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REPORT FROM THE COMMISSION

on the 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 2022 – 2024

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Report on the 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 2022 – 2024

The information contained in this document has been compiled by the Commission from individual reports submitted by Member States in accordance with Article 17 of Directive 2009/41/EC of the European Parliament and of the Council on the contained use of genetically modified micro-organisms[1] (GMMs).

INTRODUCTION

Directive 2009/41/EC ("the Directive") provides that every three years Member States are to send to the Commission a summary report on their experience with the Directive[2] and that the Commission is to publish a summary based on these reports[3]. The Commission has so far published six reports pursuant to the Directive or to the preceding Council Directive 90/219/EEC[4], for the periods 1999-2003, 2003-2006, 2006-2009, 2009-2014, 2014-2018 and 2019-2021[5].

The present report covers the period from January 2022 to December 2024 and is based on 27 Member States' and two EEA EFTA States'[6] individual reports.

The national reports are based on a questionnaire prepared by the Commission services on Member States' experience with the general implementation of the Directive, including their notification and approval systems, inspection and enforcement activities, waste disposal measures, accidents, public consultation and an overview of contained uses for GMMs authorised in their territories.

The Directive does not regulate the contained use of genetically modified organisms (GMOs) other than GMMs, i.e. genetically modified (GM) plants and animals. However, Directive 2001/18/EC on the deliberate release into the environment of GMOs[7] provides that, in some cases, the principles of containment set out in Directive 2009/41/EC are also relevant to other GMOs. This is the case where GMOs other than GMMs are made available to third parties *'to be used exclusively for activities where appropriate stringent containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment'* (Article 2(4), 2nd subparagraph, 2nd indent). In such cases, according to the same provision, '*the measures should be based on the same principles of containment as laid down in Directive 90/219/EEC'.* If the principles of containment of Directive 2009/41/EC are not met, the transfer of the GMO to a third party constitutes 'placing on the market' within the

[1] 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 (OJ L 125, 21.5.2009, p. 75).
[2] Article 17(2).
[3] Article 17(3).
[4] Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms (OJ L 117, 8.5.1990, p. 1).
[5] The reports are available on this European Commission webpage
[6] Annex XX to the EEA Agreement (which lists, amongst others, the EU GMO legislation applicable under that Agreement) provides that *'[f]or the purposes of this Annex and notwithstanding the provisions of Protocol 1, the term "Member State(s)" contained in the acts referred to shall be understood to include, in addition to its meaning in the relevant EC acts, Iceland, Liechtenstein, Norway'*. Therefore, reference to 'Member States' in this document also includes the EEA EFTA States who replied to the questionnaire (Iceland and Norway).
[7] 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/EEC (OJ L 106, 17.4.2001, p. 1).

meaning of Article 2(4) of Directive 2001/18/EC and is subject to the requirements of that Directive.

In a number of Member States, the relevant national legislation regulates the contained use of other GMOs as well. Therefore, the Commission extended the scope of its questionnaire to allow Member States to share their experience in regulating the contained use of those organisms at national level.

The report focuses on changes from previous reports and highlights new issues and implementing challenges raised by Member States and the way they were addressed.

Disclaimer: The information contained in this report relating to Member States is based on Member States' individual reports.

Neither the European Commission nor any person acting on its behalf is responsible for the content of that information and of any use made of it.

The individual reports submitted by Member States are not published and are only used as a basis for the Commission's summary report.

PART I: GENERAL IMPLEMENTATION OF THE DIRECTIVE

1. Notification and approval systems (and relevant changes)

According to Articles 6 to 9 of the Directive, any person planning to use premises for the first time for the contained use of GMMs must notify its intended uses to the national competent authorities, providing details on the GMMs, premises, protective measures, and risk assessment. Classes 2, 3 and 4 contained uses require prior consent: class 2 only before the first use, while classes 3 and 4 require consent before first and subsequent uses.

No major changes since the previous reporting period were reported concerning the national legislation implementing the Directive.

However, a number of Member States implemented several reforms aimed at **improving efficiency or increasing digitalisation, or restructured competent authorities and processes**:

- France streamlined the rules concerning the uses raising negligible risks and, as of June 2022, a new competent authority[8] oversees notifications for the contained use of GMMs in the context of clinical trials of investigational medicinal products using a dedicated online platform;
- Iceland replaced the earlier competent authority by the newly established Environment and Energy Agency;
- Italy improved its notification system with a digital platform to manage notifications and developed a networking tool to train and connect researchers, safety officers and institutions and to enhance skills and compliance with the Directive[9];
- Cyprus developed a new confidential notification system requiring notifications to be now submitted through a standardised format and payment of application fees;
- Lithuania changed the competent authority. As of January 2023, the Environmental Protection Agency under the Ministry of Environment oversees notifications and authorisations for the contained use of GMOs and GMMs;
- Hungary restructured its competent authority, merging two institutions[10], and introduced a new system with application and risk assessment forms for contained use activities and providing guidance to users[11];
- Norway launched a new web-based portal for GMM notifications in 2024, improving user experience and enabling better traceability of applications and facility approvals[12];
- Slovenia renamed its competent authority and inspectorate, reflecting structural changes in government departments. The Ministry of Environment, Climate and Energy now replaced the former Ministry of Environment and Spatial Planning;
- Sweden introduced a new system that requires providing notifications for classes 3 and 4 through secure registered mail.

[8] *Agence nationale de sécurité du médicament et des produits de santé* (*ANSM*).
[9] www.biotechsafety.org
[10] The National Institute of Pharmacy and Nutrition (OGYÉI) has been merged with the National Center for Public Health and Pharmacy (*NNGYK*).
[11] Forms and guidance are available at gmo.kormany.hu
[12] https://gmo.helsedirektoratet.no/

Several Member States[13] reported **challenges** such as delays in processing notifications within the statutory timeframe due to understaffing and increased workload, administrative burdens, limited digital infrastructure, difficulties handling notifications for mobile laboratories and increase of applications for biopharmaceutical products involving GMMs.

2. Waste disposal

For the contained use of GMMs, Article 5(1) of the Directive requires the application of appropriate containment and other protective measures listed in Annex IV to the Directive corresponding to the class of the contained use, including waste disposal measures.

In this respect, most Member States did not report significant changes or challenges concerning waste disposal management during the reporting period.

Some Member States reported specific developments:

- Belgium reported adoption of new waste legislation. The Brussels Capital Region[14] and the Walloon Region adopted a framework to streamline regulations and promote circular economy goals. Both regions are testing alternative inactivation methods, including microwave technology and shredding with sterilisation. Incineration of fermentation residues was also tested and flagged as costly and inefficient, with anaerobic digestion as a sustainable waste disposal being considered for low-risk waste, pending on-site validation.
- Germany noted no major changes but highlighted technical challenges. These included the need for vacuum-enabled autoclaves, validating complex waste matrices and bioindicator use for hydrogen peroxide fumigation. One case of GMMs waste mismanagement prompted improved training and labelling. There are requests from operators for a publicly available list of validated inactivation alternatives to autoclaving.
- Hungary indicated that its new application forms for contained use activities include dedicated sections on waste management. Users must describe the type and form of waste to be generated, its treatment, final form, and destination. Waste containing GMMs must be treated as hazardous, autoclaved on-site, and transported to an authorised disposal company. A copy of the transportation contract must also be submitted to the competent authority.
- Austria reported ongoing user requests for the use of microwave technology as an alternative to autoclaving for inactivating GMMs, mainly in contained use activities involving negligible or low risks. As this method was deemed unsuitable for higher-risk waste, enveloped viruses and virus stock solutions by the Austrian Scientific Committee for Working with GMO in Contained Use, the competent authorities advised continuing the use of autoclaving and called for guidelines to validate alternatives to it.
- Finland reported reduced autoclaving use due to cost and occupational hazard concerns, along with a decline in the availability of effective disinfectants compliant with the relevant EU legislation. This has led to increased waste incineration. The competent authority has encouraged users to explore alternative inactivation methods and is providing case-specific advice.

[13] Belgium, Germany, Ireland, France, Croatia, Italy, Hungary, Finland and Sweden.
[14] BRUDALEX 2.0.

3. Inspection and enforcement issues

According to Articles 10 and 16 of the Directive, the competent authorities of the Member States must organise inspections and other enforcement measures to ensure compliance.

The majority of Member States reported no changes in their inspection and enforcement activities.

Several Member States provided information on improvements to enforcement and control activities during the reporting period:

- Belgium reported region-specific practices, with the Walloon Region increasing collaboration with scientific experts for more in-depth inspections;
- The Czech Republic returned to standard on-site inspections after temporarily relying on remote controls during the COVID-19 pandemic;
- Ireland noted a threefold increase in enforcement activities compared to the previous period, which had been affected by the COVID-19 pandemic;
- France enhanced its capacity by appointing 'sworn inspectors' who now conduct regular monthly inspections;
- Italy improved its inspection system by validating procedures through simulated activities, appointing and training inspectors, and sharing these validated procedures within the European Enforcement Project[15];
- Cyprus introduced a risk-based inspection approach focused on higher-risk facilities such as universities and laboratories, alongside improved reporting and follow-up activities.

The issues most frequently encountered during inspections reported by some Member States were related to deficiencies in:

- Documentation and administrative procedures[16]

  Member States identified missing or outdated biosafety documentation, incomplete GMM records, failure to notify changes (e.g. new premises, biosafety officer), lack of internal audits, insufficient or unclear risk assessments.

- Infrastructure and biosafety measures[17]

  Some physical and procedural shortcomings were noted, such as outdated or inadequately maintained equipment, improper use of biosafety cabinets and incomplete waste management systems.

- Notification and approval[18]

[15] The European Enforcement Project on GMOs is a network of regulators from inspectorates across the European Union (and beyond) responsible for the inspection of activities involving GMOs. The network was founded in 1997.
[16] The Czech Republic, Germany, Ireland, Italy, the Netherlands, Austria, Slovenia, Slovakia and Finland.
[17] Germany, Spain, Italy, the Netherlands, Norway and Austria.
[18] France, Italy, Norway and Austria.

Member States reported issues such as starting GMM use without prior notification, using facilities not approved for the required containment level or delayed notifications on any changes of uses to authorities.

- Inspection and enforcement practices[19]

  Several Member States reported variations in inspection frequency, especially following adjustments made during the COVID-19 pandemic. Nonetheless, most Member States have since reinstated regular procedures and enhanced their inspection protocols where needed.

- Resources, training & personnel oversight[20]

  In some cases, inspections revealed lack of training records or programmes, missing certificates or unclear responsibilities among staff. A few Member States[21] noted challenges in maintaining dedicated biosafety expertise in the competent authorities due to limited resources.

Member States reported enforcement actions taken following inspections. When non-compliance was identified, measures such as reports, warnings or fines were applied, and users usually implemented the corrective actions requested by the authorities within the given timeframe, which was verified through follow-up inspections. While a range of minor issues was identified during inspections, they were not deemed critical, and they were typically resolved during or shortly after the inspections to avoid adverse effects on human health or the environment.

The constraints related to the available biosafety expertise in the competent authorities were mitigated through training initiatives, inter-agency cooperation and capacity-building efforts.

4. Accidents

According to Articles 14 and 15 of the Directive, the competent authorities of the Member States must take the necessary measures to ensure that, in the event of an accident, the user is required immediately to inform the competent authority and provide specific information regarding the accident, the GMMs involved, information necessary to assess the effects on health and the environment and the measures taken.

No accidents (according to the definition of 'accident' in Article 2(d) of the Directive[22]) were reported.

In some Member States[23] criteria were provided by the competent authorities to enable users to assess whether a release was significant, based on factors such as the nature and quantity of the GMMs released, its potential hazard to human health or the environment and their containment level.

Some Member States[24] reported incidents that did not meet the threshold for a significant release. These included power outages, waste misclassification, minor leaks, equipment failures

[19] The Czech Republic, Ireland and Sweden.
[20] Germany, Ireland, Italy, the Netherlands and Finland.
[21] France and Luxembourg.
[22] 'Accident' means any incident involving a significant and unintended release of GMMs in the course of their contained use which could present an immediate or delayed hazard to human health or the environment.
[23] The Czech Republic, Germany, Ireland, Italy, the Netherlands and Finland.
[24] Germany, Ireland, France, the Netherlands and Finland.

and minor laboratory errors, all of which were judged by the competent authorities not to pose significant risks to health or the environment.

In most cases, national authorities rely on biosafety officers' case-by-case evaluations to assess the significance of GMM releases, rather than apply fixed criteria.

5. Public information and consultation

According to Article 12 of the Directive, Member States may consult the public on certain aspects of the proposed contained use, if they deem such consultation appropriate, while applying the confidentiality requirements set out in Article 18.

In this context, most Member States reported no changes in the provision of information to the public on contained uses of GMMs since the previous reporting period.

Belgium reported changes to the publicly available information as regards permits for contained use activities, aiming to prevent potential misuse of information for biosecurity reasons, without prejudice to the requirements of Article 18 of the Directive.

The reported public consultations concerned class 3 and class 4 contained uses. Belgium and Ireland reported having received input from the public, addressed during the review process. Belgium reported concerns raised by the public related to opposition to animal experimentation and to perceived biological risks to humans and animals living in the vicinity. Other Member States[25] that conducted public consultations reported that no comments were received.

Some Member States[26] reported no public consultations during the reported period, often because the notifications concerned lower-risk class activities.

A number of Member States[27] did not provide information on public consultations.

6. Interpretation of the Directive

Nine Member States[28] reported that they did not meet any specific challenges regarding the interpretation of the Directive.

By contrast, seven Member States[29] identified difficulties interpreting and implementing the Directive, particularly due to scientific and technological advancements such as new genomic techniques (NGTs), self-cloning and novel delivery systems like viral-like particles and lipid nanoparticles.

Those Member States noted that the receipt of more complex applications has led to challenges in interpreting the GMO/GMM definitions and determining the legal status of organisms. Several competent authorities pointed out that these issues would benefit from discussion at the Regulatory Committee established by the Directive, with consideration given to providing guidance supporting a harmonised approach.

In particular, the following difficulties were raised:

[25] Germany, Iceland, Spain, Hungary, Romania and Slovakia.
[26] Bulgaria, the Czech Republic, Norway, Portugal and Finland.
[27]Denmark, Greece, France, Croatia, Cyprus, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Slovenia and Sweden.
[28] Estonia, Greece, Cyprus, Latvia, Lithuania, Poland, Portugal, Slovenia and Slovakia.
[29] Belgium, Germany, Denmark, Ireland, Italy, the Netherlands and Finland.

- Denmark reported difficulties in applying the Directive in several cases concerning the administration of medicinal products that contain or consist of GMMs in patients' homes and noted the importance of establishing common regulatory approaches across Member States to avoid cross-border inconsistencies;
- Germany reported feedback from some federal states' competent authorities regarding uncertainties about the interpretation of the GMO definition and the applicability of the interpretation regarding the mutagenesis exemption in Directive 2001/18/EC made by the Court of Justice in 2018[30] to the Directive, leading in certain cases to varying interpretations among federal states;
- Croatia and Italy referred to the complexity in distinguishing between contained use and deliberate release as regards clinical trials with GMOs/GMMs, and Italy highlighted that different interpretations and approaches create difficulties for the competent authorities, companies and users;
- Sweden reported uncertainty regarding how to apply requirements for GMMs used in mobile or temporary laboratories with changing locations.

To address the above-mentioned difficulties, some Member States implemented various solutions, including internal expert consultations[31], updated national guidance on NGTs[32], enhanced scientific input and coordination between competent authorities (Spain).

To address questions relating to the interpretation of the GMO/GMM definitions, the Netherlands established an ad-hoc group of national experts supported by a Dutch research project that received input from other Member States' experts. The findings[33] were published in November 2024 and presented to the Regulatory Committee established in Directive 2001/18/EC in December 2024[34] and to the Regulatory Committee established in Directive 2009/41/EC in September 2025[35].

Belgium shared their approach to Do-It-Yourself practices and experience in applying biosafety requirements, e.g. identifying and raising awareness of the open science community on regulatory requirements of GMMs contained use.

7. Overview of contained uses

Several Member States[36] reported a stable or slightly increasing number of notifications for contained uses of GMMs compared to the previous reporting period.

However, differences are observed in the number of notifications for classes of contained uses among the reporting Member States. In particular:

- Belgium confirmed that class 2 accounts for most contained uses (71 % of notifications);
- The Netherlands reported a decrease in class 2 and class 3 notifications and suggested that the decrease in class 2 activities may be partly due to some viral vector systems now being classified as class 1 and possibly because broad-scope notifications (with more general descriptions of vector systems and donor sequences) resulted in a

[30] Judgment of 25.7.2018, Case C-528/16, Confédération paysanne and Others (ECLI:EU:C:2018:583).
[31] Germany and the Netherlands.
[32] France and Italy.
[33] Perseus report on Interpretation of the GMO definition in EU Member States
[34] 11 December 2024, point A.03.
[35] 26 September 2025, point A.07
[36] Bulgaria, Ireland, Cyprus, Norway, Slovakia and Sweden.

reduction in the number of amendments of earlier notified Class 2 activities with such descriptions;
- France mentioned a 39% decrease in class 1 notifications and a similar rise in class 2 notifications;
- Austria observed an increase in class 1 commercial notifications but noted a decrease in total number of notifications;
- Slovenia noted a shift from class 1 to class 2 notifications and an increase in commercial notifications;
- Finland observed a slight overall decline in notifications but reported steady commercial and research notifications.

Class 3 notifications are fewer overall but have increased in several Member States, for example Spain and France, mostly related to research. Hungary also reported an increase in class 3 uses and the authorisation of one class 4 activity. On the other hand, Italy reported a significant decrease in such notifications.

As regards the type of activities notified, research and development (R&D) continue to prevail in contained uses, although commercial activities are increasingly prominent in a few Member States. For instance, Belgium reported that 51% of notifications were related to R&D, with commercial activities comprising 36%, and the use of GMMs in healthcare institutions accounting for 13%. Slovakia highlighted growing commercial use focused on improving health and the environment.

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

Clinical trials involving investigational medicinal products (IMPs) that contain or consist of GMMs (GMMs-IMPs) fall under both the clinical trials[37] and the GMO legislation, particularly Directives 2001/18/EC and 2009/41/EC.

Member States reported no major changes in the manufacturing and administration of GMM-IMPs for human and veterinary use.

Several Member States have adapted their procedures to streamline approvals for clinical trials with GMMs-IMPs. Belgium has introduced national guidance and simplified assessment and approval procedures. Austria has adapted its national regulations on the use of GMOs for medicinal purposes in line with Directive 2001/18/EC and has simplified the environmental risk assessment by accepting common application forms. Spain and Sweden reported applying Directive 2001/18/EC to such products, incorporating additional steps such as public consultation. Germany highlighted improved coordination between the competent authorities responsible for clinical trials and those overseeing GMMs. France noted that in certain cases, if there is a doubt on the classification or on the environmental risk, the competent authority can seek an opinion of the Committee of contained use of GMOs hosted by the GMO competent authority of contained use, namely the Ministry of Research.

Some Member States[38] reported ongoing efforts to further develop their approaches for such products, particularly in assessing specific cases such as home-based trials[39] and the use of biopharmaceutical products involving use of GMMs in clinical trials.

[37] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ L 158, 27.5.2014, p. 1.
[38] Denmark, Croatia and Finland.
[39] Administration of investigational medicinal products at home during a clinical trial.

Germany and Italy emphasised the need for enhanced collaboration between national authorities and their counterparts in other Member States to ensure a harmonised approach in conducting clinical trials and to streamline the application of regulatory requirements for users across Member States.

Bulgaria and Italy considered that maintaining digital records for GMMs-related clinical activities would improve traceability at the EU level.

Finland reported operational challenges, including language barriers when using common application forms, as these sometimes conflict with the language requirements in national legislation, and issues related to the requirements applicable to cross-border movement of GMM-IMPs manufactured outside the EU.

PART III: CONTAINED USE OF GMOs OTHER THAN GMMs

Most Member States[40] have national legislation regulating the contained use of GMOs other than GMMs, i.e. GM plants and animals. Overall, where national legislation exists, Member States have largely aligned their procedures with Directive 2009/41/EC.

Several Member States[41] reported no challenges in applying the measures set out in the Directive to the contained use of GMOs other than GMMs.

Difficulties were reported by some Member States regarding the identification of appropriate containment measures, deciding on the GMO status of certain organisms and differentiating between deliberate release and contained use in some cases:

- Germany noted that while facilities working with GM animals or plants rarely pose major issues, specific difficulties arise with containment for insects and the safe inactivation of large animal carcasses treated with GMMs. These issues were discussed among national authorities and referred to the relevant national committee for guidance. Additionally, one authority highlighted legal uncertainty concerning the containment measures to apply to NGT animals.
- Spain reported that, in some cases, scientific discussions were needed to determine whether certain organisms meet the definition of GMO. The national biosafety advisory body consults its experts and informs the competent authority.
- The Netherlands reported difficulties in distinguishing between contained use and deliberate release in cases such as large-scale animal trials, biofuel production using GMMs or the use of GMMs as biosensors. Questions were also raised about the status of GM animals, or of animals exposed to GMMs, after the experiments.
- Sweden noted that, unlike for GMMs, it does not rely on predefined containment classes for GMOs, and all facilities must be individually authorised. While not seen as a challenge, the Swedish Board of Agriculture is reviewing whether the current system is proportionate to the actual risk.
- Finland reported diverse applications of NGTs in animal research, often involving modifications without the insertion of foreign DNA or with limited heritability, which complicates the assessment of GMO status by the competent authority and the determination of whether containment requirements should apply. Additionally,

[40] Belgium, the Czech Republic, Denmark, Germany, Ireland, Iceland, Spain, Latvia, Lithuania, Hungary, the Netherlands, Norway, Austria, Portugal, Slovenia, Slovakia, Finland and Sweden.
[41] The Czech Republic, the Netherlands and Austria.

questions have arisen regarding the transport of gene edited fish embryos from third countries, particularly whether regulations on the transport of dangerous goods are applicable.

Some Member States[42] reported that they require consent from, or involve consultation (Portugal) of, multiple authorities for the contained use of GMOs other than GMMs. Italy reported that users may voluntarily ask the competent authority under Directive 2001/18/EC to verify the application of containment measures set out in Annex IV to Directive 2009/41/EC to GMOs other than GMMs.

CONCLUSIONS

As regards the **overall implementation** of the Directive, the national reports show that Member States have adopted the provisions and established the structures and procedures to ensure that the necessary measures are taken to avoid adverse effects on human health and the environment which might arise from the contained use of GMMs, with continued improvements in administrative efficiency, digital transformation and administrative coherence. While no major structural changes were reported in the notification and approval systems, several Member States have reported targeted reforms to modernise, clarify and streamline processes to adapt to evolving technological progress.

However, certain **operational challenges** have been reported, including staff shortages, digital infrastructure limitations, administrative complexity and regulatory uncertainties— particularly in emerging areas such as mobile laboratories and novel biopharmaceutical products.

Waste disposal management remained largely unchanged, though several Member States explored alternative methods for GMM inactivation in response to the technical and financial constraints of traditional autoclaving. Member States and the Commission have exchanged views on practices on this issue at the meeting of the Regulatory Committee on Directive 2009/41/EC on 20 September 2023[43] and on 26 September 2025[44].

Inspection and enforcement activities have continued as in previous reporting periods. Overall, competent authorities appear to maintain effective oversight. Inspections generally revealed only minor administrative or procedural deficiencies that were addressed promptly to prevent adverse effects on human health or the environment. While inspection frequency was temporarily impacted by the COVID-19 pandemic, routine procedures have since resumed.

No **accidents**, as defined in the Directive, were reported during the reporting period, suggesting a high level of containment and biosafety oversight.

Public information and consultation practices remained largely unchanged and generally result in low levels of public engagement.

During the reporting period, Member States have exchanged information on their national measures and best practices on various other issues relating to the application of biosafety requirements set out in the Directive in the context of the meetings of the Regulatory Committee. These exchanges concerned national experiences identifying and raising awareness within the open science community about regulatory requirements of contained use of GMMs[45], national guidelines to assess antibiotic resistance marker genes in contained use applications

[42] Slovenia and Slovakia.
[43] 20 September 2023, point A.01.
[44] 26 September 2025, point A.02
[45] 20 September 2023, point A.02.

and activities by users for the phasing out of these genes[46]. In 2025, the Regulatory Committee discussed several issues raised by the Member States during the reporting period. These included the inspection of high-containment facilities, the transport of GMMs, waste disposal management, and the prevention and protection of health and the environment in relation to new biotechnological techniques[47].

The **interpretation of the Directive** continues to pose certain challenges for some Member States, linked e.g. to the classification of certain organisms and applications. General issues related to the interpretation of the GMO definition are regularly discussed in the meetings of the Regulatory Committee established in Directive 2001/18/EC. Several issues specifically relating to the interpretation of the GMM definition and the appropriate safety measures under the contained use of GMMs (e.g., in the case of bacteriophages) have been discussed at the meetings of the Regulatory Committee established in Directive 2009/41/EC during the reporting period[48] and on 26 September 2025[49].

One Member State reported that there is still internal uncertainty regarding the applicability to the contained use of GMMs under Directive 2009/41/EC of the Court of Justice ruling in 2018 regarding the mutagenesis exemption in Directive 2001/18/EC. In that regard, the Commission refers to the clarifications provided in its 2014-2018[50] and 2019-2021[51] reports.

The reported **numbers of notifications** of contained uses appear to be stable or slightly increasing, with class 1 and class 2 activities prevailing. Commercial applications are gaining relevance alongside research and education, with notifications increasingly managed through digital systems.

In the area of **GMMs-IMPs**, most Member States reported no major developments. Some Member States highlighted again the complexity of authorisation procedures under different regulatory frameworks for GMMs-IMPs i.e. under the GMO legislation and Regulation (EU) No 536/2014 on clinical trials, and differences in Member States' approaches as regards the environmental risk assessment of clinical trials with GMMs-IMPs. Several Member States expressed the need for improved EU-level guidance, enhanced digital tracking of clinical trials and clearer rules for cross-border movement of GMMs.

In this regard, it should be noted that, on 26 April 2023, the Commission adopted proposals for a Regulation and a Directive on the revision of the pharmaceutical legislation[52], reviewing the requirements for the authorisation and supervision of medicinal products for human use. Amendments to Regulation (EU) No 536/2014 aim to streamline the authorisation process for clinical trials involving investigational medicinal products that contain or consist of GMOs, enabling a single authorisation under that Regulation. A new centralised procedure is proposed for conducting environmental risk assessments as part of these clinical trial authorisations, seeking to eliminate fragmented national requirements and improve the clinical trial framework for GMO medicines across the EU. The ordinary legislative procedure on these legislative proposals is ongoing.

For the contained use of **GMOs other than GMMs**—i.e. GM plants and animals—most national frameworks are aligned with Directive 2009/41/EC. While no major issues were

[46] 20 September 2023, point A.03.
[47] 26 September 2025, points A.03 to A.07
[48] 20 September 2023, point A.04.
[49] 26 September 2025, point A.05
[50] COM(2021) 266 final
[51] COM(2023) 75 final
[52] COM (2023) 192 final and COM(2023) 193 final.

reported in most cases, some Member States experienced certain challenges including identifying appropriate containment measures, managing cross-border transport, and ensuring consistent risk assessment.