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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 (recast) for the period 2006 – 2009

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COMMISSION WORKING DOCUMENT

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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 (recast) for the period 2006 – 2009

The information contained in this report 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.¹

PREFACE

Article 17(2) of Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (recast) requires Member States to send a summary report on their experience with the Directive to the Commission every three years. According to Article 17(3), the Commission shall publish a summary report based on the aforementioned reports.

The two new Member States which acceded in January 2007 were required to submit reports on their experience with the Directive for the first time in 2009. The fifth Commission summary report contained information on their transposition into national law of Directive 98/81/EC, the predecessor of Directive 2009/41/EC.

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

INTRODUCTION

This report is based on a sixth series of Member States' reports. The deadline for submission of the Member States' reports was 30 May 2010. Few Member States submitted their reports before the deadline, while a great number was delayed. The latest report was received on 6th March 2012. At the time of drafting this report, national reports had been received from all Member States with the exception of two Member States. On the whole, Member States provided relevant information.

Member States were requested to provide information on:

- Activities and installations
- Notification and approval systems
- Risk assessment and classification of contained uses

¹ Every effort has been made to ensure the accuracy of the material contained in this report. Member State national legislation transposing Directive 2009/41/EC into national law has been the subject of a conformity check carried out by the Commission. This report is without prejudice to the findings of the conformity check and any potential action on behalf of the Commission in accordance with Art 258 of the Treaty on the functioning of the EU, where Member States have been found to have incorrectly transposed Directive 2009/41/EC into national legislation.

- Accidents
- Inspection and enforcement issues
- Problems with interpretation of provisions
- Clinical trials using the provisions of the Directive
- Public consultation and information
- Protection of confidential information
- Waste disposal

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 two annexes of this report, which are Commission staff working documents.

1. Overview of activities and installations

Within the framework of Directive 2009/41/EC, contained uses must be notified to the national competent authorities. In accordance with Article 2(c), 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 classes: class 1 represents activities of no or negligible risk; classes 2, 3 or 4 represent activities of low, moderate or high risk, respectively.

Premises for contained use activities as well as installations must be notified as well. Some Member States notify the installations on the reason that activities are difficult to count. Some Member States require notifications for activities with GM plants or GM animals under contained use.

According to the Member States' reports, no contained use activity involving GMMs was carried out in Bulgaria, Cyprus, Estonia, Latvia, Malta, and Romania in the reporting period.

According to the information provided, most activities fell into class 1 or class 2. Fewer class 3 and 4 activities were being carried out, but the number was increasing. Most activities were related to research. Several activities served commercial purposes such as the manufacture of diagnostics, veterinary/medicinal products.

2. Notification and approval system (and relevant changes)

The national systems differed slightly in terms of authorities involved. In many Member States, the Ministry of Environment or agencies focusing on environmental issues were the Competent Authority. In other Member States, Competent Authorities included the Ministry of Health, the Ministry of Labour and Social Insurance, the Ministry of Agriculture and Rural Development, or the Ministry of Science and Research. In Belgium and Germany the Competent Authorities were established at regional level. In several Member States additional authorities and in particular advisory bodies were involved in the authorisation process.

Under the provisions of the Directive, the first-time use of an installation for class 1 activities must be notified, the subsequent use of a class 1 activity may proceed without further notification (article 6 and 7). However, Czech legislation required a new notification in case that a new GMO was to be used (not only new premises). Class 2 activities follow a similar procedure as class 1, while class 3 and class 4 activities may not proceed without prior consent of the Competent Authority.

In Sweden, the Competent Authority has commenced to review the regulations on the contained use of genetically modified organisms for simplifying the procedure for notification of GMM activities. Portugal has started to review its national contained use legislation to strengthen the role of experts in the whole process, and for determining fees for the processing of notifications.

3. Risk assessment and classification of contained uses

Most Member States integrated into their own national legislation the Commission risk assessment guidelines, while others referred directly to these guidelines.

In the majority of Member States, activities were classified into four classes as provided for by the Directive. Finland noticed that the classification of viruses, cell cultures and of pathogens that had been attenuated was problematic in some cases.

In general, the users are required to compile their own risk assessment, as provided for under Article 4(2) of the Directive. However, in some Member States the risk assessment must be carried out or at least verified by a professional consultant and is reviewed by an expert advisory body.

4. Accidents

Few Member States (Finland, Ireland, the Netherlands and United Kingdom) reported accidents according to the definition laid down in Article 2(d) of the Directive. Finland reported one accident involving an experiment with an enterotoxin gene from *S. aureus* without safety measures which generated health consequences for the user. Ireland reported an accident generated by the breaking of the glass end Pasteur pipette during the aspiration of supernatant from a trypsinised genetically modified lentivirus-infected HeLa cell culture. The content penetrated the skin of the user. The Netherlands reported 9 incidents, without consequences on health or environment. The United Kingdom reported 7 accidents involving GMM belonging to class 2, namely two peristaltic pump failures (*E. coli* HMS174 (DE3) genetically modified to express *Neisseria meningitidis* surface proteins as well as H5N1 Influenza virus), an incubator failure (*M. tuberculosis*), a blockage of a steel pipe (vaccine influenza virus), a failure of the injection procedure (pigs injected with GM *Actinobacillus pleuropneumoniae*), and two needle stick injuries (vaccinia virus and *Leishmania mexicana*).

All the institutions where the accidents took place, made the necessary adjustments for improving the procedural aspects to avoid similar events in future, such as adapting or changing the company's standard operating procedure; in one case the risk assessment was amended; in another case the staff was trained for the new technical method which raised problems.

5. Inspection and enforcement issues

The national reports show a varying level of control in different Member States. In some Member States the inspections were conducted by the Competent Authority, while in others the inspections were managed independently from the Competent Authority. The number of inspectors involved in GMM control varied strongly per Member States. The control procedures were also quite different in EU 27.

In Denmark all activities were inspected upon notification of new premises or changes of already classified locations, while Austria only carried out spot checks. In Finland, Germany, Lithuania and the United Kingdom the inspection intensity was based mainly on class of contained use. In Finland the class 3 use was inspected more often (at least every second year) than class 1 or 2 use (at least every 5 years /4

years respectively); in the United Kingdom, sites working at class 2 were visited approximately every 5 years, sites working at class 3 approximately every 3 years and sites working at class 4 approximately every year. Lithuania inspected the premises at least every 3 years for class 1 uses, every 2 years for class 2, and every year for class 3 and 4 uses. In Finland for some specific cases, a written inspection procedure was in place.

Some Member States such as Cyprus, Denmark, Romania, Portugal, the Slovak Republic, Slovenia and the United Kingdom appointed specialist inspectors for the contained use of GMMs.

During inspections, the following improvements were found to be necessary: Users already actively engaged in the contained use of GMOs/GMMs without having first obtained the authorisation to do so; lack of knowledge regarding the consent conditions issued in respect of the contained use activity; lack of a dedicated person for dealing with legal and safety requirements; lack of training of biosafety officers or the project leaders; the notifying the location without notifying the activities; others.

6. Problems with interpretation of the provisions

Some Member States named topics which need further clarification, in relation with a necessary update of technical and scientific advancement and/or further harmonization on the European level.

In Austria, Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Malta, Portugal, Romania and Slovakia no specific problems with the interpretation of the provisions were reported. For the New Member States, in the majority of the cases the reason is the lack of activities due to the lack of notifications.

Belgium, Czech Republic, Hungary and the Netherlands encountered problems in assessing whether the application of certain new techniques resulted in a genetically modified organism and fell within the scope of Directive 2009/41/EC. At the request of the Competent Authorities of Directive 2001/18/EC the Commission set up a New Techniques Working Group in October 2007 to assess a non-exhaustive list of techniques as to whether they result in the production of a genetically modified organism or microorganism as defined under Directives 2001/18/EC and 2009/41/EC. The outcome is expected to help to clarify whether certain new techniques result in genetically modified organisms and fall within the scope of Directive 2009/41/EC.

The Netherlands, Spain, Hungary, Czech Republic, Belgium, Finland saw a need for clarification of the scopes of Directive 2009/41/EC and Directive 2001/18/EC with respect to clinical trials.

Other problems encountered in case of implementation of the Directive 2009/41/EC were the following: difficulties with the detection and identification of GMOs (Germany), lack of clarity of terminology (Germany, Finland); huge number of notifications of class 1 to be reviewed (Denmark), or huge number of inspections (Ireland); high number of notifications for viral vectors with low risk (United Kingdom) which created a significant administrative burden; difficulties in obtaining

feedback from the users working with GMO/GMM (Spain). Member States proposed different measures such as to include safe organisms in Part C of the Annex II of the Directive 2009/41/EC (Slovenia), to set up a EU GMM Working Group focusing on research activities from the perspective of Directive 2009/41/EC, and to change the requirements for notifying class 2 activities (United Kingdom).

7. Clinical trials using the provisions of the Directive

The national reports showed that the Member States addressed clinical trials in considerably different ways. Some Member States regarded clinical trials as falling exclusively under Directive 2001/18/EC (for example Sweden), while other Member States such as Denmark and Finland regarded them as falling exclusively within the scope of Directive 2009/41/EC. Other Member States (Spain, UK) decide on a case by case basis whether a clinical trial is regarded as contained use or as a deliberate release.

In terms of numbers, France has reported 228 clinical trials, a large increase in numbers compared to previous reporting periods. No clinical trials using GMO/GMM were conducted in Bulgaria, Cyprus, Estonia, Finland, Hungary, Ireland, Latvia, Lithuania, Malta, Portugal, Romania, Slovakia and Slovenia.

8. Public consultation and information

Member States generally prescribed public consultation as part of the authorisation procedure. The approach of the Member States was diverse. Some Member States focussed the public consultation only on class 3 and 4 (Austria), other Member States allowed the Competent Authorities to decide for the rest of the classes whether the public consultation was needed (Ireland, Portugal, Poland, Romania).

The majority of Member States established a web based system for regular public consultation. Some Member States had electronic registers (databases) for applications submitted under Directive 2009/41/EC. In Belgium, Bulgaria, Czech Republic, Denmark, Ireland, Lithuania, the Netherlands, Poland, Romania, Slovakia and the United Kingdom, the general public had access to the summary of the applications available in these databases.

Hungary requested from the notifier a summary of the risk assessment for public information purposes which was available for consultation at the Secretariat of the 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 information relevant in the context of Directive 2009/41/EC included public meetings of advisory bodies (the United Kingdom, Czech Republic), seminars (Czech Republic, Malta), publications such as annual reports (Belgium, Germany, Czech Republic), or leaflets (Malta). In Denmark the approved notifications were published in national and local newspapers.

9. Protection of confidential information

Article 18 of Directive 2009/41/EC provides for the protection of confidential information. The competent authority shall determine whether information submitted

by the notifier may be considered confidential in accordance with the requirements of article 18(1) of the Directive.

Generally speaking, the operator may indicate in his/her application to the Competent Authority those data he/she wishes to be treated as confidential. Most Member States decided, based on the operator's request, that some specific data be kept confidential (Ireland, Austria, Belgium). In the Netherlands a general description of the confidential parts had to be submitted in order to give the public insight into the risk assessment.

Member States took appropriate measures to protect confidential information. In the Netherlands only authorised staff had access to the rooms where confidential information was handled. The tendency of Member States was to ask for a technical dossier with non-sensitive information and, if applicable, an annex with confidential data (Belgium, the Netherlands).

10. Waste disposal

Member States addressed waste management by class or by category of waste. The Member States who did not provide any information on these aspects mentioned that either there were no change since the previous report, or explained that there was no activity in this area.

According to Directive 2009/41/EC, 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. Few Member States (Belgium, Lithuania, Portugal and Spain) prescribed that all types of residues had to be inactivated prior to disposal, thus going beyond what the Directive requires.

Starting with level 2, Member States request a description of the containment and other protective measures to be applied, including information about waste management, including the wastes to be generated, their treatment, final form and destination, in accordance with directive 2009/41/EC. For level 1, the Directive requests information on waste management as a summary.

Some Member States had waste treatment facilities dedicated to GM waste inactivation (Germany, Finland, Ireland, and the United Kingdom). In countries where there were no authorised GM waste treatment facilities the users inactivated their GMO waste themselves (Denmark) or use the general waste treatment facilities available (Hungary, Czech Republic).

11. Conclusions

Most contained use activities fell within class 1 or class 2. Significantly fewer class 3 and 4 activities were being carried out, but the number is increasing. Most activities were related to research but several serve commercial purposes such as the manufacture of diagnostics, or veterinary or medicinal products. On the whole, the Member States applied the Directive in a similar fashion. Differences arose as

Member States enacted additional legislation in almost all areas covered by the Directive.

The national reports showed that the Member States addressed clinical trials in different ways. Some Member States applied Directive 2009/41/EC on the contained use of GMMs, others Directive 2001/18/EC on the deliberate release of GMOs into the environment, and yet others applied other national legislation. These differences stem from differences in the interpretation of annexes of Directive 2001/18/EC and Directive 2009/41/EC, in particular, as the latter Directive had not been specifically designed for clinical trials. However, both Directives attribute the competence to regulate clinical trials with GM microorganisms essentially with the Member States, Directive 2009/41/EC by setting minimum standards leaving it up to the Member States to go beyond those minimum standards, and Directive 2001/18/EC by attributing the competence for authorising part B notifications to the Member States. Some Member States raise the point that further harmonization would be useful. However, most importantly, both Directives share as common objective a high level of protection so that from a safety point of view further harmonisation at Union level is at present not a priority for the Commission.