be required. Unfortunately we cannot provide this information as it is not specifically recorded.	N/A

b. Administration (clinical trials)

10.1 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**?**

10.2 Were there activities described in 10.1 notified and/or authorised in your Member State during the reporting period?

	10.1 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?	**10.2 Were there such activities notified and/or authorised in your Member State during the reporting period?**
AT	Yes	Yes
AT 2018	Yes	Yes
BE	Yes	Yes
BE 2018	Yes	Yes
BG	No	
BG 2018	No	
CY	No	
CY 2018	No	
CZ	No	
CZ 2018	No	
DE	No	
DE 2018	No	
DK	Yes	Yes
DK 2018	Yes	Yes
EE	No	
EE 2018	No	
EL	Yes	No
EL 2018	No	
ES	No	
ES 2018	No	
FI	Yes	Yes
FI 2018	Yes	Yes
FR	Yes	Yes
FR 2018	Yes	Yes
HR	No	
HR 2018		
HU	No	
HU 2018	No	

IE	No	
IE 2018	No	
IT	Yes	Yes
IT 2018		
LT	No	
LT 2018	No	
LU	Yes	No
LU 2018	Yes	No
LV	No	
LV 2018	No	
MT	No	No
MT 2018	Yes	No
NL	No	
NL 2018	No	
PL	Yes	No
PL 2018		
PT	Yes	No
PT 2018	Yes	No
RO	No	
RO 2018	No	
SE	No	
SE 2018	No	
SI	No	
SI 2018	No	
SK	No	
SK 2018	No	
UK	Yes	Yes
UK 2018	Yes	Yes

If yes, provide details:

AUSTRIA 2014-2017

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

** Report all notifications/authorisations, including those related to ATMPs*

AUSTRIA 2018

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

BELGIUM 2014-2017

Classification contained use	Total No. of notifications*	Total No. of authorisations*	No of notifications concerning ATMPs	No of authorisations concerning ATMPs
Class 1	22	22	20	20
Class 2	1	1	1	1
Class 3	0	0	0	0
Class 4	0	0	0	0
Total	23	23	21	21

BELGIUM 2018

Classification contained use	Total No. of notifications*	Total No. of authorisations*	No of notifications concerning ATMPs	No of authorisations concerning ATMPs
Class 1	43	43	43	43
Class 2	0	0	0	0
Class 3	0	0	0	0
Class 4	0	0	0	0
Total	43	43	43	43

DENMARK 2014-2017

Classification contained use	Total No. of notifications*	Total No. of authorisations*	No of notifications concerning ATMPs	No of authorisations concerning ATMPs
Class 1	4	4	4	4
Class 2	0	0	0	0
Class 3	0	0	0	0
Class 4	0	0	0	0
Total	4	4	4	4

DENMARK 2018

Classification contained use	Total No. of notifications*	Total No. of authorisations*	No of notifications concerning ATMPs	No of authorisations concerning ATMPs
Class 1	8	8	0	0
Class 2	0	0	0	0
Class 3	0	0	0	0
Class 4	0	0	0	0
Total	8	8	0	0

FINLAND 2014-2017

Classification contained use	Total No. of notifications*	Total No. of authorisations*	No of notifications concerning ATMPs	No of authorisations concerning ATMPs
Class 1	7	7	7	7
Class 2	0	0	0	0
Class 3	0	0	0	0
Class 4	0	0	0	0
Total	7	7	7	7

FINLAND 2018

Classification contained use	Total No. of notifications*	Total No. of authorisations*	No of notifications concerning ATMPs	No of authorisations concerning ATMPs
Class 1	6	6	6	6
Class 2	0	0	0	0
Class 3	0	0	0	0
Class 4	0	0	0	0
Total	6	6	6	6

FRANCE 2014-2017

Classification contained use	Total No. of notifications*	Total No. of authorisations*	No of notifications concerning ATMPs	No of authorisations concerning ATMPs
Class 1	néant	néant	néant	néant
Class 2	néant	néant	néant	néant
Class 3	néant	néant	néant	néant
Class 4	néant	néant	néant	néant
Total	néant	néant	néant	néant

FRANCE 2018

Classification contained use	Total No. of notifications*	Total No. of authorisations*	No of notifications	No of authorisations

			concerning ATMPs	concerning ATMPs
Class 1				
Class 2				
Class 3				
Class 4				
Total				

ITALY 2014-2017

Classification contained use	Total No. of notifications*	Total No. of authorisations*	No of notifications concerning ATMPs	No of authorisations concerning ATMPs
Class 1	7	4	7	4
Class 2	53	47	53	47
Class 3	0	0	0	0
Class 4	0	0	0	0
Total	60	51	60	51

UNITED KINGDOM 2014-2017

Classification contained use	Total No. of notifications*	Total No. of authorisations[7]*	No of notifications concerning ATMPs	No of authorisations concerning ATMPs
Class 1	Unable to provide this information (see below)	Unable to provide this information (see below)	Unable to provide this information (see below)	Unable to provide this information (see below)
Class 2				
Class 3				
Class 4				
Total				

UNITED KINGDOM 2018

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

10.3 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.)?

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

	10.3 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.)?	**10.4 What in your opinion should be done or is done already to address these challenges?**
AT	not applicable, due to specific regulations in Austria	not applicable
AT 2018	none	not applicable
BE	In Belgium, depending on the characteristics and mode of administration of the medicinal product, it is possible that the GMO aspects of clinical trials with medicinal products for human use containing or consisting of GMOs do not require an authorisation under the deliberate release frameworks (Directive 2001/18/EC – Part B). When there is no possible release of the GMO in the environment that may confer a risk to human health or the environment (e.g. in case of GM medication taken at home, no risk of shedding, spreading,…), or if proper management procedures and/or working practices are taken to prevent any possible release conferring a risk, then a 'contained use' procedure will generally be sufficient. However, if there is a probability of possible release that may confer a risk to human health or the environment which cannot be avoided by proper management procedures or working practices, a notification under 'deliberate release' is also required. The applicant does not always know what procedure should be applied ("contained use only" or deliberate release and contained use).	If the framework to be followed is not clear to the applicant, it is strongly advised to request a national scientific-technical advice (STA) from the Federal Agency for Medicines and Health Products (FAMHP) prior to the submission of the clinical trial application.

BE 2018	In Belgium, depending on the characteristics and mode of administration of the medicinal product, it is possible that the GMO aspects of clinical trials with medicinal products for human use containing or consisting of GMOs do not require an authorisation under the deliberate release frameworks (Directive 2001/18/EC – Part B). When there is no possible release of the GMO in the environment that may confer a risk to human health or the environment (e.g. in case of GM medication taken at home, no risk of shedding, spreading,…), or if proper management procedures and/or working practices are taken to prevent any possible release conferring a risk, then a 'contained use' procedure will generally be sufficient. However, if there is a probability of possible release that may confer a risk to human health or the environment which cannot be avoided by proper management procedures or working practices, a notification under 'deliberate release' is also required. The applicant does not always know what procedure should be applied ("contained use only" or deliberate release and contained use).	If the framework to be followed is not clear to the applicant, it is strongly advised to request a national scientific-technical advice (STA) from the Federal Agency for Medicines and Health Products (FAMHP) prior to the submission of the clinical trial application. The SBB in collaboration with the Belgian federal agency for medicines are preparing a document "guideline" aiming to help applicants in determining the regulatory procedures they must follow
BG	Administration of investigational medicinal products for human use that contain or consist of GMOs is notified under Directive 2001/18/EC as it is considered to involve release into the environment. There is no clear procedure to distinguish whether a clinical trial of products containing genetically modified organisms (both for human and for veterinary use) should be considered contained use and when release into the environment. It is not entirely clear to us how the provisions of the Directive 2009/41/EC should be applied when GMM is administered in hospital during clinical	We expect that the current process on the interplay between EU medicine and GMO legislation will clarify most of the issues identified and common approaches will be adopted by the EU member states regarding clinical trials of GMO medicinal products.

	trial but the patients are not kept under contained conditions for the duration of the trial. In application for clinical trials in Bulgaria, the applicant is required to provide information on the containment measures for each hospital (which should be registered as such under the Bulgarian legislation) where the medicinal product will be administered. That information is not considered formal notification. All applications examined so far involved only Class 1 activities.	
BG 2018	Administration of investigational medicinal products for human use that contain or consist of GMOs is notified under Directive 2001/18/EC as it is considered to involve release into the environment. There is no clear procedure to distinguish whether a clinical trial of products containing genetically modified organisms (both for human and for veterinary use) should be considered contained use and when release into the environment. It is not entirely clear to us how the provisions of the Directive 2009/41/EC should be applied when GMM is administered in hospital during clinical trial but the patients are not kept under contained conditions for the duration of the trial. In application for clinical trials in Bulgaria, the applicant is required to provide information on the containment measures for each hospital (which should be registered as such under the Bulgarian legislation) where the medicinal product will be administered. That information is not considered formal notification. All applications examined so far involved only Class 1 activities.	We hope that the current process on the interplay between EU medicine and GMO legislation will continue and will further clarify most of the issues identified and common approaches will be adopted by the EU member states regarding clinical trials of GMO medicinal products.
CY	Not Applicable.	Not Applicable.
CY 2018	No investigation of GMOs for human use in Cyprus.	N.R.
CZ	Not applicable	Not applicable

CZ 2018	not applicable	not applicable
DE	-	With regard to the distinction between genetic engineering activities in containment and approvement of clinical trials with GMOs, an administrative agreement was reached in March 2015 between the relevant federal and competent authorities.
DE 2018	-	-
DK	None	N/A
DK 2018	None	N/A
EE	Labour Inspectorate don't deal with this area	Labour Inspectorate don't deal with this area
EE 2018	There is not such kind of premises	N/A
EL	No activities reported.	No activities reported, therefore no associated challenges.
EL 2018	N/A	N/A
ES	CLINICAL TRIALS WITH GMOs ARE AUTHORISED UNDER DIRECTIVE 2001/18/EC	CLINICAL TRIALS WITH GMOs ARE AUTHORISED UNDER DIRECTIVE 2001/18/EC
ES 2018	Differences in procedures between MS (Some MS have considered these activities as contained use and other MS as deliberate release).	Harmonise procedures between MS.
FI	1) Decision whether the clinical trial is contained use or deliberate release; and 2) classification of the GMM; and 3) interplay of various regulations concerning GMOs, pharmaceuticals, occupational safety, waste treatment, and patient rights.	Commission working group is already considering the interplay of pharmaceutical and GMO legislation, and this hopefully clarifies the situation.However, it is likely not to solve all the issues. It would be worth examining whether GMO medicinal product production and clinical trials should be legally separated from GMO directives. Also, the linkages between occupational safety, patient rights and waste treatment issues outside hospital environment (e.g. in homecare) should be considered.
FI 2018	1) Decision whether the clinical trial is contained use or deliberate release; this is easier when the medicinal product has already a marketing approval as the shedding issues have been examided during the approval proecess.	Commission working group is already considering the interplay of pharmaceutical and GMO legislation, and this hopefully clarifies the situation. However, it is likely not to solve all the issues. It would be worth

	2) classification of the GMM; and 3) interplay of various regulations concerning GMOs, pharmaceuticals, occupational safety, waste treatment, and patient rights.	examining whether GMO medicinal product production and clinical trials should be legally separated from GMO directives. Also, the linkages between occupational safety, patient rights and waste treatment issues outside hospital environment (e.g. in homecare) should be considered.
FR	néant	néant
FR 2018	Difficulté à apprécier l'utilisation confinée et disséminée dans le cas d'essais cliniques sur des personnes humaines	Le périmètre d'application de la Directive pour les essais cliniques sur des personnes humaines pourrait être clarifié
HR	not applicable	/
HR 2018		
HU	In Hungary the requirements for GMO submission in clinical trials could be accepted under the deliberate release directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EC. No. of authorisation of investigational medicinal products for human use that contain or consist of GMOs under deliberate release directive 2001/18/EC last 3 years: 3 clinical trials.	No relevance.
HU 2018	No challenges were encountered.	-
IE	Not applicable	Not applicable
IE 2018	n/a	n/a
IT	Challenge 1: difficulties for the stakeholders. They are due to different interpretations of the definitions given in Directive 2009/41/EC and in Directive 2001/18/EC (e.g. GMM vs. GMO in which the last includes also the first or to interpret the means of “deliberate release” in a context of “contained use”) and to different approaches used throughout Europe to assess the risk for the humans and environment. The different interpretations lead EU	Harmonization of the different point of views of the different Countries at European level should be the primary aim. The work and the documents, produced by Commission Services, focused to optimize the interplay between the GMO, GMM and the medicinal products legislation, are to consider as very useful approaches for the Italian GMM CA and the involved stakeholders. Challenge 1: could be faced and settled

	Member States to follow different procedures and users/sponsors to comply to different rules in order to get the same type of authorizations in different Countries. Challenge 2: difficulties for the user and the sponsor related to different approaches among the EU Countries. Though the Directive 2009/41/EC lays down common measures for the contained use of GMMs, the installations, in which a clinical trial is carried out, and the contained activities, by which the IMPs containing or consisting of GMMs, are administered, can be subject, in several European Countries, to authorizations issued according to Directive 2001/18/EC. The above mentioned not harmonized approach could entail that a deliberate release authorization is issued notwithstanding the user risk assessment reports and proves a priori that there is no deliberate release in the environment of GMMs. Challenge 3: to avoid misunderstandings among the involved stakeholders and GMM CA whether an application, for a clinical trial in which an IMP consisting of GMM is used, has to be or not submitted to get an authorization to deliberate release according to the Part B of the Directive 2001/18/EC). Part of these cases can be found among the clinical studies listed on the website of the Joint Research Center (http://gmoinfo.jrc.ec.europa.eu/gmo_browse.aspx) that were submitted, in compliance with the article 6 of the Directive 2001/18/EC, assuming and giving for sure that an intentional deliberate release of GMM occurs although this in conclusion is not or would not be confirmed. Challenge 4: find a simplified approach,	amending the Directive 2009/41/EC and Directive 2001/18/EC with ad hoc provisions focused on clinical trials in which IMPs are administered. Challenge 2 and 3: provide the user a clear information, previously shared with the involved National CAs, to be published on the CAs institutional web sites. With regard to the challenge 3, an additional analysis shared at European level could further simplify the approaches followed by involved CAs, users and sponsors. The scope is also to keep the European Commission and Member States informed about the type of Clinical Trials authorized under the Directive 2009/41/EC and to publish the relevant information on the Commission web site. Challenge 4 and 5: could be dealt importing at national level the approach reported in the mentioned documents produced by Commission service or producing harmonized documents among the European Member States.

	where possible, according to the Directives provisions. Without prejudice to the right of each European Country to apply on their territory the legislation that is considered more appropriate, it is presumable that an harmonized approach could result more adequate in terms of human resources and time spent by the CAs to assess the notification and by the premises holder, user and sponsor to prepare the notification. Challenge 5: to establish the relevant cases for which a risk assessment by a notification has to be submitted or not if a medicine used in the clinical trial has obtained the marketing authorization by EMA centralized procedure. In these cases, the risks to consider could be different for a new clinical trial if compared to those assessed in order to obtain the marketing authorization. This last aspect need to be assessed on a case by case basis by the Italian GMM CA and it is also for this reason that in Italy, to conduct a clinical trial for which a deliberate release can be excluded, the GMM CA issues the authorizations for the premise and the GMM contained activity performed in it.	
IT 2018		
LT	-	-
LT 2018	-	-
LU	Directive not yet transposed	Transposition of the directive is ongoing
LU 2018	Directive not yet transposed	Transposition of the directive is ongoing
LV	-	-
LV 2018	-	-
MT	Not applicable.	Not applicable.
MT 2018	N/A	N/A
NL	--	--

NL 2018	--	--
PL	risk assessment	sharing procedures across Member States (for example ERA, notification, etc.)
PL 2018		
PT	The legal framework of the GMOs clinical trial – deliberate release into the environment of GMOs or contained use of GMOs - is defined on a case-by-case basis taking into account the specificity of the GMO clinical trial. Therefore the clinical trials don´t fall exclusively whitin the scope of Directive 2009/41/EC or Directive 2001/18/EC. There were no activities notified and/or authorised regarding clinical trials using medicinal products for human use that contain or consisit of GMOs under Directive 2009/41/EC - contained use of GMOs. However under Directive 2001/18/EC there were submitted and authorised three notifications in 2016 for deliberate release into the environment with GMOs for clinical trials on medicinal products for human use. The CA had difficulty determinated whether the administration of investigational medicinal products for human use that contains or consist of GMOs - clinical trials, fall under the scope of Directive 2009/41/EC or under the scope of Directive 2001/18/EC. We considered that should be a harmonisation of the guidance and the procedures for the evaluation and notification of clinical trials with GMMs at Union level.	The CA would like to see clarity on the legislative framework concerning clinical trials with GMMs.
PT 2018	The legal framework of the GMOs clinical trial – deliberate release into the environment of GMOs or contained use of GMOs - is defined on a case-by-case basis taking into account the specificity of the GMO clinical trial. Therefore the clinical	The CA would like to see clarity on the legislative framework concerning clinical trials with GMMs.

	trials don´t fall exclusively within the scope of Directive 2009/41/EC or Directive 2001/18/EC.	
RO	Not applicable.	Not applicable.
RO 2018	Not applicable	Not applicable
SE	No challenges experienced yet.	n.a.
SE 2018	-	-
SI	-	-
SI 2018	Administration of investigational medecinal products for humans that contain or consist of GMOs is notified and/or authorised under Directive 2001/18 in Slovenia.	-
SK	----	----
SK 2018	---	---
UK	Unfortunately we cannot provide this information as it is not specifically recorded. Some class 2 activities have definitely been notified and we would estimate that this would be between 10-15 for the reporting period. There is no notification required for class 1 activities which likely accounts for the bulk of work involving administration of IMPs. Nothing in addition to the issues raised by the industry relating to the lack of consistency across member states in relation to the requirements to notify and which regulatory route (CU v DR)	It is our understanding that the EC working groups on GMO-Pharma interplay are trying to address some of these issues through provision of better information and guidance on risk assessment for certain types of vectors etc. At a national level the CA is discussing with the medicines regulator to see if there are ways to streamline clinical trials whilst complying with requirements under the different regimes.
UK 2018	Nothing in addition to the issues raised by the industry relating to the lack of consistency across member states in relation to the requirements to notify and which regulatory route (CU v DR)	It is our understanding that the EC working groups on GMO-Pharma interplay are trying to address some of these issues through provision of better information and guidance on risk assessment for certain types of vectors etc. At a national level the CA is discussing with the medicines regulator to see if there are ways to streamline clinical trials whilst complying with requirements under the different regimes

III.2 Veterinary use

a. Manufacturing

11.1 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**?**

11.2 If yes, 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?

	11.1 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?	**11.2 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?**
AT	Yes	Yes
AT 2018	Yes	No
BE	Yes	Yes
BE 2018	Yes	No
BG	No	
BG 2018	Yes	No
CY	No	
CY 2018	No	
CZ	Yes	No
CZ 2018	Yes	No
DE	Yes	Yes
DE 2018	Yes	Yes
DK	No	
DK 2018	No	
EE	No	
EE 2018	No	
EL	Yes	No
EL 2018	Yes	No
ES	Yes	Yes
ES 2018	No	
FI	Yes	No
FI 2018	Yes	No
FR	Yes	Yes
FR 2018	Yes	No
HR	No	
HR 2018		
HU	Yes	Yes
HU 2018	No	

IE	No	
IE 2018	Yes	No
IT	Yes	No
IT 2018		
LT	No	
LT 2018	No	
LU	Yes	No
LU 2018	Yes	No
LV	No	
LV 2018	No	
MT	No	No
MT 2018	No	No
NL	No	
NL 2018	No	
PL	No	
PL 2018		
PT	Yes	No
PT 2018	Yes	No
RO	No	
RO 2018	Yes	No
SE	No	
SE 2018	No	
SI	No	
SI 2018	Yes	No
SK	No	
SK 2018	No	
UK	Yes	Yes
UK 2018	Yes	Yes

If yes, provide details:

AUSTRIA 2014-2017

Classification contained use	**No. of notifications**	**No of authorisations**
Class 1	no data available	
Class 2	no data available	
Class 3	--	
Class 4	--	
Total		

BELGIUM 2014-2017

Classification contained use	No. of notifications	No of authorisations
Class 1	0	0
Class 2	1	0
Class 3	0	0
Class 4	0	0
Total	1	0

GERMANY 2014-2017

Classification contained use	No. of notifications	No of authorisations
Class 1		
Class 2		
Class 3		
Class 4		
Total		

GERMANY 2018

Classification contained use	No. of notifications	No of authorisations
Class 1		
Class 2		
Class 3		
Class 4		
Total		

SPAIN 2014-2017

Classification contained use	No. of notifications	No of authorisations
Class 1		
Class 2		
Class 3		
Class 4		
Total		

FRANCE 2014-2017

Classification contained use	No. of notifications	No of authorisations
Class 1	néant	néant
Class 2	néant	néant
Class 3	néant	néant
Class 4	néant	néant
Total	néant	néant

HUNGARY 2014-2017

Classification contained use	No. of notifications	No of authorisations
Class 1	0	0
Class 2	10	10
Class 3	0	0
Class 4	0	0
Total	10	10

UNITED KINGDOM 2014-2017

Classification contained use	No. of notifications	No of authorisations
Class 1	Unfortunately we do not have this information but we cannot recall any being submitted.	Unfortunately we do not have this information but we cannot recall any being submitted.
Class 2		
Class 3		
Class 4		
Total		

UNITED KINGDOM 2018

Classification contained use	No. of notifications	No of authorisations
Class 1		
Class 2		
Class 3		
Class 4		
Total		

11.3 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.)?

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

	11.3 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.)?	**11.4 What in your opinion should be done or is done already to address these challenges?**
AT	none	not applicable
AT 2018	none	not applicable
BE	/	/
BE 2018	/	/

BG	Bulgaria has no experience with manufacturing of investigational medicinal products for veterinary use that contain or consist of GMOs.	No specific opinion, see reply to Question 10.
BG 2018	Bulgaria has no experience with manufacturing of investigational medicinal products for veterinary use that contain or consist of GMOs.	No specific opinion, see reply to Question 10.
CY	Not Applicable.	Not Applicable.
CY 2018	No investigation of GMOs for veterinary use in Cyprus.	N.R.
CZ	Not applicable	Not applicable
CZ 2018	not applicable	not applicable
DE	In Germany, the manufacturing of an ATMP requires further authorization by the CA responsible for good clinical practices. In relation to the implementation of 2009/41/EC (GenTG) there is no destinction between GMO status and ATMP status. Evaluation of numbers of manufactured ATMPs is not possible with our database.	-
DE 2018	comment (no challenge): In Germany, the manufacturing of an ATMP requires further authorization by the CA responsible for good clinical practices. In relation to the implementation of 2009/41/EC (GenTG) there is no destinction between GMO status and ATMP status. Evaluation of numbers of manufactured ATMPs is not possible with our database.	-
DK	None	N/A
DK 2018	N/A	N/A
EE	Labour Inspectorate don't deal with this area	Labour Inspectorate don't deal with this area
EE 2018	There is not such kind of premises	N/A
EL	No activities reported.	No activities reported, therefore no associated challenges.
EL 2018	None	N/A
ES	This question has been addressed in previous section	This question has been addressed in previous section
ES 2018	Differences in procedures between MS (Some MS have considered these activities as contained use and other MS as deliberate release).	Harmonise procedures between MS.
FI	Basically the same as for human ATMPs, except that it is harder to find any national experts on the risk assessment.	A network of experts that the CAs could approach when necessary would be most welcome.
FI 2018	Not encountered during the reporting period.	-

FR	néant	néant
FR 2018		
HR	not applicable	/
HR 2018		
HU	No.	Not relevant.
HU 2018	No challenges were encountered.	-
IE	The CA has not received any applications of this type. Investigational medicinal product is defined as "A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form".	Not applicable
IE 2018	n/a	n/a
IT	Manufacturing of an investigational medicinal products or marketed medicinal products for veterinary use that contain or consist of GMMs is regulated under Directive 2009/41/EC and the GMM CA expects that notifications of the involved premises and the contained activities are submitted and authorized. To date the information required through the notifications do not include explicitly if the investigational medicinal product is for veterinary use or if it is marketed and such type of information can be acquired only in part by the context of the information provided by the user. To date no notifications have been submitted to GMM CA.	To improve the exchange of the information required by EU Commission cooperating with the Directorate-General for Animal Health and Veterinary Medicines of the MoH that is the CA for the monitoring of manufacturing of veterinary medicinal products.
IT 2018		
LT	-	-
LT 2018	-	-
LU	Directive not yet transposed	Transposition of the directive is ongoing
LU 2018	Directive not yet transposed	Transposition of the directive is ongoing
LV	-	-
LV 2018	-	-
MT	Not applicable.	Not applicable.
MT 2018	N/A	N/A
NL	--	--

NL 2018	--	--
PL	not applicable	sharing procedures/experiences across Member States (for example ERA, notification, etc.)
PL 2018		
PT	The CA didn't encounter any challenges in implementing the Directive in relation to this subject.	The CA didn't encounter any challenges in implementing the Directive in relation to this subject.
PT 2018	The CA didn't encounter any challenges in implementing the Directive in relation to this subject.	The CA didn't encounter any challenges in implementing the Directive in relation to this subject.
RO	Not applicable.	Not applicable.
RO 2018	Not applicable	Not applicable
SE	All GMO that are medicinal products are handled as deliberate release. Only preparations and sample analysis may be notified as any other contained use of GMMs. A challenge is that applicants can be confused what part is contained use and what part is not. But MPA and SWEA cooperates in order to make the process for applicants smooth.	Possible future actions can be implementation of ERA for inspectors of the GMP (good manufacturing practice) qualification.
SE 2018	-	-
SI	-	-
SI 2018	We have not encountered any challenges for the time being.	-
SK	-----	-----
SK 2018	---	---
UK **UK 2018**	None None. Unfortunately we do not have this information	Not applicable. N/A

b. Administration (clinical trials)

12.1 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**?**

12.2 Were there activities described in 12.1 notified and/or authorised in your Member State during the reporting period?

	12.1 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?	**12.2 Were there any such activities notified and/or authorised in your Member State during the reporting period?**
AT	Yes	Yes

AT 2018	Yes	No
BE	Yes	Yes
BE 2018	Yes	No
BG	No	
BG 2018	No	
CY	No	
CY 2018	No	
CZ	No	
CZ 2018	No	
DE	No	
DE 2018	No	
DK	No	
DK 2018	Yes	No
EE	No	
EE 2018	No	
EL	Yes	No
EL 2018	No	
ES	No	
ES 2018	No	
FI	Yes	No
FI 2018	Yes	No
FR	Yes	Yes
FR 2018	No	No
HR	No	
HR 2018		
HU	No	
HU 2018	No	
IE	No	
IE 2018	No	
IT	Yes	No
IT 2018		
LT	No	
LT 2018	No	
LU	Yes	No
LU 2018	Yes	No
LV	No	
LV 2018	No	
MT	No	No
MT 2018	No	No
NL	No	
NL 2018	No	

PL	No	
PL 2018		
PT	Yes	No
PT 2018	Yes	No
RO	No	
RO 2018	No	
SE	No	
SE 2018	No	
SI	No	
SI 2018	Yes	No
SK	No	
SK 2018	No	
UK	Yes	Yes
UK 2018	Yes	Yes

If yes, provide details:

AUSTRIA 2014-2017

Classification contained use	**No. of notifications**	**No. of authorisations**
Class 1	no data available	
Class 2	no data available	
Class 3	--	
Class 4	--	
Total		

BELGIUM 2014-2017

Classification contained use	**No. of notifications**	**No. of authorisations**
Class 1	0	0
Class 2	1	1
Class 3	1	1
Class 4	0	0
Total	2	2

FRANCE 2014-2017

Classification contained use	**No. of notifications**	**No. of authorisations**
Class 1	néant	néant
Class 2	néant	néant
Class 3	néant	néant
Class 4	néant	néant
Total	néant	néant

UNITED KINGDOM 2014-2017

Classification contained use	No. of notifications	No. of authorisations
Class 1	1	1
Class 2		
Class 3		
Class 4		
Total		

UNITED KINGDOM 2018

Classification contained use	No. of notifications	No. of authorisations
Class 1		
Class 2		
Class 3		
Class 4		
Total		

12.3 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.)?

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

	12.3 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.)?	**12.4 What in your opinion should be done or is done already to address these challenges?**
AT	none	not applicable
AT 2018	none	not applicable
BE	For veterinary use, it is not easy to know if the notifications are clinical trials or research and development.	/
BE 2018	For veterinary use, it is not easy to know if the notifications are clinical trials or research and development.	/
BG	Bulgaria has no experience with administration of investigational medicinal products for human use that contain or consist of GMOs. Whether a clinical trial will be	No specific opinion, see reply to Question 10.

	considered to involve contained use of GMO or release into the environment will be decided on a case-by-case basis.	
BG 2018	Bulgaria has no experience with administration of investigational medicinal products for human use that contain or consist of GMOs. Whether a clinical trial will be considered to involve contained use of GMO or release into the environment will be decided on a case-by-case basis.	No specific opinion, see reply to Question 10.
CY	Not Applicable.	Not Applicable.
CY 2018	No investigation of GMOs for veterinary use in Cyprus.	N.R.
CZ	Not applicable	Not applicable
CZ 2018	not applicable	not applicable
DE	The administration of VIMP containig GMOs is under the scope of 2001/18/EC. The authorization of field trials with GMOs is challenging especially due to public consultations.	-
DE 2018	-	-
DK	None	N/A
DK 2018	N/A	N/A
EE	Labour Inspectorate don't deal with this area	Labour Inspectorate don't deal with this area
EE 2018	There is not such kind of premises	N/A
EL	No activities reported.	No activities reported, therefore no associated challenges.
EL 2018	N/A	N/A
ES	CLINICAL TRIALS WITH GMOs ARE AUTHORISED UNDER DIRECTIVE 2001/18/EC	CLINICAL TRIALS WITH GMOs ARE AUTHORISED UNDER DIRECTIVE 2001/18/EC
ES 2018	Differences in procedures between MS (Some MS have considered these activities as contained use and other MS as deliberate release).	Harmonise procedures between MS.
FI	Not encountered during the reporting period, but in an earlier case we encountered the same challenges as for human clinical trials. However, the issues related to GMM shedding were different when the test subjects were dogs.	The commission working group is already tackling the challenges.
FI 2018	Not encountered during the reporting period, but risk management methods are a challenge, if the test subjects are pets or companion animals.	-
FR	néant	néant
FR 2018		

HR	not applicable	/
HR 2018		
HU	No relevance.	No.relevance.
HU 2018	No challenges were encountered.	-
IE	None	None
IE 2018	n/a	n/a
IT	Administration of an investigational medicinal products or marketed medicinal products for veterinary use that contain or consist of GMMs is considered, if a deliberate release has been excluded, a contained activity and consequently it is regulated under the Directive 2009/41/EC. GMM CA expects that notifications of the involved premises and the contained activities are submitted to be authorized. To date the information required through the notifications do not include explicitly if the investigational medicinal product is for veterinary use or if it is marketed and such type of information can be acquired at least in part by the context of the information provided by the user. To date no notifications have been submitted to GMM CA.	To improve the exchange of the information required by EU Commission cooperating with the Directorate General for Animal Health and Veterinary Medicines of MoH that is the CA for the protection of animals used for scientific purposes.
IT 2018		
LT	-	-
LT 2018	-	-
LU	Directive not yet transposed	Transposition of the directive is ongoing
LU 2018	Directive not yet transposed	Transposition of the directive is ongoing
LV	-	-
LV 2018	-	-
MT	Not applicable.	Not applicable.
MT 2018	N/A	N/A
NL	--	--
NL 2018	--	--
PL	risk assessment	sharing knowledge/experiences/solutions with other Member States
PL 2018		
PT	The legal framework of the GMOs clinical	We considered that should be a

	trial – deliberate release into the environment of GMOs or contained use of GMOs - is defined on a case-by-case basis taking into account the specificity of the GMO clinical trial. Therefore the clinical trials don´t fall exclusively whitin the scope of Directive 2009/41/EC or Directive 2001/18/EC. There were no activities notified and/or authorised regarding clinical trials using medicinal products for veterinary use that contain or consist of GMOs under Directive 2009/41/EC - contained use of GMOs.The CA had difficulty determinated whether the administration of investigational medicinal products for veterinary use that contains or consist of GMOs - clinical trials, fall under the scope of Directive 2009/41/EC or under the scope of Directive 2001/18/EC.	harmonisation of the guidance and the procedures for the evaluation and notification of clinical trials with GMMs at Union level.
PT 2018	The legal framework of the GMOs clinical trial – deliberate release into the environment of GMOs or contained use of GMOs - is defined on a case-by-case basis taking into account the specificity of the GMO clinical trial. Therefore the clinical trials don´t fall exclusively whitin the scope of Directive 2009/41/EC or Directive 2001/18/EC. There were no activities notified and/or authorised regarding clinical trials using medicinal products for veterinary use that contain or consist of GMOs under Directive 2009/41/EC - contained use of GMOs. The CA had difficulty determinated whether the administration of investigational medicinal products for veterinary use that contains or consist of GMOs - clinical trials, fall under the scope of Directive 2009/41/EC or under the scope of Directive 2001/18/EC.	We considered that should be a harmonisation of the guidance and the procedures for the evaluation and notification of clinical trials with GMMs at Union level.
RO	Not applicable.	Not applicable.
RO 2018	Not applicable	Not applicable
SE	A future challenge may be a Clinical trial with caged animals.	Swedish authorities will discuss and agree if and when a Clinical trial with caged animal will be applied for.
SE 2018	-	-
SI	-	-
SI 2018	-	Administration of investigational medecinal products for veterinary use

		that contain or consist of GMOs is notified and/or authorised under Directive 2001/18 in Slovenia.
SK	------	-------
SK 2018	---	---
UK	None.	None.
UK 2018	None. Unfortunately we do not record this information but we can recall one as an example of a first use on a premises notification	N/A

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.

13.1 Has your Member State taken any measure regarding gene drive modified organisms under the Directive?
If yes, provide details:

AT	No	
AT 2018	No	
BE	No	
BE 2018	No	
BG	No	
BG 2018	No	
CY	No	
CY 2018	No	
CZ	No	
CZ 2018	No	
DE	Yes	Involvement of the advisory board ZKBS (position statement in Febr. 2016): Genetic engeneering procedures to generate gene drive organisms are allocated to class 2. The recommendation of specific safety measures will be done by the ZKBS in a case by case assessment .
DE 2018	No	
DK	No	
DK 2018	No	
EE	No	
EE 2018	No	
EL	No	
EL 2018	No	

ES	No	
ES 2018	No	
FI	No	
FI 2018	No	
FR	Yes	
FR 2018	No	
HR	No	
HR 2018		
HU	No	
HU 2018	No	
IE	No	
IE 2018	No	
IT	No	
IT 2018		
LT	No	
LT 2018	No	
LU	No	
LU 2018	No	
LV	No	
LV 2018	No	
MT	No	
MT 2018	No	
NL	Yes	The Netherlands amended its rules on contained use of GMO's to accommodate applications for gene drive modified organisms, in such a way that in all cases a permit instead of a notification is required. This amendment of the Ministerial Order came into force on 1 July 2016.
NL 2018	No	
PL	No	
PL 2018		
PT	No	
PT 2018	No	
RO	No	
RO 2018	No	
SE	Yes	For contained use of GM plants, any consent holder should inform the Swedish Board of Agriculture if a modification can function as a gene driver. For contained use of GM animals, the form for notification will be amended if there will be future notifications concerning gene drive animals. For contained use of GMMs, gene drive may be of interest only if a GMM is based on an eukarytic organism and the organism can give rise to new organisms. A cell culture is

		probably not enough fit to give rise to new organisms. If a GMM would be modified with a gene drive mechanism, it should be contained use of at least Class 2. The risk assessment should catch the risks in this case, given that the consequences if the GMM escapes from the containment will be more than neglible.
SE 2018	Yes	Swedish Board of Agriculture- GM plants/animals
SI	No	
SI 2018		
SK	No	
SK 2018		
UK	Yes	NB the directive only covers GMMs. The only notifications which would be required under the directive would be modification of a microorganism (e.g. yeast). However, the CA has issued guidance on gene editing and drive (prepared by SACGM) to advise users of configurations of CRISPR Cas9 that would raise concerns.
UK 2018	Yes	The only notifications which would be required under the directive would be modification of a microorganism (e.g. yeast). However, the CA has issued guidance on gene editing and drive (prepared by SACGM) to advise users of configurations of CRISPR Cas9 that would raise concerns.

13.2 Are there any notifications on gene drive modified organisms submitted under your contained use legislation?
Questionnaire 2018: Have you received notifications on gene drive modified organisms submitted under your contained use legislation?

	2014-2017	**2018**
AT	No	No
BE	No	No
BG	No	No
CY	No	No
CZ	No	No
DE	Yes	No
DK	No	No
EE	No	No
EL	No	No
ES	No	No
FI	No	No
FR	Yes	No
HR	No	
HU	No	No
IE	No	No

IT	Yes	
LT	No	No
LU	No	No
LV	No	No
MT	No	No
NL	No	No
PL	No	
PT	No	No
RO	No	No
SE	No	No
SI	No	No
SK[10]	Yes	Yes
UK	No	No

If yes, list all notifications (one notification per line):

GERMANY 2014-2017

For each notification	**Type of organism**	**Scope**	**Classification of contained use***
a	Drosophila melanogaster	2009/41/EC basic research	1

FRANCE 2014-2017

For each notification	**Type of organism**	**Scope**	**Classification of contained use***
a	néant	néant	néant
b	néant	néant	néant
c	néant	néant	néant
d	néant	néant	néant
e	néant	néant	néant

ITALY 2014-2017

For each notification	**Type of organism**	**Scope**	**Classification of contained use***
a	GM Culicidae: Anopheles gambia and Anopheles arabiensis	Development of genetically modified mosquitoes for the malaria	Class 2. The premise is certified in accordance with Arthropod Containment Level 2 (ACL2) by a private third-party firm

[10] Slovakia provided a clarification, after the submission of its individual reports, that organisms reported in this part of its report were organisms obtained via new genomic techniques such as CRISPR-Cas (and not gene drive modified organisms).

		control	

SLOVAKIA 2014-2017[11]

For each notification	**Type of organism**	**Scope**	**Classification of contained use***
a	Escherichia coli, Saccharomyces cerevisiae, CHO cells expressing CaV 2.2 channel	basic research (using CRISPR-Cas9)	1
b	Escherichia coli, Saccharomyces cerevisiae	ABF2 and LEU2 gene basic research (using CRISPR-Cas9)	1
c	CHO cells expressing CaV 2.2 channel	basic research gene for Grina - Glutamate receptor, ionotropic, N-methyl D-aspartate-associated protein 1 (using CRISPR-Cas9)	1

SLOVAKIA 2018

For each notification	**Type of organism**	**Scope**	**Classification of contained use***
a	bacteria, yeast	Basic research on introducing point mutations or deletions into the genes studied. – no success to date	risk class 1

[11] Slovakia provided a clarification, after the submission of its individual reports, that organisms reported in this part of its report were organisms obtained via new genomic techniques such as CRISPR-Cas (and not gene drive modified organisms).

* 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.

13.3 Are you implementing specific containment measures for gene drive modified organisms?
If yes, provide details:

AT	No	
AT 2018	No	
BE	No	
BE 2018	No	
BG 2018	No	
CY	No	
CY 2018	No	
CZ	No	
CZ 2018	No	
DE	Yes	- access doors are kept closed at all times and are provided with brushes or rubber lips - all doors have lock cylinders preventing an escape of fruit flies - it was also recommended to secure the access doors with a gauze curtain in animal husbandry rooms - works with flies are only carried out in internal rooms without windows and with gauze secured exhaust and air supply lines - suitable Drosophila traps are set up - no nutrient media are stored in the animal husbandry rooms - the flies are killed by freezing for 12 hours at -20 °C before disposal - before opening the culture containers and during the works, the flies are constantly anesthetized with CO2
DE 2018	Yes	case by case assessment
DK	No	
DK 2018	No	
EE	No	
EE 2018	No	
EL	No	
EL 2018	No	
ES	No	
ES 2018	No	
FI	No	
FI 2018	No	
FR	Yes	néant
FR 2018	No	
HR	No	
HR 2018		
HU	No	
HU 2018	No	

IE	No	
IE 2018	No	
IT	No	
IT 2018		
LT	No	
LT 2018	No	
LU	No	
LU 2018	No	
LV	No	
LV 2018	No	
MT	No	
MT 2018	No	
NL	Yes	We are still considering what containment measures are necessary and need to be implemented. Here we provide more general observations on this topic. The classification system of Dir. 2009/41 and corresponding containment measures is focused on pathogenicity of (micro-)organisms. There are no specific general containment measures implemented for gene drive modified organisms. However, the biology of gene drive modified organisms may require different containment measures. The risk assessment, as well as the containment measures most suited for a specific gene drive modified organism, is therefore always carried out on a case-by-case basis. The GMO Decree gives room for imposing specific containment measures on top of, or as an alternative for, the general containment measures.
NL 2018	Yes	Next to the fact that our National Health Institute wrote a report on risk analysis on gene drive organisms and suggested containment measures, please find some general observations on this topic. The classification system of Dir. 2009/41 and corresponding containment measures is focused on pathogenicity of (micro-)organisms. There are no specific general containment measures implemented for gene drive modified organisms. However, the biology of gene drive modified organisms may require different containment measures. Therefore we bring again the report of our National Health INstitute to your attention and urge you to organise on short notice a meeting where this report, the suggested measures and the (legal) framework to implement these can be discussed with Commission and Member States.
PL	No	
PL 2018		
PT	No	
PT 2018	No	
RO	No	
RO 2018	No	
SE	No	
SE 2018	No	
SI	No	
SI 2018	No	

SK	No	
SK 2018	No	
UK	No	
UK 2018	No	

13.4 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.)?
If yes, provide details:

AT	No	
AT 2018	No	
BE	Yes	A GDO will be considered as a GMO. Belgium has integrated contained uses of GMOs (plants and animals) in its regional legislation implementing Directive 2009/41/EC. As such, principles for risk assessment and management of contained use of GDOs will be those followed for GMOs. Similarly, same administrative procedures will be applied (notification, authorisation, control). In the processes of risk assessment and management, the SBB is of the opinion that specific characteristics of the GDO should be considered. The most relevant being: - The rapid spread of the GDO-carried modification through several generations of target or non-target organisms; - The early developmental stage of the technology; - Generally, GDOs will be not pathogen and the environment will be the only at risk. These features highlight uncertainties about environmental risk assessment and have to be taken into consideration for the containment of activities with GDOs, for example regarding: - The adaptation of the containment to a technology still in development ("balanced" containment); - The adaptation of the containment to organisms such as arthropods.
BE 2018	Yes	A GDO will be considered as a GMO. Belgium has integrated contained uses of GMOs (plants and animals) in its regional legislations implementing Directive 2009/41/EC. As such, principles for risk assessment and management of contained use of GDOs will be those followed for GMOs. Similarly, same administrative procedures will be applied (notification, authorisation, control) In the processes of risk assessment and management, the SBB is of the opinion that specific characteristics of the GDO should be considered. The most relevant being:

		- The rapid spread of the GDO-carried modification through several generations of target or non-target organisms; - The early developmental stage of the technology; - Generally, GDOs will be not pathogen and the environment will be the only at risk; These features highlight uncertainties about environmental risk assessment and have to be taken into consideration for the containment of activities with GDOs, for example regarding: - The adaptation of the containment to a technology still in development ("balanced" containment); - The adaptation of the containment to organisms such as arthropods;
BG	Yes	So far the experience with contained use of gene drive modified organisms is limited which makes risk assessments more difficult. In addition different groups of modified organisms have different reproductive and ecological characteristics which will make it even more important to use the case-by-case approach. We expect that most gene drive modified organisms will be animals and plants and will be outside of the scope of Directive 2009/41/EC.
BG 2018	Yes	So far the experience with contained use of gene drive modified organisms is relatively limited which makes risk assessments more difficult. In addition different groups of modified organisms have different reproductive and ecological characteristics which will make it even more important to use the case-by-case approach. We expect that most gene drive modified organisms will be animals and plants and will be outside of the scope of Directive 2009/41/EC.
CY	No	
CY 2018	No	
CZ	No	
CZ 2018	No	
DE	No	
DE 2018	No	
DK	No	
DK 2018	No	
EE	No	
EE 2018	No	
EL	No	
EL 2018	No	
ES	No	
ES 2018	Yes	Spanish CA have not received notification on gene drive modified organism under contained use legislation. However, CA will attend expert meeting hosted by EFSA to gain operational experience and improve knowledge on these organisms.

FI	Yes	If the notifier has an existing notification of Class 1 use, they can take new Class 1 organisms into use without a new notification. This means that if the user has classified the gene drive organism in the risk assessment into Class 1, the licencing CA does not necessarily get to know about the gene drive organism before the point where the supervisory authority performs an inspection.
FI 2018	Yes	We have not had experience of gene drive cases, so it is not clear what the problems would be un-der existing legislation, but risk assessment, correct classification and risk management measures are likely issues meriting further discussion.
FR	Yes	néant
FR 2018	Yes	La question de la spécificité des mesures de confinement à prévoir pour le Gene Drive mériterait d'être évaluée au niveau communautaire
HR	No	
HR 2018		
HU	No	
HU 2018	No	
IE	Yes	Risk assessment and what additional data (if any) should be included / looked for in a risk assessment.
IE 2018	Yes	Risk assessment and what additional data (if any) should be included / looked for in a risk assessment. Risk management.
IT	Yes	It is difficult to interpret the Directive 2009/41/EC regarding the contained activities of gene drive modified organisms as no specific provisions are laid down in it. Additional measures, in addition to those provided by the user, may be requested by the BHTC on the basis of the evaluation of the notification submitted. Italy has not issued any decree including provisions regarding gene drive modified organisms under the Directive 2009/41/EC. To date the different aspects regarding such type of notifications are assessed case by case. The containment measures to apply to the contained uses of gene drive modified organisms are not regulated at European level and provisions of Directive 2009/41/EU are not directly applicable e.g. to Genetically Modified Arthropods (GMAs), therefore additional requirements are necessary to ensure that performed activities with gene drive modified organisms can be considered safe for the humans, animals and environment. Examples in this regard are: the availability of appropriate primary barriers, the GMAs can be identified individually, they actively hide, they can react differently to the light or humidity, they can adhere on different surfaces and follow the air flows.
IT 2018		
LT	No	
LT 2018	Yes	There is no experience how to handle such type of Applications and what

		criteria to use for risk assessment and how to assess the risk itself.
LU	No	
LU 2018	No	
LV	No	
LV 2018	No	
MT	No	
MT 2018	No	
NL	Yes	As indicated in 13.3 there is a discrepancy between the containment measures needed for pathogenic micro-organisms (as these are stipulated in the Directive) and those needed to contain gene drive modified organisms appropriately. Consequently different control measures may be required also.
NL 2018	Yes	As indicated in above there is a discrepancy between the containment measures needed for pathogenic microorganisms (as these are stipulated in the Directive) and those needed to contain gene drive modified organisms appropriately. Consequently different control measures may be required also.
PL	No	
PL 2018		
PT	No	
PT 2018	No	
RO	No	
RO 2018	No	
SE	Yes	Formally, GM plants are not included under Directive 2009/41/EC. But there will probably be need for a higher containment level for GM plants with gene drive modifications. For GM animals, the risk assessment and notification procedure will probably be more challenging.
SE 2018	No	
SI	No	
SI 2018	No	
SK	No	
SK 2018	No	
UK	Yes	The directive only covers GMMs and the vast majority of potential gene drive organisms are likely to be insects and rodents so no notification would be required. Only yeast would be considered a GMM and therefore captured by the directive. At the moment there is limited work being done in this area and the regulator is fully aware of it but if it increases it may be difficult to regulate. Risk assessment is difficult as GDOs pose unique challenges although it should be noted that an individual in the UK CA is about to publish a paper jointly with colleagues from NL, DE and BE on using the framework in 2009/41/EC to risk asses GDOs for contained use. This paper has been accepted in Applied Biosafety and will be published imminently.
UK 2018	No	

13.5 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?

AT	Basic questions have to be clarified first

AT 2018	Not applicable. Until now no gene drive applications have been received by the CA.
BE	Some adaptations should be considered for the particular case of GDOs. However considering that risk assessment is a case-by-case procedure, Directive remains appropriate for protection of (the human health and) the environment during contained use of GDOs. The Biosafety and Biotechnology Unit (SBB) has participated in the elaboration of guidelines that could help users and competent authorities in the classification and management of such activities with GDOs (in press, Biosafety Journal, 2018).
BE 2018	Some adaptations should be considered for the particular case of GDOs. However considering that risk assessment is a case-by-case procedure, Directive remains appropriate for protection of (the human health and) the environment during contained use of GDOs. The Service Biosafety and Biotechnology (SBB) has participated in the elaboration of guidelines that could help users and competent authorities in the classification and management of such activities with GDOs (Applied Biosafety Journal, Vol. 23(1), 2018).
BG	It may be appropriate to consider initially that any gene drive modified organisms will pose high risk for the environment and to apply stringent containment measures. Such measures should use at least two different containment strategies suitable for the specific modified organism. Less stringent containment can be used on a case-by-case basis if it is demonstrated that the risks are lower. In principle, gene drive modified organisms can move across borders so it is important to establish mechanisms for fast and effective cooperation between EU member states when such organisms are released into the environment, deliberately or accidentally.
BG 2018	It may be appropriate to consider initially that any gene drive modified organisms will pose high risk for the environment and to apply stringent containment measures. Such measures should use at least two different containment strategies suitable for the specific modified organism. Less stringent containment can be used on a case-by-case basis if it is demonstrated that the risks are lower. In principle, gene drive modified organisms can move across borders so it is important to establish mechanisms for fast and effective cooperation between EU member states when such organisms are released into the environment, deliberately or accidentally.
CY	Not Applicable.
CY 2018	N.R.
CZ	Not applicable
CZ 2018	not applicable
DE	-
DE 2018	-
DK	N/A
DK 2018	N/A
EE	Labour Inspectorate don't deal with this area
EE 2018	N/A

EL	No notifications or measures applicable to date.
EL 2018	Not Applicable due to no implementation of measures regarding gene drive under the framework of Directive 2009/41/EC
ES	It would be desirable to have harmonised Guidelines at EU level (from the Commission) regarding notifications for contained uses of gene drive modified organism.
ES 2018	Expert meetings hosted by EFSA or the European Comission.
FI	Gene drive is not an issue for those Member States regulating GM plants and GM animals, as long as necessary containment measures are maintained. However, in the Member States which only regulate GMMs, additional legal measures may be necessary.
FI 2018	Directive 2009/41/EC does not cover GM plants and animals, so there is no harmonised legislation on them.
FR	néant
FR 2018	Clarifier au niveau UE les mesures de confinement à prévoir dans le cas du Gene Drive.
HR	/
HR 2018	
HU	We propose detailed discussions at EU level regarding this important issue.
HU 2018	No relevance.
IE	As above
IE 2018	as above
IT	The Directive 2009/41/EU could be amended and a detailed and harmonized guiding document, that would clearly report the required specifications with the needed explanations, could be adopted by European Member States and issued by Commission services. Such type of requirements may be adopted and applied, on voluntary basis, by MSs also before that the Directive is amended.
IT 2018	
LT	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.
LT 2018	It would be helpful clearer explanation of GM gene drive and what risk assessment methodology and safety measures to use. Harmonized EU legislation for Gene drive would be welcome.
LU	transposition of directive is ongoing
LU 2018	transposition of directive is ongoing
LV	-
LV 2018	-
MT	No past experience to comment on this
MT 2018	No past experience to comment on this.
NL	An active and frequent exchange of information and experiences regarding the contained use of gene drive modified organisms should be arranged at EU-level. This should result in a guidance document or eventually a change of the directive. Also EU-guidance on how to inform member states in case a high risk incident with GMM or GMO should be explicitly extended to gene drive modified organisms, as these organisms may pass borders.

NL 2018	An active and frequent exchange of information and experiences regarding the contained use of gene drive modified organisms should be arranged at EU-level. This should result in a guidance document or eventually a change of the directive. Also EU-guidance on how to inform member states in case a high risk incident with GMM or GMO should be explicitly extended to gene drive modified organisms, as these organisms may pass borders. The fact that in Italy a contained use experiment with living gene drive modified mosquitos is now taking place, adds to the necessity of a swift action from your side!
PL	knowledge/experience flow between Member States
PL 2018	
PT	The CA didn't encounter any challenges in implementing the Directive in relation to this subject.
PT 2018	The CA didn't encounter any challenges in implementing the Directive in relation to this subject.
RO	Not applicable.
RO 2018	Not applicable
SE	Since gene drive concerns eukarytic organisms, the issue may be more relevant for Directive 2001/18/EC. SWEA believes that a proper risk assessment of a GMM use will catch any risk with such organisms that are GMMs. The containment levels 2-4 in the Directive 2009/41EC is enough to protect the environment and workers also for contained use of GMMs with gene drive modifications.
SE 2018	-
SI	-
SI 2018	Management of Genetically Modified Organisms (MGMO) Act (OJ RS 23/2005 and amended OJ RS 21/2010) specifies the requirements for the content of the notifications. Notifiers have to provide information on the intended use of Class 1 organisms together with the notification of the premises. Furthermore the notifiers are obliged to submit a yearly report on all activities with GMOs, including new Class 1 organisms that were not notified yet. The notification and the yerly reports are assessed by the Scientific Committee. We observed no intent to use gene drive modified organisms. Therefore no special measures for gene drive organisms were taken in Slovenia.
SK	----
SK 2018	----
UK	It is difficult to regulate GDOs (under the directive) as it is only applicable to GMMs. A number of member states include GM plants and animals in their national legislation (as does the UK) but in the UK there are no activity notification requirements (or class of work) for GM plants/ animals. There is a lack of consistency in the approach across member states with regard to this type of work.
UK 2018	It is difficult to regulate GDOs (under the directive) as it is only applicable to GMMs. A number of member states include GM plants and animals in their national legislation (as does the UK) but in the UK there are no activity notification requirements (or class of work) for GM plants/ animals. There is a lack of consistency in the approach across member states with regard to this type of work.

PART V: ADDITIONAL COMMENTS

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

2014-2017	
AT	no comments
BE	
BG	Regarding the EU legislation on the contained use of GMO we think important open issues at present are: 1. Harmonization of requirements for contained use of GMO other than GMM between the member states, in particular with regard to gene drive modified organisms; 2. Clarifying the requirements and procedures applicable to medicinal products that contain or consist of GMOs, in particular with regard to clinical trials.
CY	No comments.
CZ	
DE	-
DK	
EE	N/A. I hope that Estonian Medicine Agency will answer parts III and IV
EL	
ES	
FI	
FR	néant
HR	
HU	No.
IE	
IT	Waste disposal As additional information it is to point out that the waste disposal plants must be authorized according to Legislative Decree No. 152 of 03/04/2006. The applications must to be submitted to the Region or, in some circumstances to the Province/Metropolitan City when they are delegated to issue the authorizations. Copy of the application has to be sent to the Municipality and to the Italian National Institute for Environmental Protection and Research ISPRA (Istituto Superiore per la Protezione e la Ricerca Ambientale). The issued authorizations expire after 10 years. More detailed information can be obtained on the following web site: http://www.catasto-rifiuti.isprambiente.it/index.php?pg=comaut. The controls are applied by all the subjects that contribute to the issue of authorizations and to the various police forces that carry out activities on the national territory. The Provinces, the Regional Environmental Protection Agency, the Local Health Authority and other Bodies are responsible for monitoring the operations of the plant operators, which must be carried out in compliance with the regulations in-force and the specific provisions contained in the authorizations (Legislative Decree No 152/2006, articles 208 and 214).

	Transfer of waste The transfer of waste material is organized by firms registered in the National Environmental Operators Register, that is laid down with the art. 212 of Legislative Decree No. 152/2006, and that is currently regulated by the Decree of the Ministry for the Environment and Protection of the Territory and the Sea No. 120/2014. The professional register consists of a national committee at Ministry for Environment, Land and Sea Protection and in regional or provincial committees established at the Chambers of Commerce of the regional capitals and of the autonomous provinces of Trento and Bolzano. The reference legislation and the consultation of the registered operators are reported in the ministerial web site: www.albonazionalegestoriambientali.it. Furthermore the transfer of waste has to comply with the Legislative Decree n. 35 of 27/01/2010 (transposition act of the Directive 2008/68/EC on the inland transport of dangerous goods - as amended). The CA is the Italian Ministry of Infrastructures and Transport.
LT	
LU	
LV	Latvia had very limited experience with contained use of GMM many years ago. For this moment there is no activities in this filed.
MT	
NL	non
PL	
PT	
RO	The most relevant and not yet resolved problem of interpretation regards the question whether clinical trials with GMOs fall within the scope of to the contained use or the environmental release directives. In fact some Member States treated trials with GMMs in clinical settings as deliberate release of GMOs, while some others considered the GMM clinical trials as contained use. Needs and priorities for further guidance on risk assessment of: - LM fish - LMOs produced through synthetic biology - LM soil dwelling organisms - LM birds - potential implications for Risk Assessment of Gene Drive Experiments
SE	Directive 2000/54/EG on the protection of workers from risks related to exposure to biological agents at work is currently under revision concerning technical changes of the Annexes. There might be a change of some safety measures in Annexes V and VI of that Directive. Maybe this can impact on the containment measures in Annex IV of Directive 2009/41/EC?
SI	

SK	In Annex - Glossary of terms (for the purposes of the questionnaire for the years 2017 to 2020) please provide an example what it means „contained combined uses of GMMs and GMOs“: 1. step: stable transfection of genetic materials into the MDA-MB-231 NucLight Red cells, + 2. step: application of the genetically modified MDA-MB-231 NucLight Red cells to mice. Note to answer on number of notifications of CONTAINED USES submitted for risk class 1: Since 1 January 2013 the users of genetic technologies and genetically modified organisms aren't obliged to notify the start of the new activity classified to the risk class 1 to Ministry of the Environment of the Slovak Republic. Once every 6 months, the users of GMOs and GMMs submit a summary notification on all the GMOs and GMMs classified in the risk class 1, which they have carried out activities with, including their storage in the reporting period.
UK	

2018	
AT	
BE	/
BG	Regarding the EU legislation on the contained use of GMO we think important open issues at present are: 1. Harmonization of requirements for contained use of GMO other than GMM between the member states, in particular with regard to gene drive modified organisms; 2. Further clarifying the requirements and procedures applicable to medicinal products that contain or consist of GMOs, in particular with regard to clinical trials.
CY	
CZ	
DE	-
DK	
EE	
EL	
ES	Contained used activities and their correspondent premises with GM cells have been also notified to Spanish CA under Directive 2009/41/EC. GM cells are not included in Part II of this survey.
FI	As the concept of circular economy is gaining ground in the EU, the legislative issues on recycling large quantities of GMM waste or byproducts should be addressed. Also, the relationship between GMO legislation and the regulations on the transportation of dangerous goods should be clarified.
FR	L'édition génomique et les nouvelles techniques de mutagenèse : La France n'est pas actuellement en mesure de traiter l'ensemble des utilisations correspondant au champs de la directive dans le cadre de la réglementation en vigueur et élargi par l'arrêt de la CJUE du 25 juillet 2018.
HR	
HU	
IE	
IT	

LT	
LU	
LV	
MT	
NL	non
PL	
PT	
RO	
SE	
SI	
SK	
UK	