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Delegations will find attached document COM(2016) 808 final.

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COMMISSION WORKING DOCUMENT

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 (recast) for the period 2009-2014

{SWD(2016) 445 final}

COMMISSION WORKING DOCUMENT

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 (recast) for the period 2009 – 2014

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Details are available in the accompanying Commission staff working document.

COMMISSION WORKING DOCUMENT

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 (recast) for the period 2009 – 2014

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 on the contained use of genetically modified micro-organisms. Directive 2009/41/EC is a recast of Directive 90/219/EEC amended by Directive 98/81/EC.

INTRODUCTION

Directive 2009/41/EC on the contained use of genetically modified micro-organisms[1] (GMMs) requires the Commission to publish every three year a summary report on Member States experience with that Directive[2], based on individual reports to be sent by the Member States to the Commission[3]. The present report covers the period from June 2009 to June 2014 following the previous report for the period 2006-2009[4].

This report is based on 26 Member States' reports[5], given that two Member States did not submit individual reports. Croatia, which became a Member State of the Union in July 2013, was requested to submit the report on its experience with the Directive for the first time as of 2013.

Member States were requested to provide information on:

- Activities and installations
- Notification and approval systems
- Accidents
- Inspection and enforcement issues
- Problems with interpretation of provisions
- Clinical trials using the provisions of the Directive

[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 (recast), OJ L 125, 21.5.2009, p. 75
[2] Article 17(3) of Directive 2009/41/EC
[3] Article 17(2) of Directive 2009/41/EC.
[4] 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 (recast) for the period 2006 – 2009, COM(2012) 398 final, 17.7.2012.
[5] The information for each Member State, as submitted, is available on …(internet site)

– Public consultation and information

– Waste disposal

The information contained in this report is based on Member States individual reports and, therefore, does not represent the position of the European Commission[6].

Neither the European Commission nor any person acting on its behalf is responsible for the content of this report and of any use made of the information contained in this report.

The following text summarises the information given by Member States under the headings provided and highlights similarities of and differences between the experiences of the Member States. Further details from the individual Member States' three year reports are provided in the accompanying Commission staff working document.

[6] In particular, this report is without prejudice to any potential action in accordance with Article 258 of the Treaty on the Functioning of the European Union.

1. Overview of activities and installations (reporting period 06.06.2009 – 05.06.2014)

In accordance with Article 2(c) of Directive 2009/41/EC, contained use shall mean "*any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with the general population and the environment*".

Contained use activities are classified into four containment classes: Class 1 represents activities of no or negligible risk; Classes 2, 3 or 4 represent activities of low, moderate and high risk, respectively.[7]

Within the framework of Directive 2009/41/EC, the premises for contained use activities must be notified to the national competent authorities when they are to be used for the first time. Following this notification subsequent class 1 contained use may proceed without further notification, whereas higher containment class levels require additional specific notification. The Czech Republic is currently amending its legislation which requires a new notification in each case of contained use even for Class 1 activities.

According to the information provided, most contained use activities in the Member States fell into class 1 or class 2. Fewer class 3 and 4 activities were being carried out. According to its national report, there were no GMMs contained use activities in Romania during the reporting period.

Most activities were related to research. Several activities served commercial purposes such as the manufacture of diagnostics, of veterinary/medicinal products or involving clinical trials. Activities were also carried out in hospitals, public institutions, education (universities) or in detection laboratories.

2. Notification and approval system (and relevant changes)

National systems differed slightly in terms of authorities involved.

In many Member States (Bulgaria, the Czech Republic, Denmark[8], Ireland, Lithuania, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, and Slovenia), the Competent Authorities for the notification and approval were the Ministry of Environment or Agencies focusing on environmental issues. In other Member States (Austria, Croatia, Cyprus, Estonia, France, Hungary, Italy, Latvia, the United Kingdom), the tasks of the Competent Authorities were carried out by other Ministries alone or in collaboration with others like the Ministry of Health (Austria[9], Croatia[10], Italy, United Kingdom), the Ministry of Labour (Cyprus, Estonia), the Ministry of Agriculture and Rural Development (Hungary, Latvia), the Ministry of National/Higher Education, Science and Research (France), specific authorities for

[7] Article 4(3) of Directive 2009/41/EC
[8] Together with the Danish Working Authority
[9] Together with the Ministry of Science, Research and Economy
[10] Together with the Ministry of Science, Education and Sports

Biotechnology/Biosafety (Belgium, Finland, Spain), Work Environment (Sweden) or Food and Consumer Protection (Germany).

Some Member States also employ advisory scientific bodies in the risk assessment/authorisation process. In Belgium and Germany, the Competent Authorities are established at regional level, and in Spain and the United Kingdom certain competences are delegated to the regional authorities.

Denmark has started to review its national procedures in order to facilitate the process for both companies and authorities.

With the exception of Cyprus and Romania, Member States have extended the transposed provisions of Directive 2009/41/EC on GMM to the contained uses of GM plants and GM animals. Poland provided no information on this aspect.

In general, with a small number of exceptions, Member States declare processing notifications within the statutory timeframe. When delays occurred, they were mostly due to requests for additional information, lack of clarity on the notification submission requirements on the part of applicants, the involvement of more than one national body in the approval process, and delays in the delivery of the opinion by the scientific advisory body responsible for the assessment of the notifications.

3. Accidents

Few Member States (Finland, the Netherlands, Slovakia, Sweden and United Kingdom) reported accidents according to the definition laid down in Article 2(d) of Directive 2009/41/EC and the procedures laid down in Articles 14 and 15 of that Directive.

Finland received few notices of mild accidents (i.e. needle pricks) in class 2 activities with no consequences. The Netherlands reported 13 incidents, without consequences on health or environment, namely a small fire in a biosafety cabinet in a laboratory, a small collision in a corridor while transporting wastes (class 2 micro-organism was present in the waste), a centrifuge failure (GM *Neisseria*), an ice-machine failure, a needle accident with a low titre of GM Influenza, 2 incidents with an isolator housing animals with GM Influenza, damages to a glass wall of a laboratory, a technical defect, a mistake in the technical construction of a ventilation system, and a cell line infected with GM SARS-virus was fixed with an old fixative which although expired, proved to be effective.

Slovakia reported 3 accidents caused by fire in different facilities including the Institute of Virology (class 1 and 2 GMOs), the Institute of Neuroimmunology (class 1 and 2 GMOs), and the Slovak University of Technology (class 1 GMOs). Sweden reported one accident involving a needle accident (student accidentally stuck herself with a syringe containing a GM virus vaccine).

The United Kingdom reported 8 accidents involving contained use of GMMs or GMOs. Of the eight accidents reported, six involved class 2 GMMs, and two involved class 3 GMMs. The reported accidents included two needle stick injuries (*Toxoplasma gondii and Mycobacterium marinum*), a, instrument measurement failure, an accidental splashing, (a droplet of culture of *Pseudomonas aeruginosa* splashed into the eye), a drop of a box of plates containing 36 plates of *Yersinia pestis*, a centrifuge failure which could potentially led to an

aerosol of GM *Legionella pneumophila* exposure, a drainage system failure (*Fusarium graminearum*), and two filtration failures with GM viruses (Lentivirus vector with inserted sequence encoding for shRNA against KIAA0020 and Hepatitis C virus).

Belgium reported one accident (fire) in a biological waste storage room without the competent authority having been informed.

According to the information provided by the Member States, when accidents occurred, corrective measures were taken for both the procedural and structural safety aspects, and for the safety of humans and the environment. The institutions involved made the necessary adjustments to avoid similar events in the future, such as adapting or changing the standard operating procedures, amending the risk management procedures, improving containment practices, and providing training for staff. Affected personnel were given prophylactic treatment and/or vaccination, and were monitored to ensure full recovery (in the cases of accidental sticking with needles).

4. Inspection and enforcement issues

The national reports showed both similarities and differences in the implementation and enforcement processes required by articles 10 and 16 of Directive 2009/41/EC in the Member States.

In some Member States inspections were conducted by specialised inspectors from the Competent Authority, while in others inspections were carried out at the request of the Competent Authorities by specialised inspectors from other ministries or services. The number of inspectors involved in GMM control also varied among Member States.

The control procedures included regular annual inspections according to set criteria (periodicity, class of risk, etc.), ad hoc unannounced inspections, audits of facilities approved for the first time, sampling of materials, and audits of documentation and processes.

In Austria, inspections were organised and conducted on the basis of the characteristics of the activity (e.g. risk class, large scale equipment, inoculation of animals). In Belgium, the inspections were organised in the three regions by different inspectorates on a regular basis, and concerned contained uses of GMMs including pathogens.

In the Czech Republic and in Bulgaria, the inspections were carried out on the basis of annual schedule.

In Denmark, all activities were inspected upon notification of new premises or of changes in existing ones. The Danish authorities informed the Commission that this procedure is about to change to allow Class 1 GMM work to start based on the notification alone with inspections following after the start of operations.

In Finland, Ireland, Lithuania, and the United Kingdom, the inspection intensity was based mainly on the Class of the contained use activity.

In Germany, although the way inspections were conducted varied among the federal states in terms of periodicity, common approaches based on risk classification and the use patterns of the facility were followed.

Three Member States (Estonia, Lithuania, and Malta) considered that specific training programmes for inspectors and joint inspections with other Member States would improve the inspection process.

During inspections, some issues were identified with regard to: waste management; inaccurate or outdated documentation; lack of knowledge regarding the newest GM technologies; insufficient recording of the training of the staff; contained use of GMOs/GMMs without having obtained the proper authorisation; poor or missing identification and signalisation of genetic engineering facilities or laboratories; adequacy of standard control measures; and in some instances, insufficient biosafety measures (decontamination, protective clothing, restricted access, etc.).

In terms of enforcement, in all Member States which provided individual reports, when inspections identified situations requiring corrective actions, the competent authorities declare to have used a number of instruments (warnings, infraction notices, etc.) to ensure remedial action and compliance on the part of operators within a set timeframe. In all reported instances, operators promptly complied and implemented the corrective actions requested by the authorities.

5. Problems with interpretation of the provisions

In Austria, Croatia, Cyprus, Germany, Italy, Latvia, Lithuania, Malta, Portugal, Romania and Slovakia, no specific problems with the interpretation of the provisions were reported.

Belgium had difficulties interpreting the provisions of the Directive 2009/41/EC concerning commercial activities involving bacterial transformation. In one instance, a GMM falling within the scope of 2009/41/EC was produced using techniques (self-cloning) which do not fall under the scope of Directive 2009/41/EC. In another instance, a commercially available (via the internet) bacterial transformation kit was used to produce a Class 1 GMM. While the transformation kit is not sold in Belgium, its availability via the internet could potentially make the enforcement of the provisions of 2009/41/EC difficult. Belgium and Poland, questioned whether activities involving GM plant and animal cells should be considered as GMM activities. However, the definition of microorganism under 2009/41/EC is clear in including animal and plant cell in culture within its scope[11]

Belgium, the Czech Republic, Finland, Hungary, the Netherlands, Spain and the United Kingdom encountered problems in assessing whether the application of certain new techniques resulting in a GMM fell within the scope of Directive 2009/41/EC. They considered that the Union regulatory framework for the new techniques should be reviewed to clarify whether organisms obtained with these new techniques fall under the scope of the Directive.

Belgium, Finland, Slovenia, the United Kingdom and Sweden pointed out that the large number of notifications, the high information requirements for each notification, the detailed reporting system, and the complexity of the different procedures can result in a heavy administrative burden for both authorities and notifiers. Spain and France also pointed to the

[11] Article 2(a) of Directive 2009/41/EC

burden of the large number of inspections required in order to enforce the provisions of Directive 2009/41/EC. Belgium considered that the procedures regarding the notification of contained uses of GMMs and pathogens should be made more uniform. In Hungary, a lot of consultations are necessary between the notifiers and the Competent Authority on the documentation and information requirements before the submission and/or after the submission of the notification. In Slovenia, delays occurred when the external experts (Scientific Committee) or another national body was involved in the processing of a notification.

The Netherlands reported a number of specific technical issues including differences in the (strict) GMO-regulations and the less strict regulation of wild type pathogens (Netherlands). The Netherlands also believed there is a need for simplification and harmonisation of disinfectants used as biocides in laboratories.

In Belgium, some problems were encountered with the interpretation of the terms "subsequent contained use activity" following the first time notification of premises for a particular containment class activity. The notifier does not always know when an activity is considered to be a subsequent contained use of the same containment class, especially in cases when the authorised activity is modified. Moreover, it is not always possible to distinguish the amendments to earlier notifications from other types of subsequent contained use activities (continuation of activity or new activity). In the Brussels-Capital Region some problems were encountered in the notification process due to the Brussels legislation which has set up numerous different procedures regarding the class of risk (8 in total).

In Finland, the classification of viruses, cell cultures, and especially of pathogens, which have been attenuated, has also been problematic. On the same subject, Finland, the Netherlands, and the United Kingdom would like to see that the definitions in the Directive be reviewed to take into account new techniques or technological advances.

Finland also added that, as research groups may move from one institution to another, the need for new notifications of the new premises each time creates additional administrative work.

Ireland and Denmark considered that there is a need for deregulation of Class 1 GMMs as the requirements under Annex II, Part B of the Directive is considered to be rather heavy given the 'non harmful' status of Class 1 GMMs. Similarly, Spain, Sweden, and the United Kingdom, would like to simplify the procedures for Class 1 and 2 activities. For Slovenia, the inclusion of safe organisms in Part C of the Annex II of Directive 2009/41/EC could contribute to the reduction of the number and size of notifications.

Belgium, Hungary, Lithuania, the Netherlands and the Czech Republic would welcome better explanation, early guidance and harmonised views across the EU on gene therapy, on synthetic biology, and on other new techniques or technological advances.

Lithuania, Estonia, and Malta would welcome more exchanges on experiences and training among Member States.

6. Clinical trials using the provisions of the Directive

The national reports showed that Member States addressed clinical trials in considerably different ways. Some Member States regarded clinical trials as falling exclusively under Directive 2001/18/EC (Sweden or Netherlands), while other Member States, (Denmark and Finland) regarded them as falling exclusively within the scope of Directive 2009/41/EC.

Another reported issue was the potential borderline situation between contained use and deliberate release in clinical trials with GM-viruses in which it cannot be excluded that patients' or experimental animals' excretions may contain the tested viruses.

Other Member States (Spain, United Kingdom) decide on a case by case basis whether a clinical trial is regarded as contained use or as a deliberate release. In Austria, there are special legal national provisions for applications concerning gene therapy in clinical trials.

Bulgaria, the Czech Republic and Hungary considered that there is a need to discuss whether clinical trials fall under the scope of Directive 2009/41/EC or under the scope of Directive 2001/18/EC. Bulgaria, Finland, Hungary, Spain and the Czech Republic showed support for harmonisation of the guidance and the procedures for the evaluation and notification of clinical trials with GMMs at Union level.

Some Member States (Belgium, Denmark, France, Finland, Italy, Poland, Slovenia and Spain) reported increase in the notifications for gene therapy clinical trials, while in Germany the number has decreased.

There were no clinical trials using GMMs in Austria, Croatia, Cyprus, the Czech Republic, Estonia, Hungary, Ireland, Latvia, Lithuania, Malta, and Portugal.

Bulgaria, Spain and the Czech Republic, would like to see clarity on the legislative framework concerning clinical trials with GMMs.

7. Public consultation and information

Member States generally conducted public consultations as part of the authorisation process, as foreseen under Article 12 of Directive 2009/41/EC. The approaches of public consultations varied among the Member States. Some Member States (Austria, Czech Republic, France, Ireland, Romania and Spain) focussed the public consultation only on class 3 and 4. Others (Poland), allowed the Competent Authorities to decide whether a public consultation was needed on the basis of the Class of the activities.

The majority of Member States established a web based system for regular public consultations. Some Member States had electronic registers (databases) for applications submitted under Directive 2009/41/EC.

In Belgium, the Czech Republic, Latvia, Poland, Romania, Slovakia, Slovenia, Spain and the United Kingdom, the public had access to the information or summary of the applications available in the data bases.

In Hungary, the notifications published on the internet contain a summary of the risk assessment available at the Secretariat of Gene Technology Advisory Board.

In the Netherlands, only the notifier's name, the title of the project and the issuing date of the licence were published but members of the public could request access to an issued licence.

Other approaches to communicate to the public relevant information in the context of Directive 2009/41/EC, included public meetings of advisory bodies and seminars (the Czech Republic), publications of annual reports (Croatia, the Czech Republic, Germany, Spain and the United Kingdom), local or national newspapers (Denmark, Netherlands), brochures (Estonia), competent Ministry publications (Slovakia), and publications of the minutes of meetings (the United Kingdom). In Malta there were two radio interviews.

In some Member States (Austria, Bulgaria, Cyprus, Finland, Portugal and Sweden), no public consultations were carried out, because no application was received during the reporting period for the classes under Directive 2009/41/EC which the national provisions call for a public consultation.

With the exception of Slovenia and the United Kingdom, Member States received no responses to public consultations and information made publicly available under Directive 2009/41/EC during the reporting period. In the two Member States which received responses, the summaries of the comments were made available on the Competent Authorities' website. In Ireland, the Competent Authority received a letter from a member of the public; seeking additional information on the implications/risk associated with class 3 GMM contained use activity (GM strains of Hepatitis).

8. Waste disposal

In general, Member States declare addressing waste management by class or category of waste in accordance with the requirements of Article 5 and of Annex IV of Directive 2009/41/EC. The Member States which did not provide any information on these aspects explained that there was no activity in this area.

Few Member States (Belgium, Lithuania, Poland and Portugal), prescribed that all types of residues had to be inactivated prior to disposal. In Spain, the waste inactivation is optional for class 1 and obligatory for class 2, 3 and 4 but the Competent Authority recommends operators to inactivate the GMOs in all cases.

Most Member States use autoclave or chemical treatment to dispose of GMM waste, and/or incinerate GM plants and animals. In Germany, there are two genetic engineering facilities where large animals can be disposed of with the help of a digester (alkaline hydrolysis).

Some Member States (Germany, France, Ireland, Lithuania and the United Kingdom), had waste treatment facilities dedicated to GM waste inactivation. In Austria, the Netherlands, and Finland, there is one waste treatment facility dedicated to GM waste inactivation, otherwise the operators inactivate it themselves. In countries where there are no authorised GM waste treatment facilities, the users inactivate their GMO waste themselves (Denmark, Estonia) or use the general waste treatment facilities available (Belgium, Bulgaria, Hungary, the Czech Republic, Spain and Sweden).

9. Summary and Conclusions

During the period 2009-2014 most contained use activities declared by Member States fell within class 1 or class 2. Although there are significantly fewer class 3 and 4 activities being carried out, their number is increasing. Most activities were related to research but several served commercial purposes such as the manufacture of diagnostics, veterinary and medicinal products.

Member States applied the Directive in a similar fashion in terms of administration, handling of the notifications, inspections, waste disposal and public consultation and information. Differences arose in those areas covered by the Directive on which Member States have either enacted additional legislation as for example, in extending the provisions of Directive 2009/41/EC to cover GM plants and animals, maintaining the requirements for notification for each Class 1 activity, or when they apply the provisions of 2009/41/EC as in requiring for all Classes, inactivation of waste before disposal or employing independent advisory scientific bodies for the assessment of notifications.

The national reports showed that, in the Member States, several and at times different authorities, ministries and/or agencies are involved in the notification and approval process and in inspection and enforcement. The process of notification and approval is similar and timelines well respected. Inspections are conducted systematically and on an ad hoc basis in all premises or in specific class (classes 3 and 4) activities using specialised staff.

When inspections identified areas for improvement, national reports indicated that the competent authorities ensured that notifiers acted to rectify the situation within set deadlines.

Accidents in the reporting Member States were few and minor in significance in terms of human health and the environment. In all reported cases, Member States reported that the appropriate corrective measures were undertaken in all accidents involving humans/personnel, on the processes and operating procedures, and the contained used premises and/or installations.

The national reports show that problems of interpretation of the provisions of the Directive arise in some reporting Member States, particularly in the cases of the definition of genetic modification in the Directive, in the case of notifications involving modifications using novel techniques, in the assessment of the various classes of GMMs, in the subsequent 'contained use' activity, and as regards to clinical trials in the context of the Directive. In their reports, several Member States, stressed that the problems mentioned above and the actual administration of the process (number of notifications, processing of notifications and approval, inspections, etc.) result in a significant administrative burden which merits examination with the view to harmonise and simplify to the extent possible.

In terms of public consultation and information, almost all reporting Member States have implemented provisions for conducting public consultations, and for informing the public on the outcome of their activities under the Directive. Although the internet was primarily used, other means of communication (seminars, meetings, brochures, etc.) were employed. In general, there were no responses to public consultations.

Finally, in terms of waste disposal, all reporting Member States have declared having enacted waste management provisions according to the GM class. In some instances, Member States required the most stringent waste management treatment for all classes of GMMs. Both specialised and no specialised waste treatment facilities were used.