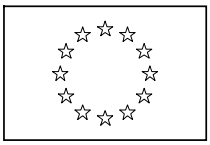

COMMISSION OF THE EUROPEAN COMMUNITIES

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REPORT FROM THE COMMISSION

BASED ON THE REPORTS OF MEMBER STATES CONCERNING THEIR EXPERIENCES WITH DIRECTIVE 90/219/EEC ON THE CONTAINED USE OF GENETICALLY MODIFIED MICRO-ORGANISMS

FOR THE PERIOD 1996 – 1999

SUMMARY

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BASED ON THE REPORTS OF MEMBER STATES CONCERNING THEIR EXPERIENCES WITH DIRECTIVE 90/219/EEC ON THE CONTAINED USE OF GENETICALLY MODIFIED MICRO-ORGANISMS

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SUMMARY

PREFACE

Directive 90/219/EEC[1] on the contained use of genetically modified organisms, was adopted on 23 April 1990 and entered into force on 23 October 1991.

Article 18.2 of Directive 90/219/EEC provides that Member States submit a report to the Commission every three years summarising their experiences with this Directive, the first time being 1 September 1992. The subsequent Article 18.3 requires that the Commission publish its own summary report based on the afore-mentioned national reports from Member States. The first summary report was published by the Commission in 1994 and encompassed the experiences of Member States with the Directive during the early 1990s.

This is the third summary report to be published by the Commission and covers the period 1996 – 1999. The Commission report is based upon a third series of reports from Member States that were due in September 1999 but only received during a period from October 1999 to November 2000. The contents of these national reports were largely based upon an outline submitted by the Commission to Member States in an attempt to improve the quality of information and harmonisation of responses.

On the whole, national reports were vastly improved in comparison to previous submissions and contained detailed information on relevant issues and experiences concerning both Directive 90/219/EEC and transposition of the amending Directive 98/81/EC into national laws.

Directive 90/219/EEC was founded on scientific knowledge available in the early 1980's and on the limited practical experience with genetically modified micro-organisms (GMM) in industrial applications. However, extensive use of genetic modification techniques in research laboratories and industrial facilities during the ensuing ten years dramatically increased the scientific knowledge base and understanding of the technology. It was recognised that the administrative procedures and notification requirements were not appropriately related to the risk of the contained uses and that the continued safe and responsible use of genetic modification techniques must account for wider scientific knowledge and experience.

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1 OJ L 117 of 08.05.1990

Against this background, the Commission in consultation with Member States and other interested parties undertook an extensive review of the provisions of Directive 90/219/EEC. A Proposal[2] to amend the Directive was subsequently adopted by the Commission in December 1995 and presented to the Council of Ministers. The Proposal importantly included measures to improve the operation of the Directive by linking administrative procedures and notification requirements to the risk arising from activities with GMMs rather than the process. Further clarification was sought by introduction of a classification scheme requiring placement of GMMs into one of four risk groups and specifying the minimum containment and control measures to be applied to each class of risk for all contained use activities. The amendments also included streamlined administrative procedures but only in situations where safety would not be compromised.

Directive 98/81/EC[3], amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms, was adopted on 26 October 1998 and importantly included;

i. abolition of the current requirements for classification of GMMs and categorisation of activities according to purpose and scale;

ii. administrative procedures and notification requirements directly linked to the risk of the contained use activities involving GMMs;

iii. streamlined administrative procedures and reduced notification periods;

iv. possibility for exemptions (under defined criteria) from the Directive of GMMs that are recognised as safe for human health and the environment;

v. description in general terms of the elements to be considered to perform risk assessment;

vi. improved tables of containment and control measures, to ensure harmonisation and adequate environmental protection;

vii. increased flexibility for amendment of the technical annexes, allowing timely adaptation to scientific and technical progress.

Member States were required to transpose Directive 98/81/EC in national law before 5 June 2000. At the time of writing this report, Finland, Denmark and Sweden had transposed the amended Directive into national law but the transposition was still ongoing in the other Member States.

As required under the Directive 98/81/EC, the Commission has produced, via the Competent Authority Committee, guidance notes on risk assessment to further assist Member States with a harmonised approach to the central component of the Directive. Again as required under the Directive, the Commission has submitted to the Council, a Proposal with regard to criteria establishing the safety to human health and the environment of types of GMMs with the possibility of their exclusion from the provisions of the Directive. Adoption of the above measures will complete the annexes of the Directive.

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2 COM (95) 640 Final

3 OJ L 330 of 05.12.1998

It is imperative that future changes in the technology and future advances in scientific knowledge are accounted for in the regulatory process and this requires continued interaction and consultation with Member States and interested parties. Articles 18.2 and 18.3 of the Directive remain in place and the reporting system requiring submission of reports by Member States with regard to their experiences with the Directive should, in future, encompass experiences with the above amendments. Member States are required to submit their next reports by September 2002 and the Commission intends to prepare an updated summary report to cover the period 1999 – 2002 shortly afterwards.

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

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1. AN OVERVIEW OF INSTALLATIONS AND ACTIVITIES

Austria

During the period from 1996 to 1998, a total of 73 operations carried out in 54 installations were notified to the Federal Minister for Women's Affairs and Consumer Protection and a further 105 operations in 44 installations to the Federal Minister for Science and Transport. The majority of operations were classified within safety levels 1 and 2. There were only two activities within safety level 3 and both were Type A operations.

Belgium

Since 1994, 280 operations have been conducted in 97 installations all of which have been assessed by the Service of Bio-safety and Biotechnology (SBB). Of these, 264 operations have been classified as Type A and 16 as Type B. The majority of these operations involved GMMs classified within Group I and were conducted at safety level 1. Only five operations involving Group II GMMs have been categorised within safety level 3 during this time period. No activities were conducted at safety level 4 and there was a single operation of Group II Type B work of safety level 3.

The Belgian summary report documented that 16 dossiers for first use permits involving 120 operations (received in 1998-1999) were still under review by the SBB.

Since March 1996, eight human clinical trial protocols have been approved in Belgium. All trials were carried out in academic hospitals and were aimed at testing viral vectors in cancer therapy. The authorisation process of clinical trials involving GMM's as a matter of course involves consultation and meetings of the ad hoc Scientific Committee of the Bio-safety Advisory Council for risk assessment.

Denmark

In the period from October 1995 to November 1999, 11 installations conducting activities with 31 different GMMs/GMOs were notified for Group I work. A total of 247 research projects incorporating Group I organisms and 71 projects involving Group II organisms were notified. The majority of these were Type A operations with 146 and 99 projects involving Group I and Group II organisms respectively. A general time limit of five years is applied to research projects.

Finland

Since the transposition of Directive 90/219/EEC into national legislation (June 1995), the Finnish Board for Gene Technology had received 250 notifications by the end of August 1999. Of these notifications, 211 were classified as small-scale operations with 152 and 39 of the notifications incorporating Group I and Group II GMMs respectively. A further 39 notifications involved large-scale (Type B) operations, 38 of which involved Group I GMMs with only one incorporating Group II organisms.

France

During the reporting period, a total of 614 new consents for contained use activities involving GMOs or GMMs were granted by the French Authorities. Four hundred and four consents were granted for work with Group I GMMs, of which 336 were granted to installations in the public sector and 68 to privately owned installations. These consents represented a total of 1498 projects at risk class 1.

In addition, 197 consents were granted for activities involving Group II GMMs, of which 175 were granted to installations in the public sector. The remaining 22 consents were granted to organisations in the private sector. A further 13 consents were granted for work involving both Group I and Group II GMMS. The above consents represented a total of 684 projects at risk class 2 or above.

Approximately 14% of consents granted for activities involving Group II GMMs involved work at risk class 3. Consent was only granted for one project at risk class 4, which was carried out at the Jean Mérieux high security installation at Lyon.

Germany

In the period from 1 July 1990 to 21 September 1999, a total of 3377 genetic engineering installations were notified to the Robert Koch Institute (RKI) by the competent authorities of the Federal Länder. Most (2522) of these installations were notified for Group I Type A operations only. Although 16 installations were notified for Group II Type B work, only seven operations at this level have been carried out to date.

During the above period, a total of 5 253 activities were notified, involving mainly operations with Group I Type A (3 117) and Group II Type B (1 937). Of these operations, 47%, 18% and 17% were conducted in the fields of cell biology, virology and bacteriology respectively. Less than 10% of operations concerned gene therapy and botany.

Since the entry into force of Directive 90/219/EEC, there has been a steady increase in the approval of both new genetic engineering installations and operations. Compared to the figures presented in the previous report, pursuant to Article 18.2 of the Directive, the number of notified installations has risen from 2 181 to 3 377 and operations from 3 376 to 5 253.

Greece

No notifications were submitted during the period from 1996 to 1999 although a notification from the Alexander Fleming Biological Research Institute is expected in 2000. The Laboratory of Genetics and Plant Breeding of the Aristolean University of Thessaloniki submitted a report concerning use of the micro-organisms *Agrobacterium tumaciens* and *Escherichia coli* for the transformation of higher plants. A full list of bacterial strains, plasmids and plants was included in this report as well as relevant laboratory protocols. The laboratory had taken all necessary measures for containment of the micro-organisms and for the protection of human health and the environment. The report was not, however, considered to be a notification given that it did not follow the format of the annexes to the Directive.

Ireland

In the period from July 1996 to October 1999, a total of 80 contained uses were notified. The majority of these activities were of Group I Type A. Eight of these notifications concerned Group I Type B operations and a further six concerned Group II Type A operations. Only one notification involved Group II Type B operations. Seven of the above contained uses ceased operation during this period, six operations being of Group I Type A and one of Group I Type B.

Italy
From 1996 to 1999, 85 installations were notified of which 82 were given consent to operate. During the same period, 146 operations were notified of which 132 were approved.

Luxembourg
Four institutions have appropriate facilities to conduct activities involving the contained use of GMMs and GMOs. Essentially, these institutions were research laboratories, where part or all of the work is devoted to research projects involving GMOs or GMMs. These research projects were classified within the broader fields of biomedicine and 'agrobiology'.

The Netherlands
It was reported that approximately 150 institutes, universities and companies were licensed in the Netherlands for contained use activities with GMMs/GMOs. From March 1996 to October 1999, 875 notifications were submitted of which 865 received approved. Ten notifications were refused because of lack of information. In addition, 367 modifications for existing notifications were submitted as well as 243 notifications of minor changes.

Portugal
Only one notification concerning the contained use of GMMs/GMOs has been submitted since Directive 90/219/EEC entered into force. This notification incorporated a fermentation process for research and development purposes and authorisation was granted.

Spain
Since the entry into force of Directive 90/219/EEC, 25 installations have been notified for contained use activities with GMMs/GMOs. Of these notifications, 15 have been for Group I Type A and five for Group I Type B operations. Five installations have notified activities involving Group II GMMs, four of which were Type A operations.

A total of 37 activities have been notified by these installations, the majority of which have involved Group I GMMs. Of these, 16 have been notified as Type A operations and 13 as Type B operations. A further eight operations - mainly for educational, research and development purposes - have included Group II GMMs. Research work carried out in registered installations has largely focused on the use of GMMs for development of molecular characterisation programmes, production of new biological substances and for use in gene therapy.

Sweden
According to the present Swedish legislation, there are no requirements to notify installations that have been in use before 1 January 1995. Neither are there any requirements for notification of Type A activities concerning contained use of animals and plants. On this basis, the Swedish Authorities are not able to provide information on all installations conducting contained use activities.

Ten notifications from installations working with genetically modified plants and 40 from installations working with genetically modified animals were submitted to the Swedish Board of Agriculture during the reporting period. The National Board of Occupational Safety and Healthy received notifications for 20 Group I Type A, four Group I Type B and 20 Group II Type A operations, the majority of which were submitted by pharmaceutical companies and universities. No notifications were submitted for Group II Type B activities.

United Kingdom
In total, 458 premises have been notified in the United Kingdom. From April 1995 to October 1999, 228 new Group II Type A activities and a further 16 activities classified as Group I Type B were notified to the UK competent authority. There have been no notifications for Group II Type B activities or for GM animals or plants during this period. Notifications for GM plants or animals are only required if they present a greater hazard to human health in containment than the non-modified parental organism.

2. CLASSIFICATION AND RISK ASSESSMENT

In accordance with Article 2 of the Directive, all activities have to be classified into either Type A or Type B operations. Similarly, in accordance with Article 4 of the Directive, GMMs must be classified within either Group I or Group II.

Austria
Operations involving GMMs/GMOs are to be classified into Type A and Type B and further into safety level 1 (no risk), 2 (low risk) and 3 (moderate risk) dependent upon the pathogenic risk they present for humans, animals and plants. For operations involving GMMs/GMOs at safety level 2 and 3, the operator has to appoint a project head responsible for planning, managing and supervising the operation. For every installation, a designated person and Committee holds responsibility for biological safety. The Committee has a role in reviewing the safety classification and safety protective measures proposed by the operator.

Belgium
Risk assessment strategy is defined in regional regulations and has to be followed by the notifier and the Advisory Authority. Operations are classified into one of four biological risk classes. Assessment takes several risk assessment data into account, including for example reference lists of micro-organisms classified into different risk classes. In 1999, the Advisory Authority published a catalogue of Internet sources relating to bio-safety issues as a means to assist notifiers with risk assessment.

Denmark
The competent authorities ensure that applicants provide the information required. A concrete assessment is then made on the basis of the instructions outlined in the Directive and the Commissions' guidelines for classification. Before GMOs may be used, risks must be assessed both in relation to research, large-scale trials and production.

Finland
Classification system and risk assessment procedures in Annexes II and III of Directive 90/219/EEC respectively have been transposed unchanged into the Gene Technology Act and into additional administrative actions laid under this Act.

France

Risks are classified according to the French law arising from transposition of the Directive. Containment levels specified in the consent are directly related to the potential risk of the use as described in the notification. Under certain conditions, such as activities involving animals (A2) or work in glasshouses (S2), containment level 2 conditions may be imposed for notifications of risk class 1. Conversely, consents for notifications involving work that normally requires consent for Group II GMMs (A1 or S1) may in certain cases allow the work to be conducted at containment level 1. Certain consents are granted for uses of both Group I an II GMMs. These consents are deemed necessary due to a combination of uses at risk classes 1, 2 or 3.

Certain uses at risk class 2 present relatively low risk, close to risk class 1 uses but others may be closer to risk class 3 due to conjunction of the trinomial vector-insert-host. Therefore, containment associated with risk class 2 uses can not be rigid and in the main, are determined on a case-by-case basis, taking account of the use.

Germany

The national Genetic Engineering Law stipulates that operations must be classified into one of four safety levels. Specific requirements for the risk assessment are laid down in the Genetic Engineering Safety Regulations.

A list of donor and recipient organisms, where risk has already been assessed into safety levels, is being updated and published in the Journal of the Federal Health Office. A database held by the Robert Koch Institute details genetic engineering operations that have been assessed and is also available for consultation. In the case of safety levels 3 and 4, the Central Advisory Committee for Biological Safety (ZKBS) is consulted for opinions on safety measures. For operations at safety level 2, the Committee has to be consulted if it has not previously assessed any comparable operations.

Greece

A committee was established (Ministerial Decision 21484/3469/5-11-96) for evaluating notifications submitted under Directive 90/219/EEC (and also under Directive 90/220/EEC). The committee was also established to perform risk assessment and implement precautionary measures where necessary. Members of the committee include representatives of the Ministries (Ministry for the Environment, Physical Planning and Public Works, Ministry of Finance – State Chemical Laboratory, Ministry of Agriculture, Ministry of Health and Public Care, Ministry of Labour and Social Security). The committee also comprises two expert scientists, nominated by the Director-General for the Environment according to the expertise required.

Ireland

Users commencing contained use activities must carry out risk assessment in accordance with the Genetically Modified Organisms Regulations. GMMs are classified as Group I and Group II organisms by the notifier and the classification is reviewed by the Agency.

Italy

The competent authority is the Ministry of Health, which is supported by the Biotechnology Committee and the Scientific Committee for the evaluation of biological risks.

Luxembourg
Research projects involving the contained use of GMOs or GMMs were all classified as Type A operations, i.e. operations for research or development and of a small scale. The categories of all GMOs or GMMs fell within Group I as defined under Article 4 of the Directive. This group equated to Risk Group I (low risk) as defined in national legislation, which similarly provides for classification of GMMs/GMOs into one of four risk groups.

The Netherlands
A general risk assessment procedure, laid down in the Ministerial Order on Genetically Modified Organisms, has been developed for standard activities. This procedure is based on the characteristics of host, vector and insert. Where the proposed contained use aligns with one of the standard risk assessments, notifiers can perform risk analysis by referring to the relevant article in the Ministerial Order on GMOs.

Portugal
The user refers to the risk assessment in the notification.

Sweden
The competent authority ensures that all relevant aspects for risk assessment have been taken into consideration in notifications. According to the competent authority, the borderline between Group I and Group II is not always obvious and there is a need for further guidance on classification into different bio-safety levels, particularly with regard to future interpretation of the provisions of Directive 98/81/EC. Risk assessment based on the intrinsic properties of the GMM should, as far as possible, be the same for GMMs in contained use and deliberate release although the risk assessment for a particular use of a GMM should consider other factors.

United Kingdom
The GMM classification criteria for determining Group I and Group II GMMs were amended in 1996 and detailed national guidelines on interpretation of the new criteria were published. In 1997, on the advice of the Advisory Committee on Genetic Modification (ACGM), a revised Compendium of Guidance was issued to all centres undertaking genetic modification work. Guidance is currently under further revision to update it to technical progress and prepare for implementation of the amendment to the contained use Directive.

3. NOTIFICATION AND APPROVAL SYSTEM (AND RELEVANT CHANGES)

Austria
Notifications are submitted to the Federal Minister for Science and Transport or to the Federal Minister for Women's Affairs and Consumer Protection. The competent authorities examine the risk assessment and safety classification submitted by the operator as well as the proposed safety measures, qualifications of the project head, the person responsible for biological safety and members of the Committee for Biological Safety. Prior to granting consent for first time, large-scale operations at safety levels 1 to 4 and small-scale operations at safety levels 3 and 4, the competent authority must seek the opinion of the Scientific Committee of the Genetic Engineering Commission. The competent authority must also seek the opinion of the Committee prior to approval of subsequent operations at safety levels 3 and 4 on a large scale.

Following amendment of the 1994 Austrian Genetic Law, relevant changes concerning ad hoc special provisions on compensation entered into force on 1998. These amendments encompass liability for the operator concerning all damage caused to persons, property and

environment resulting from effects of genetic modifications. The amendments place an obligation on the operator to repair damage to the environment or pay the costs of such repairs as well as an obligation to show causality of damage and to take out civil liability insurance for all operations involving GMOs. There were also amendments concerning financial penalties in the case of infringements of the 1994 Genetic Law and failure to take out the civil liability insurance.

Belgium

Under the Belgian system, individual Regions are responsible for public information, follow-up of administrative procedures, legal decisions, appeals and inspections although the procedures differ slightly from Region to Region. The Service of Bio-safety and Biotechnology (SBB) evaluates notifications on a scientific basis employing a centralised system. The SBB also advises the regional authorities on authorisations and defines the criteria to be implemented in a given installation. The Belgium competent authorities are advised by the Bio-safety Advisory Council, which is a formal committee comprised of representatives of competent and concerned organisations assisted by ad hoc scientific committees.

Under regional regulation, contained use of GMM's/GMO's and pathogens requires an environmental permit. This only granted following the submission of a Biosafety dossier to the authorities and subsequent appraisal. Responses are transmitted within the time limits set out in the Directive. Type A (risk class 2) and Type B (risk class 1) activities may commence 60 days after submitting the dossier and can proceed for up to three years. However, in practice, the majority of notifiers request a written authorisation from the authorities.

Denmark

In 1999, responsibility for administrating the national law implementing Directive 90/219/EEC was transferred from the Environmental Protection Agency to the National Forest and Nature Agency, both of which are under the Ministry of the Environment and Energy. There were no amendments to the administrative procedure for notification and approval due to change. These procedures are perceived to be satisfactorily.

All notifications are recorded in the joint product register of the Labour Inspectorate and the National Forest and Nature Agency. The above-mentioned authorities have direct access to the register and other authorities can request access to information in relation to their work.

Finland

The Board for Gene Technology grants approval for use of premises. Following approval, Group I activities may be initiated without further notice to the Board provided that the user keeps a record of the activity. Group II activities are dealt with on a case-by-case basis and can not be initiated without approval of the Board.

France

The risk assessment and classification of use are carried out after examination of the notifications submitted by applicants. These notifications must be compiled in accordance with a format that takes into account all elements required for the assessment, in accordance with annexes of the Directive as transposed in the national law of 13 July 1992. Experts of the Commission de Génie Génétique examine confidential informtion and conclusions drawn after discussion in plenary session. The president of the Commission draws up an opinion and this submitted to the Ministry for Research, which grants consent except in situations where the Ministry of the Environment does not agree with this opinion. However, this has not yet been the case.

Germany
First-time genetic engineering operations and installations are subject to compulsory notification. Authorisation of operations and installations falls within the competence of the Federal Länder, which subsequently inform the Robert Koch Institute of the decisions taken under the Genetic Engineering Law. Using a standard format, applicants submit, to the competent authorities of the Federal Länder, details of the planned operations and existing safety measures as well as a risk assessment of the planned operations.

Ireland
The Environmental Protection Agency ensures that the applicant complies with notification requirements stipulated in the GMO Regulations of 1994 and may impose additional conditions as it deems necessary. A fee is requested from the notifier with respect to the notification dependent on whether the contained use constitutes a Group I/II organism, Type A/B operation.

Group I Type A/B and Group II Type A contained use activities may proceed 90 days after receipt of a notification by the Agency in the absence of an indication to the contrary or at an earlier date as agreed by the Agency. Group II Type B contained use activities may not proceed unless consent from the Agency has been received. All conditions/requirements imposed by the Agency have been complied with prior to commencement.

Italy
Documents are examined by experts of the Biotechnology Committee and if needed, by "ad hoc" experts appointed by the Committee. The Ministry of Health only grants authorisation following a positive opinion from the Biotechnology Committee.

Luxembourg
National legislation on the contained use of GMMs and GMOs was finalised only recently and consequently, only four notifications for approval had been submitted at the time of the report. These notifications concerned Type A operations involving GMOs and GMMs in risk category I.

No applications for Type A operations involving GMOs or GMMs in risk category II were received or for Type B operations involving GMOs or GMMs in risk categories I or II.

The Netherlands
The COGEG Advisory Committee, assigned by the Minister of Housing, Spatial Planning and the Environment, provides advice on safety issues with respect to individual notifications and alerts the relevant authorities if there are important ethical or social aspects linked to activities involving GMOs.

After receipt of the notification, the competent authority evaluates whether the information is complete. For approximately two-thirds of notifications, the competent authority has requested additional information. Consent is granted following appraisal of the notification and if the information is complete and no advice is required from the Advisory Committee. Where complex issues are presented, or where the notification is under Article 10.2, advice from the Advisory Committee is requested. Responses are transmitted within the time limits set out in the Directive.

The notifier additionally requires a licence for the physical containment of the installation. This is issued under the Environmental Protection Act by local authorities.

Spain
Regulation and authorisation of activities concerning GMMs/GMOs falls under the competence of the Autonomous Communities (authorities with a regional scope) and in some cases, under the competence of the State General Administration.

Sweden
The Swedish notification and approval system follows that under Directive 90/219/EEC.

United Kingdom
Notifications from organisations within England, Scotland and Wales (Great Britain) are submitted to the Health and Safety Executive (HSE) in England. On receipt, notifications are acknowledged and circulated to other members of the national competent authority (DETR, MAFF) for review. HSE collates all responses and replies to the notifier with either agreement for work to proceed, consent or a request for further information. Responses are transmitted within the time limits set out in the Directive.

In Northern Ireland, the Health and Safety Executive for Northern Ireland (HSENI) receives notifications but by arrangement, these notifications are forwarded to HSE in England for scrutiny. Where necessary, HSENI responds to the relevant notifiers in advance of a reply from its counterpart in England.

Where a notification presents highly novel work, or if the experts within the competent authority require additional advice, the notification is reviewed by independent experts of the Technical Sub-Committee of the Advisory Committee on Genetic Modification (ACGM).

4. ACCIDENTS

Over the period covered by this report, no accidents were reported to the competent authorities under the requirements of the Directive in Austria, Belgium, Denmark, Finland, Germany, Greece, Ireland, Italy, France, Luxembourg, Portugal, Sweden or in the United Kingdom.

In the Netherlands, four different accidents were reported to the competent authority during this period. In two of the cases, a greenhouse was damaged during a hailstorm and the GM plants were removed to another greenhouse. Another case involved damage to a greenhouse by a truck and again, the GM plants were removed to another greenhouse. In the final case, the bedding of an animal-housing unit in which test animals were infected with a GMO was not inactivated prior to release into the sewage system. Following this case, the protocol for handling such waste was reviewed and adapted by the company to prevent further accidents.

In Spain, one installation gave notice of an accident following identification of a type 3 pathogenic fungus in its P2-type microbiology laboratory. The Safety Committee of the organisation concerned immediately sterilised the samples detected and disinfected the laboratories by fumigation. Information with respect to the pathogen was compiled to carry out risk analysis and to evaluate any need for further action.

5. INSPECTION AND ENFORCEMENT ISSUES

Austria
During the reporting period, 'spot checks', either announced or unannounced, of premises and operations were carried out by the Federal Minister for Women's Affairs and Consumer Protection and the Federal Minister for Science and Transport. These checks did not give rise to any official action.

Belgium
Inspections are conducted by the 'Environment Inspection Services' of the Regions. Remedial action can be enforced following complaints by individuals or groups and also on the request of any authority.

For the last ten years, scientists of the SBB have developed laboratory expertise for tracking of genes in the environment, industries, wastes, bio-mass and products such as foods, feeds, seeds, plants and animals. The SBB is presently co-ordinating the "Network of Federal Laboratories for the Tracing and Authentication of GMOs" and expertise from this network is made available to the inspectorates if required.

Denmark
The Labour Inspectorate monitors conformity within the applicable terms of the legislation. Enforcement orders have been given with respect to inadequate signs, passage through classified areas, smoking, eating or storing food and failure to use overalls. Orders have also been given with regard to experiments with GMOs conducted outside of classified laboratories.

Administrative districts are responsible for inspecting the production facilities. The National Forest and Nature Agency is not aware of any orders or injunctions that have been issued in connection with the inspections.

Finland
Inspection of facilities working with Group II GMM/GMOs, including facilities for animals infected with such GMMs, commenced in 1997. Approximately two thirds of these facilities were inspected during the reporting period but no legal action was necessary.

France
During examination of notifications, inspection of the relevant installation may be conducted by the Commission de Génie Génétique to help the experts with their assessment. The texts regulating the control of installations and uses are currently under development.

Germany
Inspection of installations is carried out at regular intervals by the authorities of the Federal Länder. During these inspections, the applicant's records of operations are checked and, in individual cases, samples are taken to confirm the effectiveness of containment and the identity of organisms. In cases where shortcomings are observed, approvals may be deferred or revoked. Experience has shown that inspection of facilities prior to the granting of consent linked with regular on-site inspections of the activities, is an appropriate way of guaranteeing a high safety level.

Ireland
The competent authority has the power to grant or refuse consent, to impose licence conditions or to impose revised conditions for a proposed contained use. All first use facilities are issued with conditions for operation of the contained use where deemed necessary and reviewed by a technical inspector.

All facilities are inspected once every three years for compliance with the principles of good microbiological practice and the principles of good occupational safety and hygiene as outlined in Article 7 of the Directive.

Italy
At the request of the Biotechnology Committee, inspection of installations is carried out by governmental officials and "ad hoc" experts.

Luxembourg
The legislative provisions governing post-authorisation inspections and controls have yet to be implemented.

The Netherlands
The Inspectorate for the Environment is responsible for enforcement of the Genetically Modified Organisms Decree. The Inspectorate works in close contact with the competent authority entrusted with GMM/GMO authorisations and indirectly with the Advisory Committee (COGEM).

Spain
The Autonomous Communities (authorities with a regional scope) and the State General Administration are responsible for the monitoring and inspection of installations working with GMM/GMOs. Protocols for inspection plans and programmes for each type of installation and class of hazard were drawn up by the Ministry for the Environment in 1998. The protocols will be applied in 2000.

Sweden
In addition to visits in connection with notifications, inspections have been conducted in a number of research departments and pharmaceutical companies. Correction notes have often been given, but no legal actions have been taken so far. Joint inspections within the European Joint Enforcement Project have been performed in Sweden together with inspectors from the UK and Denmark.

United Kingdom
In England, Scotland and Wales (Great Britain), the UK regulations implementing Directive 90/219/EEC are enforced by specialist inspectors from the Health and Safety Executive. In Northern Ireland, inspectors from the Health and Safety Executive of Northern Ireland enforce the relevant legislation.

Between April 1995 and October 1999, four improvement notices were issued as a means to improve safety measures with respect to the operations. No prohibition notices (where people must stop work immediately or as otherwise instructed by the inspector) were issued) and one prosecution was taken. The prosecution proceedings were instigated for failure to conduct adequate risk assessment although the activities involved were low risk. On another occasion, the Health and Safety Executive withdrew the permission for activities to continue.

6. EUROPEAN ENFORCEMENT PROJECT

A European project on enforcement of the contained use regulations has been successfully completed. The project was initiated by the UK and Dutch Inspectorates, and included three conferences attended by inspectors from the competent authorities of twelve Member States as well as Norway and Switzerland. The conferences were convened in The Hague, Netherlands (October 1998), Hamburg, Germany (March 1999) and Manchester, United Kingdom (September 1999).

The major objective of this series of conferences was the harmonisation of inspection and enforcement action under the provisions of Directive 90/219/EEC and overviews of the following actions were presented in line with this objective:

i. Exchange of relevant Internet site addresses and establishment of links with other relevant sites

ii. Exchange of current inspection checklists

iii. Joint inspection visits

iv. Preparation of a Newsletter

v. Preparation of a bibliography containing relevant literature

vi. Establishment of ad-hoc groups in relation to specific and universal problems

vii. Arrangement of periodic plenary meetings

viii. Compilation of a 'Who's Who' directory of inspectors

ix. .Exchange of information on risk assessment procedures/formats

x. Measures to increase the efficiency of inspections

xi. Detection of non-notified activities

Reports were produced following each conference and detailed the action points, discussion and conclusions.

7. PROBLEMS WITH INTEPRETATION OF THE PROVISIONS

Belgium

A number of problems were reported with respect to interpretation of the provisions of the Directive:

– With regard to the definition of contained use, it was suggested that there are certain cases where storage of GMMs or GMOs only involves transport or distribution with no intermediary use. In such cases, it is reported that applying fully the provisions of the regulations would lead to an unnecessary administrative burden and disproportionate safety measures considering the lack of risk from such activities. Consequently, it was proposed that such operations, in accordance with Article 5 of the Directive, should be declared but not notified to the extent of operations that include use. Such a declaration would be assessed by the SBB but managed under transport regulations.

– There has apparently been a lack of understanding amongst users concerning the distinction between Type A/B operations. Moreover, industry raised concerns regading differences between the two types of operation in terms of procedural requirements (and corresponding delays), particularly where rapid approval was sought.

– In relation to risk assessment, the SBB has been provided with poor and limited scientific information by notifiers. It was suggested that this is due, at least in part, to the structure and content of Annex III of Directive 90/219/EEC, which does not provide real tools for risk assessment. It is hoped that Annex III of the revised Directive will contribute to improve the quality of the assessment and will speed-up the reviewing and authorisation procedures.

– There have been problems concerning recycling of residual materials from industrial operations and further delivery of products to third parties, namely if Directive 90/220/EEC or other regulations should be applied to residual materials or not. The distinction between products and recycled residual materials is not clear, such as the use of 'fermenter cakes' in agriculture as soil amendments. If there is a requirement under Directive 90/219/EEC to inactivate wastes by validated means, it is assumed that inactivation does not mean that all organisms have to be killed. It was suggested that such problems would be amplified under the revised Directive 98/81/EC. Indeed, at containment level 1, inactivation of waste is foreseen as optional but waste has to be contained. Clarification was requested with respect to interpretation of 'containment' and 'inactivation' in the context of the Directive and in particular their 'boundaries'.

Finland

A request was made for provision of guidelines for the commercial contained use of GMMs as well for gene therapy trials.

France

The only issue of concern is where an overlap of competence could occur between Directive 90/219/EEC and Directive 90/220/EEC for clinical trials involving gene therapy for which both two directives apply. Whilst Directive 90/219 would apply to containment trials in hospital room, Directive 90/220/EEC applies for patients in the open environment.

Germany

A uniform and objective application of the provisions is ensured through the involvement of the Länder Committee for Genetic Engineering (LAG), which is a consultative and decision making body of the Länder dealing with questions of interpretation of the provisions under the Genetic Engineering Law. Moreover, the ZKBS examines and evaluates safety- related questions on the basis of the provisions of the Law and advises the competent authorities.

Spain

No disagreements have arisen regarding interpretation of the provisions of Directive 90/219/EEC in relation to 90/220/EEC. The only discrepancy has been that the National Biosafety Commission has viewed operations involving gene therapy clinical trials with GMMs as deliberate releases. According to the Bio-safety Commission, containment conditions are not fulfilled when patients taking part in these clinical trials enter and leave facilities and as a result it is not possible to ensure that GMMs are contained.

Sweden
A number of problems with interpretation of the provisions of the Directive were reported:

– A number of the terms in Annex 1, for example transformation and mutagenesis, are often interpreted in different ways and this may lead to uncertainty regarding exemption from the Directive.

– There have been problems interpreting which of the provisions are applicable when GMMs, intended for contained use only, are placed on the market or made available to others.

– Interpretation of Type B activities may differ between authorities.

– The interpretation of contained use is not always clear other than that physical containment is required. There have been discussions concerning the interpretation of contained use in relation to clinical trials.

United Kingdom
Interpretative difficulties experienced in the UK revolve around the following:

– Lack of a common understanding of risk assessment;

– lack of comprehensive containment tables – especially with measures suitable for laboratory scale activities;

– classification - using type A/B and Group I/II – which are not wholly risk based and are difficult to decide in some cases;

– need for some technical updating of the annexes to reflect developments in the technology.

It was noted that these aspects have been addressed by revision of the Directive.

8. PUBLIC CONSULTATION AND INFORMATION

Austria
The competent authority is required to carry out a consultation procedure for first time, large-scale operations at safety levels 2 and 3 and for all operations at safety levels 4. No consultation procedures have, as yet, been carried out.

Belgium
A common language “public dossier” is submitted by the notifier in addition to their technical dossier and is made available through public hearing. All decisions are available to the public for a period to allow for the introduction of appeals. The SBB has an Internet site entitled “Belgian Biosafety Server”, which provides the public with information on general scientific and administrative information.

Denmark
The National Forest and Nature Agency consult local authorities and any other interested parties before giving an approval on production applications. Notifications that have been granted are published in local and national newspapers. Appeals against decisions may be submitted to the Environmental Appeal Board within four weeks of the publication.

All activities relating to genetic engineering in Denmark are recorded in the Labour Inspectorate and the National Forest and Nature Agency's joint product register. The public can have access to the register on application under the rules of the Danish Law on public access.

Finland
To date, no public consultations have been carried out although the Advisory Board provides information to the public through the likes of Internet sites and publications.

France
Installations holdings Group II, risk class 3 and 4 consents, provide their local town council with a public information file approved by the relevant Ministry. This file contains information on the proposed use and nature of the GMM's, and also on measures in the event of an accident.

Germany
The Genetic Engineering Law stipulates that decisions concerning level 3 and 4 operations for commercial purposes (Group II, Type B) must be preceded by a public consultation procedure. This is also the case for level 2 commercial operations, where an approval procedure is necessary under section 10 of the Federal Emission Protection Law. In addition, the approvals for genetic engineering installations at levels 2 to 4 (Group II, Type A and B) for commercial and research purposes must be published in official gazettes and in regional newspapers.

The public can obtain information on genetic engineering operations and installations in Germany via a number of different means:

– annual activity reports published by the ZKBS

– overviews of genetic engineering operations and installations published by the RKI and the Bavarian State Ministry for Regional Development and Environmental Questions

– reports from the Federal Government on the experience with the Genetic Engineering Law

– access to environmental information held by the authorities in accordance with the Law on Environmental Information

– the authorities involved in the approval procedure provide information on request

Ireland
A register of GMM/GMO users is available at the Environmental Protection Agency Headquarters for inspection by any member of the public. In addition, the Agency's Internet site provides the public with information on the Regulation of the contained use and deliberate release of GMMs and GMOs in Ireland.

Luxembourg
Under national legislation, consultation of the public is envisaged prior to the first use of GMMs/GMOs, which meet the criteria applicable to the category of uses that pose an average or high risk to human health or the environment. At present, only contained uses meeting the criteria laid down in Risk Group I are envisaged.

The Netherlands
A list of the issued licences is published and made available to the public. Further information can be requested from the Competent Authorities, who prepare and transmit a dossier containing non-confidential information. Notifications under Article 10.2 of Directive 90/219/EEC are stored in the library of the Ministry and are directly accessible to the public in their entireties.

Spain
Non-confidential information contained in applications is made available to the public via the Ministry's Internet site. Operations with a high risk for human health and environment must be submitted for public scrutiny although to date, no operation has been considered in this light by the National Bio-safety Commission.

Sweden
To date, the public has only been provided with general information and there has been no consultation for specific cases.

United Kingdom
Under the 1992 national regulations, information with respect to contained use activities subject to consent is required to be placed on a public register. These information requirements are in accordance with Article 19.4 of the Directive and registers are held at local and head offices of HSE. Similar arrangements apply for the Northern Ireland 1994 Regulations and information is held at the office of HSENI in Northern Ireland. In addition, any non-confidential information that has been notified is disclosed to members of the public on request.

9. ACCIDENT AND EMERGENCY PLANS

Austria
Emergency plans are included as part of the notifications, submitted to the competent authorities, for Type A operations at safety levels 3 and 4 and Type B operations at safety levels 2, 3 and 4. Local administrative authorities and fire services must also be informed of safety instructions and measures for inactivation of GMM/GMOs escaping from containment. Consents are not granted if emergency plans are not submitted.

Belgium
Both Flemish and Brussels regional regulations implementing Directive 90/219/EEC require that emergency plans are submitted in cases of Type B operations at risk classes 2, 3 and 4. Under the Wallonian regulations, the requirement for emergency plans is restricted to operations at containment levels 3 and 4.

Denmark
Accident and emergency plans are not required for low risk plants, but there are instructions for procedures in the case of an accidental spillage of GMM/GMOs. In these circumstances, a series of measures take effect in accordance with Article 15 of the Directive.

Finland
According to Finnish legislation, emergency plans must be drawn up. In the case of an accident, the user is required to inform the Board immediately.

Germany
Accidents and unforeseen incidents must be notified to the competent authorities of the Federal Länder, which in turn inform the RKI.

Under the 1997 Genetic Engineering Emergency Regulations, the competent authority must draw up an external emergency plan for genetic engineering operations at safety levels 3 and 4. Should a potential accident affect other states, the implementation of emergency measures must additionally be agreed with those states. Information on emergency plans must be accessible to the public.

Ireland
Contained users are required to draw up emergency plans, where a risk assessment shows that an accident would create a significant risk to human health or the environment or where required by the competent authority. The plan should be drawn up in consultation with emergency services and in such a manner as may be specified by the competent authority to ensure protection of human health and the environment outside the facility. Notifiers of contained use facilities for Group I Type B and Group II GMM work are required to have emergency plans in place.

Italy
Emergency plans should be drawn up in consultation with emergency services, local authorities and relevant parts of the health service network. All individuals on site, including visitors, who may need to be evacuated in the case of an emergency, should be aware of its provisions. In the event of an accident, the user is required to inform the Ministry of Health. The information requested should contain at least the information mentioned in Article 15 of the Directive.

Portugal
Accident and emergency plans are included as part of the notification submitted to the competent authority.

Sweden
Accident plans are required with respect to all Group II activities. Emergency plans are considered necessary only for activities at safety level 3 or for large-scale activities at safety level 2. No such activities have as yet been notified.

United Kingdom
Emergency plans are required where the risk assessment demonstrates that there is a risk to human health or the environment. The plan has to be prepared in consultation with emergency services, other relevant bodies and the public who might be affected. In addition, it must be ensured that everyone employed at the premises is aware of the plan and its contents. Even where emergency plans are not required, users are encouraged to inform the emergency services of the nature of any potentially harmful organisms. There have been no cases where emergency plans have had to be implemented.

10. PROTECTION OF CONFIDENTIAL INFORMATION

Austria
Claims for commercial confidentiality can be accepted by the competent authority as part of the notification procedure.

Belgium
In accordance with Article 19 of the Directive, the regional regulations give the notifier the possibility to indicate which information should be kept confidential for reasons of commercial competitiveness. The SBB makes a decision at to the commercial confidentiality of information on the basis of a justified proposal.

Denmark
Competent authorities consider, on a case by case basis, which information should be kept confidential under the regulations in force.

Finland
Confidential information is not divulged to third parties. The information requirements under Article 19.4 of Directive 90/219/EEC are not considered confidential under the Finnish Act.

France
Confidential information is maintained and archived in secure premises. Experts examining such information must commit to maintain confidentiality.

Germany
Confidential information included as part of the notification procedure is made available only to relevant parties involved. Consideration must be given to Article 19.4 of the Directive, which states that certain information must not be kept confidential. As in the previous report of 1995, there were no reports of any problems in dealing with confidential information.

Ireland
Requests for confidentiality must be supported by a full justification and if approved, are respected with the exception of information provided under Article 19 of the Directive. Confidential information is stored separately from the notification and may only be assessed by employees who have signed a declaration to respect confidentiality.

Italy
The notifier may request that information, other than that under Article 19.4 of the Directive, be kept confidential on the grounds of commercial interests. The request for confidentiality to the Ministry of Health must be accompanied by full justification.

The Netherlands
Policy is to limit confidentiality of information, which must be justified in terms of protection of commercial or scientific interests, to a minimum. The competent authority decides in response to a written request whether data can or can not be kept confidential.

Portugal
Confidential information is not divulged to third parties in accordance with the regulations in force.

Spain
The Ministry for the Environment has the necessary means and resources to guarantee confidentiality.

Sweden
The provisions of Article 19 of the Directive have been incorporated into the Swedish legislation concerning protection of confidential information. There has been some uncertainty about the interpretation of confidentiality within the authorities, particularly with respect to the potential release of products from research and clinical trials.

United Kingdom
Claims for commercial confidentiality or intellectual property rights must be supported by a full justification, which if accepted by the competent authority will be respected. This does not, however, apply to information submitted under the requirements of Article 19.4 of the Directive. Decisions on confidentiality may be reviewed periodically and if the justification is no longer valid, the information could be disclosed. In addition to the information placed on the public register, members of the public may request disclosure of any notified information. This information will be disclosed under the UK Government's policy on openness unless confidentiality is agreed.

11. WASTE DISPOSAL

Austria

Safety level 1: All GMOs must be disposed of harmlessly and release of exhaust gases from large-scale operations must be prevented by appropriate measures.

Safety level 2: Waste and wastewater containing GMOs of risk group 2 must be inactivated before disposal. Release of exhaust gases is minimised at small-scale operations; at large-scale operations they must be restricted to a minimum and uncontrolled releases of GMOs must be prevented.

Safety level 3: Waste, wastewater and exhaust gases must be sterilised within the installations.

Transgenic plants, soil and culture mediums must be rendered incapable of propagation before disposal. Wastewater from operations involving transgenic plants at safety level 2 must be inactivated and airborne dispersal of pollen and seeds prevented. The bodies of transgenic animals from safety level 2 and higher are incinerated and their excrement, bedding and cages sterilised before disposal.

Belgium
All types of GMMs must be inactivated prior to disposal. Non-intentional release of GMMs must be minimised but if bio-hazardous, leaks must be prevented. According to the experience of the SBB, inactivation of waste does not require that all organisms have to be killed. For large-scale production, controls are carried out to check that numbers of viable micro-organisms in the treated waste stream does not exceed specific acceptable levels established by the risk assessment.

There is no systematic monitoring of inactivated effluents and wastes in Belgium. It is usual that fermenter cakes resulting from large-scale production of Group I GMMs are reused in agriculture as soil fertiliser after inactivation.

Finland
All waste must be inactivated prior to disposal.

France
In all cases, including activities at risk class 1, effluents and wastes have to be inactivated before disposal.

Germany
In principle, waste must be inactivated prior to disposal, but in specific cases for operations at safety level 1, deregulation is possible. The Genetic Engineering Law lays down different requirements regarding disposal of harmless waste and wastewater, including animal carcasses and plant waste as well as disposal of equipment and filters from genetic engineering installations. Distinction is made between chemical and physical inactivation methods and certain requirements regarding the inactivation procedure, such as temperature and residence time in the case of thermal process, depending on the potential risks posed by the organisms used and the location of the inactivation process.

Ireland
All GMM-contaminated liquid/solid waste must be decontaminated before disposal. Contaminated materials undergoing decontamination at a site other than the laboratory must be placed in a leak-proof container prior to removal from the laboratory. To date the Irish competent authority is not aware of any failure on behalf of the user to decontaminate waste prior to disposal.

Spain
Treatment and management of waste are covered by national measures and by regulations laid down by the Autonomous Communities.

Sweden
All waste has to be inactivated before disposal from the contained use.

United Kingdom
Legislation requires that contact between GMMs and the general population and environment is limited. The Regulations recognise three types of waste, each of which has slightly different requirements for disposal:

– Exhaust gases need not to be treated at containment level 1, requires treatment to minimise release at level 2 and treatment to prevent release at levels 3 and 4.

– Waste from hand wash basins, showers etc. need not be inactivated at containment levels 1 and 2. Inactivation at level 3 is on a case by case basis depending on the risk and there is a requirement to inactivate at containment level 4.

– Waste such as spent media, cultures and other significantly contaminated material (pipettes, glassware, filters etc.) from hazardous GMMs has to be completely inactivated before disposal. Waste from activities involving GMMs of negligible risk has to be inactivated prior disposal, but the degree of inactivation may not need to be 100% in all cases.

12. PROGRESS WITH THE TRANSPOSITION OF DIRECTIVE 98/81/EC INTO NATIONAL LEGISLATION

Austria
At the time of this report, the Federal Ministery for Women’s Affairs and Consumer Protection were dealing with the transposition.

Belgium
A working group was organised by the Flemish Region for revision of the Flemish degree on contained use with regard to the provisions of Directive 98/81/EC. Proposals from the Flemish Region, the SBB, industry, bio-safety experts and local bio-safety committees have been submitted for discussion by the Regions in the framework of the Co-operation Agreement.

Denmark
Competent authorities are working on the transposition. No legal amendments will be required, but Orders issued pursuant to the Law on the environment and genetic engineering will have to be amended. Implementation of the provisions was finalised before the deadline.

Finland
Transposition of Directive 98/81/EC required amendment of the Act. The amendments were presented to the Finnish Parliament by the end of 1999 and brought into force on 5 June 2000.

France
The legal text arising from the transposition of the Directive 98/81/EC into French law is currently being validated by in the Minister of the Research and will be submitted to other competent Ministers at the beginning of autumn 2000. The implementation of Directive 98/81 should not present a problem insofar as protocols for classification in the Directive are already implemented.

Greece
Transposition of Directive 98/81/EC into national law was underway at the time of the report but has not as yet been completed. It was considered expedient to hold open consultations with Universities and Research Institutes that are involved with contained use activities as a means to determine the appropriate implementation of the new Directive. It is hoped that the consultations will lead to the formation of an effective and reliable mechanism of notification evaluation and inspections.

Germany
The Federal Government has established the basis for transposing Directive 98/81/EC into the national law. The Federal Ministry for Health is currently drawing up a draft report.

Ireland
The Directive is currently undergoing transposition into Irish law.

Luxembourg
Directive 90/219/EEC will be transposed into national law under the Law of 13 January 1997 concerning the control of use and release of genetically modified organisms. This Law has been supplemented by the following regulations:

Grand-Ducal Regulation of 17 February 1997 determining the organisation and mode of operation of the Inter-Ministerial Committee provided for in Article 29 of the Law of 13 January 1997 concerning the control of use and release of genetically modified organisms.

Grand-Ducal Regulation of 17 March 1998 determining the information to be provided in applications for the authorisation of projects involving the deliberate release into the environment of GMOs and for the authorisation of projects for the marketing of GMOs.

Grand-Ducal Regulation of 12 June 1998 concerning the labelling and packaging of products consisting of genetically modified organisms or containing such organisms.

Grand-Ducal Regulation of 6 December 1999 laying down criteria for the classification of genetically modified organisms and their uses and defining safety measures and methods of containment relating to such uses.

Grand-Ducal Regulation of 10 March 2000 determining the information to be provided in applications for the authorisation of projects involving the contained use of genetically modified organisms.

Directive 98/81/EC will be transposed into national law mainly through the introduction of amendments to the Grand-Ducal Regulation of 6 December 1999 laying down criteria for the classification of genetically modified organisms and their uses and defining safety measures and methods of containment relating to such uses. It should be stressed that Annex IV to Directive 98/81/EC (Containment and other protective measures) is already an integral part of this Grand-Ducal Regulation.

The Netherlands
The Ministry of Environment is preparing to adapt the Decree on genetically modified organisms in line with Directive 98/81/EC.

Portugal
The Directive was under transposition at the time of the summary report although the date of the publication in the Official Gazette could not be predicted.

Spain
Work is currently in progress to transpose the Directive, which requires amendment of Law No 15/1997 and Royal Decree No 951/1997.

Sweden
An analysis on the need for amendments has been undertaken. The necessary amendments were completed by 5 June 2000.

United Kingdom
During consultation with respect to the proposed draft Regulations, the removal of the Group I/II and Type A/B classifications system in particular was strongly supported. The new direct link between risk assessment, containment, control measures and activity classification were well received and so were the new risk assessment procedures. There was some criticism concerning the balance between protection of confidential information and the public's right of access to the information notified and also to the proposed requirements to inactivate all culture media waste (except hand wash basin waste or exhaust gases) from class 1 activities prior to disposal.

The new Northern Ireland Regulations have been issued for consultation and were expected to come into force at about the same time as the proposed Great Britain Regulations.