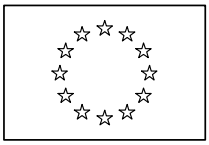

COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMISSION STAFF WORKING DOCUMENT

Fifth summary report on the experience of Member States with Directive 90/219/EEC, as amended by Directive 98/81/EC, on the contained use of genetically modified micro-organisms for the period 2003 – 2006

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COMMISSION STAFF WORKING DOCUMENT

Fifth summary report on the experience of Member States with Directive 90/219/EEC, as amended by Directive 98/81/EC, on the contained use of genetically modified micro-organisms for the period 2003 – 2006

The information contained in this report has been compiled by the Commission from individual reports submitted by Member States in accordance with Article 18 of Directive 98/81/EC amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms. Every effort has been made to ensure the accuracy of the material contained in this report

Member State national legislation transposing Directive 98/81/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 226 of the EC Treaty (infringement procedure), where Member States have been found to have incorrectly transposed Directive 98/81/EC into national legislation.

PREFACE

Article 18(2) of Directive 90/219/EEC[1], as amended by Directive 98/81/EC[2], on the contained use of genetically modified micro-organisms requires Member States to send a summary report on their experience with the Directive to the Commission every three years. According to Article 18(3), the Commission shall publish a summary report based on the afore-mentioned Member States reports.

The ten new Member States which acceded in May 2004 were required to submit reports on their experience with the Directive, for the first time in 2006. The last Commission report contained information on their transposition of Directive 98/81/EC into national law.

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 fifth series of Member State (MS) reports. The deadline for submission of the Member State reports was 5 June 2006. Some Member States submitted their reports before the deadline, but a great number were delayed. At the time of drafting this report, national reports had been received from all Member States with the exception of Greece. On the whole, Member States provided relevant and detailed information.

As in previous reporting periods, the Commission had provided a framework for the national reports in order to ensure a harmonised format. The following text summarises the information given by Member States under the headings provided and highlights similarities

[1] OJ L 117 of 8.5.1990
[2] OJ L 330 of 5.12.1998

and differences between the Member States' experiences. Further details from the individual MS three-year reports are provided in the annexes of this report.

1. Overview of activities and installations

Within the framework of Directive 90/219/EEC, 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*". Premises for contained use activities (i.e. installations) must be notified as well.

On the whole, the number of installations and activities carried out in the European Union has increased. Germany has the largest number of activities with 2,434 activities having been notified during the reporting period 2003 - 2006, resulting in 10,752 activities in total. No activities involving GMMs are carried out in Cyprus and Malta.

Contained use activities are classified into four classes: class 1 represents activities of no or negligible risk; class 2, activities of low risk; class 3, activities of moderate risk; and class 4, activities of high risk. According to the information provided, most activities belong to class 1 or class 2. Fewer Class 3/4 activities are being carried out but the number is increasing.

Most activities are related to research. Several serve commercial purposes such as the manufacture of diagnostics, veterinary/medicinal products, etc.

2. Notification and approval systems (and relevant changes)

The national systems differ slightly in terms of authorities involved. In many Member States, the Ministry of Environment is the competent authority. Examples of competent authorities in other Member States include the Ministry of Health, the Ministry of Labour, the Ministry of Agriculture or the Ministry of Science. In Belgium, Germany and Spain, competent authorities are established at regional level. In several Member States additional authorities such as advisory bodies are involved in the authorisation process. The table in Annex II provides details of the competent authorities and other authorities involved for each Member State.

Under the provisions of the Directive, the first-time use of an installation must be notified; the subsequent use of a class 1 activity may proceed without further notification. Class 2 activities must be notified to the Competent Authority while class 3/4 activities may not proceed without the prior consent of the competent authority.

Belgium, the Czech Republic, Denmark, Lithuania and the Slovak Republic require subsequent class 1 activities to be notified to the Competent Authority.

As to relevant changes, in Italy, the competencies regarding GMMs and GMOs have been split between the Ministries of Health and Environment, which evaluate GMM and GMO notifications respectively. Latvia has seen a change of competent authority, with the Ministry of Agriculture now being the responsible Competent Authority.

3. Risk assessment and classification of contained uses

Most Member States have integrated the Commission's risk assessment guidelines into their own national legislation while others have referred notifiers directly to the Commissions risk assessment guidelines.

In the majority of Member States, activities are classified into four classes as provided for by the Directive. National legislation in Sweden has provided for 3 administrative categories: F activity which provides for Class 1 activities; L activity which provides for small scale Class 2 activities; and R activity which provides for large scale Class 2 activities, Class 3 and Class 4 activities. Malta uses the criteria for classification laid down in Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work.

In general, the users compile their own risk assessment, as provided for under Article 5(2) of the Directive. In the Czech Republic, however, the risk assessment must be carried out or at least verified by a professional consultant and is reviewed by an expert advisory body. In France and Germany, the competent authority and the federal expert advisory body both make statements on the classification of contained use activities.

The Czech Republic raised the concern that new GMO applications such as gene therapy might lead to problems with the risk assessment guidelines. Finland reported that many operators seemed to have difficulties in compiling a thorough risk assessment and that there was some confusion concerning the classification of GM viruses. Sweden reported that users often do not seem to read or understand the risk assessment guidelines and that the risk assessments often contain insufficient or irrelevant information. According to the UK report, common problems in risk assessments are a poor definition of scope, lack of detail, lack of justification of statements and an inadequate environmental assessment.

4. Accidents

Apart from the UK, no Member State reported any accidents according to the definition laid down in Article 2(d) of the Directive. The UK reported four accidents: a needle-stick injury (vaccinia virus); a failure of syringe (vaccina virus Western Reserve); a failure of incubator (*M.tuberculosis*); and a failure of silicone tubing (*E.coli*).

5. Inspection and enforcement issues

The national reports show a varying level of control in different Member States.

In Denmark and Estonia, all activities are inspected, while Austria only carries out spot checks. Finland has focused on the supervision of class 2 activities. The Flemish and Brussels Capital Regions in Belgium only inspect class 2 and 3 installations while it is the policy of the Walloon region to visit all installations. Belgium reported the discovery of unauthorised facilities as did Poland.

The UK prioritises inspections on the basis of class of the contained use, confidence in management systems, time since last inspection and issues arising from the notification. Premises involved in Class 1 activities only are inspected less frequently than those involved in Class 2 – 4 activities, and inspections concentrate on the evaluation of the Risk Assessments and the correctness of the final classification.

In Sweden, large-scale GMM activities, activities with GMMs in animals and plants and laboratory activities are inspected. Lithuania provides for the inspection of Class 1 activities once every three years, Class 2 activities once every two years and Class 3 and Class 4 activities annually.

Some Member States such as Cyprus, the Slovak Republic, Slovenia and the UK have appointed specialist inspectors for the contained use of GMOs.

Inspections in Lithuania, Portugal and Spain mainly aim at confirming the effectiveness of containment measures.

6. Problems with interpretation of the provisions

Austria, Cyprus, Denmark, Estonia, Ireland, Italy, Lithuania, Luxemburg, the Netherlands and Slovenia have not reported any problems.

Several Member States pointed out that it remains unclear whether clinical trials should be regulated as contained use in accordance with Directive 90/219/EEC or as deliberate release in accordance with Directive 2001/18/EC. The UK made particular reference to the lack of containment tables appropriate to a clinical setting and clinical working practices under Annex IV of the Directive. This has caused difficulty for UK users and required the introduction of additional guidance.

The status of DNA vaccination and whether or not it falls within the remit of the Contained Use Directive was raised by both the Czech Republic and the UK. The UK similarly queried the status of 'siRNA' (small interfering RNA) and indicated that guidance from the Commission would be helpful.

Spain raised the question whether premises used for the storage of GM seeds should be notified under the Contained Use Directive.

Poland, Malta and the Czech Republic sought clarification regarding the extension of the scope of the Directive to include contained use activities involving GM plants, animals and fish in addition to GMMs.

Slovakia, Sweden Finland and Germany sought clarification on the interpretation of certain terms used in the Directive. Slovakia and Sweden made particular reference to self-cloning (Annex II, Part A). According to Slovakia, scientific authorities define self-cloning in a different way to the Directive. Finland sought clarification on the scope of the Directive and the definition of a GMM where transient transformation was concerned. According to Germany, the term "mutagenesis" in Annex II Part A of the Directive can be interpreted too broadly.

Spain asked for clarification on the interpretation of GMM transport in Article 4 of Directive 90/219/EEC.

7. Clinical trials using the provisions of the Directive

The national reports show that the Member States address clinical trials in considerably different ways. Some Member States regard clinical trials as falling exclusively under Directive 2001/18/EC (for example Germany, the Netherlands, Sweden), while other Member States such as Denmark and Finland regard them as falling exclusively within the scope of

Directive 90/219/EEC. Other Member States decide on case by case basis whether a clinical trial is regarded as contained use or as deliberate release (for example Malta, Spain, UK).[3]

In terms of numbers, the UK has reported a large increase in the numbers of clinical trials taking place in the UK. No clinical trials have been conducted in Cyprus, Denmark, Estonia, Latvia, Lithuania, Luxemburg, Portugal, Slovakia and Slovenia.

8. Public consultation and information

Public consultation is required as part of the authorisation procedure for class 3 and class 4 contained use activities in Austria (large-scale class 3 activities only), Czech Republic, Germany (plus certain cases of class 2 activities), Ireland (plus class 2 activities at the discretion of the Competent Authority), Luxemburg, Slovenia and Spain.

The Netherlands provide for public consultation in the case of large-scale production facilities. In Cyprus, Poland and Portugal, the public is consulted when the Competent Authoity considers it appropriate; a proposal for a similar provision has been launched in Latvia. Belgium and Lithuania invite the submission of comments concerning all contained use activities, whereas Sweden has not established a system for regular public consultation. Belgium, Denmark and the Netherlands allow members of the public to object to decisions by the competent authority.

Many Member States have set up websites in order to inform the public about contained use activities. The notifications or a register of contained use are published on the internet in the Czech Republic, Denmark, Finland, Germany, Hungary, Lithuania, Poland, Slovakia, Slovenia, Spain and the UK. Only the notifier's name, the title of the project and the authorisation date are published by the Netherlands, but members of the public can request access to the full dossier. Sweden has not established a public register of notifications, but members of the public can request a list of the information held by the competent authority provided it is not deemed to be confidential.

9. Accident and emergency plans

Many Member States require emergency plans for every contained use (Czech Republic, Cyprus, Estonia, Ireland, Latvia, Lithuania, Netherlands, Poland, Portugal and Slovenia). In Slovakia, emergency plans must be drawn up for contained use activities greater than class 1. In Austria and Sweden, an emergency plan must be submitted in respect of class 3 and class 4 activities and large-scale class 2 activities while in Spain, emergency plans are required only in respect of class 3 and class 4 activities.

German legislation provides for external emergency plans only in certain cases of class 3 and 4 activities; no external emergency plans have been deemed necessary to date. In Belgium, federal law prescribes internal emergency plans for all contained use activities greater than class 1. The Brussels and Walloon regions prescribe external emergency plans for contained use activities greater than class 1 while the Flemish region requires the establishment of external emergency plans for class 3 and 4 contained use activities.

[3] The Commission has commissioned an analysis of the applicability of the contained use legislation for clinical trials. The report which provides an in-depth analysis of the issue was finalised on 4 July 2006 and comes to the conclusion that harmonisation of the approaches to clinical trials is needed.

In the UK and Denmark emergency plans are only required where serious off-site risks to people and/or the environment have been identified.

Some Member States require the user to submit the emergency plan to local authorities, for example the fire brigade and the mayor.

10. Protection of confidential information

Article 19 of Directive 90/219/EEC 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 19(3) of the Directive. In accordance with Swedish law, all information relating to an activity to which a consent has been issued is, in principle, public. However, information as set out under Article 19(3) is deemed confidential as is select information required to protect the integrity of a person, his innovation, income source of company. In the Netherlands, notifiers submitting confidential information must still submit a general description of the confidential parts in order to give the public an insight into the basis of the risk assessment.

Member States take different measures to protect confidential information. In Ireland, confidential information is stored in a locked fireproof secure cabinet. In the Netherlands, only authorised staff has access to the rooms where confidential information is handled. In Slovakia, only the persons in charge of the dossier can access confidential information which is archived separately.

11. Waste disposal

Many Member States require all waste to be inactivated prior to disposal (Belgium, Czech Republic, Germany, Ireland, Latvia, Lithuania, Netherlands, Poland, Spain, UK). In Austria, class 2 to 4 GMMs capable of reproduction must be inactivated prior to disposal. Inactivation of waste from class 1 activities is optional in Slovakia, but in practice, users inactivate all waste prior to disposal. Swedish legislation provides that waste containing GMMs from large-scale class 2 activities and from class 3 and 4 activities must be inactivated before leaving the premises. Waste arising from small scale Class 2 activities and Class 1 activities may be sent off site for incineration. However, it must be contained in appropriately marked containers and must be transported in accordance with the transport regulations.

In Ireland, class 1 GMM waste may be sent to one facility licensed to handle GMM waste for purposes of decontamination; waste stemming from class 2 or higher class activities must be inactivated on site.

In the Netherlands, waste inactivation and disposal has to be performed in-house in principle and if this is not possible, it must be transported to a dedicated waste facility.

In Poland effluents arising from hand washing sinks, showers, drains etc in Class 3 and Class 4 activities are required to be inactivated while in Slovakia this practice is confined to Class 4 activities.

12. Conclusion

The number of contained use activities in the EU is steadily increasing. Most activities belong to risk class 1 or 2 and serve research purposes.

On the whole, the Member States apply the Directive in a similar fashion. Different approaches exist with regard to inspection, public consultation during the authorisation procedure and emergency plans.

Many Member States raised the question whether clinical trials fall within the scope of Directive 90/219/EEC or whether they shall be regarded as deliberate release under Directive 2001/18/EC. The Commission is currently exploring this issue in more detail with Member States.

A number of Member States were unclear with regard to interpretation of the requirements for the contained use of GMOs other than GMMs. The Commission would like to point out that the contained use of GMOs is subject to the same containment principles as GMMs as established in Directive 90/219/EEC.

Annexes

1. ANNEX I – DETAILS FROM INDIVIDUAL MEMBER STATE THREE-YEAR REPORTS

1.1. An overview of activities and installations (particularly new ones and those involving GMOs – animals, fish and plants – as well as GMMs (Genetically Modified Micro-organisms))

1.1.1. Austria

During the reporting period, 47 installations and 374 activities involving the contained use of GMMs and GMOs have been received or approved. 324 activities are classified as class 1, 49 as class 2 and 1 as class 3.

1.1.2. Belgium

In Belgium, three different regional decrees apply. These regional decrees fully implement Directive 98/81/EC but also extend their scope to GMOs and pathogens. During the reporting period, 414 activities involving GMMs and 99 activities involving GMOs were notified. Sixty-eight activities involved GMMs as well as GMOs. In comparison with the previous reporting period (1999 – 2002), the number of installations and contained use activities falling under the Belgian contained use legislation has almost doubled. The majority of contained use activities are classified as class 1 or 2, six activities are classified in class 3 and there are no class 4 activities.

The bulk of activities are engaged in research and are carried out by university research laboratories or pharmaceutical companies. Sometimes GMMs are used for teaching purposes or for the production of enzymes, vaccines and therapeutic molecules.

1.1.3. Czech Republic

During the reporting period 2003 – 2006, more than 120 notifications have been received by the Ministry of Environment. Sixty installations have been authorised for the contained use of GMMs and GMOs in the Czech Republic of which 50 installations have been authorised for the contained use of GMMs.

All contained use activities have been classified as Class 1 or Class 2 and the majority of these activities take place in universities or research institutions.

1.1.4. Cyprus

Directive 98/81/EC amending Directive 90/219/EEC on the contained use of GMMs was transposed into national law in February 2004. The Minister of Labour and Social Insurance through the Department of Labour Inspection has been identified as the Competent Authority. During the reporting period 2003 – 2006 no activities involving the contained use of GMMs were notified in Cyprus. The Department of Labour Inspection has inspected various premises in order to verify whether GMMs are used, but has not identified any premises falling within the scope of the Directive.

1.1.5. Denmark

During the reporting period, 7 new production installations were approved for work involving class 1 GMMs. In total, 76 GMMs have been authorised in Denmark for production purposes, of which 27 belonging to Class 1 were authorised during the reporting period. Sixty research projects involving class 1 organisms and 9 research projects involving class 2 organisms were notified and most involved both GMOs and GMMs. Most of the dossiers involved research within laboratories, glasshouses and animal units. 95 class 1 and 15 class 2 laboratory classifications were granted.

1.1.6. Estonia

There are five users of GMMs in Estonia. All the users carry out class 1 activities and two users also carry out class 2 activities.

1.1.7. Finland

During the reporting period 122 notifications of GMMs, GM animals and GM plants were authorised, of which 97 were in respect of GMMs, 10 were in respect of GM animals and 7 were in respect of GM plants. A further 7 notifications involved both GMMs and GM plants while 1 involved both GMMs and GM animals. There were 103 individual operators of which 16 were companies. The majority of operators were research groups or other units from universities and research facilities. Most notifications concerned class 1 contained use activities. Less than half of all notifications involved class 2 use and two notifications included the use of Class 3 GMMs.

1.1.8. France

During the reporting period 2003 – 2006 the competent authority of France authorised 1016 installations and activities of which 720 originated from the public sector and 296 from the private sector. In total, 3189 installations and activities are authorised in France.

In accordance with national legislation GMMs are classified into two groups: group I containing non-pathogenic class 1 organisms and group II containing pathogenic micro-organisms belonging to classes 2, 3 and/or 4. During the reporting period, 527 group I notifications, 160 group II notifications and 329 mixed group I+II notifications were submitted and authorised by the Competent Authority.

1.1.9. Germany

During the reporting period, 1189 installations for research purposes and 25 installations for commercial purposes were notified, giving rise to a total of 6279 installations for research purposes and 142 installations for commercial purposes. In terms of activities, 2391 activities for research purposes and 43 activities for commercial purposes were notified during the reporting period, adding up to 10,405 activities for research purposes and 347 activities for commercial purposes.

The majority of notifications concerned class 1 and 2 uses, with a few notifications concerning class 3 uses and one notified class 4 activity.

1.1.10. Hungary

In Hungary eight installations for the contained use of Class 1 GMMs and GMOs have been authorised for purposes of research. One authorisation was issued for the contained use of a Class 1 GMM for commercial purposes and it was scheduled to commence in January 2007.

1.1.11. Ireland

Since June 2003, the Irish Competent Authority - the Environmental Protection Agency (EPA) - received 21 notifications for the contained use of class 1 GMMs and 24 notifications for class 2 GMMs. The Register of GMO users contains 208 entries for contained use (including contained use of GMOs). The majority are carried out in universities or hospitals affiliated to universities. These are predominantly research and development related activities and involve relatively small-scale use of GMMs and/or GMOs. Other activities include industrial/commercial activities engaged in commercial production/development/diagnostics and waste inactivation as well as activities carried out under the control of public authorities and/or State Agencies.

1.1.12. Italy

Since June 2003, 92 installations and 70 activities have been authorised in Italy.

1.1.13. Latvia

No notifications for the contained use of GMMs have been received by the competent authority during the reporting period, i.e. between Latvia's accession to the EU in May 2004 and June 2006. Seven contained use activities were authorised in 2003 all of which were classified as class 1 activities and were undertaken in the Biomedical Research and Study centre.

1.1.14. Lithuania

Five notifications relating to class 1 activities were submitted to the Ministry of Environment during the reporting period. The majority of activities were for research and development purposes.

1.1.15. Luxemburg

Luxembourg reported little change during the reporting period 2003 – 2005. In the previous report (1999 – 2002), Luxemburg reported five contained use installations. One of these installations has since moved, but is continuing to carry out the same contained use activities as originally notified. One contained use installation is involved in the contained use of GMOs. The majority of activities belong to classes 1 and 2.

1.1.16. Malta

No application for the contained use of GMMs or GMOs has been submitted to the Malta Environment and Planning Authority (MEPA), the Competent Authority of Malta.

1.1.17. Netherlands

In the Netherlands the total number of installations is steadily growing. During the reporting period, 33 installations were authorised. 22 of which were involved solely in the contained use of GMMs. The remaining activities involved both GMMs and GMOs. This gives rise to a total of 194 institutes and companies involved in GMM/GMO contained use activities. 472 notifications and 770 amendments of earlier notifications were also received during the reporting period. The majority of authorised activities belong to class 1 (947) or class 2 (703). Some activities were assigned to class 3 (91), but no activities were assigned to class 4.

1.1.18. Poland

Since Poland's accession to the EU in May 2004 a total of 75 GMM and 72 GMO related activities have been authorised in Poland. All GMM activities belong to class 1 or 2.

1.1.19. Portugal

Two installations comprising three activities for the contained use of Class 1 and Class 2 GMMs were notified and approved in Portugal during the reporting period 2003 – 2006.

Two activities were classified as Class 1 while the other was classified as Class 2.

1.1.20. Slovakia

In Slovakia consents were issued in respect of 19 contained use activities during the reporting period 2003 – 2006. Fourteen consents were issued in respect of Class 1 activities while 5 were in respect of Class 2 activities. The majority of facilities utilise GMMs while two installations utilise GM plants. No notifications have been received in respect of GM animals. Two users are commercial production companies.

The Ministry of Environment has issued 41 consents for the first-time use of installations and has assessed 60 Class 1 notifications and 6 class 2 notifications since April 2002.

1.1.21. Slovenia

In Slovenia 22 installations for the contained use of GMMs and/or GMOs have been notified of which 18 belong to class 1 and 4 to class 2. Twelve installations are located in universities, 5 in institutes and 5 in industry. A slight majority of the installations carry out GMM contained use activities, the remainder work with GM animals, plants or fungi. Six notifications for contained use activities were pending at the time of reporting.

1.1.22. Spain

In Spain during the reporting period 2003 - 2006, 36 installations have been notified for the contained use of GMMs and/or GMOs. Forty-nine research and development related activities were notified, the majority thereof belonging to class 1 or class 2. Four applications were received in respect of premises carrying on class 3 activities; 11 notifications relating to Class 3 contained use activities were received.

1.1.23. Sweden

In Sweden approximately 500 GMM contained use activities are carried out by about 70 users.

Since June 2003, 54 new notifications have been submitted. Despite the new notifications, the overall number of activities and users has remained at the same level as in the last reporting period, which is due to the fact that some activities have stopped and others have changed location or ownership.

No class 4 contained use activity is carried out in Sweden. Up to the end of the reporting period 2003 – 2006, four Class 3 contained use activities were approved as well as 125 small scale class 2 activities and 375 Class 1 activities. Of these approximately 100 relate to Class 1 and small scale Class 2 in industry and small biotech companies. The remaining 300 or so activities were notified by universities and other academic users, the majority of which were class 1 activities but there were 75 small scale Class 2 activities and some containment level 3 activities. As regards the contained use of GMOs, 2 new installations for the contained use of plants and 9 new installations for the contained use of animals have been notified during the reporting period. There are some activities where GMMs are used in GM animals and GM plants. Nineteen universities and secondary schools use GMMs as part of an education programme.

1.1.24. United Kingdom

Great Britain has 523 notified centres covering 1312 premises. Eighty new centres were notified during the reporting period comprising 419 activities of which 4 were class 4, 38 Class 3 and 377 class 2. Northern Ireland has 9 notified centres of which three were notified during the reporting period. Two of the new premises conduct class 1 activities and the remaining centre is a class 2 centre involved in a multi centre clinical trial.

Work involving GM animals or plants is only notifiable under the Contained Use Regulations if it involves a risk to human health. Consequently, there are few notifications of this type. No work involving GM animals or plants has been notified during the reporting period.

1.2. Notification and approval systems (and relevant changes)

1.2.1. Austria

The Federal Ministry of Health and Women and the Federal Ministry of Education, Science and Culture are the competent authorities in Austria. Each installation and activity has to be notified to or approved by one of these authorities. The Federal Ministry of Education, Science and Culture is competent for work at universities and scientific institutions within its area of responsibility. The Federal Ministry of Health and Women is competent for all remaining activities.

The notifier of an installation has to establish a Representative for Biological Safety and a Committee for Biological Safety not subject to any instructions by the user. The Committee for Biological Safety must check the risk assessment and the proposed safety measures. For activities of class 2 or higher, the user must appoint a project leader responsible for the planning, management and supervision of the activities. In addition to checking the risk assessment and the proposed safety measures, the competent authority also checks the

qualification of the project leader, the Representative for Biological Safety and the members of the Committee for Biological Safety.

Before determining a class 3 and/or 4 contained use activity or activities involving transgenic vertebrates where the boundary between species is broken through for other than biomedical or biological development purposes, the competent authority must seek the opinion of the scientific committee of the Genetic Engineering Commission.

1.2.2. Belgium

The contained use of genetically modified micro-organisms (GMMs) is regulated in Belgium at the regional level and the three regions involved are Brussels capital, Wallonia and Flanders. The scope of the Belgian regional legislations covers GMMs and has been extended to genetically modified organisms and pathogenic organisms for humans, animals and plants. The risk assessment is submitted for advice to the Division of Biosafety and Biotechnology (SBB)**,** who acts as technical expert for the Regions.

1.2.3. Czech Republic

In the Czech Republic, the Ministry of the Environment is the Competent Authority. Copies of notifications received are forwarded to the Czech Commission for the use of GMOs and genetic products, which gives its opinion, as well as to the Ministry of Agriculture and the Ministry of Health, which may make comments or raise objections.

Going beyond the Directive, subsequent class 1 use must also be notified.

1.2.4. Cyprus

The Minister of Labour and Social Insurance through the Department of Labour Inspection is the competent authority in Cyprus.

Following receipt of a notification, the CA is required to reply to the notifier in writing within 15 days.

Class 2, 3 and 4 uses require a license. Before taking a decision on the licence, the CA is advised by the Licensing Technical Committee composed of representatives of six Ministries (Ministry of Labour and Social Insurance, Ministry of Agriculture, Natural Resources and Environment, Ministry of Health, Ministry of the Interior, Ministry of Commerce, Industry and Tourism, Ministry of Communications and Works). Within 28 days of a decision being taken by the CA, the user may appeal the decision to the Council of Ministers.

1.2.5. Denmark

The competent authorities in Denmark are the Forest and Nature Agency (under the Environment Ministry) and the Working Environment Authority (under the Employment Ministry). Dossiers are dealt with in close collaboration between the two authorities. All notifications and applications for research and large-scale trials must be received by the Forest and Nature Agency and the Working Environment Authority's joint product register which registers all genetic engineering activity in Denmark.

Going beyond the Directive, Danish legislation requires that subsequent class 1 uses also have to be notified (accompanied by a risk assessment) and approved.

1.2.6. Estonia

The Labour Inspectorate is the Competent Authority for the contained use directive in Estonia.

1.2.7. Finland

The Board for Gene Technology is the competent authority in Finland. Two new decrees of the Ministry of Social Affairs and Health entered into force in early 2006, one setting standards for the risk assessment and containment of GMMs as well as other protective measures and the other providing more detailed provisions on different notification procedures and record-keeping.

1.2.8. France

The Ministry of Research is the French competent authority. The Commission de genie génétique (Genetic Engineering Commission) makes statements regarding the classification of contained uses for industrial production and gene therapy.

1.2.9. Germany

In Germany, the respective Bundesländer are responsible for the implementation of the Directive. Hence the Länder authorities receive notifications and issue consents. However, the federal government set up an expert advisory body, the ZKBS (Zentrale Kommission für die biologische Sicherheit) which provides statements and advises on safety measures with regard to proposed class 3/4 activities and new or disputable Class 2 activities. The competent Länder authorities inform the competent federal authorities of decisions made. Since March 2003, the BVL (Federal Office for Consumer Protection and Food Safety) is the competent federal authority.

The notification and approval system precisely follows Art. 7 – 10 of the Directive.

1.2.10. Hungary

The competent authority in Hungary is the Ministry of Agriculture and Rural Development (hereinafter: Genetic Engineering Authority). As part of the authorisation procedure, the Genetic Engineering Advisory Board is consulted. The Board is a 17-member advisory body composed of representatives of the Hungarian Academy of Sciences, the relevant government ministries and civil society organisations in the field of environmental protection, health, biotechnology and consumer protection.

1.2.11. Ireland

The Environmental Protection Agency (EPA) is the competent authority in Ireland. As regards first time class 1 and 2 contained uses, Irish legislation prescribes that the EPA must communicate its decision within 45 days. As foreseen in the Directive, subsequent class 1 contained use may proceed without further notification. Where subsequent class 2 contained use activities are concerned, a notification review is required (different to what is provided in the Directive) which shall be completed within10 days.

1.2.12. Italy

Authorisations for GMM contained use are issued by the Ministry of Health after a positive opinion of the Biotechnology Committee. The Ministry of Health as well as the Ministry of Environment are represented in the Biotechnology Committee.

During the reporting period, the competences regarding GMMs and GMOs were split and a specific Committee for GMOs has been established.

1.2.13. Latvia

Latvia has seen a change of competent authority during the reporting period 2003 - 2006. The Ministry of Agriculture is the competent authority for the purposes of implementing Directive 98/81/EC amending Directive 90/219/EEC. Since 1 January 2006, the Food and Veterinary Service under the jurisdiction of the Ministry of Agriculture has been appointed to review notifier's activities and issue an opinion which forms the basis for the decision of the competent authority.

1.2.14. Lithuania

The notification and approval systems are determined in the Order on Regulation on Contained Use of Genetically Modified Micro-Organisms. The Ministry of Environment is the competent authority. Upon receipt of a notification, it is forwarded to the Steering Committee on GMOs and other relevant state authorities (Ministry of Agriculture, Ministry of Health, State Food and Veterinary Service) who must submit their opinion within 10 days. The Steering Committee on GMOs is a political advisory body composed of members appointed by the relevant state authorities, non-governmental organizations, universities and scientific institutes. The final decision is taken by the Ministry of Environment which considers all opinions.

Lithuanian legislation requires a written notice to the Ministry of Environment for subsequent class 1 use.

1.2.15. Luxemburg

Contained use must be authorised by the Ministry of Health after consultation with concerned administrations and services.

1.2.16. Malta

The competent authority in Malta is the Malta Environment and Planning Authority (MEPA). MEPA forwards notifications to the Biosafety Coordinating Committee (BCC) for review and assessment. MEPA takes the final decision on the notification, taking into account the advice given by the BCC.

1.2.17. Poland

The Ministry of the Environment is the competent authority in Poland. After receipt and verification of the notification, the Ministry forwards the notification to the Commission on GMOs for assessment by reviewers. The consent for contained use of GMOs shall be issued within three months of receipt of the notification.

1.2.18. Portugal

The Institute for the Environment, belonging to the Ministry of Environment, Spatial Planning and Regional Development, is the competent authority in Portugal.

1.2.19. Slovakia

The Ministry of Environment is the competent authority. The Minister established the Commission for Biological Safety as an expert advisory body, composed of representatives from the Ministries of Agriculture, Health and Education, scientists and representatives from NGOs and the business sector. The decision of the Ministry of Environment on an application is based on the recommendation of the Commission for Biological Safety.

The notification and approval system is more strict than the minimum requirements established by the Directive. Before the first-time use of an installation, an application for consent must be submitted, containing *inter alia* details on technical equipment, protective measures, the code of practice and waste management. Following the issue of a consent in respect of the first time use of the facility, the Ministry is required to be notified of the commencement of Class 1 and 2 activities. Furthermore a notification is required to be submitted in respect of

Class 3/4 activities,

where class 3/4 activities have been assigned to a lower class,

risk class 2 activities where consent has been issued only in respect of class 1 activities and

the continuation of activities suspended upon inspection of the facility.

1.2.20. Slovenia

The Ministry of Environment and Spatial Planning is the competent authority. It is assisted by the Scientific Committee for work with GMOs in containment, consisting of seven scientific experts.

1.2.21. Spain

To facilitate the notification process 3 different application forms must be completed for every notification - one for premises, one for activity and one for Risk Assessment. The National Commission on Biosafety (CNB) evaluates the notification/application, conducts an inspection and then issues a favourable or unfavourable report. Taking into account this report, the competent authority decides on the authorization. Usually the Autonomous Communities act as the competent authority. In the case of the development of products to be incorporated into medicines for human and veterinary use or products possibly representing a risk to human health and research programs carried out by Government Institutions, the Interministerial Council on Genetically Modified Organisms (part of the General State Administration) is the competent authority.

1.2.22. Sweden

The Swedish Work Environment Authority (SWEA, in Swedish: Arbetsmiljöverket) is the competent authority.

1.2.23. United Kingdom

The competent authority is made up of the Health and Safety Executive (HSE), Department of Environment, Food and Rural Affairs and the Scottish Executive.

Notifications are scrutinised by technical assessors in the competent authority. In accordance with the Directive, subsequent class 1 contained use does not need to be notified. Notification periods correspond to those provided in the Directive and over 90 % of notifications are processed within the statutory timescales.

The notification and approval system involves the charging of fees for the notification of premises and activities. As research projects are likely to change and evolve, users are encouraged to notify connected programmes of work in a single notification. Users are asked to notify "significant changes" to the notified programme, but the definition of "significant changes" is the subject of a lot of discussion.

1.3. Risk assessment and classification of contained uses (including effectiveness of the risk assessment guidelines)

1.3.1. Austria

Austrian legislation precisely follows the classification system of the Directive.

1.3.2. Belgium

The risk assessment principles of Annex III have been integrated into national law. The risk assessment must also assess the compatibility between different activities within the same building.

1.3.3. Czech Republic

Principles and rules for the risk assessment are laid down in the Czech Act on GMOs with details specified in the implementing Decree. The risk assessment must be carried out or at least verified by a professional consultant appointed by the user. The risk assessment and the classification of contained use provided by the user/notifier are in each case reviewed by an expert advisory body to the Ministry of the Environment - the Czech Commission for the use of GMOs and genetic products.

The Czech Republic raised the concern that new GMO applications, e.g. gene therapy, might lead to problems with the application of the existing risk assessment guidelines.

1.3.4. Cyprus

The provisions on risk assessment contained in the Law on Genetically Modified Micro-organisms (Contained Use) are in accordance with the provisions of the Directive.

1.3.5. Denmark

A risk assessment must be carried out for research, large-scale trials and production regardless of the class of GMM.

Risk assessments must follow Annex III of Directive 98/81/EC and the risk assessment guidelines drawn up by the Commission. The Working Environment Authority and the Forest and Nature Agency – as the Competent Authorities – are responsible for ensuring that the information requirements of Annex III of Directive 98/18/EC are fulfilled.

1.3.6. Estonia

All users compile their own risk assessment.

1.3.7. Finland

The risk assessment procedure is based on Commission Decision 2000/608/EC. Despite the guidelines, many operators seem to have difficulties in compiling a thorough risk assessment.

1.3.8. France

In the case of notifications of the contained use of GMOs in industrial production as well as in clinical trials, the Biotechnology Commission makes statements on the classification of the contained use.

1.3.9. Germany

As described above, the ZKBS makes statements as regards the classification of activities in cases of expected classification in class 3 or 4 and of new or disputable cases of expected class 2 classification. In these statements, the activities are broken down to separate steps and each step is classified separately. Therefore the activities are often assigned not only one, but several classifications.

1.3.10. Hungary

Users have to keep a record of the risk assessment and review it annually before each renewal of the authorisation. The Genetic Engineering Authority may conduct checks in connection with this review. The risk assessment and the resulting classification into classes 1 to 4 must also be reviewed in the cases mentioned in Art. 6(2)(a) and (b) of Directive 98/81/EC amending Directive 90/219/EEC on the contained use of GMMs.

1.3.11. Ireland

The risk assessment format implemented by the EPA is similar to the one set out in the EU Guidance notes for Risk Assessment. Users are also asked to refer to these Guidance notes. Examples of risk assessments for class 1 and class 2 activities have been placed on the EPA website for guidance.

1.3.12. Italy

No new information

1.3.13. Latvia

The national regulation - 'The Regulation on contained use, deliberate release and placing on the market of genetically modified organisms and procedure on monitoring', - sets out the classification of contained uses and the criteria for the risk assessment, in accordance with

Directive 90/219/EEC, as amended by Directive 98/81/EC. The risk assessment carried out by the user should be completed in accordance with the risk assessment guidelines produced by the European Commission.

1.3.14. Lithuania

Rules on risk assessment and classification of contained uses are laid down in the 'Order on Criteria for GMMs Classification'. The requirements for the risk assessment follow the lines of Directive 98/81/EC and the risk assessment guidelines by the Commission.

1.3.15. Luxemburg

Contained use activities are classified into four categories, as foreseen by the Directive. General principles and containment measures for each class are set out in a national regulation.

1.3.16. Malta

Malta uses the criteria for classification laid down in Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work.

1.3.17. The Netherlands

The Ministerial Regulation on genetically modified organisms lays down standards for risk assessment and classification of contained use activities. Contained use activities are assigned to one of four groups (laboratory work, GMMs in association with plants in growth chambers, GMMs in association with plants, GMMs in association with animals). Each group is sub-classified in four containment levels. The Regulation also lists safe hosts and vectors.

1.3.18. Poland

A Regulation of the Ministry of the Environment lays down detailed rules for the risk assessment, closely following the Commission's risk assessment guidelines.

1.3.19. Portugal

Risk assessment and classification of contained use is carried out in accordance with Decree No. 2/2001 transposing Directive 98/81/EC.

1.3.20. Slovakia

Risk assessment and classification is conducted in accordance with Directive 90/219/EEC as amended by Directive 98/81/EC and the Commission's risk assessment guidelines. The Ministry of Environment published a handbook titled "Procedure of risk assessment when using GMOs". Since the implementation of national regulations in 2002, sixty-six risk assessments have been reviewed by the Slovak authorities, 60 belonging to risk class 1 and 6 to risk class 2.

1.3.21. Slovenia

The GMO risk assessment must be carried out in accordance with the "Regulation on risk assessment of use of genetically modified organisms in containment". The classification of

contained use is based on four safety classes and must be carried out in accordance with the "Decree on classification of contained use of GMOs into the safety classes, containment measures and other safety provisions for safety classes". Both of these instruments implement the provisions of Directive 98/81/EC amending Directive 90/219/EEC and include GM plants and animals.

1.3.22. Spain

A risk assessment must be submitted with every notification. The notifier must complete a risk assessment form which is available on the website of the Ministry of Environment.

1.3.23. Sweden

The website of the Swedish Work Environment Authority (SWEA) contains guidelines on how to perform a risk assessment with links to the EU guidelines on Risk Assessment and to the British HSE guidelines. Sweden expressed some confusion over the fact that the Commission's risk assessment guidelines indicates that it is the use of a GMM and not only the GMM itself which must be risk assessed but in the end it is the GMM that is classified and not the entire use. A risk assessment must always be included with the notification of contained use of a GMM.

Sweden indicated that users often do not read or understand the risk assessment guidelines. The submitted risk assessments often contain insufficient or irrelevant information.

Classification of activities closely follows the system established by Directive 90/219/EEC, but large scale class 2 activities are classified in the same category as class 3 and class 4 activities. Three different categories of activities exist: F activities (class 1), L activities (class 2 small scale), R activities (class 2 large scale, class 3 and 4).

1.3.24. United Kingdom

Considerable amounts of scientific and technical guidance on risk assessments have been published by the competent authority and are available on the Health and Safety Executive's (HSE) website: http://www.hse.gov.uk/biosafety/GMO/acgm/acgmcomp/index.htm A revised version of the guidance will be published in early 2007. Talks and workshops offered by specialist inspectors cover risk assessment as a main topic.

Scrutiny of the risk assessments forms a key part of any inspection.The quality of risk assessments varies, but appears to be improving. Common problems are a poor definition of scope, lack of detail, lack of justification of statements and an inadequate environmental assessment.

1.4. Accidents

No accidents were reported by Austria, Belgium, the Czech Republic, Cyprus, Denmark, Estonia, Finland, Hungary, Ireland, Latvia, Lithuania, Luxemburg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia and Sweden.

1.4.1. Germany

The competent Länder authorities shall inform the BVL about any incidents relevant for safety. No accidents according to the definition in Art. 2(d) Directive 90/219/EEC were reported during the reporting period.

Nine minor incidents have been reported to the BVL:

Three needle stick injuries which had no negative consequences;

A further needle stick injury occurred during work carried out with recombinant Vaccinia Virus;

Two fires occurred in installations, but no GMOs were released.

A glasshouse was destroyed from outside, but without any GMOs being released.

1.4.2. Italy

No information given

1.4.3. Spain

In 2004, a fire broke out in the air-conditioning system of a class 3 laboratory in the Department of Pharmacy and Technology of the University of Navarre. At the time the fire started there were no GMM cultures in the laboratory. GMM cultures were however stored in the freezer which did not incur any increase in temperature owing to the fire but the air-conditioning system, the CO_2 supply system and the deionised water system were affected After the fire, the competent Authority of Navarre conducted an inspection and issued a report restricting the GMM activity to zones that had not been affected by the fire until the original state of the laboratory was restored.

1.4.4. United Kingdom

Four accidents were notified in Great Britain under the Contained Use Regulations during the reporting period: a needlestick injury (Vaccinia Virus), a failure of syringe (Vaccinia Virus Western Reserve), a failure of incubator (*M.tuberculosis*) and a failure of silicone tubing (*E.coli*). All these accidents were reported to the European Commission.

1.5. Inspection and enforcement issues

1.5.1. Austria

During the reporting period, the two competent authorities have carried out spot checks of contained uses of different sorts (small-scale basic research, food examinations and large-scale production), partly announced, partly unannounced. The checks have not given grounds for administrative action.

1.5.2. Belgium

Inspections were organized in the three different regions on a regular basis. In the Flemish region only installations belonging to classes 2 and 3 were inspected. The same applies in the

Brussels Capital Region with the exception that all class 3 facilities were inspected first. In the Walloon Region all installations were inspected. The SBB took part in inspection visits organised by the inspectorates of each region and offered scientific and technical support.

An inspection round carried out in the Flemish Region during the period 2003-2005 revealed some negative points: some installations still did not have the requested authorisations, the biosafety equipment was not controlled on a regular basis and waste inactivation was often not validated.

1.5.3. Czech Republic

In the Czech Republic, the Czech Environmental Inspectorate regularly carries out inspections of the installations authorised under the Directive, targeted specially on compliance with the requirements for the contained use, documentation, waste treatment etc. It has already imposed several fines.

1.5.4. Cyprus

A Chief Inspector and Inspectors have been appointed according to the law on GMMs. They are vested with powers of inspection such as access to the premises in question and may issue an Improvement Notice or a Prohibition Notice.

1.5.5. Denmark

Inspections are always performed upon notification of new premises. Moreover, the Working Environment Authority verifies compliance with the conditions of all approvals. Injunctions have been issued as a result of the absence of signage, passage through classified areas, smoking, eating, not wearing overalls and in one case for trials with GMOs outside classified laboratories and for trials with unapproved GMOs.

In terms of production facilities, the county council municipalities verify compliance with the conditions concerning the protection of the environment and health. The Forest and Nature Agency has not received any information that injunctions were issued.

1.5.6. Estonia

Within one year after obtaining a licence for contained use, all users are inspected by a labour inspector. So far no violations of the law have been detected.

1.5.7. Finland

The National Product Control Agency for Welfare and Health has been the supervisory authority responsible for inspection since September 2004. It has focused on the supervision of class 2 activities. During the reporting period, 68 inspections have been carried out.

1.5.8. Germany

After the notification or the consent, the competent Länder authorities regularly carry out inspections on the premises. They check the records of activities and, in individual cases, take samples which are examined in monitoring laboratories in order to check the identity of the organisms and the containment's efficiency.

1.5.9. Hungary

The monitoring authority regularly monitors the contained use activities, but has not come across any irregular activities.

1.5.10. Ireland

When issuing consent, the EPA sets consent conditions. The conditions concern, inter alia, the establishment of a Biological Safety Committee, avoidance of adverse effects on human health, the periodic review of risk assessment and containment measures and the submitting of annual reports and keeping of log books. The facilities are inspected for compliance with the consent conditions. During the reporting period, 92 site inspections were carried out.

1.5.11. Italy

No information given

1.5.12. Latvia

The inspection of contained use activities should be conducted by the State Labour Inspection subordinated to the Ministry of Welfare.

1.5.13. Lithuania

The Ministry of Environment as the competent authority inspects the containment and other applied safety measures, at least every 3 years for class 1 uses, every 2 years for class 2 uses and every year for class 3 and 4 uses. The major objective of inspection is to confirm the effectiveness of the respective containment level and to evaluate compliance with relevant approval conditions.

An administrative penalty can be imposed when activities are carried out without approval or when the relevant requirements are not fulfilled. In case of deficiencies with safety measures, approvals can be suspended or revoked.

1.5.14. Luxemburg

Inspections have been carried out with two objectives: control and prevention, i.e. consulting users setting up an installation.

1.5.15. Malta

As no contained use activities take place in Malta, no inspections have been carried out. However, laboratories with the equipment and potential to perform contained use activities have been identified.

1.5.16. Netherlands

As class 1 activities are defined in the Ministerial Regulation (list of host organisms, list of vectors, definition of material to be inserted), no requests for assessment of class 1 contained uses have been received. In practice, most notifiers notify class 1 activities and activities belonging to other classes at the same time.

1.5.17. Poland

Three authorities carry out inspections of contained use installations: The State Labour Inspection is in charge of the safety and hygiene of work; they inspect the labelling of facilities, the safety measures and the equipment used. The State Sanitary Inspection controls biological factors, whereas the Environmental Protection Inspection is in charge of the control of wastes from contained use activities. These three authorities can carry out inspections on their own initiative or upon request by the Ministry of Environment.

The State Labour Inspection has conducted 13 inspections. Frequent offences detected were the lack of an emergency plan and the lack of signage on entrances to laboratories where GMO activities are carried out. Two activities lacking the consent of the Ministry of Environment were found.

The Environmental Protection Inspection conducted controls in five installations. In some installations, the formal requirements had been violated, e.g. waste produced was not properly recorded.

1.5.18. Portugal

Inspections are conducted in installations working with GMMs in order to confirm the effectiveness of the containment measures. Inspections are carried out by the General Inspectorate for the Environment and Spatial Planning and the Institute for the Development and Inspection of Labour.

1.5.19. Slovakia

A special body of state supervision for genetic engineering, the Inspection Authority for Biosafety, was founded in 2003. It carries out the state supervision of contained uses and imposes fines for procedural offences. When assessing notifications and applications, the Ministry may oblige the Inspection Authority to carry out inspections at certain intervals and to a certain extent. If the inspection reveals violations of responsibilities, the Inspection Authority may impose a duty to resolve within an adequate period; in case of imminent danger to human health, the Inspection Authority shall prohibit the further use. Three fines for procedural offences have been imposed so far.

1.5.20. Slovenia

Two environmental inspectors have been trained over the last four years, partly under the framework of a bilateral pre-accession project between Slovenia and the Netherlands and UNEP-GEF Project: Development of Biosafety Framework for Slovenia. The inspectors are members of the European GMO Inspectors' Network. A manual to be used by GMO inspectors for the inspection of contained use installations is to be published soon.

1.5.21. Spain

Inspections are carried out before the authorization of an installation. They are conducted either by the Autonomous Communities or by the General State Administration, depending on the distribution of competence. Where class 3 contained uses are concerned, the inspections are carried out by the competent authority and some expert from the National Commission on Biosafety. During the inspection, the information provided by the notifier is verified and the

containment measures are checked for their adequacy. If problems are detected, authorizations can be revoked or postponed until the problems are solved.

1.5.22. Sweden

Activities are inspected by SWEA. The same administrative officers handle notifications and perform inspections. At the time of reporting only 3 inspections were carried out in accordance with the provisions of the amended Directive owing to the large number of notifications received. Visits have also been made in connection with handling of notifications.

1.5.23. United Kingdom

Great Britain has 12 specialist inspectors covering GM contained use (and wild-type dangerous pathogens). Northern Ireland has one inspector.

Inspections are prioritised taking into account the class of the contained use, the confidence in the management systems, time since the last inspection and issues arising from notification. Hence premises conducting class 1 contained uses are inspected less frequently than others. Inspections concentrate on an evaluation of the risk assessments, including the final classification. The most frequently encountered problem tends to be insufficient or inappropriate risk assessments. Inspectors have several enforcement options, including written advice, Prohibition Notice requiring the immediate cessation of work and withdrawal of consent. No enforcement action had to be taken during the reporting period.

1.6. Problems with interpretation of the provisions (possibly with conflict in defining work use with respect to Directive 2001/18/EC)

No problems with interpretation have been reported by Austria, Cyprus, Denmark, Estonia, Ireland, Italy, Lithuania, Luxemburg, the Netherlands, Portugal and Slovenia.

1.6.1. Belgium

Applications for clinical trials in humans submitted under Directive 2001/18/EC; part B, sometimes also require an authorisation under Directive 98/81/EC, thereby causing a double authorisation regime.

1.6.2. Czech Republic

As the Czech Act on GMOs covers all GMOs including plants and animals while the Directive only covers GM micro-organisms, problems of interpretation sometimes occur with respect to the requirements for contained use of GMOs other than micro-organisms, e.g. classification and containment measures.

In cases of clinical trials where a small possibility of release of viable GMMs into the environment exists, it is difficult to decide whether they fall under contained use or under deliberate release provisions.

DNA vaccines raise the question which steps in production and testing of the vaccines fall under the scope of the Directive.

1.6.3. Finland

The scope of the Directive remains unclear, especially regarding the definition of a GMM in the case of a transient transformation.

1.6.4. Germany

The interpretation of the term "mutagenesis" in Annex II Part A is problematic as this term can be interpreted very broadly.

1.6.5. Hungary

It is unclear whether clinical trials fall within the scope of Directive 90/219/EEC or Directive 2001/18/EC.

1.6.6. Latvia

It is unclear whether clinical trials should be considered under the Contained Use or Deliberate Release Legislation.

1.6.7. Malta

Malta requests clarification on several points:

1) Is the contained use of genetically modified plants and animals covered by Directive 90/219/EEC since the title of the Directive clearly refers to GMMs?

2) When a genetically modified plant cell is cultured in a growth medium, it grows into a plant. Is the plant still considered as a microbiological entity although it has become a macrobiological entity, that is, a GMO?

3) Once it has grown into a plant with its own root system, it is then transferred into a pot to grow further. Once this happens it is no longer in culture so the definition of a GMM is no longer valid. Do you still apply the legislation to regulate the containment of these plants? (the same question applies to GM animals)

4) Why is it that Annex IV of Directive 98/81/EEC and specifically Tables I B and I C present additions to and modifications of Table I A (minimum requirements for laboratory activities) for glasshouse/growth-room activities and for activities with animals involving GMMs respectively, if both plants and animals are not GMMs but GMOs?

5) Does the interpretation of the term *GMMs* mean tests using GMMs in or on plants/animals or should it include tests using GM plants and GM animals performed under contained use?

1.6.8. Poland

It is unclear how activities involving plant and animal cells should be classified – as GMM activities or activities involving GM plants or animals. Several notifications involving the contained use of *Saccharomyces* have been submitted in Poland. So far, these activities have been classified as contained use. Poland also requests clarification as to the appropriate risk class for activities with GM higher plants and GMs.

1.6.9. Slovakia

Users do not use the option mentioned in Article 9(2) of the Directive to request a decision on a formal authorisation from the Competent Authority because this would delay the commencement of the activity.

The opinions of scientific authorities on the definition of self-cloning differ from the definition contained in the Directive.

1.6.10. Spain

There is an overlap between Directive 90/219/EEC and Directive 2001/18/EC as regards clinical trials. The same problem occurs with regard to premises used for storing GM seeds that are subsequently used in experimental field trial releases: it is unclear whether they have to be notified as contained use installations. Spain also asks for clarification as to the interpretation of GMM transport in Article 4 Directive 90/219/EEC.

1.6.11. Sweden

Three points have been raised by Sweden, concerning the interpretation of self-cloning, product control and labelling of GMO intended for contained use and clinical trials.

SWEA interprets Annex II, Part A, paragraph 4, last sentence as comprising vectors containing inserts from other organisms than the organism in which the cloning takes place and they intend to make a list of vectors and their host organisms which can be considered to fulfil this criteria for exclusion from the legislation based on the Directive.

According to Sweden, the labelling of GMOs intended for contained use with the words "This products contains GMOs" in accordance with Article 26 Directive 2001/18/EC is not sufficient as this does sufficiently clarify that the GMOs in question are not authorised for placing on the market, but strictly intended for contained use.

There is need for clarification with regard to the interpretation of Directive 90/219/EEC and Directive 2011/18/EC in the context of clinical trials.

1.6.12. United Kingdom

Additional guidance is needed to provide users with appropriate control measures in respect of clinical applications, as none of the containment tables under Annex IV of Directive 90/219 describes measures typically encountered in a clinical setting.

The borderline between the Contained Use Directive and the Deliberate Release Directive is not always clear and some guidance is required. In this context, the status of DNA vaccination in particular has attracted a lot of queries.

1.7. Clinical trials using the provisions of the Directive

1.7.1. Austria

According to Austrian legislation, clinical trials do not fall under the provisions regulating the contained use of GMMs. However, approval by the Federal Ministry of Health and Women is required in accordance with genetic engineering laws and drug laws.

1.7.2. Belgium

Clinical trials can be authorised under the Regional biosafety regulations (covering contained use) as soon as they involve GMMs and if the treatment occurs in a contained area (such as a hospital). Between June 2003 and June 2006, four human clinical trials have been approved under the Regional Biosafety Regulations and at the time of reporting one application was under review. Two trials were involved in the treatment of cardiovascular disease, two involved cancer therapy and one was aimed at treating an infectious disease. All of these trials were multicentric.

1.7.3. Czech Republic

One clinical trial has been authorised in the Czech Republic, and at the time of reporting a further two were being assessed. According to the Czech Act on GMOs, the hospital participating in the study and the company providing the product to be tested must each submit a notification, which represents a considerable administrative burden.

1.7.4. Cyprus

No clinical trials with GMMs have taken place in Cyprus to date.

1.7.5. Denmark

Clinical trials with GMOs are regarded as falling within the scope of Directive 98/81/EC amending Directive 90/219/EEC, but no such trials were conducted during the reporting period.

1.7.6. Estonia

No clinical trials have taken place in Estonia to date.

1.7.7. Finland

In Finland clinical trials with GMMs are classified as contained use (class 1-2).

1.7.8. France

One hundred and twenty-two (122) clinical trials have been carried out in France between 2003 and 2005.

1.7.9. Germany

Clinical trials are regarded as falling within the scope of Directive 2001/18/EC. Only preparations of clinical studies, such as the production or the storage of the viral vector to be used, fall under the provisions of Directive 90/219/EEC.

1.7.10. Hungary

No information given

1.7.11. Ireland

No human clinical trials have taken place under Directive 98/18/EC amending Directive 90/219/EEC. One gene therapy trial was granted consent under the provisions of Directive 2001/18/EC.

1.7.12. Italy

No information given

1.7.13. Latvia

No clinical trials have been notified to the competent authority during the period 2003 – 2005.

1.7.14. Lithuania

Clinical trials with GMOs for human medical and veterinary purposes are regarded as falling within the scope of Regulation 2309/93 and Regulation 726/2004 (laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use). The notifier of clinical trials must receive consent from the Ministry of Health (in case of human use) or the State Food and Veterinary Service (in case of veterinary use) respectively and additionally the consent of the Ministry of Environment for the deliberate release into the environment of GMOs for research and development purposes.

A clinical trial was notified in Lithuania on 31 December 2005

1.7.15. Luxemburg

No notifications concerning clinical trials have been submitted.

1.7.16. Malta

The Maltese Environment and Planning Authority (MEPA) indicated that there was an overlap between Directive 90/219/EEC and Directive 2001/18/EC with respect to clinical trials and suggested that this be further discussed at EU level. No clinical trial applications have been submitted in Malta to date. Clinical trial applications would fall under the scope of Directive 90/219/EEC or Directive 2001/18/EC. In addition to MEPA, the approval of the Malta Medicines Authority would have to be obtained.

1.7.17. Netherlands

Clinical trials are handled under Directive 2001/18/EC.

1.7.18. Poland

According to the Act on Pharmaceuticals (which implements Directive 2001/20/EC concerning the conduct of clinical trials), the Ministry of Health is the competent authority for clinical trials. Clinical trials with GMMs also require decisions of the Ministry of Health, the Ethical Committees and the Ministry of Environment.

1.7.19. Portugal

No clinical trial applications have been submitted during the reporting period.

1.7.20. Slovakia

No clinical trials have taken place in Slovakia to date.

1.7.21. Slovenia

No clinical trials have taken place in Slovenia to date.

1.7.22. Spain

The National Biosafety Commission decides on a case by case basis if a certain clinical trial should be notified as contained use or as deliberate release.

A few notifications of gene therapy activities have been submitted during the reporting period. One class 2 clinical trial which has not yet been authorised as the inspection visit is pending. Three gene therapy class 3 activities were notified and will be carried out in an installation which has already been authorised.

1.7.23. Sweden

At the time of reporting SWEA had approved 2 notifications for clinical trials for the year 2006. These applications were also considered under the legislation for medicinal products which falls under the remit of the Medical Products Agency in Sweden.

1.7.24. United Kingdom

There has been a large increase in the numbers of clinical trials carried out under Contained Use, mostly involving gene therapy. Clinical trials with GM vaccines are sometimes carried out under the Contained Use Directive and sometimes under the Deliberate Release Directive. HSE planned to issue guidance on the use of GMMs in a clinical setting in November 2006 in order to help stakeholders in determining the appropriate regulatory route. According to the UK, DNA vaccination does not fall within the scope of the Directive and therefore not covered.

1.8. Public consultation and information

1.8.1. Austria

No public consultation has taken place during the reporting period because no applications for large-scale class 3 activities or class 4 activities had been received.

The Ministry of Health and Women and the Ministry of Education, Science and Culture inform the public about genetic engineering via two websites. General enquiries are answered by e-mail.

1.8.2. Belgium

Public consultation takes place under the general procedures under regional environmental laws. Information to the neighbourhood is given in a "public dossier" (a short summary of the notification written by the notifier) in the Flemish and Brussels Capital Regions; a similar procedure is established in the Walloon Region.

The regional competent authorities take comments, observations or objections regarding contained uses into account when drafting the final decision. The final decision is made available to the public for a limited time and within that period, appeals against the decision may be submitted.

General information on contained use activities is provided on the website of the three regional competent authorities. Scientific and technical information is to be found on the "Belgian Biotechnology Server", a website maintained by the SBB.

1.8.3. Czech Republic

Public consultation forms part of the approval procedure for class 3 and 4 notifications. Immediately after having checked the notification for completeness, the Ministry of the Environment makes a summary of the notification available to the public over the internet, on the official board of the Ministry and in the municipality where the contained use is intended to take place. If, within 30 days of the publication, members of the public express concern about health and environmental issues, the Ministry of the Environment has to arrange a public hearing before deciding on the notification.

The Ministry of the Environment publishes on its website a register of the users and the GMOs in use.

1.8.4. Cyprus

The Competent Authority may ask the opinion of interested parties and the public when considered appropriate.

1.8.5. Denmark

All notifications are recorded in the genetic engineering register in the Product Register and the information is in principle publicly available. No requests to inspect dossiers were received during the reporting period.

Before the Forest and Nature Agency takes a decision on a production dossier, a draft decision is submitted to the municipal and county council authorities and any other interested parties. Agency decisions to approve production are publicly announced both locally and nationally. Complaints against a decision can be lodged to the Environmental Complaints Board up to four weeks after the announcement.

1.8.6. Estonia

All users must inform nearby institutions.

1.8.7. Finland

There have not been any public consultations concerning contained use. Neither have summaries nor statistics of the contained use activities been published. However, all notifications delivered to the Board for Gene Technology enter the public domain (excluding confidential information). Information on specific contained uses has been given to any interested party on request.

1.8.8. Germany

The BVL publishes the annual progress report as well as general statements of the ZKBS (the federal expert advisory body) in the Federal Gazette. On its website (www.bvl.bund.de), the BVL informs about installations and activities as well as about statements made by the ZKBS regarding risk assessments, classifications and safety measures.

18 GenTG provides for public hearings as part of the authorisation procedure for installations for class 3 and class 4 activities and certain cases of class 2 use. As no such installations have been notified so far, no public hearings have taken place.

1.8.9. Hungary

The Biotechnology Advisory Board ensures that civil society organizations are involved in the authorisation procedure.

The records department of the Gene Technology 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 abstract of the risk assessment for public information purposes, which can be consulted at the Secretariat of the Gene Technology Advisory Board.

1.8.10. Ireland

According to Irish legislation, members of the public must be notified of class 3 and class 4 activities. The EPA may, at its own discretion, also require the user to notify the public of class 2 GMM activities which are notified for the first time, but such notification has not been required to date.

When the EPA received one notification in respect of a class 3 GMM contained use, an advertisement was placed in a newspaper circulating in the district inviting representations from members of the public, but no representations were received.

1.8.11. Italy

A GMM database has been installed, but due to the reorganisation of the Ministry's website, some difficulties may be encountered during consultation.

1.8.12. Latvia

No public consultations have taken place date. However, a proposal has been launched to introduce a provision into the National Regulation that the competent authority can promote consultation procedures if considered appropriate.

1.8.13. Lithuania

Public consultation and information is regulated in the "Order on Regulation on Public Information and Participation in Authorization of Consents for Use of GMOs".

The user must inform the public of the intention to use GMOs, inviting the public to deliver comments. The public is entitled to receive free information about the usage of GMOs. Notifications and information on contained use of GMMs are contained in the national GMO database accessible via the internet. Following approval of an activity, the Ministry of Environment has to publish the information on the consent on the GMO database and in the Official Gazette within a period of 10 days. Within the same period, the user must inform the public via different mass media about the consent received and – in case of class 2, 3 and 4 uses – about the emergency plans.

1.8.14. Luxemburg

Public consultation is envisaged before the first authorisation of class 3 and class 4 contained use activities. However, only class 1 and class 2 uses have been authorised during the reporting period.

1.8.15. Malta

The MEPA, with the help of a UNEP-GEF project, has published a leaflet on contained use which incorporates guidance notes on the applicable legislation and the application procedures and the timeframes involved. It has also organised a one day public awareness seminar on GMOs, during which presentations were given on the obligations arising from the contained use legislation.

1.8.16. Netherlands

In case of large-scale production, the dossier is made public by an advertisement in a national newspaper in order to give the public the opportunity to make objections before the license is issued. All other dossiers are made public after the license is issued. The notifier's name, the title of the project and the issuing date of the licence are published on the internet and anybody can request access to the dossier at the GMO office. Concerned members of the public can object to a licence issued. No objections were received during the reporting period.

1.8.17. Poland

The provisions for public participation in the authorisation procedure require public access to the notification while restricting public access to confidential information. Notifications are published on the register available on the internet, http://gmo.mos.gov.pl.

1.8.18. Portugal

Portuguese legislation provides for a public consultation procedure carried out by the competent authority where considered appropriate. The public was not consulted regarding two contained use notifications received in 2003. Regarding the notification received in 2006, however, a public consultation procedure was carried out in order to increase transparency. Information on the consultation was published in two national newspapers and the dossier was made available both online and at the local town council.

1.8.19. Slovakia

The Biosafety Department of the Ministry of Environment in accordance with national legislation is obliged to provide general information. Applications are made publicly available via the internet and if considered appropriate in the daily press together with a call for submission of comments within a certain period. Other information regarding GMOs is published on the Ministry's website www.enviro.gov.sk and www.gmo.sk. These websites contain the register of GMO users, information on received applications and links to the web sites where the public can send comments.

In the case of notifications in respect of class 2 activities, the Ministry may oblige the notifier to provide a simplified notification for purposes of publication and information to the public. Where consent for contained use is required, civil associations aiming to protect the environment or consumers can participate in the proceedings.

The Biosafety Department has organized several workshops and seminars for the general public, consumer associations, school teachers, environmental inspectors and scientists.

1.8.20. Slovenia

Notifications concerning class 3 and 4 require public consultation. A summary of the notification, the risk assessment and the opinion of the Scientific Committee must be made publicly available. A public hearing must take place which has to be announced in public media.

Relevant biosafety data from all notifications concerning all classes of activity must be published in the GMO register on the internet.

The Slovenian government set up an independent Commission for GMO management for monitoring conditions and developments in the area of GMO management. One of its primary functions is to inform the public about developments in the field of genetic engineering and GMO management.

1.8.21. Spain

The public must be consulted in the case of contained use activities belonging to class 3 or higher. As to contained uses falling under the competence of the General State Administration, public consultation is carried out through the Ministry of Environment website: http:/www.mma.es/calid_amb/seg_bio/confinada_proc.htm

A summary of every notification (excluding confidential information) is published on this website for a period of 30 days. Comments can be submitted by e-mail and will be considered by the Commission on Biosafety. So far, no comments have been received. If the contained use falls within the competence of one of the Autonomous regions, the public is consulted according to the procedure set up by the relevant Region.

Non-confidential information is accessible to any person who has requested it through an official petition, and it may be accessed in a public archive in the Ministry of Environment. A list of all notified installations and activities and general information on each one is published on the website of the Ministry of Environment.

1.8.22. Sweden

SWEA has not established a system for regular public consultation nor a public register on notifications. However, anyone can request a list of the non-confidential information held by SWEA.

1.8.23. United Kingdom

Public consultation has been carried out on all proposed changes to the UK's Contained Use Regulations.

Details of notifications are placed on a public register, with the exception of those withheld for reasons of national security. The public register is held at the HSE Headquarter offices and is accessible to the public. Since autumn 2005, the public register is accessible through the Competent Authority's website as well.

Extensive scientific and technical guidance on GM contained use activities is available as a priced publication or free through the internet.

1.9. Accident and emergency plans

1.9.1. Austria

An emergency plan must be submitted as part of the notification of class 3 and class 4 activities as well as of large-scale class 2 activities. The emergency plan must contain necessary measures and safety measures with regard to employees and the fire brigade, a scheme for notification of relevant authorities and measures for inactivation of released GMOs. If no emergency plan is submitted, the activity must be prohibited.

1.9.2. Belgium

Article 14 Directive 98/81/EC has been partly transposed at regional level and partly at federal level. In the Brussels Region and the Walloon Region, the user must submit information needed to establish external emergency plans for risk classes 2, 3 and 4. In the Flemish Region, the user must submit information needed to establish external emergency plans for risk classes 3 and 4. On the federal level, internal emergency plans are required for all contained uses except class 1 uses; external emergency plans are only needed for class 3 and 4 and large scale class 2 contained uses.

The external emergency plan is drawn up by the local and provincial authorities based on information submitted by the notifier. The internal emergency plan is drawn up by the user and must be transmitted to the mayor.

1.9.3. Czech Republic

An emergency plan must be submitted as part of the notification and every subsequent five years or in the case of new information concerning the risks. The emergency plan must also be submitted to the municipalities where the contained use is to take place the fire service the regional authority and on request to persons directly affected by the accident. The Ministry of the Environment makes information on emergency plans publicly available and is also obliged to forward the plan to the competent Authority of a Member State that could be affected by the accident. The Czech Environmental Inspectorate checks if the emergency plan

has been submitted to all relevant authorities and if the staff and the premises are prepared for the envisaged emergency plan.

1.9.4. Cyprus

An emergency plan has to be drawn up before commencing a contained use, unless such an emergency plan has already been drawn up under other national legislation. The emergency plans should be re-examined and revised as needed and have to be tested periodically in suitable time intervals not exceeding three years.

1.9.5. Denmark

The notification of new premises must contain an emergency plan if there is the possibility of risks to the staff or the environment, which is rarely the case for class 1 uses in practice. Emergency plans are not required for production as it presently involves only class 1 activities in Denmark, but instructions are given to the company on how to react to the accidental escape of GMMs. In the event of an accident, a series of procedures are set in motion in accordance with Art. 15 of Directive 98/81/EC amending Directive 90/219/EEC.

1.9.6. Estonia

All users have established their own accident and emergency plans in accordance with the risk assessment.

1.9.7. Finland

The requirements regarding the contents of an emergency plan are laid down in the decree (272/2006). If the user is not legally obliged to compile an emergency plan, it is obliged to have a plan for unexpected situations in order to maintain adequate containment of the GMOs at all times.

1.9.8. Germany

§ 3 GenTNotfV provides for external emergency plans in certain cases of class 3 and 4 uses. So far, the ZKBS has not deemed such external emergency plans necessary when examining such uses.

1.9.9. Hungary

The competent authority examines the accident and emergency response plans as part of the authorisation process. If deemed necessary, the notifier is requested to provide further information or to modify the plans.

1.9.10. Ireland

It is a condition of consent for all classes of containment that the Principal Investigator in cooperation with the Biological Safety Committee informs the Emergency services and in particular the Fire Services of the use of GMMs and provides information that would assist Fire Officers in the event of a fire. The user is required to forward a copy of this correspondence to the Competent Authority.

1.9.11. Italy

No information given

1.9.12. Latvia

In Latvia, accident and emergency plans are a mandatory part of every notification. The user has to provide and update the plan in accordance with the National Regulation.

Accidents at national level are dealt with according to the procedures laid down in the Law on Civil Defence.

1.9.13. Lithuania

Emergency plans are required for all classes of containment. They must be available at each location where activities are conducted.

The emergency plan must ensure that, in the case of an accident, Civil Security, Environmental Protection and other relevant institutions will be informed. The Ministry of Environment must inform the Commission and provide affected Member States with details of the circumstances of the accident.

1.9.14. Luxemburg

No information given

1.9.15. Malta

As of yet no procedure for emergency plans has been established. Upon receipt of an application, MEPA will consult with the Maltese Civil Protection Department and other competent authorities in the EU as regards appropriate and effective emergency plans.

1.9.16. Netherlands

Accident and emergency plans must be available at each installation. In case of large-scale production, these plans are part of the notification. In case of class 3 and 4 operations, accident and emergency plans must be submitted to the local authorities (mayor, fire brigade).

1.9.17. Poland

Emergency plans must be submitted with every notification. A plan of the installation must be provided with the evacuation path clearly indicated. All notifications so far have concerned class 1 and 2 contained use activities and consequently the emergency plans are very similar to safety instructions used widely in different kinds of laboratories.

1.9.18. Portugal

Accident and emergency plans must be submitted with the notifications. In the case of an accident, the notifier is required to inform the competent authority, as provided by Article 15 Directive 98/81/EC amending Directive 90/219/EEC.

1.9.19. Slovakia

Emergency plans must be drawn up for all activities belonging to class 2 or higher. The emergency response plan must be made publicly available via the internet or in other appropriate manner prior to the commencement of contained use activity. The user must also provide substantial information on the content of the emergency response plan to persons likely to be affected by accidents, to the Ministry of Environment and, in case of class 3 or 4 activities, to the district authority and the municipality. The Emergency Response Plan must be reviewed and updated by the user, if there are changes to the contained use activity, the emergency response plan itself or the consent issue in respect of the contained use activity.

1.9.20. Slovenia

The emergency plan is a mandatory part of every notification. It must be made available to the local community and public services such as the fire department, the police and the local health service. The emergency plan must be updated at least every two years.

1.9.21. Spain

Internal emergency plans must be submitted with notifications in respect of class 3 and 4 activities.

Currently a basic regulation is being prepared on Emergency Plans Guidelines for biological risks under the framework of the Spanish Civil Protection Law or Autonomous legislation.

1.9.22. Sweden

Emergency plans must be submitted in respect of notifications for large scale class 2 activities, class 3 and class 4 activities. Guidance is given in connection with the form for notification.

1.9.23. United Kingdom

Emergency plans are only required where there is an identified serious off-site risk to people or the environment. Only a small number of sites in Great Britain and none in Northern Ireland conduct work falling within this category. Plans for dealing with accidents are required for all premises.

1.10. Protection of confidential information

1.10.1. Austria

The notifier may indicate information that should be treated as confidential. The competent authority then decides which information will be treated as confidential.

1.10.2. Belgium

All three regional decrees make provision for the notifier to identify and submit confidential information.

1.10.3. Czech Republic

The Czech legislation closely follows Art.19 of Directive 98/81/EC amending Directive 90/219/EEC. So far, no confidential business information has been provided in the notifications received with the exception of clinical trials.

1.10.4. Cyprus

The Cypriot legislation closely follows Art. 19 of Directive 98/81/EC amending Directive 90/219/EEC.

1.10.5. Denmark

According to Denmark, the requirements of Article 19 Directive 98/81/EC amending Directive 90/219/EEC correspond to the Danish confidentiality requirements in the Transparency in Public Administration Act.

1.10.6. Estonia

The Labour Inspectorate guarantees the confidentiality of data which have been declared confidential by the user.

1.10.7. Finland

The Finnish legislation closely follows Art. 19 of Directive 98/81/EC amending Directive 90/219/EEC.

1.10.8. Germany

No information given

1.10.9. Hungary

The national legislation transposing Directive 98/81/EC specifies which information may not be kept confidential. If the notifier requests so, all other information will be kept confidential.

1.10.10. Ireland

The Irish legislation follows closely follows Art. 19 of Directive 98/81/EC amending Directive 90/219/EEC. Confidential information is stored in a locked fireproof secure cabinet.

1.10.11. Italy

No information given

1.10.12. Latvia

The competent authority decides, after consultation with the notifier, which information will be kept confidential. The handling of confidential information as well as public access to official documents is regulated in the Law on Freedom of Information.

1.10.13. Lithuania

The Lithuanian legislation follows Art. 19 of Directive 98/81/EC amending Directive 90/219/EEC. The Ministry of Environment is responsible for the protection of confidential information and for administrative, technical and other measures protecting confidential information from illegal destruction, alteration and use.

1.10.14. Luxemburg

No information given

1.10.15. Malta

MEPA has established a system for the protection of confidential information which it currently operates in respect of Directive 2001/18/EC Part C applications. To date the Maltese Competent authority has not received any applications in respect of contained use activities.

1.10.16. Netherlands

When a notifier claims confidentiality, they must still submit a general description of the confidential parts in order to give the public an insight into the entire risk assessment. All confidential parts must be submitted in confidential annexes. Only authorised personnel have access to the rooms where the dossiers are handled and stored.

1.10.17. Poland

Confidentiality can only be sought in respect of data concerning patents or intellectual property. A notifier must provide verifiable justification as to why such information should be treated as confidential. Confidential information can only be accessed by reviewers, the Commission on GMOs and competent authorities.

1.10.18. Portugal

Where the notifier requests that certain information be viewed as confidential for reasons of commercial competitiveness, the competent authority will determine which information will be treated as confidential.

1.10.19. Slovakia

Only information protected by intellectual property rights or considered as trade secret can be considered confidential. The Ministry of Environment decides on requests by users to keep information confidential. Confidential information is archived separately in order to ensure that only the persons in charge of the dossier have access to the information. If the confidential information is needed to investigate criminal offences, the Minister of Environment and/or the notifier may lift the obligation of secrecy.

1.10.20. Slovenia

A notifier may request to keep information protected by intellectual property rights or considered as trade secret confidential, with the exception of information specified in Art. 19(3) of Directive 98/81/EC amending Directive 90/219/EEC. The Ministry shall issue a decision within seven days.

1.10.21. Spain

After consultation with the notifier, the competent authority decides which information will be kept confidential. Confidential information will only be available to the Commission on Biosafety and the competent authorities.

1.10.22. Sweden

The basic principle of Swedish legislation is that all information is public. Nevertheless, some information may be kept confidential to protect the integrity of a person, intellectual property rights, a person's income source or company. In accordance with Article 19(3) of Directive 98/81/EC, certain information may not be regarded as confidential and this article is implemented as an exemption in the Swedish confidentiality legislation.

1.10.23. United Kingdom

The GMO (Contained Use)(Amendment) Regulations 2005 altered the disclosure of information provisions so that they align with the Environmental Information Regulations (EIR) 2004 and the equivalent Scottish Regulations. Notification information must be made publicly available by putting it on the Public Register. However it is necessary to determine at the time of receipt of the notification whether there are grounds to refuse disclosure of information in the event of a disclosure request from a member of the public. When a request for information is received by the Competent Authority (CA) it must be determined if that information is covered by any of the exceptions outlined in EIR 2004. In making this decision the CA must decide whether or not it is in the public interest to withhold or divulge that information and in order to assist them in this, guidance has been issued to notifiers asking them to consider if any of the information provided should be kept confidential.

Notification forms have been designed to separate out confidential information from non-confidential information.

1.11. Waste disposal

1.11.1. Austria

GMMs of class 2 to 4 which are capable of reproduction under environmental conditions have to be inactivated prior to disposal. Waste is mainly inactivated through thermal or chemical means. Inactivated waste is mainly disposed of through thermal means.

The question of waste disposal has to be taken into account during the risk assessment.

1.11.2. Belgium

Federal legislation requires inactivation of all GM waste by appropriate and validated means. This requirement is complemented by specific regional 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.

1.11.3. Czech Republic

Prior to disposal, any viable organisms in the waste must be inactivated. As there are no categories for GMO waste in the Czech Catalogue of Waste, the inactivated waste is

categorized and classified according to the place and process of their origin, e.g. as waste from human or animal health care and/or related research.

1.11.4. Cyprus

The risk assessment shall specifically take into account the question of disposal of waste and effluents.

1.11.5. Denmark

The requirements for waste disposal have not changed in connection with the implementation of Directive 98/81/EC amending Directive 90/219/EEC

1.11.6. Estonia

All users have special plans for waste maintenance and decontamination.

1.11.7. Finland

No information given

1.11.8. Germany

Pursuant to § 13 GenTSV, waste must be inactivated or sterilised prior to disposal.

Germany points out one problem: Large contaminated devices such as HEPA filters from sterile workbenches or the ventilation system of class 3 or 4 installations must be disposed of in installations using genetic engineering. However there are hardly any autoclaves of suitable size. Incineration in a furnace could be ideal, but it is not always possible to notify or to authorise a furnace as an installation using genetic engineering. A special provision would be helpful.

1.11.9. Hungary

Waste from biotechnological activities (both dangerous and non-dangerous) is treated under the national legislation concerning dangerous waste.

1.11.10. Italy

No information given

1.11.11. Ireland

All waste material containing viable GMMs must be inactivated prior to disposal. Where on site inactivation is not feasible Class 1 GMM waste may be sent to one facility in Ireland licensed to handle GMM waste. Class 2 GMM waste must be inactivated on the same site as the contained use activity. Weekly control measures must be applied and records of inactivation, validation protocols and logbooks recording control measures must be retained for inspection by the Competent Authority. Presently no Class 3/4 activities have been authorised.

1.11.12. Latvia

All waste has to be stored and inactivated in accordance with the National Regulation.

1.11.13. Lithuania

All GMM waste must be inactivated prior to disposal.

1.11.14. Luxemburg

No information given

1.11.15. Malta

Plans for waste disposal must be submitted by the notifier and will be assessed by the Biosafety Coordinating Committee.

1.11.16. Netherlands

The Ministerial Regulation on GMOs provides that all waste must be inactivated by validated means prior to disposal. An annex lays down rules for waste storage. In general, waste inactivation and disposal has to be performed in-house. If this is not possible, the waste has to be transported to dedicated waste facilities in accordance with the Act on the movement of dangerous substances.

1.11.17. Poland

The notifier must provide information about the foreseen quantity of aerosols and contaminated sewages resulting from the contained use activity. Information about storage and inactivation methods must be provided. All waste must be inactivated prior to disposal if it is not guaranteed that no harmful effects will occur otherwise. In case of class 3 and 4 activities, the water from sinks, showers, glass houses and animal houses must be inactivated as well.

1.11.18. Portugal

Waste, effluents and residues from all contained use activities, including class 1 activities, must be inactivated prior to disposal.

1.11.19. Slovakia

The application for consent must include information on waste management and disposal. Inactivation of GMMs in contaminated material and waste is optional for class 1 activities and required for activities assigned to class 2 or higher. Inactivation of GMMs in effluents from hand-washing sinks or drains and showers is not required for class 1 and 2 activities, optional for class 3 activities and required for class 4 activities. According to the Biosafety department of the Ministry ad the Slovak Environmental Inspection's practical experience, users inactivate all waste prior to disposal. Special regulations on disposal of waste must also be followed. Fines shall be imposed in case of violation of the legislation.

1.11.20. Slovenia

The risk assessment must provide details on waste treatment, inactivation procedures and final disposal of waste and effluents. The waste disposal procedure outlined in the risk assessment must be taken into consideration by the Scientific Committee before the premises is approved for the contained use of GMMs.

1.11.21. Spain

The Commission on Biosafety considers waste management and disposal as being one of the most important aspects of the risk assessment. In general, all GMMs and GMOs must be inactivated prior to disposal. Inactivated waste is handled by an authorised agent in most cases, depending on the relevant legislation. All contaminated materials must undergo a decontamination process.

1.11.22. Sweden

Waste containing GMMs from class 2 large scale activities, class 3 and class 4 activities must be inactivated before leaving the premises. Waste containing GMMs from class 1 activities or small scale class 2 activities may only leave the premises if sent for incineration and appropriately marked and transported in accordance with the Transport Regulations. The waste treatment plant must notify the treatment as a contained use activity.

GMM waste may be inactivated within the premises by heat treatment (autoclave) or by chemical means provided the inactivation methods are validated. Inactivated waste may be disposed of as common waste as long as no living GMMs can be detected.

1.11.23. United Kingdom

All waste must be inactivated by validated means prior to disposal. Compliance is checked as part of inspections. Autoclaving is mostly used, but the number of incinerators registered to deal with waste containing GMMs has increased. These are primarily used for waste arising from Class 1 activities e.g. in animal bedding or clinical waste from gene therapy trials.

2. ANNEX II – TABLE OF COMPETENT AUTHORITIES

Member State	Competent Authority	Other authorities involved
Austria	Federal Ministry of Education, Science and Culture (work at universities and scientific institutions) Federal Ministry of Health and Women (remaining activities)	
Belgium	Competent authorities in the three regions (Brussels Capital, Flemish Region, Walloon Region) SBB (Section Biosécurité et Biotechnologie) as federal advisory body	
Czech Republic	Ministry of the Environment	Czech Commission for the use of GMOs and genetic products (opinion), Ministry of Agriculture and Ministry of Health (may make comments or raise objections)
Cyprus	Department of Labour Inspection (Ministry of Labour and Social Insurance)	Licensing Technical Committee (advice)
Denmark	Forest and Nature Agency (under the Environment Ministry) and Working Environment Authority (under the Employment Ministry) in collaboration	
Estonia	Labour Inspectorate	
Finland	Board for Gene Technology	
France	Ministry of Research	Commission de genie génétique (Genetic Engineering Commission)
Germany	Länder authorities Competent federal authority: BVL (Federal Office for Consumer Protection and Food Safety)	Zentrale Kommission für die biologische Sicherheit (ZKBS, expert advisory body) (makes statements on classification)

Hungary	Genetic Engineering Authority (Ministry of Agriculture and Rural Development)	Genetic Engineering Advisory Board (consulted)
Ireland	Environmental Protection Agency (EPA)	
Italy	Ministry of Health	Biotechnology Committee (positive opinion required)
Latvia	Food and Veterinary Service (Ministry of Agriculture)	Expert Committee (opinion)
Lithuania	Ministry of Environment	Steering Committee on GMOs (political advisory body), Ministry of Agriculture, Ministry of Health, State Food and Veterinary Service (opinions)
Luxemburg	Ministry of Health	
Malta	Malta Environment and Planning Authority (MEPA)	Biosafety Coordinating Committee (assessment)
Netherlands	Ministry of Housing, Spatial Planning and the Environment	
Poland	Ministry of the Environment	Commission on GMOs (assessment)
Portugal	Institute for the Environment (Ministry of Environment, Spatial Planning and Regional Development)	
Slovakia	Ministry of Environment	Commission for Biological Safety (expert advisory body) (recommendation)
Slovenia	Ministry of Environment and Spatial Planning	Scientific Committee for Work with GMOs in Containment (assistance)
Spain	Autonomous Communities	National Commission on Biosafety (CNB)

	Interministerial Council on Genetically Modified Organisms (activities representing a risk for human health, research programs)	(evaluation, inspection, favourable or unfavourable report)
Sweden	Swedish Work Environment Authority (SWEA)	
United Kingdom	Health and Safety Executive (HSE)	