Survey on the implementation of Directive 2009/41/EC

regulations in Europe on the contained use of genetically modified organisms

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Colophon

Title:	**Survey on the implementation of Directive 2009/41/EC** ***regulations in Europe on the contained use of genetically modified organisms***
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Preface

The authors of this report warmly thank all those who have provided us with information and their insights. Without their cooperative assistance we would not have been able to collect the vast amount of valuable information and relevant viewpoints for this survey.

We hope that results of this survey will contribute to revitalising the exchange of experiences between the Competent Authorities in this field.

Ameco Environmental Services, Utrecht, The Netherlands
Horizons sprl., Lasne, Belgium

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Contents

List of abbreviations

BSO	–	Biosafety Officer
CA	–	Competent Authority
CEN	–	European Committee for Standardization
COGEM	–	Netherlands Commission on Genetic Modification
EC	–	European Community
EEC	–	European Economic Community
EEP	–	European Enforcement Project
EU	–	European Union
IBC	–	Internal Biosafety Committee
IBS	–	Internal Biosafety System
GM	–	Genetic modification / genetically modified
GMM	–	Genetically modified micro-organism
GMO	–	Genetically modified organism
OECD	–	Organisation for Economic Co-operation and Development
WHO	–	World Health Organisation

Executive summary

The efficacy and credibility of biosafety regulations depend largely on the extent to which the rules are proportional to the levels of risk involved. Therefore, both 'under-' and 'overregulation' are to be avoided as much as possible. For this purpose, the Netherlands Commission on Genetic Modification (COGEM) established a Working Group on Deregulation to look at such issues.

To support the work of this Working Group, COGEM commissioned Ameco and Horizons to conduct a survey on the implementation of EU Directive 2009/41/EC on the contained use of genetically modified micro-organisms (GMMs). While the scope of the Directive is limited to GMMs, the scope of the survey also included genetically modified plants and animals.

The survey was conducted in 11 EU Member States, with the aim to identify commonalities and differences in the implementation of the Directive in terms of: procedures; administration; substantive requirements; and enforcement. The survey comprised desk research, questionnaires, telephone interviews, followed by face-to-face interviews in 8 Member States with representatives of Competent Authorities (CA), inspectorates, advisory bodies, Internal Biosafety Committees and applicants.

The main conclusions of the survey are:

1. There are many commonalities as well as some significant differences in the procedural, administrative and technical implementation of Directive 2009/41/EC in the 11 Member States.
2. In general, the representatives of CAs, advisory bodies, inspectorates and applicants interviewed in the 11 Member States are of the opinion that the procedures and technical requirements for contained use of GMMs and GMOs in their Member States do not pose insurmountable challenges.
3. There is nevertheless a general consensus amongst the interviewed that there are various topics where there is a need for further clarification, updating to technical and scientific advancements, and/or further harmonization on the European level.

Specific findings of the survey include:

- In most regulatory systems, the definitions used are the same or similar to the corresponding definitions in Directive 2009/41/EC.

- However, the interpretations of some of those definitions differ between Member States, and sometimes even within Member States. Elements that were suggested as deserving further clarification, updating and/or harmonisation include: the definition of terms as 'GMO', 'inactivation', and 'accident'.
- Little, if any, use is made of the existing exemption of self cloning. The possibility to define more exemptions under the Directive (i.e. Article 3(b)) is not widely known. Applicants who are familiar with this possibility believe that the information that needs to be submitted to obtain an exemption is too case-specific.
- There are significant differences in the procedural requirements. Some Member States have applied the same procedures as in Directive 2009/41/EC, while other Member States have established procedures that go significantly beyond the procedures of the Directive, e.g. in some Member States notifications or permits are required in cases where the Directive does not require a notification or permit. The transposition of the key procedure articles 6, 7, 8 and 9 of the Directive in the national legislation of the involved Member States is summarized in Table 18 in Chapter 4 (page 70) of this report.
- Generally, the classification and the related procedures do not cause insurmountable obstacles. However, there are some concerns, which focus on a) unnecessary procedural requirements for class 1; and b) technical requirements for class 2.
- There is a desire for more harmonization regarding BSOs and IBCs within the EU, taking into account also the work that is conducted by the European Committee for Standardization (CEN).
- In most cases, risk assessments are conducted on a case-by-case basis, based on the proposals by the applicants. In two countries a standardized system of assigning containment levels is available for applicants.
- Most of the challenges and discussions on containment requirements seem to focus on class 2, and in particular in the 'high end' of class 2 (see footnote #55 – page 48).
- In general, CAs do not receive many reports of accidents, and only in very few cases are accidents reported to the European Commission. Suggestions were made to initiate a discussion on EU level on the definition of accidents and the purpose of reporting accidents.
- There are significant differences between Member States in the way inspections are organised.

In light of the above, one of the key recommendations of virtually all representatives interviewed in this survey, is to revitalise the CA meetings at EU level to take stock of the experiences gained over the past years in the various Member States and to further harmonize the implementation of the Directive.

Nederlandse samenvatting

De werkzaamheid en geloofwaardigheid van regelgeving op het gebied van bioveiligheid hangt met name af van de mate waarin de voorschriften zich verhouden tot de risiconiveaus. Derhalve dient zowel 'onder-' als 'overregulering' zoveel mogelijk te worden voorkomen. Met dit doel heeft de Nederlandse Commissie Genetische Modificatie (COGEM) een werkgroep op het gebied van deregulering opgezet om te kijken naar dergelijke kwesties.

Vervolgens heeft de COGEM opdracht gegeven aan Ameco en Horizons om onderzoek te doen naar de implementatie van EU Richtlijn 2009/41/EG inzake het ingeperkte gebruik van genetisch gemodificeerde micro-organismen (ggm's). Hoewel de werkingssfeer van de Richtlijn beperkt is tot ggm's, richtte het onderzoek zich op alle genetisch gemodificeerde organismen (ggo's).

Het onderzoek richtte zich op 11 lidstaten van de EU, met als doel het identificeren van overeenkomsten en verschillen in de wijze waarop de Richtlijn wordt uitgevoerd. In het bijzonder met betrekking tot de volgende onderwerpen: procedures; administratie; verplichtingen; en handhaving. Het onderzoek bestond uit een combinatie van deskresearch, enquêteformulieren en telefonische interviews, gevolgd door persoonlijke interviews in 8 lidstaten met vertegenwoordigers van het bevoegd gezag, inspecties, adviesorganen, interne bioveiligheidscommissies en aanvragers.

De belangrijkste conclusies van het onderzoek zijn:

1. Er zijn veel overeenkomsten en een aantal aanzienlijke verschillen in de procedurele, administratieve en technische implementatie van Richtlijn 2009/41/EG in de 11 EU-lidstaten.
2. De ondervraagden zijn van mening dat de procedures en technische voorschriften voor het ingeperkt gebruik van ggm's en ggo's in hun landen geen onoverkomelijke uitdagingen met zich brengen.
3. Er is een algemene consensus onder de geïnterviewden dat er verschillende onderwerpen zijn waarbij behoefte is aan verdere verduidelijking en harmonisatie op Europees niveau, en tevens dat deze op peil dienen te worden gebracht met de technische vooruitgang en nieuwe wetenschappelijke inzichten.

Meer specifieke bevindingen uit het onderzoek zijn de volgende:

- In de meeste regelgevende systemen zijn de gebruikte definities gelijk of nagenoeg gelijk aan de overeenkomstige definities van Richtlijn 2009/41/EG.

- Echter, de interpretatie van een aantal definities verschilt tussen de lidstaten en soms binnen de lidstaten zelf. Elementen die verdere verduidelijking en harmonisatie behoeven zijn onder andere de definities van termen als 'ggo', 'inactiveren' en 'ongeluk'.
- Er wordt weinig tot geen gebruik gemaakt van de bestaande vrijstelling van zelfklonering. De mogelijkheid om meer vrijstellingen te definiëren aan de hand van de Richtlijn (artikel 3 (b)) is niet algemeen bekend. Aanvragers die wel vertrouwd zijn met deze mogelijkheid zijn van mening dat de informatie die moet worden voorgelegd om een vrijstelling te verkrijgen te case-specifiek is.
- Er zijn significante verschillen in de procedurele vereisten: sommige lidstaten hebben dezelfde procedures toegepast als in Richtlijn 2009/41/EG, terwijl andere lidstaten procedures hebben ingevoerd die aanzienlijk verder gaan dan de richtlijn. Zo is in een aantal lidstaten een notificatie of een vergunning nodig voor bepaalde activiteiten, terwijl de richtlijn in die gevallen geen notificatie of vergunning verplicht stelt. De omzetting van de procedurele sleutelartikelen 6, 7, 8 en 9 van de Richtlijn in de nationale wetgeving van de betrokken lidstaten is samengevat in tabel 18 in hoofdstuk 4 (pag. 70) van het rapport.
- In het algemeen leiden de classificatie en de daarmee samenhangende procedures niet tot onoverkomelijke obstakels. Er is echter enige bezorgdheid die zich richt op a) onnodige procedurele eisen voor klasse 1 activiteiten, en b) de technische eisen voor klasse 2 activiteiten.
- Er is behoefte aan meer harmonisatie met betrekking tot biologischeveiligheidsfunctionarissen en interne bioveiligheidscommissies binnen de EU; dit in het licht van het werk dat wordt uitgevoerd door de Europese standaardiseringsorganisatie CEN.
- In de meeste gevallen worden risicobeoordelingen per aanvraag apart uitgevoerd, op basis van de voorstellen van de aanvragers. In twee landen zijn gestandaardiseerde inschalingsartikelen beschikbaar voor aanvragers.
- De meeste uitdagingen en discussies met betrekking tot inperkingsveresiten lijken te richten op klasse 2, en dan met name op klasse 2 ‘hoog’ (zie voetnoot # 55 – pag. 48).
- In het algemeen ontvangen de competente autoriteiten weinig meldingen van ongelukken, en slechts enkele autoriteiten melden ongelukken aan de Europese Commissie. Een aantal suggesties is gedaan om een discussie op EU-niveau te initiëren over de definitie van ongelukken en het beoogde doel van het melden hiervan.
- Er zijn significante verschillen in de manier waarop de lidstaten inspecties organiseren.

De belangrijkste aanbeveling is om de CA-bijeenkomsten op EU-niveau nieuw leven in te blazen, teneinde de balans op te maken van de ervaringen die de afgelopen jaren zijn opgedaan in de verschillende lidstaten en ten behoeve van de verdere harmonisatie van de uitvoering van de Richtlijn.

1 Introduction

1.1 Background

The efficacy and credibility of biosafety regulations depend on the extent to which the rules are proportional to the levels of risk involved. Therefore, both 'under-' and 'overregulation' are to be avoided as much as possible, in order to ensure an adequate level of safety, understanding and acceptance in daily practice, and to avoid unnecessary administrative burden. For this purpose, the Netherlands Commission on Genetic Modification (COGEM) established a Working Group Deregulation (*'Werkgroep Deregulering'*) to look at such issues.

Alerted through informal contacts that there may be substantial differences between Member States in the regulation of contained use of genetically modified organisms (GMOs) in EU Member States, COGEM decided to conduct a survey on the legal and practical implementation of Directive 2009/41/EC. While the scope of the Directive is limited to genetically modified micro-organisms (GMMs), the scope of this survey includes genetically modified plants and animals as well.

COGEM assigned Ameco and Horizons to conduct this survey in a representative selection of EU Member States.

Note: when the term 'GMO' is used in the report, it implies GMMs as well as GM plants and animals.

1.2 Methodology

A selection of 11 Member States was made to include large- and small size Member States as well as Member States with a centralised- and a decentralised governmental system.

The following Member States were included in the survey:

1. *Austria*
2. *Belgium*
3. *The Czech Republic*
4. *Denmark*
5. *France*
6. *Germany*
7. *The Netherlands*
8. *The Slovak Republic*
9. *Spain*
10. *Sweden*
11. *United Kingdom*

As a start of the survey, representatives of the CAs of these Member States were asked to complete a brief questionnaire with a set of general questions (see Annex 1). Subsequently, telephone interviews were held to discuss in more detail the implementation of Directive 2009/41/EC in the respective national regulatory frameworks. For this purpose, a matrix was developed, comprising a number of questions regarding important articles in the Directive (see Annex 2).

In the next phase, 8 Member States were visited for face-to-face interviews with representatives of the CAs, inspectorates, advisory bodies, and applicants, where possible through Internal Biosafety Committees (IBCs) and/or Biosafety Officers (BSOs). The face-to-face interviews were held in Austria, Belgium, Denmark, France, Slovakia, Sweden, The Netherlands, and the United Kingdom.

The results of the survey are presented per Member State in Chapter 3, whereby the results of the interviews with applicants are combined in a separate section. In Chapter 4, the main conclusions drawn from this survey are presented and the transposition of the key articles 6, 7, 8 and 9 of Directive 2009/41/EC in the national legislation of the involved Member States is summarized.

Where available, this report offers links to publicly available documents.

2 EU regulation on contained use of GMOs

Following the international debate in the 1970s on the safety of – as it was then called – work with recombinant DNA (rDNA) organisms, several European countries established national regulations for rDNA work in the late 1970s (e.g. The Netherlands, 1979) and early 1980s (e.g. Denmark, United Kingdom).

In a recommendation in 1982[1], the Council of the European Communities recognized the importance of harmonization of national provisions, and called upon member states to provide information on national approaches.

The publication in 1986 of the *OECD Blue Book* with recombinant DNA safety recommendations and of the US coordinated framework revitalised the debate in the European Community about the need for harmonization of biosafety regulations in the EU. The European Commission produced the first outlines of EC Directives on GMOs in 1987. Much of the content of these drafts, including definitions and basic principles such as 'case-by-case' and 'step-by-step', were based on the discussions that lead to the OECD Blue Book.

The drafts were discussed between the Member States and the Commission in the years that followed, resulting in the adoption of two Directives in 1990:

- Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms.
- Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms.

Key elements of Directive 90/219/EEC:

- The legal basis of the Directive was the 'Environmental Protection article' of the Treaty of Rome;
- The objective was to lay down common measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment;
- The scope was contained use of genetically modified micro-organisms;
- The procedures were differentiated, based on levels of potential for risk:
  - Record keeping;
  - Notifications;
  - Permits.

[1] Council Recommendation of 30 June 1982 concerning the registration of work involving recombinant deoxyribonucleic acid (DNA) (82/472/EEC).

– Risk assessment and definition of levels of biosafety and containment.

Eight years after Directive 90/219/EC came into force, an amending Directive was introduced: Directive 98/81/EC. In this Directive, the terms 'contained use' and 'genetically modified micro-organism' were refined and the classification system was amended: Directive 90/219/EEC divided operations involving the use of GMMs into type A (small-scale operations for research, teaching, development and non-industrial or non-commercial purposes) and type B (all others); while GMMs themselves were classified as Group I or Group II according to their potential hazard. Notification procedures were based on the type of the activity and the Group of the GMM. However, this system was deemed too complex and insufficiently risk-based, and was thus amended by Directive 98/81/EC. The new system removed the Type A/Type B and Group I/Group II classifications and based notification on the outcome of a risk assessment (Institute for European Environmental Policy[2], 2010).

In November 2007, the Commission published a new proposal for a Directive on the contained use of GMMs (COM(2007)736). The intention of the proposal was to recast Directive 90/219/EEC, as amended by Directive 98/81/EC in order to allow the incorporation of necessary amendments and consolidate the earlier amended texts. The inclusion of the adjustment of the comitology procedure was the only new element in the recast Directive 2009/41/EC (see Annex 3), which was published in May 2009 (Institute for European Environmental Policy, 2010).

In 2009 and 2010, the functioning of the EU regulatory system for GMOs was evaluated. These evaluations primarily focussed on releases into the environment.

[2] www.europeanenvironmentalpolicy.eu/view/meep/MEEP_0906.xml

Box: EU Regulatory Framework – Background and History

1982 Council Recommendation 82/472/EEC, stressing the need for harmonisation

1986 Publication of the OECD Blue Book rDNA safety recommendations

1986 Publication of the US coordinated framework for regulation of biotechnology

1987 First outlines of EC Directives on GMOs

1990 EC Directives on GMOs:
- contained use of GMM (90/219/EEC) – 'Environment Directive'
- release of GMOs (90/220/EEC) – 'Internal Market Directive'

1996 *Gaining experience with EU regulatory system – steady increase in approvals since 1990*

1997 *Change in public attitude – decline of market approvals*

1998 Revision of Directive 90/219/EEC: Directive 98/81/EC
- amendments of the procedures, waste treatment
- add experience, e.g. list of exemptions of safe GMMs

1998 *'De facto' moratorium for market approvals*

1999 *The EU Council of Ministers proposes to:*
- *adopt more stringent rules for 'placing on the market'*
- *put in place rules on traceability and labelling*

2001 *Revised EC Directive 90/220/EEC: Directive 2001/18/EC*

2002 EU Strategy: Life sciences and biotechnology (COM(2002)27)

2003 *Regulations on Novel Food, Traceability and Labelling*

2009 Consolidation of changes in the Directive for contained use: Directive 2009/41/EC

2010 Review of the EU Regulatory system for GMOs

3 Results of the survey in Member States

3.1 Introduction

The survey addressed the following topics concerning the national implementation of Directive 2009/41/EC:

- *General, e.g. the number of contained use facilities/activities in the Member States, overall regulatory structure, CAs and advisory bodies*
- *Scope and definitions, including existing and (planned) exemptions*
- *General requirements, e.g. BSOs and IBCs*
- *Classes of activities and procedures*
- *Risk assessment and assignment of containment levels*
- *Public consultation*
- *Emergency plans and accidents*
- *Inspections*
- *Confidential information*

These categories are presented in the aforementioned matrix in Annex 2, which was used in the interviews.

In the following Sections, a summary for each Member State is given. The outcomes of the interviews with applicants are presented in Section 3.13.

3.2 Austria

Introduction

In Austria there are over 160 facilities in which contained use with GMOs is conducted, of which the vast majority is conducted with GMMs.

Directive 2009/41/EC is implemented in Austria by the Austrian Gene Technology Act (Gentechnikgesetz[3]), which entered into force in January 1995 and which has been amended in 1998, 2002, 2004 and 2005. The Act regulates contained use, deliberate release, placing on the market of GMOs and the application of biotechnology in human medicine (gene analysis and gene therapy). The Act has several implementing ordinances.

The Ordinance on Work with GMOs in Contained Use of 2002[4] regulates this part of the law in more detail, such as the procedure for risk assessment of GMOs, the necessary containment measures for laboratories according to classification and scale.

The responsibility for the implementation is shared between the Federal Ministry for Health[5] and the Federal Ministry of Science and Research[6].

The Act lays down the rules for the installation and work of the Advisory Board on Gene Technology (Gentechnikkommission) and its three scientific committees.

The Advisory Board has published a Book of Gene Technology[7], which documents the present 'state of the art' in the field of biotechnology and genetic engineering, taking into account the pace at which modern biotechnology is advancing. The book has the status of an expert opinion. If necessary, chapters of the book can be transformed into ordinances and thereby become binding.

Every 3 years, the Advisory Board sends a report[8] to Parliament regarding the implementation of the Act and the broader context.

Scope and definitions

The Act covers GMMs, GM plants and GM animals. The definitions in the Act are the same as the corresponding definitions in the Directive. The Act contains similar exemptions as the

[3] www.bmg.gv.at/cms/site/attachments/7/8/8/CH0817/CMS1226929588865/510_1994.pdf
[4] www.bmgfj.gv.at/cms/site/attachments/4/3/2/CH0817/CMS1085737053374/systemverordnung-2002.pdf
[5] www.gentechnik.gv.at
[6] http://bmwf.gv.at/startseite/forschung/national/forschungsrecht/gentechnik/
[7] www.bmgfj.gv.at/cms/site/standard.html?channel=CH0817&doc=CMS1201093533126
[8] www.bmgfj.gv.at/cms/site/attachments/2/1/3/CH0808/CMS1113215228099/vierter_bericht_der_gtk.pdf

Directive. Requests for additional exemptions in accordance with Annex II Part B and C have not been submitted.

General obligations

BSOs and IBCs are mandatory under the Act. An IBC must have external members. All planned contained use activities must be submitted to the IBC. Guidance[9] for IBCs and BSOs is available.

Classes of activities and procedures

The Act applies the classification of the Directive for GMMs.

Table 1: Procedures for first and subsequent GMM uses in Austria

	Class 1 GMMs		Class 2 GMMs		Class 3 + 4 GMMs	
	First use	**Subsequent use**	**First use**	**Subsequent use**	**First use**	**Subsequent use**
Requirement	Notify[10] + 30 or 45 days[11]	Start after IBC approval[12]	Notify + 30 or 45 days	Notify + start	Notify + permit	Notify + permit

For GM plants and animals the following applies:

Table 2: Procedures for first and subsequent uses of GM plants and animals in Austria

	GM plants – animals[13]	
	First use	**Subsequent use**
Requirement	Class 1: notify + 45 days	Class 1: start
	Higher class: permit	Higher class: notify + start

- Notifications are signed by the person who is legally responsible for the facility; for class 2 or higher notifications are also signed by the project leader.
- The CAs always respond in writing to notifications, either by a letter acknowledging receipt or by a decision document (e.g. a permit).
- Responses by the CAs are usually given within the legal time frames. As with the Directive, the clock stops when additional information is requested.

[9] www.bmgfj.gv.at/cms/site/attachments/5/3/9/CH0809/CMS1186058333103/informationen_fuer_beauftragte_fuer_die_biologische_sicherheit_(bbs)_und_den_projektleiter_sowie_das_komittee_fuer_die_biologische_sicherheit.pdf

[10] Notification to Ministry of Health or Ministry of Science and Research, depending on whether the applicant is private or public.

[11] First use may start after 30 days in case the notification is accompanied by a protocol from the respective IBC; in other cases after 45 days.

[12] These internal approvals are verified during inspections.

[13] When it concerns vertebrates, notification and permit requirements are linked to animal welfare legislation.

- Records of work in small scale class 1 and 2 must be kept at least 3 years after termination and 5 years in all other cases.
- Planned contained use activities by private sector companies are notified to the Federal Ministry of Health and planned activities by public sector institutes (e.g. universities) are notified to the Federal Ministry of Science and Research. Contained use activities with GM vertebrate animals also require authorization under the Law on protection of experimental animals[14] which is issued by the provinces (Länder).
- Electronic application forms and guidance documents are available on the website of the Federal Ministry of Health[15]. Final applications must be submitted in a signed hard copy.
- The CAs have regular contacts with applicants, which is considered very positive by all involved. The CAs sometimes hold instruction meetings with first time applicants. In cases where animals are involved, special attention is given to the relationship between contained use requirements and the animal welfare requirements. Work with animals (i.e. GM animals or activities with GMMs on animals) is mainly conducted by public research institutes.

Risk assessment and assignment of containment levels

The IBC of the applicant conducts – or verifies – the risk assessment and assigns the containment levels. The criteria for class 1 are laid down in Article 6 of the Act. Assignment for levels higher than class 1 is done on a case-by-case basis, for which guidance is available in the third chapter of the aforementioned Book of Biotechnology. Almost all notifications come to the right conclusions regarding the required containment level(s). In some cases there is communication between the CA and the applicant about the level of detail of the justification of the proposed containment levels.

Public consultation

The Ordinance on Public Hearings[16] has entered into force in 1997 and has been amended in 1998. It prescribes the administrative procedures that have to be followed in the cases required by the Gene Technology Act. These cases are: applications for deliberate release of GMOs into the environment and contained use of GMOs in higher classes and at large scale.

Emergency plans and accidents

Emergency plans have to be drawn up for class 2 (large scale) activities and class 3 and higher activities.

[14] http://bmwf.gv.at/fileadmin/user_upload/forschung/recht/tvgesetz.pdf
[15] www.bmgfj.gv.at/cms/site/standard.html?channel=CH0812&doc=CMS1086176168146
[16] www.bmgfj.gv.at/cms/site/standard.html?channel=CH0817&doc=CMS1086177626938

Accidents are only notified to the CA if they can result in significant risk for human health or the environment. Over the last 15 years, two accidents have been reported to the CAs.

Inspections

Inspections are conducted by the CAs, primarily focusing on class 3 and 4 activities. Inspection activities at the Ministry of Health involve 3 people who combined spent about 6 – 10 days per year on inspections. There is no formalized inspection plan.

Confidential information

Confidential information is treated in conformity with Directive 2009/41/EC. An estimated 50% of the notifications contain some confidential information.

3.3 Belgium

Introduction

In Belgium there are over 400 facilities that are approved for contained use with GMOs and/or pathogens[17].

Directive 2009/41/EC is implemented partly on the Federal level and partly on the regional level, in a harmonized framework of Laws, Decisions, Regulations and Guidelines. The three regions (Brussels, Walloon and Flemish Region) each have their own CA for contained use of GMOs. There are no regular meetings between these CAs. Detailed information about the Belgian regulatory framework can be found on the Belgian Biosafety Server[18].

The decisions made by different administrative bodies are based on a common scientific evaluation system comprising the Biosafety Advisory Council (BAC) and the Biosafety and Biotechnology Unit (SBB).

The BAC advises the competent authorities about the safety of any activities using GMOs and pathogens, including genetic and ecological aspects related to biodiversity. The Council can be consulted by the Regions or the SBB for contained use activities. The BAC must be consulted for the deliberate release of GMOs in the environment and the placing on the market of all GMOs and GMOs-based products. More information is available on the website of the Biosafety Advisory Council[19].

[17] In Belgium, the scope of the contained use regulation has been extended to non-GM human-, animal- and plant pathogens.
[18] www.biosafety.be/GB/LegGB.html
[19] www.bio-council.be

The SBB acts as biosafety expert for the CAs and as the secretariat of the BAC. The SBB is composed of an administrative secretariat and a multidisciplinary group of scientists. The SBB Expertise Laboratory, which recently separated from the SBB and became a unit on its own, coordinates the National Reference Laboratories (NRL) for GMO detection in Belgium and is involved in the development and validation of GMO detection methods.

This common advisory system is based on a Cooperation Agreement concerning Biosafety[20].

Directive 2009/41/EC has been transposed at regional level as a part of the regional environmental laws for classified installations.

Scope and definitions

The contained use regulations cover all GMOs. The definitions of GM, GMM and contained use are the same as the corresponding definitions in Directive 2009/41/EC. Given that in Belgium the scope of the contained use regulation has been extended to non-GM human-, animal- and plant pathogens, pathogens are also included in the definition of contained use.

The regional regulations contain the same exemptions as Directive 2009/41/EC. However, some exemptions have been added in the case of storage of GMOs of risk class 1: storage of GMOs in the frame of temporary exhibitions or for commercial purpose is excluded from the contained use regulation in the Brussels and Walloon region, but not in the Flemish Region. Requests for additional exemptions in accordance with Annex II Part B and C have not been submitted.

General obligations

The installation of BSOs is mandatory in all three regions. The CAs review the level of education prior to formally approving a BSO. The installation of IBCs is mandatory in Brussels and Walloon Region; not in the Flemish Region.

In all three regions, internal biosafety manuals are mandatory for each institute and are subject to screening during inspections.

Classes of activities and procedures

The regulations follow the Directive's classification of four risk classes and four containment levels for GMMs. Up to 2010, there have been no activities of risk class 4 or facilities of containment level 4 in Belgium. GM plants and animals are considered being risk class 1.

[20] www.biosafety.be/COOPAG/COOPAGEN.html

In Annexes to the regional decrees, containment requirements are described for laboratories, animal facilities, greenhouses, large scale facilities and hospital rooms (for gene therapy or vaccination with GMMs). For greenhouses and hospital rooms, only 3 containment levels exist.

Table 3: Procedures for first and subsequent GMM uses in Belgium

	Class 1 GMMs		Class 2 GMMs		Class 3 + 4 GMMs	
	First use	**Subsequent use**	**First use**	**Subsequent use**	**First use**	**Subsequent use**
Requirement	Notify + start	Notify + start	Permit	Notify + start[21]	Notify + permit	Notify + permit
Comments	Notify to CAs and SBB	Notify to SBB	Together with environmental permit for the installation	Notify to SBB	Together with environmental permit for the installation	Notify to CAs and SBB

For GM plants and animals the following applies:

Table 4: Procedures for first and subsequent uses of GM plants and animals in Belgium

	GM plants – animals	
	First use	**Subsequent use**
Requirement	Notify + start	Notify + start
Comments	Notify to CAs and SBB	Notify to SBB

- Notifications are signed by the legal representative of the applicant, the BSO, and the responsible user or researcher.
- For first use class 1 GMMs and first use GM plants and animals, the notification is submitted to the CA and the SBB.
- For subsequent use class 1 GMMs and subsequent use GM plants and animals: notifications are submitted to the SBB only. The SBB sends a letter to the involved CA, either confirming that the activity is indeed of risk class 1 or informing the CA in case there is a query with respect to the proposed risk class.
- For first use of class 2 and higher a permit is required, which is considered together with an environmental permit for the installation.
- For subsequent activities class 2: notifications are submitted to the CA and the SBB, whereby the notifier can request a written permit.

[21] Work may start the day after the notification is made, but the applicant can ask for a written authorization.

- For subsequent activities class 3 and higher, a permit is always required.
- Details of notification requirements vary per region.
- Electronic application forms and guidance documents are available on the website; applications must be submitted in hard copy in the language of the regional CAs.
- Regular contacts with applicants are practice and are considered very positive.

Risk assessment and assignment of containment levels

Risk assessment is conducted by the notifier on a case-by-case basis, resulting in a proposal for containment measures. Guidance documents are available online. The SBB analyses the risk assessment and the suitability of containment measures proposed by the notifier and specifies particular containment measures if needed for the activity in its advice to the CAs. For example, the SBB specifies whether the containment criteria in the annexes of the regional decrees described as 'optional' or 'recommended' are required for the activity. Experience shows that applicants in almost all cases come to the right conclusions regarding containment levels.

Public consultation

Public consultation takes place in the context of an 'environment permit' for the installation, but not for subsequent use.

Emergency plans and accidents

Requirements for emergency plans of the Directive have been transposed by the Ministry of Internal affairs. Emergency plans are required for large scale class 2, and class 3 and 4 applications of GMMs. The emergency plans are drawn up externally, i.e. either by the local community or by the regions, depending on the case.

Requirements in case of accidents are the same as in the Directive. Until now no accidents with GMMs have been reported to the CAs.

Inspections

Inspections are conducted by the environmental inspection services of the regions, and in the Flemish Region also by inspectors of the Human Health Supervision Department. The SBB often accompanies inspections to provide guidance.

In the period 2006-2009, 144 inspections were conducted by the inspectorates, of which the SBB participated in 44 inspections.

Confidential information

Confidential information is treated in conformity with Directive 2009/41/EC. There is a sense that the last few years less information is submitted as confidential compared to some years ago.

3.4 The Czech Republic

Introduction

In the Czech Republic, there are currently about 90 institutes that carry out contained use activities with GMOs.

The Czech Act on GMOs, which transposes Directive 2009/41/EC, covers all GMOs. The objective of the Czech legislation is the same as of the Directive. The Act is implemented by a Decree that deals with both contained use and deliberate release activities in the Czech Republic.

Complete texts of the Czech legislation on GMOs and other documents (in English) are published on the Czech Biosafety Clearing House[22].

The Ministry of the Environment of the Czech Republic is the CA under the Directive and has an expert advisory body – the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products – consisting of 17 members and 30 additional experts. If necessary, the Ministry of Health and the Ministry of Agriculture can be consulted in authorisation procedures as well.

Scope and definitions

The contained use regulations cover all GMOs. The definitions of GM and contained use are the same as the corresponding definitions in Directive 2009/41/EC. No separate definition of 'micro-organism' is included in the Act.

There is no exemption for self-cloning in the Act, because the definition of self-cloning in Annex II Part A of the Directive is considered ambiguous.

General obligations

The general obligations are the same as in the Directive. In addition, the Act requires every notifier/applicant to nominate a person as a 'professional consultant' who is in charge of

[22] www.mzp.cz/biosafety

elaborating or verifying the risk assessment, organising trainings for the staff, supervising the use of GMOs within the premises, etc.

Classes of activities and procedures

The Act incorporates a similar system of classes as the Directive. The Act is a bit stricter on some issues, namely a new notification is required every time a GMO is to be used for the first time (not only in case of new premises). This rule applies to all classes of contained use.

The aim is to enable the CA to check the risk assessment provided by the notifier together with the resulting assignment of the containment level, before or shortly after commencement of the activities. In this way, potential errors in classification can be identified.

Table 5: Procedures for first and subsequent GMO uses in the Czech Republic

	Class 1		Class 2		Class 3 + 4	
	First use	**Subsequent use**	**First use**	**Subsequent use**	**First use**	**Subsequent use**
Requirement	Notify + start	Notify + start	Notify + 45 days	Notify + start	Notify + permit	Notify + permit

- Class 1 activities may commence after the notification is submitted.
- Class 2 activities may start 45 days after the submission of the notification, in absence of any objections from the CA, or it may begin earlier upon an agreement with the CA. This time limit enables experts of the CA to review the risk assessment.
- Class 3 and class 4 activities may only commence on the basis of a permit – issued by the CA. The administrative procedure for granting the consent for contained use is laid down in the Act on GMOs and is similar to the procedure for authorisation of deliberate release of GMOs under part B of Directive 2001/18/EC. No notifications for class 3 or class 4 have been submitted in the Czech Republic so far.

Applicants often discuss potential problems with the CA and the Czech Environmental Inspectorate (see below), prior to commencing contained use activities. The authorities provide the applicants with specific methodologies, guidance and formats for various aspects of contained use, e.g. advice on equipment of the premises according to the containment level, formats for yearly reports and other documentation, guidance for notification of clinical trials, recommendations for transport of laboratory animals, etc. As a result of this approach, the number of deficiencies decreased considerably over the years.

Permit holders are obliged to submit a brief report on their activities to the CA each year. In case they terminate their activities with GMOs, a detailed 'final report' must be submitted.

Risk assessment and assignment of containment levels

A containment level is assigned based on the risk assessment of the intended contained use. The risk assessment is prepared by the applicant.

There is no list of GMOs and their corresponding containment levels. The assignment of containment levels is conducted by the applicant on a case-by-case basis.

The risk assessment of GMOs and other aspects of intended contained use are reviewed by experts from the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products and, where necessary, the classification and the conditions of the use can be amended.

The applicant keeps a record of the risk assessment of the activity and reviews it: a) every 5 years, b) in case new information becomes available, or c) if any changes occur in the use that could affect the risk assessment. These reviews are sent to and checked by the CA and the Environmental Inspectorate.

Public consultation

The public is to be consulted within the authorisation procedure for class 3 and class 4 contained use activities.

The CA keeps an updated register of subjects authorised for contained use ('Register of Users') on its website (see above). The Register contains the name and address of the user, specification of the GMOs, purpose of the use(s) and the classification(s). Summaries of the corresponding emergency plans are published as well.

Emergency plans and accidents

An Emergency Response Plan is required as part of the notification of activities in all classes. This requirement has to be met by the applicant before the activities commence. The Emergency Response Plan should be reviewed every 5 years and also in case of any changes that could affect the emergency measures.

The Emergency Response Plan has to be submitted to the CA, to the regional and municipal authority, to the local Rescue-Fire Brigade and on request also to persons that may be directly affected in case of an accident. The Environmental Inspectorate checks on fulfilment of these obligations.

An 'accident' is defined similarly as in the Directive. Until now, no such accidents have been reported to the CA in the Czech Republic.

Inspections

The authority responsible for the state supervision of the use of GMOs is the Czech Environmental Inspectorate. The Environmental Inspectorate cooperates with other state supervision bodies in fulfilling this task. The Environmental Inspectorate regularly carries out inspections in accordance with a yearly schedule, based on the information provided by the CA and other authorities. Inspections are targeted on compliance with the requirements for the premises, record keeping, waste treatment, transport of GMOs, equipment of the premises, training of personnel, etc.

The Environmental Inspectorate consists of a head office and 10 regional inspectorates. Within each of these offices, one inspector has been trained on the supervision of GMOs, although it represents only a part of their daily agenda, depending on the number of GMO facilities in the region (in 3 Czech regions, no activities with GMOs take place, nevertheless inspectors were trained there as well). Currently, 10 regional inspectors and 1 person at the Inspectorate's head office deal part-time with inspections under Directive 2009/41/EC.

In total, about 25 inspections of contained use premises are carried out each year and an inspection is always performed by 2 inspectors.

The Environmental Inspectorate prepares an annual inspection plan: 1/3 of the work is planned on forehand, 2/3 is more or less ad hoc and filled in during the year. Such a plan is not publicly available.

Confidential information

Confidential information is treated in conformity with Directive 2009/41/EC. No confidential information has been submitted yet.

3.5 Denmark

Introduction

Currently, approximately 100 institutes in Denmark are involved in contained activities with GMOs.

Danish legislation on GMOs goes back to 1986, when the Parliament adopted the first Act on the Environment and Genetic Engineering with the objective to establish an adequate regulatory response to the uncertainties and risks from these new technologies. Denmark can be regarded as one of the forerunners in GM legislation in the European Union.

Nowadays, genetic engineering in Denmark is still regulated by the Act on the Environment and Genetic Engineering (Consolidated Act No. 981 of 3 December 2002)[23]. The purpose of this Act is to contribute to the safeguarding of nature and the environment, and to protect human health with regard to genetic engineering.

This Act implements, among other things, Directive 2009/41/EC into Danish national legislation. Provisions concerning definitions, exceptions, requirements for applications, notification, approval, fees, and supervision and enforcement are laid in more detail in an executive order at the Working Environment Authority[24] and in several executive orders of the Environmental Protection Agency[25].

The CAs in Denmark are the Environmental Protection Agency, which resorts under the Environment Ministry; and the Working Environment Authority that resorts under the Employment Ministry. Notifications are handled in close collaboration between the two authorities. All notifications for contained use must be received by the Environmental Protection Agency's (production activities and facilities) and the Working Environment Authority's (production, large scale and research activities and facilities) joint product register, which registers all genetic engineering activity in Denmark.

Both authorities maintain regular contact and two times a year an official meeting is organised.

There is no separate advisory body that provides (scientific) advice to the CAs in Denmark.

[23] www.sns.dk/biosafety/english/Lovbekendtgoerelse_eng.pdf
[24] www.at.dk/da/REGLER/~/link.aspx?_id=08A27461DAF64285B8EB5E6D27E9E656&_z=z
[25] www.mst.dk

Scope and definitions

The scope of the transposing legislation is extended to the contained use of GM plants and animals. The definitions of GM, GMM and contained use are the same as the corresponding definitions in Directive 2009/41/EC. Clinical trails fall exclusively within the scope of contained use regulation, but gene therapy has not been conducted lately. In 1990, the Danish Parliament decided that self-cloning is not excluded from the Act.

General obligations

In Denmark, an Internal Biosafety System (IBS) is established for the working environment when deemed necessary by the applicant. A BSO is not obliged by law, but instead a so-called 'daily safety leader' is appointed by the applicant, who is responsible for safety issues within a company or an institute, going beyond biosafety alone.

The risk assessments, the containment levels, protective measures and other relevant issues of the notification must be reviewed periodically by the applicant.

Classes of activities and procedures

Decisions on the contained use of GMOs are made at the national level. The Danish regulation on contained use makes an administrative distinction between:

1. Applications for research and large scale experiments. Such applications are processed by the Danish Working Environment Authority and, in some specific cases, include consultation of the Danish Environmental Protection Agency.
2. Applications for the commercial production of GMOs. These are processed by both the Danish Environmental Protection Agency and the Working Environment Authority.

Table 6: Procedures for first and subsequent GMO uses in Denmark

	Class 1		Class 2		Class 3 + 4	
	First use	**Subsequent use**	**First use**	**Subsequent use**	**First use**	**Subsequent use**
Requirement	Notify + permit (facility *and* activity)	Notify + start	Notify + permit (facility *and* activity)	Notify + permit	Notify + permit (facility *and* activity)	Notify + permit

- When premises are to be used for the first time, the Danish Working Environment Authority has to be notified and approval must be obtained. In Denmark, this includes an approval of both the facility and the first activity.
- If the Working Environment Authority does not reply to the applicant within 45 days after sending the notification for first class 1 activities, the work may start.

- Going beyond the Directive, Danish legislation requires that subsequent class 1 uses also have to be notified and accompanied by a risk assessment. The contained use may proceed immediately following the new notification.
- In principle, first and subsequent class 2 activities must be notified and approved. However, if the Working Environment Authority does not reply to the applicant within 45 days after sending the notification, the work may start without the permit.
- Up till now, Denmark has not approved activities with GMOs for contained use in classes 3 and 4, but, similar to the Directive, a permit would be needed and the work may not start until the permit is granted.
- Notification forms[26] are available online, at the website of the Working Environment Authority. Forms can be submitted in English.

Risk assessment and assignment of containment levels

Denmark does not have pre-defined lists to assign a containment level to a certain application, but in Directive 89/391/EEC (99/0188(COD)), specific guidance on wild types (class 2 to 4) is included that can be used as a reference. The CAs review the information provided by the applicant and the proposed containment levels on a case-by-case basis. Guidance[27] on how to make a risk assessment is offered online.

Public consultation

When the Act on Environment and Genetic Engineering was revised in 2002, a provision on public participation was adopted. Only for large scale contained use activities, public hearings are organised. Before the Environmental Protection Agency takes a decision on a production notification, a draft decision is submitted to the municipal and county council authorities and any other interested parties. The Agency's 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.

All notifications are recorded in the genetic engineering register in the Product Register[28] and the information is publicly available.

Emergency plans and accidents

The notification of new premises should contain an emergency plan, but only if there is the possibility of risks to the staff or the environment.

Emergency plans are not required for production activities; however, instructions from the CAs are given to the applicant on how to react to an accidental escape of GMMs. In the

[26] www.at.dk/~/link.aspx?_id=4FF8CADB67AE44E7B7C54B9A4C238619&_z=z
[27] www.at.dk/Vejledninger/C-0-5?sc_lang=da
[28] www.at.dk/ENGELSK/Produktregistret/Om-Produktregistret.aspx?sc_lang=en

event of an accident, a series of procedures are set in motion in accordance with the Directive.

Inspections

Both the Environmental Protection Agency and the Working Environment Authority perform inspections in Denmark. Inspections are mostly performed upon notification of new premises. In addition, the Working Environment Authority verifies compliance with the conditions of all (changes in) approvals. In terms of production facilities, the county council municipalities verify compliance with the conditions concerning the protection of the environment.

The Environmental Protection Agency has two inspectors who spend approx. 40 days inspecting new approvals per year. The Working Environment Authority spends approx. 130 days per year on inspections, divided amongst 7 inspectors.

Confidential information

Confidentiality requirements in the Transparency in Public Administration Act are in conformity with the requirements of Directive 2009/41/EC.

3.6 France

Introduction

In France, nearly 1,200 contained use activities have been approved to date.

The objective of the contained use regulation[29] in France is the same as in Directive 2009/41/EC. The Directive has been transposed by law into the French national regulatory system. An Order on the Procedures for Contained Use of GMOs is currently under development.

The Ministry of Higher Education and Research[30] is the CA in the field of contained use of GMOs.

Established in 2009, the federal expert advisory body is the High Council for Biotechnology (Haut Conseil des Biotechnologies[31]). This Council is mandated to inform the government on all questions concerning GMOs and of formulating opinions and advice regarding the evaluation of risks for the environment and public health. It gives advice on each notification to the

[29] www.legifrance.gouv.fr/affichCode.do;jsessionid=708B583833A3430CC072B9E7A6B85ACC.tpdjo11v_2?idSectionTA=LEGISCTA000006159283&cidTexte=LEGITEXT000006074220&dateTexte=20100825
[30] www.enseignementsup-recherche.gouv.fr/cid28895/utilisation-d-ogm-en-milieu-confine.html
[31] www.ogm.gouv.fr/rubrique.php3?id_rubrique=94

CA, regarding the granting of permits. The Council replaces two previous commissions, namely the Biomolecular Engineering Committee and the Commission on Genetic Engineering.

Scope and definitions

The scope of the legislation is extended to the contained use of GM plants and animals. The definitions of GM, GMM and contained use are nearly the same as the corresponding definitions in Directive 2009/41/EC. Mutagenesis, hybridomas and self cloning are not excluded.

General obligations

Institutes and companies working with GMOs are obliged to implement strict Internal Biosafety Systems. A BSO is required and detailed logbooks need to be kept up-to-date. For class 3 and 4 contained use activities, the system requires that an internal specialist team is responsible for maintaining safety. Also obligatory is the appointment of a 'legal officer' and a 'chief scientist'. These persons both have to sign notifications.

Classes of activities and procedures

Within the national legislation, GMOs 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 or 4.

Currently, notification forms must be submitted in hard-copy, but France is working on the option to submit such applications via the internet. The present forms are being revised by the CA in close cooperation with the High Council for Biotechnology.

Before notifications are formally submitted to the CA, it is common that there is informal contact with the applicant to discuss possible uncertainties in the notification process.

Table 7: Procedures for first and subsequent GMO uses in France

	Class 1		Class 2		Class 3 + 4	
	First use	**Subsequent use**	**First use**	**Subsequent use**	**First use**	**Subsequent use**
Requirement	Notify + start	Notify + start	Notify + 45 days	Notify + start	Notify + permit	Notify + permit

- Both first and subsequent class 1 contained use must be notified, but work can start immediately and there is no simplified procedure for small changes.
- Procedures regarding class 2, 3 and 4 activities are exactly the same as in the Directive. No simplified procedure for small changes is available.

Risk assessment and assignment of containment levels

The applicant is responsible for performing the risk assessment when submitting a notification, including a proposed containment level for the intended contained use activities. The notification is submitted in threefold to the CA.

For class 1 and 2 activities, two experts of the scientific section of the High Council for Biotechnology verify the notification. When both experts agree on the containment level, the Council decides accordingly in its monthly meeting. If the experts have different opinions, the notification is discussed within the Council.

For class 3 or 4 activities, the notification is also verified by two experts of the scientific section of the High Council for Biotechnology, and in addition, it is always reviewed in more detail during the meeting of the Council.

Public consultation

In France, a distinction is made between public consultation and public information. Currently, a specific system for public information has not yet been established in France, but when the notification involves industrial (production) or large scale research activities of class 3 or 4, an announcement is published in the local Gazette and the general public is offered the opportunity to provide input to the Environmental Permit procedure. Public consultation is only utilized when proposed environmental laws (bills) are passed.

Emergency plans and accidents

The preparation of specific emergency plans is only obliged for class 3 and 4 activities. No accidents have been reported to the CA thus far.

Inspections

In May 2008, the 'Office for the Inspection of Contained Use Installations and Activities' was established under the responsibility of the CA. Since that date, the compliance control activities have been largely aimed at reviewing the submitted notifications. Due to budgetary constraints, one part-time inspector has been appointed to perform these controls, which mostly take place via telephone and which for the most part consist of reminding applicants of the fact that certain additional information ought to be submitted to the CA.

Since the establishment of the Inspectorate, two major institutes have been visited: one private and one public. No inspection plans are available yet and the number of days for inspection available per year is not specified in advance.

The French control system relies strongly on self compliance and on the own responsibilities of institutes and companies to carry out regular internal checks, hence the obligation to implement strict Internal Biosafety Systems (see above).

Confidential information

Confidential information is treated in conformity with Directive 2009/41/EC. Up to now, no requests by members of the general public about access to the information has been put forward to the CA.

3.7 Germany

Introduction

In Germany, over 6,000 contained use facilities have been approved to date. Of this number, almost 75% concerns class 1 contained use activities. More than 80% involves public research activities.

In Germany, the Genetic Engineering Law (GenTG[32]) regulates nearly all activities with GMOs. In addition, a series of implementing ordinances are in place, which jointly form a framework that sets out the procedures for authorising contained use activities, defining the parameters relevant for risk assessment and prescribing the appropriate safety measures at the physical, technical, organisational and experimental level.

In Germany, CAs are established at the regional level: the 16 Bundesländer are responsible for the implementation of Directive 2009/41/EC. Generally, the Environmental Departments of the Bundesländer are involved, but sometimes the responsibilities are assigned to the departments of Health. Since 1 April 2004, the Federal Office for Consumer Protection and Food Safety (BVL) is the Competent Federal Authority.

The BVL, through its expert advisory body, the Zentrale Kommission für die Biologische Sicherheit (ZKBS[33]), advises the Federal Government, as well as the Bundesländer and involved bodies, on issues of biological safety in genetic engineering. This is either general advice or refers to specific applications/activities. The ZKBS is comprised of 20 members and 20 deputy members and reaches its decisions either at a general meeting or via a written procedure. The meetings are not public, but the ZKBS publishes general position statements and reports on its work to the public each year.

[32] http://bundesrecht.juris.de/bundesrecht/gentg/gesamt.pdf
[33] www.bvl.bund.de/cln_007/nn_491798/DE/06__Gentechnik/093__ZKBS/gentechnik__zkbs__node.html

Information on legislation, involved organisations, genetic engineering operations and genetic engineering facilities, as well as on organisms, cell lines and vectors used in genetic engineering operations, is provided on the website of the BVL[34].

Scope and definitions

The German Law covers GMMs, GM plants and GM animals. The definitions of GM, GMM and contained use are nearly the same as the corresponding definitions in Directive 2009/41/EC, be it with sometimes different terminology. For example, instead of 'contained use' the definition refers to 'closed system'.

Clinical trials fall exclusively under Directive 2001/18/EC on the deliberate release into the environment of GMOs. 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 2009/41/EC. Self cloning is exempted from German GMO legislation.

General obligations

The appointment of a BSO is obligatory for each institute or company handling GMOs. In case of small institutes, a BSO can be contracted externally. A 'Project Leader', who is responsible for the work in the lab and is in regular contact with the Inspectorate. The Bundesländer review the level of education prior to formally approving a BSO or a Project Leader. An official contact person on behalf of the institute (e.g. the Head of a University), should be appointed as well.

The assessment, containment and other measures are to be reviewed periodically by the project leader and the BSO.

Classes of activities and procedures

The same classes as in the Directive apply.

The respective Bundesländer are responsible for the implementation of the Directive and receive notifications from the applicants and issue consents. The Bundesländer inform the BVL on the decisions made. These decisions are compiled in a national database which is accessible to all CAs in Germany. The BVL does not have the competence to correct Bundesländer -decisions, because the final decision is made by the Bundesländer.

The ZKBS participates in the risk assessment procedure to an increasing extent when the class of the activities is higher or under dispute. In addition, the ZKBS provides general guidelines on safety precautions for common activities plus underlying criteria for comparability, which simplify and accelerate the approval process.

[34] www.bvl.bund.de/gentechnik

Table 8: Procedures for first and subsequent GMO uses in Germany

	Class 1		Class 2		Class 3 + 4	
	First use	**Subsequent use**	**First use**	**Subsequent use**	**First use**	**Subsequent use**
Requirement	Notify + start	Start	Notify + 45 days	Notify + start	Notify + permit	Notify + permit

- When premises are to be used for the first time, the applicant should notify the CAs.
- At the websites of the Bundesländer (e.g. Hamburg[35]), notification forms (valid nation-wide) are available online.
- The notification and approval system follows exactly the procedures of the Directive. For small changes, simplified procedures apply.
- In Germany, the term 'application' is used when referring to a notification for first class 2 uses and for first and subsequent class 3 and 4 uses.

Risk assessment and assignment of containment levels

The assignment of containment level is done by means of a risk assessment, carried out by the Bundesländer for expected class 1 and 2, or by the ZKBS for expected class 3 and 4, and uncertain class 1 and 2. However, since the Bundesländer are the CA, the ZKBS only advises the Bundesländer to assign a certain activity as class 1, 2, 3 or 4. In case the Bundesland has a differing opinion about the classification of an activity, the assignment of the Bundesland prevails.

When the ZKBS makes assessments for the classification of activities, 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.

The criteria for the risk assessment and the corresponding containment levels are laid down in the Gene Technology Safety Regulations[36]. A list of pre defined risk classes[37] of organisms (bacteria, virus, fungi) as hosts helps to assign the appropriate level.

Public consultation

Public consultation is required as part of the authorisation procedure for commercial class 3 and class 4 contained use activities, plus certain cases of commercial class 2 activities[38].

[35] www.hamburg.de/start-formulare/103164/formulare-start.html
[36] www.gesetze-im-internet.de/gentsv/__7.html
[37] www.bvl.bund.de/cln_007/nn_491822/DE/06__Gentechnik/094__Register__Datenbanken/gentechnik__register__datenbanken__node.html
[38] Only if an authorization procedure under §10 of the German Federal Pollution Control Act (Bundes-Immissionsschutzgesetzes) is required. See §18 of the Genetic Engineering Law (GenTG).

The BVL publishes their annual progress report as well as general statements of the ZKBS in the Federal Gazette. On its website, the BVL informs about installations and activities as well as about statements made by the ZKBS regarding risk assessments, classifications and safety measures.

Emergency plans and accidents

The applicant is required to develop external (off-site) emergency plans in certain cases of class 3 and 4 activities. This is regulated by means of the Genetic Engineering Emergency Plan Ordinance (Gentechnik-Notfallverordnung[39]).

The Bundesländer are obliged to inform the BVL about any incidents or accidents.

Inspections

After the notification or the consent, the Bundesländer regularly carry out inspections on the premises. They check the records of activities (logbooks) and, in individual cases, take GMO samples which are examined in monitoring laboratories to check the identity of the organisms and whether the containment level corresponds. Approvals can be suspended or revoked where deficiencies in organizational and safety measures are discovered.

Every Bundesland has its own inspection plan and priorities are set according to the risk level involved: class 1 and 2 activities are inspected once every three years; class 3 and 4 every year. Inspection plans contain a list of all the facilities, divided into 4 risk categories, and cover more than only GM, e.g. also general emission controls.

Exact numbers on how many inspectors are involved in contained use inspections are not available.

Confidential information

Confidential information is treated in conformity with Directive 2009/41/EC.

[39] www.gesetze-im-internet.de/bundesrecht/gentnotfv/gesamt.pdf

3.8 The Netherlands

Introduction

In The Netherlands, currently there are about 180 installations for contained use in which in total approximately 2,150 permitted activities are conducted.

Directive 2009/41/EC is implemented through the Environmental Management Act: Decree on Genetically Modified Organisms (GMO Decree[40]). This Decree regulates the use of GMOs under Dutch law. The first version of the GMO Decree dates back to 1990.

The Ministerial Order on GMOs (GMO Order[41]) is linked to the GMO Decree and lays down more detailed rules for the contained use of GMOs.

The Ministry of Infrastructure and Environment[42] is the CA and is responsible for the regulations that protect the environment and human health in relation to activities involving GMOs and is tasked with developing policy and regulations. The CA is responsible for the assessment of the development and use of GMOs, and for the issuing and control of contained use permits, on the basis of the GMO Decree. Municipalities and/or Provinces are involved in the issuing and control of environmental permits (see below).

The GMO Office[43] – part of the Expertise Centre for Substances (SEC) of the National Institute for Public Health and the Environment (RIVM) – supports the CA in administrative and technical/scientific aspects by handling the applications and supporting policy development. The GMO Office receives all notifications for contained use activities in The Netherlands, determines the risks to the environment and human health, and decides whether activities may commence. The CA holds final responsibility for decisions made by the GMO Office.

The Commission on Genetic Modification (COGEM)[44] is an independent scientific body that advises the Minister of Infrastructure and Environment and the GMO Office on risks to the environment and human health associated with the use of genetically modified organisms and any safety measures that have to be taken.

Scope and definitions

The contained use regulations cover all GMOs. The definitions of GM, GMM and contained use are the same as the corresponding definitions in Directive 2009/41/EC.

[40] http://wetten.overheid.nl/BWBR0004703/geldigheidsdatum_02-12-2010
[41] http://wetten.overheid.nl/BWBR0009653/geldigheidsdatum_02-12-2010
[42] This Ministry is formerly known as the Ministry of Housing, Spatial Planning and the Environment (VROM)
[43] http://bggo.rivm.nl/Index.htm
[44] www.cogem.net

The GMO Decree contains similar exempted techniques as the Directive. One request for a GMO to be exempted in accordance with Annex II Part B and C has been submitted. This request will be handled with in accordance with the regulatory procedure with scrutiny referred to in Article 20(2) of Directive 2009/41/EC.

General obligations

In the GMO Order, requirements are listed for the internal biosafety organisation of a permit holder with regard to contained use activities. A distinction is made between the legal body (permit holder), the BSO and the 'responsible researcher':

- The legal body is the permit holder and may, for example, be represented by the Board of Directors of an institution. The legal body has final responsibility for the execution of the GMO Decree in conformity with the GMO Order. This responsibility is delegated to the BSO and the responsible researcher.
- The BSO is appointed by the legal body as required by the GMO Order. This person is an employee of the institution and the BSO is formally approved by the CA[45].
- The responsible researcher is appointed by the legal body as required by the GMO Order. This person is an employee of the institution and is responsible for performing activities involving GMOs and supervising biosafety in the actual working space for contained use. The responsible researcher must ensure that activities involving GMOs are carried out in conformity with the GMO Order and the permit that has been issued. His or her affiliation is known to the CA.

Classes of activities and procedures

Notifications (i.e. applications for permits) for contained use of GMOs must be submitted to the GMO Office. This may be done in Dutch or English. Every notification should include a risk assessment. Guidance documents[46] on, among other things, risk assessments are available online.

Dutch legislation differentiates activities with GMOs in category A (small scale (max. 10 litres) and non-commercial and non-industrial) and B (other) activities. Different notification forms for category A en B are available on the website of the CA[47]. GMOs are divided into three groups:

- Group I: GMMs that meet the criteria of the second paragraph of Article 2 of the GMO Decree, or that meet the criteria for inclusion in group I after applying the forth paragraph of the same article[48].
- Group II: other GMMs.

[45] Previous to the approval of a BSO, the level of education of this person is reviewed by the CA.
[46] http://bggo.rivm.nl/Paginas/doc-ig.htm
[47] http://bggo.rivm.nl/Paginas/vv-ig.htm
[48] This implies the following: hosts must be mentioned in Annex 1 of the GMO Order; vectors in Annex 2 (2.1.1); host/vector system in Annex 3; and inserts may not include sequences as mentioned in Annex 2 (2.2).

– Group III: other GMOs, i.e. GM plants and GM animals.

This results in the following combinations of activities and GMOs: IA, IB, IIA, IIB and III. Different notification procedures apply to each of these combinations.

Table 9: Procedures for first and subsequent GMO uses in The Netherlands

	Class 1		Class 2		Class 3 + 4	
	First use	**Subsequent use**	**First use**	**Subsequent use**	**First use**	**Subsequent use**
Requirement	*Group IA*[49] – Notify + permit (28 days)	*Group IA* – Start	Notify + permit (45 days)	Notify + permit (45 or 28* days)	Notify + permit (45 days)	Notify + permit (45 or 28* days)
	Not group IA – Notify + permit (45 days)	*Not group IA* – Notify + permit (45 or 28* days)	*Group IIB* – Notify + permit (87 days)	*Group IIB* – Notify + permit (45 days)	*Group IIB* – Notify + permit (87 days)	*Group IIB* – Notify + permit (45 days)

* = *small changes*[50]

– Activities with GMOs may only start after the permit – or the amendment in the permit – is granted (except subsequent Group IA activities).
– The procedure starts after the notification is received by the GMO Office. This period is extended when the information received is incomplete and the GMO Office asks for additional information in writing. The same applies to notifying small changes.
– In addition to a contained use permit, an environmental permit must be obtained for the facility in which activities involving GMOs will be taking place. This permit is known as a 'Wm-vergunning' (Environmental Management Act, Establishments and Permits Decree) and should be obtained from the Municipality or Province where the site, installation or equipment is located or from central government.

Risk assessment and assignment of containment levels

Biosafety levels are based on combinations of requirements such as laboratory practices and techniques, equipment and laboratory facilities. To classify the relative hazard of micro-organisms, four classes of pathogenicity (1 to 4) are used. This classification, along with several other factors, e.g. types of vector and insert, helps to determine the biosafety level

[49] The majority of activities in The Netherlands concern Group IA activities.
[50] In case of a 'small change', the text of the permit remains unchanged. A small change means that the addition of a similar vector, host strain and/or donor sequence does not lead to a different containment level than specified in the permit, and it corresponds to the original description of the project as well.

on which a GMO should be contained. The final assignment of the biosafety level is based on the potential hazard of the GMO in conjunction with the type of activity and laboratory.

The following Annexes of the GMO Order[51] serve as guidance for the assignment of the containment level:

- Annex 1: criteria for hosts that are suitable for the construction of GMOs belonging to group I, as well as a list of hosts is included that have been approved so far.
- Annex 2: criteria for vectors and inserts, and a list of approved vectors and inserts that are unsuitable for constructing group I GMOs.
- Annex 3: a list of HV-2 host/vector-systems, that have proven to be very safe and for which a lower containment level is needed.
- Annex 4: facility design criteria that must meet the biosafety level requirements are listed in the GMO Order.
- Annex 5: a table which describes the relevant factors in the risk analysis and its outcome of specific GMOs. More specific the outcome of the risk analysis defines the containment level and the set of provisions that should be followed for activities with that GMO. There are, for instance, different sets of provisions for activities with GMOs in laboratories, glass houses, or animal units.

Public consultation

Within the procedure for an environmental permit (Environmental Management Act, Establishments and Permits Decree), public consultation is obligatory, as well as in case of so-called 'IIB-activities' (see above).

The CA has set up a website[52] to inform the public about contained use activities. However, with the exception of IIB notifications, only the notifier's name, the title of the project and the authorisation date are published, but members of the public can request access to the full dossier.

Emergency plans and accidents

In accordance with the GMO Order, the permit holder must ensure that procedures are established for accidents, incidents and emergencies. Criteria for reporting to the CA are described in the explanatory notes attached to the reporting forms for incidents related to contained use activities.

In case a permit holder carries out class 3 and 4 activities, the Decree on Information on Disasters and Major Accidents (BIRO) applies. This means that information should be pro-

[51] http://bggo.rivm.nl/Paginas/doc-reg.htm
[52] http://bggo.rivm.nl/Paginas/vdb.htm

vided to the municipality in which the application takes place. This information is provided to the CA and therefore does not have to be made available separately by the permit holder.

Inspections

The VROM-Inspectorate[53] monitors the implementation of the regulations for the contained use of GMOs. This implies checking whether contained use activities are carried out as described in the permit and e.g. take place according to the established working conditions and within the correct facilities.

Per year, the Inspectorate inspects about 50 institutions with a permit for contained use activities. The rules and regulations appear generally well respected and breaches are mostly minor administrative issues.

In general, each permit holder is visited at least once every 4 years; but larger institutes can expect a visit once or twice a year. Annually there are approximately 225 person-days available for inspection on contained use activities.

Confidential information

Confidential information is treated in conformity with Directive 2009/41/EC.

[53] www.vrominspectie.nl/onderwerpen/milieu/genetisch-gemodificeerde-organismen

Proposals for regulatory changes in The Netherlands

In The Netherlands, the CA is preparing a number of significant regulatory changes. These changes will probably come into force in the next few years and can be summarized as follows:

The procedure will be determined by the results of the risk assessment, which will remain unchanged (Annex 5 GMO Order). The risk assessment does not result in class 1-4 as in the Directive, but directly into containment level 1-4. The containment level can be derived from the name/type of the workspace.

Table 10: Planned procedures in The Netherlands

Containment level 1	Containment level 2 'low'	Containment level 2 'high'[54] and 3	Containment level 4
Start immediately after notification	Notification, proceed after 45 days	Apply for permit, with a 45-day term	Apply for permit, with a 90-day term
Change in activity resulting in the use of a new set of provisions: notification and start immediately Other cases: record in logbook, without notifying	Notify changes on forehand and start immediately Small changes: n.a.	Apply for change in permit, with a 45-day term Small changes: 28 days	Apply for change in permit, with a 90-day term Small changes: 28 days

[54] This includes activities with: 1) chimeric pathogens in the broadest sense; 2) pathogens whose host range can be extended by the modification; 3) pathogens that, as insert, contain one or more immunomodulatory genes; and/or 4) pathogens with uncharacterised inserts.

3.9 The Slovak Republic

Introduction

In the Slovak Republic (Slovakia) there are 21 research institutions that conduct contained use activities with GMOs in 2010, of which two are private sector research labs in manufacturing facilities, and the others are public sector institutes, such as academic institutes and Government research institutes. Most of the contained use activities concern GMMs (95% in 2010).

Directive 2009/41/EC is implemented in Slovakia through the GMO Act[55] and implementing regulations[56].

The CA for the execution of the GMO Act and the implementing regulations is the GMO Department of the Ministry for the Environment of the Slovak Republic.

The CA receives technical advice from a Biosafety Committee, which is established by the GMO Act. The Committee has 11 permanent members and 15 external experts. The administration of the Committee is conducted by the CA's GMO Department.

Scope and definitions

The GMO Act covers contained use activities with GMMs, GM plants and GM animals. The definitions of GM, GMM and contained use are the same as the corresponding definitions in Directive 2009/41/EC.

While self cloning is, in accordance with the Directive, exempted from the Act, the CA assumes that not many activities with self cloning take place in Slovakia. No requests for additional exemptions have been submitted.

General obligations

The GMO Act has a general 'provision of care', and further requires each company and public research institute to establish an internal biosafety system specified in the implementing regulations, including the appointment of an IBC and a BSO.

IBCs must have at least 5 members, of which more than half must be external. The BSO is the head of the IBC.

A BSO must have a relevant University degree and 3 years of experience in the field for which he/she is BSO. Before being appointed, BSOs receive one day training from the GMO

[55] www.sizp.sk/doc/legislativa/legbb/suv_subory/ACT__GMO_2010.pdf
[56] www.sizp.sk/doc/legislativa/legbb/htmramec.php?htmsubor=Zoznam_platnych_pravnych_predpisov_9_2010.htm

Department, focusing on the regulations and the administrative aspects of submitting applications. The GMO Act specifies that BSOs receive additional training and updates every three years.

Classes of activities and procedures

The GMO Act uses the same classification of activities as Article 4 of Directive 2009/41/EC. The procedures of the GMO Act follow the overall approach of Articles 6 – 9 of the Directive, but on various points go beyond the Directive.

Table 11: Procedures for first and subsequent GMM uses in the Slovak Republic

	Class 1 GMMs		Class 2 GMMs		Class 3 + 4 GMMs	
	First use	**Subsequent use**	**First use**	**Subsequent use**	**First use**	**Subsequent use**
Requirement	Notify + permit	Notify + start	Notify + permit	Notify + permit if indicated by the CA	Notify + permit	Notify + permit

For GM plants and animals the following applies:

Table 12: Procedures for first and subsequent uses of GM plants and animals in the Slovak Republic

	GM plants		GM animals	
Requirement	Notify + permit	Notify + start	Notify + permit	Notify + permit

- When premises are to be used for the first time a permit is required. The permit is given in connection with a broader installation permit that also covers other aspects than biosafety.
- For subsequent Class 1 activities a notification is required.
- Subsequent Class 2 contained uses must be notified, and may proceed following the notification, unless the GMO department informs the applicant that he needs to wait for a permit.
- Class 3 or Class 4 contained uses require a permit. Currently there are no class 3 or 4 activities conducted in Slovakia.
- First time applicants are invited for an informal meeting with the GMO Department prior to actual submission, to discuss the regulations and application procedures.
- Applications are signed by the head of the company or institute and the BSO.
- In case of a first time use of an installation, the GMO Department visits the installation prior to issuing the permit. Such visits usually take up to one day.

– For GM plants there is in practice only one containment level.

Risk assessment and assignment of containment levels

Proposals for containment levels are made on a case-by-case basis by the applicants, verified by the IBC.

Once the application with the proposed containment levels is submitted, the GMO Department assigns external experts to verify the proposal for containment levels made by the applicants for compliance with the principles and criteria under Directive 2009/41/EC. In almost all cases, the proposed containment levels are adequate. In some cases, the justification needs to be further detailed. The final permit is produced by the GMO Department and forwarded to the applicant.

Public consultation

In accordance with the GMO Act, information on applications is made available to the public, with a comment period of 30 days. The GMO Act requires that the CA takes 'due account' of the comments submitted. Thus far, no comments have been submitted.

Emergency plans and accidents

The GMO Act requires that emergency plans are drawn up for class 2 – 4 activities, and that in the case of accidents appropriate action is taken, including notification to the CA where necessary. 'Accidents' are understood to be incidents with the potential of significant impacts for human health or the environment. So far, no such notifications have been made to the CA.

Inspections

Inspection and enforcement of the requirements of the GMO Act lies with regional Environmental Inspectorates. Most of the GMO activities, and therewith the inspection work, is concentrated in the region Bratislava.

The Biosafety Department of the Slovak Environment Inspection[57] has 9 inspectors who are involved in inspection and enforcement under the GMO Act and inspection and enforcement under the labelling regulations.

In general, half of the time of the inspectors is dedicated to inspection and enforcement under the GMO Act and food labelling.

[57] www.sizp.sk/sizpcinnost.php?t=1291366108&tab=bb

The work of the Inspectorates is organised in quarterly plans, whereby the aim is to conduct a visit to every applicant at least once per year. Visits take around one day and are conducted by two inspectors.

Preparation for the inspections includes reading the current permits, previous inspection reports, scientific publications, and the internal biosafety manual, which is submitted at the first use notification. Biosafety manuals are about 10-15 pages.

Inspections are usually announced beforehand. The BSO and the project leaders are required to be present[58]. Inspections start with talks with the heads of the institute and with the project leaders, after which the actual inspection is conducted in the presence of the project leaders and the BSO. Inspections are conducted in accordance with a checklist attached as an annex to the GMO Act, which includes amongst other the verification of the lab journal or 'log'. Unlike inspections for field trials, samples are rarely taken during contained use inspections.

Inspection reports are discussed with the applicant, and in case of non compliance, an infringement procedure starts, but the applicant gets a certain period to reach compliance. The overall experience is that infractions are mostly minor administrative issues.

Confidential information

In accordance with the Directive and the GMO Act, the notifier may indicate the information that should be treated as confidential.

Confidentiality is not often requested, and primarily by private sector companies.

[58] The BSO and the project leader can be one and the same person.

3.10 Spain

Introduction

In Spain there are around 170 facilities where contained use activities with GMOs are conducted. In 2009 there were 200 notified activities. This number should be understood in the context of the fact that some institutes have one permit that includes several facilities and other institutes have a permit per each facility.

Directive 2009/41/EC is implemented by the GMO Act of 2003[59], and two Decrees; one Decree implementing the procedural and technical requirements and one Decree addressing stakeholder involvement.

Spain has 18 CAs for contained use, 1 on the national level and 17 in the autonomous regions. The CA on the national level is the Directorate General of Sustainable Development for Rural Affairs of the Ministry of the Environment, Rural and Marine Affairs.

The scientific work and secretariat of the National Biosafety Commission[60] is conducted by the Directorate General for Environmental Quality and Assessment. Some autonomous regions have also regional biosafety committees that advise the regional CAs.

Information on legislation, involved organisations, notifications, etc., is available at the website of the national CA[61].

Scope and definitions

The scope of the transposing legislation is extended to the contained use of GM plants and animals. The definitions of GM, GMM and contained use are the same as the corresponding definitions in Directive 2009/41/EC.

The Act contains similar exemptions as the Directive and requests for additional exemptions in accordance with Annex II Part B and C have not been submitted.

General obligations

BSOs and IBCs are mandatory under the Act. For BSOs and IBCs, specific guidelines are available.

[59] www.mma.es/secciones/calidad_contaminacion/omg/legislacion_general/pdf/Ley_9_2003_.pdf
[60] www.mma.es/portal/secciones/calidad_contaminacion/omg/cnb/
[61] http://www.mma.es/portal/secciones/calidad_contaminacion/omg/

Classes of activities and procedures

The Act applies the classification of the Directive to all GMOs.

Table 13: Procedures for first and subsequent GMO uses in Spain

	Class 1		Class 2		Class 3 + 4	
	First use	**Subsequent use**	**First use**	**Subsequent use**	**First use**	**Subsequent use**
Requirement	Notify + start	Start	Notify + 45 days	Notify + start	Notify + permit	Notify + permit

- Notifications are signed by the institute's Director, the BSO, and the responsible user or researchers.
- In the case of notification requirements, applicants usually wait for the response of the CA and the National Biosafety Committee report.
- In general, activities by the private sector companies and regional public research institutes are notified to the CAs of the autonomous regions, which coordinate with the National CA, whereas activities in the federal public research sector are notified to the National CA, which coordinates with the CAs of the autonomous regions.
- Details of notifications vary per region.
- Activities with GM plants and animals are mostly class 1 and class 2 and follow the same procedures as for the GMMs.
- Electronic application forms and guidance documents are available online (see above); final applications must be submitted in hard-copy.
- Handling notifications for class 2 first use activities and class 3 activities usually takes between 1-2 months – sometimes longer. To date, there have been no class 4 activities.
- Simplified procedures for small changes in notifications are applied.
- The CA has regular informal contacts with applicants which are considered to be very positive.

Risk assessment and assignment of containment levels

Assignment of containment levels is proposed by the applicant and verified by the CA. Assignment of containment levels is conducted on a case-by-case basis, there are no standardized assignments.

Public consultation

Public consultation takes place in case of class 3 and 4 activities.

Emergency plans and accidents

This element of emergency plans of the Directive has been transposed by the GMO Law in conjunction with the Ministry of the Interior.

Notifiable accidents are defined as accidents that may have significant human health or environmental risks. Only one accident has been notified several years ago.

Inspections

Prior to permitting a first use, the CA visits an installation, often accompanied by representatives of the regions. Inspections are conducted by the autonomous regions.

Confidential information

Confidential information is treated in conformity with Directive 2009/41/EC. Not much information is submitted as confidential.

3.11 Sweden

Introduction

In Sweden, approximately 90 institutes are currently involved in activities concerning the contained use of GMOs. This accounts for about 160 sites and 530 facilities were activities take place. Of all the institutes, around 25% is public sector.

Most of the activities are class 1 activities (or 'category F' as it is called in Sweden, see below) with GMMs. Half of all the contained use activities in Sweden take place in and around the capital Stockholm.

The use of GMOs in Sweden is regulated in Chapter 13 of the Swedish Environmental Code[62]. Other provisions of this Code are also relevant for the use of GMOs, such as the general rules of consideration in chapter 2 and the provisions on biotechnical organisms in chapter 14. The purpose of the rules is to protect human health and the environment and to ensure that particular attention is paid to ethical concerns in connection with genetic engineering activities.

The Swedish Environmental Code is supplemented by a number of ordinances, e.g. the Contained Use of Genetically Modified Organisms Ordinance (SFS 2000:271)[63] and regulations, e.g. the Provision on the Contained Use of Genetically Modified Micro-organisms (AFS 2000:5)[64], which set out more detailed rules on when consents or notifications are required for genetic engineering activities.

[62] www.sweden.gov.se/content/1/c4/13/48/385ef12a.pdf
[63] www.notisum.se/rnp/sls/lag/20000271.htm
[64] www.av.se/dokument/inenglish/legislations/eng0005.pdf

Rules on the contained use of GMOs other than GMMs are set out in the Swedish Board of Agriculture's Regulations on the Contained Use of Genetically Modified Plants (SJVFS 2007:29[65]), the Board of Agriculture's Regulations on the Use of Genetically Modified Animals (SJVFS 1995:33[66]), and the National Board of Fisheries' Regulations on Genetically Modified Aquatic Organisms (FIFS 2004:2[67]).

Complete texts of the Swedish legislation on GMOs and other documents are available on an interdepartmental website of the various Swedish gene technology authorities[68].

The Competent Authorities for contained use in Sweden are:

- The Swedish Work Environment Authority, in the case of genetically modified micro-organisms, including cell cultures of higher organisms.
- The National Board of Fisheries, with respect to aquatic genetically modified organisms.
- The Swedish Board of Agriculture, as regards other genetically modified organisms.
- The Medical Products Agency, in relation to medicinal products (clinical trails).

The Swedish Gene Technology Advisory Board[69] monitors developments in the field of gene technology, oversee ethical issues, and give advice on the use of gene technology. The Board makes statements on applications for permits and consults the respective CAs when regulations are notified pursuant to Swedish legislation.

The Swedish authorities involved in gene technology are in regular contact with each other and meet at least twice a year.

Scope and definitions

In general, Directive 2009/41/EC is followed in Swedish legislation and the ordinances and regulations on contained use employ the same definitions of GM, GMM and contained use, as well as the same exemptions as the Directive.

General obligations

The Swedish Law does not oblige the appointment of a BSO. In general, and especially within larger institutes, it is practice that an IBC is established and that a so-called 'work leader' is responsible for the appropriate containment measures, but also for other work environment issues. The responsibilities for safety and supervision is internally organised depending on the institute and type of GM-activity.

[65] www.sjv.se/download/18.71828f571158338f31a80007828/2007-029.pdf
[66] www.sjv.se/download/18.7502f61001ea08a0c7fff49574/2003-028_r%C3%A4ttad.pdf
[67] www.fiskeriverket.se/download/18.1cb5b8de10fc4b40c748000838/2004-2-ev.pdf
[68] www.gmo.nu/gmoenglish
[69] www.genteknik.se

Periodically, the assessment, the containment, protective measures and possible other issues of the notification are reviewed internally: small changes are notified to the CA once a year, but new information relevant to the risks involved has to be notified immediately.

Guidance[70] is published by the Swedish Work Environment Authority on how to comply with the rules concerning contained use of GMMs.

Classes of activities and procedures

A contained use of GMMs is classified as either a category F, L or R activity, according to the risks involved. These categories of activity are subject to different requirements in terms of consents and notifications, as provided in the ordinance (SFS 2000:271):

Table 14: Procedures for first and subsequent GMM uses in Sweden

	Class 1 GMMs		Class 2 GMMs		Class 3 + 4 GMMs	
	First use	Subsequent use	First use	Subsequent use	First use	Subsequent use
Requirement	Notify + start	Start	Notify + 45 days	Notify + start	Notify + permit	Notify + permit

For GM plants and animals the following applies:

Table 15: Procedures for first and subsequent uses of GM plants and animals in Sweden

	GM plants and aquatic animals		GM animals	
Requirement	Notify + permit	Notify + start	Notify + permit	Notify + permit

- Category F activity (class 1): contained use of GMMs involving negligible or no risk to human health or the environment. Notification must be given of the activity (via a standard form), but notification of new uses within that activity is not required.
- Category L activity (class 2): contained use of GMMs involving a low risk of harm to human health or the environment. Notification of the activity is required, and also of every new use within a previously notified activity. The activities may proceed immediately following the notification of the new use.
- Category R activity (class 3 and 4): contained use of GMMs involving a moderate or high risk to human health or the environment. A permit must be obtained for the activity, and for every new use within an activity that has previously received a permit. Activities may not proceed without the permit.

[70] www.av.se/dokument/inenglish/themes/gmm.pdf

- Regarding activities with GMOs, not being GMMs, the applicant must always apply for permission to use new premises. GM plants must be notified before use, as well as GM aquatic animals. Activities with GM animals have to be notified, but the use of laboratory animals requires other permissions (ethical, animal protection) as well.
- In practice, the differently named categories do not differ from the Directive.
- Premises are a part of the F-, L- or R-activity, i.e. not separated from the uses and the containment level that corresponds to the activity, and are notified as a part of the notification. In case of category R activities, the Swedish Work Environment Authority visits the location prior to issuing the permit.

Risk assessment and assignment of containment levels

Containment levels are assigned on a case-by-case basis; no pre-defined list is available. The applicant prepares a risk assessment and proposes the appropriate containment level to the CA. When difficulties occur, the Swedish Work Environment Authority regularly is in contact with applicants, either by a written procedure or by visits.

Public consultation

Sweden has not established a system for regular public consultation and has not yet had to consult the public for any issue concerning contained use activities.

Emergency plans and accidents

For category R activities, protocols for dealing with emergencies and accidents must be included in the application if required, due to risks for unintended release 'which may entail serious immediate or delayed danger', as well as detailed information of the responsible work leader involved in the activities. In addition, the applicant must make clear that the local fire brigade and emergency response unit are aware of the type of activities being carried out at the respective premises.

Accidents are defined the same as in the Directive. Such accidents have not been reported to the CAs. If one should occur, the European Commission as well as the EEP (European Enforcement Project) network will be informed immediately.

Inspections

The Swedish Work Environment Authority has two inspectors that are involved in inspection and enforcement under the Contained Use Ordinance.

In general, about 5 to 10 inspection visits are made every year. When adding the informal visits made by the inspectors, the total number of visits is around 15 to 20 per year.

Confidential information

Confidential information is treated in conformity with Directive 2009/41/EC. The CAs are careful with making some details in notifications public, when the activities involve testing on animals.

3.12 United Kingdom

Introduction

In the United Kingdom[71], there are over 550 facilities for contained use activities with GMOs (2010). Most of these activities are conducted in the public research sector.

Directive 2009/41/EC is implemented through the Health and Safety at Work Act of 1974[72] and a set of 31 implementing regulations are made under the powers of the Act, complemented by guidelines[73].

The competence for the execution of the Regulations is divided as follows:

- Health and Safety Executive (HSE)[74]: human health aspects in England, Scotland and Wales.
- Department for Environment, Food and Rural Affairs (Defra): environmental aspects in England and Wales.
- Scottish Government: environmental aspects in Scotland.

The CAs have frequent contact via phone and email and the aim is to meet at least annually.

Scientific advice is provided to the CAs by the Scientific Advisory Committee for Genetic Modification (Contained Use) (SACGM(CU))[75].

Scope and definitions

The scope of the transposing legislation is extended to the contained use of GM plants and animals. The definitions of GM, GMM and contained use are the same as the corresponding definitions in Directive 2009/41/EC.

The same exemptions listed in the Directive apply, be it that their description is less explicit in the Regulations. The CA believes that the exemption of self cloning is rarely used. The

[71] The United Kingdom is Great Britain and Northern Ireland. The information provided in this report is based on communication with officials in Great Britain only. Northern Ireland has its own regulations, which are identical to the British regulations. Northern Ireland only has a small number of registered premises.
[72] www.hse.gov.uk/legislation/hswa.htm
[73] www.hse.gov.uk/pubns/priced/l29.pdf
[74] www.hse.gov.uk/biosafety
[75] www.hse.gov.uk/aboutus/meetings/committees/sacgmcu

definition in the Regulations of self cloning goes a little bit beyond the definition of the Directive.

General obligations

The Regulations require the installation of an IBC. Although the Regulations do not require the installation of a BSO[76], in practice BSOs are in place in most facilities. Likewise, while an IBS is not required by law, almost all institutions have installed an IBS.

Classes of activities and procedures

The Regulations follow the Directive's classification for GM micro organisms. GM plants and animals are not classified, and unless potentially dangerous to human health contained use activities with GM plants and animals are 'non notifiable'.

Table 16: Procedures for first and subsequent GMM uses in the United Kingdom

	Class 1 GMMs		Class 2 GMMs		Class 3 + 4 GMMs	
	First use	**Subsequent use**	**First use**	**Subsequent use**	**First use**	**Subsequent use**
Requirement	Notify + start after ackn. of receipt	Start	Notify + 45 days after ackn. of receipt	Notify + start after ackn. of receipt	Notify + permit	Notify + permit

For GM plants and animals the following applies:

Table 17: Procedures for first and subsequent uses of GM plants and animals in the United Kingdom

	GM plants	GM animals
Requirement	Notify if dangerous to humans	

- Notifications are signed by the BSO and the responsible researcher. Final responsibility lies with the head of the institute.
- Forms for installations and activities are available at the HSE website[77] and can be submitted electronically.
- The CA must send acknowledgements of receipt within 10 working days.
- The system allows for simplified procedures for small administrative changes as well as changes of the notifications.

[76] In the United Kingdom, Competency Standards for Laboratory Biosafety have been established by the Biosafety Section of the Institute of Safety in Technology and Research (ISTR): www.istr.org.uk/biosaf.shtml.
[77] https://www.hse.gov.uk/forms/genetic/index.htm

- For first time uses in installations, applicants tend to consult the CA and sometimes a meeting or visit is arranged.
- New information pertaining to the level of risk must be notified. In 2009, 9 such notifications were made.
- Examples of GM plants that are potentially dangerous to human health are plants producing biologically active medicinal components.
- The CA estimates that 99% of the activities with GM plants are non notifiable.

Risk assessment and assignment of containment levels

Assignment of containment levels is conducted on a case-by-case basis, based on the proposal by the applicant. Although specific lists of hosts and vectors are not used for the assignment of containment levels, the CA has provided guidance[78] with examples of vectors that would fit in certain classes. Similar guidance also exists for certain hosts such as EK K12.

Public consultation

The CA keeps a public register of all notifications[79]. To date, no comments or objections have been submitted to the CA.

Emergency plans and accidents

For level 4 and in some cases for level 3 activities, emergency plans must be drawn up. These are not made publicly available due to anti terrorism regulations. In 2009, 2 accidents were notified to the CA and 7 in 2010.

Inspections

The HSE has a team of 12-15 inspectors who conduct inspections in the context of GM work, as well as animal and human pathogens. Less than 50% of the inspected cases is related to contained use activities.

All level 4 premises are inspected annually, and the aim is to inspect level 3 premises every 3 years. For the other levels there is a ranking system included in the inspection plan, among others based on results of prior visits, and the type of work.

Confidential information

Confidential information is treated in conformity with Directive 2009/41/EC. Information is rarely submitted as confidential (estimated in about 5% of the cases).

[78] www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part3.pdf
[79] www.hse.gov.uk/biosafety/gmo/publicregister.pdf

3.13 Interviews with applicants

Introduction

After the desk study and interviews with representatives of CAs, advisory bodies and inspectorates, the survey was extended by interviews with representatives of private- and public sector applicants in a number of Member States, where possible in the person of the BSO. In addition, a number of representatives from private- and public research sector associations were interviewed.

The results of these interviews are summarised below, largely following the headings of the interviews and the summaries per Member State.

For proper appreciation of the feedback given by these applicants it is important to bear in mind that some comments may represent the view of many applicants, whereas other comments may represent the view of only a few applicants.

General

- The interviewed applicants from both the public- and the private sector fairly consistently expressed that in general the procedures and requirements for contained use of GMOs in their Member States do not pose insurmountable challenges. Furthermore, applicants have great appreciation for the readiness of CAs and inspectors to engage in informal communications and provide assistance, especially for 'first time' applicants.
- However, equally consistently, a number of points have been raised that in the eyes of the applicants deserve updating to technical progress and scientific insights, clarification and/or further harmonisation on the European level. These points are addressed below.

Overall regulatory framework – CAs

- In cases where activities resort under two different regulatory regimes, e.g. one for GMOs and one for non-GM biological agents, this sometimes leads to an unnecessary administrative burden or confusion. In some cases, applications require nearly the same information, and result in more or less the same issues. Some applicants call for a harmonised or even a single regulatory framework for GM and non-GM biological agents.
- In general, there is feeling that some requirements could be more streamlined, both on the European as well as the national level, such as the requirements for transport.
- Several interviewees suggested that permit fees should be more harmonised on the EU level.

Scope, definitions and exemptions

- While in most Member States the definitions used in the regulations are similar to the corresponding definitions in Directive 2009/41/EC, several of the interviewed applicants noted different interpretations of the definition of GMO between – and sometimes within – EU Member States. Some explain the definition to mean that the mere use of a GM technique by definition means that the resulting organism is a GMO, whereas others consider that the resulting organism is not a GMO if the resulting organism is indistinguishable from an organism made through conventional breeding. Only a few applicants were aware of the ongoing debate on this issue in a European Commission Working group on New Breeding Techniques.
- Little, if any, use is made of the existing exemption of self cloning, because in most cases the process involves non-self cloning steps, which would make notification or permits mandatory anyway.
- The possibility to establish more exemptions under the Directive (i.e. Article 3(b)) was not known to many of the interviewed applicants. Applicants who were familiar with this possibility believe that the information to be submitted for such an exemption is so case-specific that it is easier to just submit a regular notification. Some applicants have called for review of the criteria and information requirements for the exemptions referred to under Article 3(b) of Directive 2009/41/EC. Another question raised was which organisation has the resources to submit proposals for the benefit of the broader research community. Reference is made to the exemptions formulated by the US National Institute of Health[80].
- Some applicants urged for harmonisation of the approach of gene therapy protocols, which in some Member States fall under 'contained use' and in other Member States under 'release into the environment'.

General obligations – BSO and IBC

- All interviewed felt that the installation of one or more BSOs or 'biosafety advisors' in an institute is an important element of Internal Biosafety Systems. The views on the need for, role and composition of IBCs varied considerably. Some felt that IBCs have an essential role, given the involvement of various disciplines and external input, whereas others considered IBCs a 'bureaucratic layer'.
- Some of the interviewed BSOs (and CAs) urged that the terminology[81] and requirements for BSOs should be harmonised, whereby frequent reference was made to the ongoing work related to BSOs and IBCs at CEN[82].

[80] http://oba.od.nih.gov/oba/rac/guidelines_02/APPENDIX_C.htm
[81] Some Member States require the installation of a 'genuine' BSO, other countries require a 'biosafety advisor', and yet again others work with a 'biosafety agent' or a 'biosafety coordinator'.
[82] www.cen.eu/cen/Sectors/TechnicalCommitteesWorkshops/Workshops/Pages/WS53-BSP.aspx

Classes of activities / procedures / containment levels

- While in general the interviewed applicants can work with the classification and the procedures, some concerns were expressed about a) unnecessary procedural requirements for class 1; and b) assignment of containment levels in class 2.
- Cases where subsequent class 1 activities may not proceed without a notification, and where changes in laboratories and activities for class 1 have to be notified are considered unnecessarily time consuming.
- In some cases, work with animal cells is performed at containment level 2, because of possible presence of adventitious agents unrelated to the genetic modification.
- The requirement that application forms have to be completed in the national language is hindering international collaboration in research. In addition, some of the application forms are not easy to use, and require (additional) training.
- Certain technical developments require revision of particular technical requirements. For example, the application of single use bioreactors for animal cell cultures does not fit in the typical requirements for 'large scale'.
- Several interviewed urged for more clarification and harmonisation of the requirement of 'inactivation', which in some Member States is explained as 'sterilisation' and in other Member States as 'a process that reduces viable particles to a certain level'.

Emergency plans and accidents

In general, BSOs do not receive many reports of accidents, and of the accidents that are reported, very few – if any – are reported by the BSOs to the CAs. However, this is not the case in all Member States. For example, in the United Kingdom, several accidents have been reported to the CA, which in turn reported a number of accidents to the European Commission.

Having asked BSOs and CAs of other Member States about the type of accidents that were reported by the United Kingdom, it appeared that similar accidents have happened in other Member States, but that there is a difference in interpretation of when and why accidents need to be reported. Most interviewees are of the understanding that reporting to the CA or to the European Commission is only necessary in case of a significant risk outside the contained facility. On the other hand, BSOs, the advisory body and the CA in the United Kingdom are of the opinion that accidents should also be reported if this can contribute to fine-tuning containment levels or work procedures. It was recommended to discuss this issue further on EU level.

Inspections

- In general, the interviewed applicants do not consider inspections to be overly intrusive, because they are not very frequent and they are in most cases conducted in a pragmatic manner, whereby the inspectors are open for dialogue.

- Some applicants proposed combining GM-inspections with inspections in the context of work with non-GM biological agents.
- Regular contact between the applicants and inspectors via telephone, e-mail and visits is by several applicants considered as very valuable.

Confidential information

According to all interviewed applicants, confidential information is handled properly by the respective CAs.

4 Findings

Main conclusions

1. There are many commonalities as well as some significant differences in the procedural, administrative and technical implementation of Directive 2009/41/EC in the 11 Member States[83].

2. In general, the representatives of CAs, advisory bodies, inspectorates and applicants interviewed in the 11 Member States are of the opinion that the procedures and technical requirements for contained use of GMMs and GMOs in their Member States do not pose insurmountable challenges.

3. There is nevertheless a general consensus amongst the interviewed that there are various topics where there is a need for further clarification, updating to technical and scientific advancements, and/or further harmonization on the European level.

Below, the commonalities and differences between the various national systems are summarised, together with the topics that are considered requiring updates, clarification and/or harmonisation.

Scope and definitions

- In most regulatory systems, the definitions used are the same or similar to the corresponding definitions in Directive 2009/41/EC.
- However, interpretations of some of those definitions differ between Member States, and sometimes even within Member States. For example, there are different interpretations of the definition of 'GMO'. Some explain the definition to mean that the mere use of a technique of genetic modification by definition means that the resulting organism is a GMO, whereas others consider that the resulting organism is not a GMO if the resulting organism is indistinguishable from an organism made through conventional breeding. Other definitions that are interpreted differently include the term 'inactivation', which often leaves the final interpretation to inspectors. Also the term 'accident' needs to be further clarified as well as the reasons for reporting accidents.

[83] The functioning of regulatory systems is best judged in the light of the number of contained use activities in a Member State. A frequent observation of CAs was that the levels of activities are difficult to compare between Member States, because in some cases one permit is given for an entire university, whereas in other cases several permits are given for one institute. Furthermore, terms as 'institution', 'facility' and 'installation' are not interpreted in a harmonised fashion. This issue has been discussed in meetings in the context of the European Enforcement Project (EEP), and several suggestions were made to continue those discussions on EU level.

- Some interviewees called for a further discussion on whether or not it would be beneficial to also harmonise requirements for GM plants and GM animals.
- Little, if any, use is made of the existing exemption of self cloning, because in most cases the process involves non-self cloning steps, which would make notification or permits mandatory anyway.
- The possibility to define more exemptions under the Directive (i.e. Article 3(b)) is not widely known. Applicants who are familiar with this possibility believe that the information to be submitted to obtain an exemption is too case-specific: and consequently it is considered easier to just submit a regular notification. CAs have been called upon to review the criteria and information requirements for the exemptions referred to under Article 3(b) of Directive 2009/41/EC. Organisations are invoked to prepare submissions for exemptions for the benefit of the broader research community.
- Some applicants asked for harmonisation of permit fees.

Procedures

- As Table 18 below shows, there are significant differences in the procedural requirements. Some Member States have applied the same procedures as in Directive 2009/41/EC, while other Member States have established procedures that go significantly beyond the procedures of the Directive, e.g. in some Member States notifications or permits are required in cases where the Directive does not require a notification or permit[84].
- In general, public sector institutes have more problems with the procedural requirements than private sector companies. Where private sector companies sometimes even favour permits for reasons of certainty, public sector institutes often consider these to cause serious delays that are unnecessary given the level of risk involved.
- Generally, the classification and the related procedures do not cause insurmountable obstacles. However, there are some concerns, which focus on a) unnecessary procedural requirements for class 1; and b) assignment of containment levels in class 2,,which can result in loss of confidence among scientist in regulations
- In most Member States, the application forms have to be completed in the national language, which some consider a hindrance to international collaboration in research. Some call to follow the German, Swedish and Dutch example where application forms can be submitted in English.
- Certain technical developments require revision of particular technical requirements. For example, the application of single use bioreactors for animal cell cultures does not fit in the typical requirements for ‘large scale’.

[84] Notate bene: these procedural differences do not seem to be related to the years of experience with regulation of contained use. Some of the Member States that have had regulations in place for over 25 years follow the procedures of the Directive, whereas other Member States with over 25 years of experience go significantly beyond the requirements of the Directive.

- Some interviewees call for an integrated regulatory framework for GM and non-GM biological agents/pathogens, including human and animal pathogens, whereas others argued against such an integration.
- Several applicants urged for harmonisation of the approaches for gene therapy.

In Table 18, the formal transposition of the procedures in Articles 6, 7, 8 and 9 of Directive 2009/41/EC in national regulatory requirements in the 11 Member States is summarized. The Table only refers to the regulation of GMMs. However, some Member States do not differentiate between GMMs and GMOs as regards procedures; hence in these cases the Table applies to all GMOs.

From the Table it can be concluded that all 11 Members States follow the same procedures as in the Directive with regard to classes 3 and 4 GMMs. As regards classes 1 and 2, dissimilarities are noticeable: 6 of the Member States, i.e. Belgium, the Czech Republic, Denmark, France, The Netherlands, and the Slovak Republic, have procedures in place that are more strict than the Directive.

In one Member State, The Netherlands, a major overhaul of the regulatory system is in an advanced stage of preparation. This planned system is presented in Table 19 (see also Section 3.8).

The following colour-coding is used in the tables:

		Procedure is the same as in the Directive, or similar; e.g. instead of 'start immediately', work may start after acknowledgement of receipt of a notification
		Procedure is slightly stricter than the Directive; e.g. a waiting period, whilst the Directive allows the activity to start immediately
		Procedure is significantly stricter than the Directive; e.g. a notification or permit requirement, whilst the Directive does not require a notification or permit

Table 18: Overview procedures Directive 2009/41/EC

	Class 1 GMMs		Class 2 GMMs		Class 3 + 4 GMMs	
Use (Article)	**First use (Art. 6)**	**Subsequent use (Art. 7)**	**First use (Art. 8.1 + 8.3)**	**Subsequent use (Art. 8.2)**	**First use (Art 9.1 + 9.2b)**	**Subsequent use (Art 9.1 + 9.2a)**
Summary	**Notify + start**	**Start**	**Notify + 45 days**	**Notify + start**	**Notify + permit (90 days)**	**Notify + permit (45 days)**
Austria	Notify + 30 or 45 days	Start	Notify + 45 days	Notify + start	Notify + permit	Notify + permit
Belgium	Notify + start	Notify + start	Notify + permit	Notify + start (applicant can ask for a permit)	Notify + permit	Notify + permit
Czech Republic	Notify + start	Notify + start	Notify + 45 days	Notify + 45 days	Notify + permit	Notify + permit
Denmark	Notify + permit (facility *and* activity)	Notify + start	Notify + permit (facility *and* activity)	Notify + permit	Notify + permit (facility *and* activity)	Notify + permit
France	Notify + start	Notify + start	Notify + 45 days	Notify + start	Notify + permit	Notify + permit
Germany	Notify + start	Start	Notify + 45 days	Notify + start	Notify + permit	Notify + permit
Netherlands (current)	*Group IA* - Notify + permit (28 days)	*Group IA* - Start	Notify + permit (45 days)	Notify + permit (45 or 28 days)	Notify + permit (45 days)*	Notify + permit (45 or 28 days)
	Not Group IA - Notify + permit (45 days)	*Not Group IA* - Notify + permit (45 or 28 days)	*Group IIB* - Notify + permit (87 days)	*Group IIB* - Notify + permit (45 days)	*Group IIB* - Notify + permit (87 days)*	*Group IIB* - Notify + permit (45 days)
Slovak Republic	Notify + permit	Notify + start	Notify + permit	Notify + permit	Notify + permit	Notify + permit
Spain	Notify + start	Start	Notify + 45 days	Notify + start	Notify + permit	Notify + permit
Sweden	Notify + 45 days	Start	Notify + 45 days	Notify + start	Notify + permit	Notify + permit
United Kingdom	Notify + start after acknowledgement of receipt	Start	Notify + 45 days after acknowledgement of receipt	Notify + start after acknowledgement of receipt	Notify + permit	Notify + permit

***** *= period is less than prescribed in the Directive*

Table 19: Overview planned procedures Directive 2009/41/EC in The Netherlands

	Containment level 1	Containment level 2 'low'	Containment level 2 'high'° and 3	Containment level 4
Netherlands (planned)	Notify + start	Notify + 45 days	Notify + permit (45 days)*	Notify + permit (90 days)
	Change in existing activities: record in logbook, without notifying	Notify changes on forehand and start immediately	Apply for change in permit, with a 45-day term	Apply for change in permit, with a 90-day term
	Change in activity resulting in the use of a new set of provisions: notification and start immediately	Small changes: n.a.	Small changes: 28 days*	Small changes: 28 days*

° = *the procedures for containment level 2 'high' are stricter than the Directive – see footnote #55 for an explanation of 2 'high' (page 48)*

* = *period is less than prescribed in the Directive*

Competent Authorities

- Various situations exist in the Member States:
  - one authority on the national level
  - two authorities on the national level
  - authorities on the national, regional or local level
  - a combination of these
- In cases where applicants have to deal with two CAs for related fields (e.g. one for GMO and one for non-GM biological agents), this sometimes leads to an unnecessary administrative burden or confusion in implementation of containment regimes.

Administrative implementation

- The administrative implementation shows a high degree of common approaches. Most, if not all, Member States that were part of this survey:
  - provide guidance and/or training to applicants;
  - handle notifications in the timeframes as set in Directive 2009/41/EC;
  - have electronic application formats, but in most cases the original, signed hard-copy has to be submitted;
  - handle confidential information in accordance with Directive 2009/41/EC;
  - have frequent informal contacts between applicants and advisory- or regulating bodies.

(Scientific) advisory bodies

- With the exception of Denmark, all Member States that were part of this survey have installed advisory bodies.
- In most cases there is one advisory body that deals with both contained use and release into the environment. In the United Kingdom, there is a separate advisory body for contained use, and in Spain there are several regional advisory bodies and one national advisory body.
- The number of members varies per advisory body, and in all cases advisory bodies can make use of external experts.
- Some advisory bodies are mandated to look exclusively at safety issues, whereas other advisory bodies have a broader mandate, e.g. also socio-economic issues.

General requirements

- Most of the national regulatory systems have a general obligation of care, and include in various degrees of detail the requirement for establishing internal biosafety systems.
- Various different approaches exist with regard to BSOs and IBCs: some Member States require the installation of a BSO, some Member States require the installation of an IBC, and some Member States require both.

- In some Member States, CAs review the level of education prior to formally approving a BSO.
- Most Member States provide guidance to BSOs and/or IBCs.
- There is a wish for more harmonization regarding BSOs and IBCs within the EU, taking into account also the work that is conducted by CEN.

Risk assessment and assignment of containment levels

- In most cases, risk assessments are conducted on a case-by-case basis, based on the proposals by the applicants. In two cases, i.e. in The Netherlands and to a certain extent in Germany, a standardized system of assigning containment levels is available for applicants.
- It appeared that, on the whole, applicants make adequate proposals for containment levels. In cases where an assessment needed to be corrected, it was mainly to increase the level of detail of the scientific underpinning of the proposal.
- Most of the challenges and discussions on containment levels seem to focus on class 2, and in particular in the 'high end' of class 2 (see footnote #54 – page 50). A frequent observation is that there appears to be a gap in 'hard requirements' between containment level 2 and 3, and quite often a containment is required that is in between 2 and 3, sometimes denominated '2+'. For applicants it is important that containment level 2+ is classified as 'risk class 2' from a procedural point of view. Reference is made to the use of terms as 'class 2+' or 'class 3-' in some Member States and to the discussions under the WHO on 'class 2+'.
- Concerns were raised about general waste treatment requirements that are not proportionate to the level of risk involved.

Emergency plans and accidents

- Most Member States follow a similar approach with regard to emergency plans, i.e. these apply mostly for class 3 and 4. However, the Czech Republic requires an emergency plan as part of the notification of activities in all classes.
- In general, CAs do not receive many reports of accidents, and only very few CAs report accidents to the European Commission. Suggestions were made to initiate a discussion on EU level on the definition of accidents and the purpose of reporting accidents.

Enforcement

- There are significant differences between Member States in the way inspections are organised:
  - In some Member States the CA conducts the inspections, while in others the inspectorates operate independently from the CA.
  - In some Member States inspection is the responsibility of a national inspectorate, in others of the regional inspectorates.

- The number of inspectors involved in GMO enforcement inspections varies strongly per Member States, i.e. from 1 to more than 20[85].

- In general, the interviewed applicants do not consider inspections as being overly intrusive, primarily because of the low frequency and the pragmatic manner in which the inspections are carried out.
- One applicant stated that inspection visits can help to underpin the necessity for the renewal of certain equipment.
- Regular contacts between the applicants and inspectors via telephone, e-mail and visits are considered very valuable.

In light of the above, one of the key recommendations of virtually all representatives interviewed in this survey, is to revitalise the CA meetings at EU level to take stock of the experiences gained over the past years in the various Member States and to further harmonize the implementation of the Directive.

[85] These numbers are to be understood that in Member States with higher numbers of inspectors involved, not all of those inspectors are full time occupied with enforcement of contained use regulations, but also cover other areas such as releases of GMOs, food safety, non-GM pathogens, etc.

5 Annexes

- Questionnaire Annex 1
- Matrix Directive 2009/41/EC Annex 2
- Directive 2009/41/EC Annex 3

ANNEXES

Survey on the implementation of Directive 2009/41/EC

ANNEX 1

Questionnaire

Questionnaire

Regulations in EU Member States on contained use of GMMs

-	**Country**	
-	**Full name**	
-	**Organisation**	
-	**Position**	
-	**Involved in the following fields related to GMMs and/or GMOs**	☐ Policy making ☐ Policy implementation ☐ Scientific research ☐ Enforcement and control ☐ National coordination ☐ International coordination ☐ Other, namely
-	**E-mail address**	
-	**Telephone**	

Questions

1. Describe the way in which your country transposed the European Directive on the contained use of genetically modified micro-organisms (2009/41/EC) into national regulatory provisions.

1a. What is the scope? Only the contained use of genetically modified micro-organisms as in Directives 2009/41/EC or also the contained use of genetically modified plants and animals?	☐ Only genetically modified micro-organisms ☐ Also genetically modified plants ☐ Also genetically modified animals
1b. Which is/are the Competent Authority(ies) in your country?	☐ Centralised national level ☐ Local / provincial / regional level ☐ A combination ☐ Other, namely

1c. What are the main regulatory mechanisms?	
1. For which biosafety level(s) is record keeping sufficient?	
2. For which biosafety level(s) is notification required?	
3. For which biosafety level(s) is a permit required?	

2.	**Do the legislative provisions in your country go substantially beyond the provisions of the European Directive on the contained use of genetically modified micro-organisms?**
☐	Yes
☐	No

3.	**Are there substantial differences between your country's practical <u>implementation</u> of the regulatory system on contained use as compared to the implementation in other EU Member States with which you are familiar?**
☐	Yes
☐	No

4.	**Thank you for answering the above questions. If you have any suggestions or remarks regarding the regulation of the contained use of GMMs or regarding this questionnaire, please state them below.**

ANNEX 2

Matrix
Directive 2009/41/EC

ARTICLE	CONTENT	REMARKS – POSSIBLE QUESTIONS FOR INTERVIEWS	FEEDBACK
Preamble	Article 175(1)	How many institutions (private and public) are working with contained use activities of GMOs? Distinction between Institute, department; lab; facility. Do they participate in the EEP meetings?	
Article 1 Objective	Lay down common safety measures for the contained use of GMMs	What is the nationally the objective of the regulations	
		Scope : GMMs / All GMOs What is percentage of activities with: - GMMs - GM plants - GM animals	
		What is the structure of the regulatory framework? e.g. Act/decree/regulations Guidelines Can we get copies of or links to the existing legislation and regulations, preferably in English	
Article 2 Definitions	'micro-organism' means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, and animal and plant cells in culture;	Same definitions? Please provide exact text in national language and – if available – in English	
	'genetically modified micro-organism' (GMM) means a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;	Same definitions? Please provide exact text in national language and – if available – in English	
	'contained use' means any activity [with GMM] for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment;	Same definitions? Please provide exact text in national language and – if available – in English	
Article 3 Exemptions	this Directive shall not apply: (a) where genetic modification is obtained through the use of	Have criteria been established on EU level?	

	the techniques/methods listed in Annex II, Part A; or (b) for contained uses with GMMs meeting the criteria listed in Annex II, Part B and listed in Annex II, Part C.		
		– 2002/623 explanation of Annex II – 2004/787	
		No list C yet on EU level	
		Are countries preparing proposals for part B or part C?	
		Have countries exempted via de definition of self cloning?	
Article 4 Classes of activities		1) Same system of classes of activities? 2) How are containment levels assigned to specific categories of GMOs? 3) Who does the RA? The applicant of the CA? 4) Pre defined list available?	
	Class 1: activities of no or negligible risk, for which level 1 containment is appropriate	Same classification? Assignment of containment level Qualitative / List?	
	Class 2: activities of low risk, for which level 2 containment is appropriate	Same classification? Assignment of containment level Qualitative / List? Are further classifications made on basis of WHO?	
	Class 3: activities of moderate risk, for which level 3 containment is appropriate	Same classification? Assignment of containment level Qualitative / List?	
	Class 4: activities of high risk, that is to say activities for which level 4 containment is appropriate	Same classification? Assignment of containment level Qualitative / List?	
	A record of the assessment referred to in paragraph 2 shall be kept by the user	Obligations / practice?	
Article 5 General obligations	The user shall apply the general principles and the appropriate containment and the measures in Annex IV	General obligations – General duty of care, i.e. the obligation for management of institutions to ensure good care	

		– Internal biosafety systems – Biosafety Officers – IS there a role for a 'responsible expert / researcher'?	
	The assessment and containment and other measures shall be reviewed periodically	Obligations / practice?	
Article 6 First time use premise	When premises are to be used for the first time the user shall notify the competent authorities	Same principle?	
		Notification to whom? Who signs the request – who gets the permit (e.g. the University as a whole or a department) Are there 'Responsible Researchers' identified Is there a difference between 'responsibility' and 'liability'	
		Practice? Electronic application formats? Submittal electronically, hard-copy, or both? Can copies of application forms be obtained? Are Guidance documents available, can we get copies?	
		Practice?	
		Simplified procedure for small changes?	
		Is there a practice of informal contacts with the applicant before the formal submission is done? What is the experience with informal contacts?	
Article 7 Class 1	Subsequent Class 1 contained use may proceed without further notification.	Same procedure?	
		Simplified procedure for small changes?	
		Can we get copy of permit(s)	
		Practice of waste treatment	
Article 8 Class 2	Subsequent Class 2 contained uses must be notified, the contained use may proceed immediately following the new notification.	Same procedure?	
		Practice? Electronic application formats?	

		Submittal electronically, hard-copy, or both? Can copies of application forms be obtained? Are Guidance documents available, can we get copies?	
		Practice? What is delay in practice?	
		Simplified procedure for small changes?	
		Practice of waste treatment	
	If the premise has not been previously notified, the Class 2 contained use may proceed 45 days after notification, unless indication to the contrary from the CA	Same procedure?	
Article 9 Class 3, 4	Class 3 or Class 4 contained uses must be notified – the contained use may not proceed without the consent	Same procedure? Copy of an anonymous consent available? Who undersigns?	
		Practice? What is the delay?	
		Simplified procedure for small changes?	
Article 10	Designation of the competent authority or authorities	– One or more CAs? – If so, on different government levels? – Type of collaboration and coordination	
Article 11	New information relevant to risk must be notified	Obligations / practice	
Article 12	A Member State may consult the public	Obligations / practice	
Article 13	The competent authorities shall ensure that before a contained use commences an emergency plan is drawn up	Obligations / practice	
Article 14 Accidents	Member States shall take the necessary measures to ensure that, in the event of an accident, appropriate action is taken	Obligations / practice How is 'accident' defined?	
Article 15 Accidents	Member States consult with other Member States likely to be affected in the event of an accident and inform the Commission		
Article 16 Inspections	Member States shall ensure that inspections and other control measures are organized	Inspections plans available? Can a copy be obtained? How many institutions? How are priorities set? How many inspectors involved? How many actual days for inspection available per year?	
Article 17 Summary reports	Member States shall send – Each year a summary report on Class 3 and 4 – Every three years a summary report on their experience	Practice? Can copies of the summary reports be obtained?	

	with this Directive		
Article 18 Confidential information	The notifier may indicate the information that should be treated as confidential. Verifiable justification must be given in such cases	Obligations / practice (numbers)	
Article 19	adapting Annexes II, III, IV and V to technical progress, and Annex II, Part C, in accordance with the regulatory procedure with	New procedures – Lisbon treaty	
ANNEX I	PART A - Techniques of genetic modification	Same definitions? Please provide exact text in national language and – if available – in English	
	PART B Techniques not considered to result in genetic modification,	Same definitions? Please provide exact text in national language and – if available – in English	
ANNEX II	PART A Techniques or methods of genetic modification yielding micro-organisms to be excluded	Same exemptions? Please provide exact text in national language and – if available – in English	
	PART B Criteria establishing the safety of GMMs for human health and the environment	Criteria on EU level / national level	
	PART C Types of GMMs which meet the criteria listed in Part B	List on EU level / national level	
ANNEX III	Principles to be followed for the assessment referred to in Article 4(2)		
ANNEX IV	CONTAINMENT AND OTHER PROTECTIVE MEASURES - General principles	Same principles?	
	Table I A - laboratory activities	Same division / practice?	
	Table I B - glasshouses and growth-rooms	Same division / practice?	
	Table I C - animal units	Same division / practice?	
	Table II - other activities	Same division / practice?	
ANNEX V	Information required for notifications		

ANNEX 3

Directive 2009/41/EC on the contained use of genetically modified micro-organisms

DIRECTIVES

DIRECTIVE 2009/41/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 6 May 2009

on the contained use of genetically modified micro-organisms

(Recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 175(1) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [2],

Whereas:

(1) Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms [3] has been substantially amended several times [4]. Since further amendments are to be made, it should be recast in the interests of clarity.

(2) Under the Treaty, action by the Community relating to the environment must be based on the principle that preventive action is to be taken and must have as its objective, among other things, the preservation, protection and improvement of the environment and the protection of human health.

(3) Measures concerning the evaluation and best use of biotechnology with regard to the environment are a priority area on which Community action should concentrate.

(4) The development of biotechnology is such as to contribute to the economic expansion of the Member States. This involves the use of genetically modified micro-organisms (GMMs) in operations of various types and scales.

(5) The contained use of GMMs should be such as to limit their possible negative consequences for human health and the environment, due attention being given to the prevention of accidents and the control of waste.

(6) GMMs which are disposed of without appropriate provisions for specific containment measures to limit their contact with the general population and the environment do not fall within the scope of this Directive. Other Community legislation such as Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms [5] may apply.

(7) Micro-organisms, if released into the environment in one Member State in the course of their contained use, may reproduce and spread, crossing national frontiers and thereby affecting other Member States.

(8) In order to bring about the safe development of biotechnology throughout the Community, it is necessary to establish common measures for the evaluation and reduction of the potential risks arising in the course of all operations involving the contained use of GMMs and to set appropriate conditions of use.

(9) The precise nature and scale of risks associated with the contained use of GMMs are not yet fully known and the risk involved must be assessed on a case-by-case basis. In order to evaluate the risk to human health and the environment, it is necessary to lay down requirements for risk assessment.

[1] OJ C 162, 25.6.2008, p. 85.
[2] Opinion of the European Parliament of 21 October 2008 (not yet published in the Official Journal) and Council Decision of 30 March 2009.
[3] OJ L 117, 8.5.1990, p. 1.
[4] See Annex VI, Part A.
[5] OJ L 106, 17.4.2001, p. 1.

(10) Contained uses of GMMs should be classified in relation to the risks they present to human health and the environment. Such classification should be in line with international practice and based on an assessment of the risk.

(11) In order to ensure a high level of protection, the containment and other protective measures applied to a contained use must correspond to the classification of the contained use. Where there is any uncertainty, the appropriate containment and other protective measures for the higher classification should be applied until less stringent measures are justified by appropriate data.

(12) For all activities involving GMMs the principles of good microbiological practice and good occupational safety and hygiene should apply in accordance with relevant Community legislation.

(13) Appropriate containment measures should be applied at the various stages of an operation to control emissions and the disposal of material from contained uses of GMMs, and to prevent accidents.

(14) Any person, before undertaking for the first time the contained use of a GMM in a particular installation, should forward a notification to the competent authority so that the authority may satisfy itself that the proposed installation is appropriate for the purposes of carrying out the activity in a manner that does not present a hazard to human health and the environment.

(15) It is also necessary to establish appropriate procedures for the case-by-case notification of specific operations involving the contained use of GMMs, taking account of the degree of risk involved.

(16) In the case of operations involving high risk, the consent of the competent authority should be given.

(17) The containment and other protective measures applied to contained uses should be reviewed periodically.

(18) It may be considered appropriate to consult the public on the contained use of GMMs.

(19) People employed in contained uses should be consulted in accordance with the requirements of relevant Community legislation, in particular Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) [1].

(20) Appropriate measures should be taken to inform any person liable to be affected by an accident on all matters relating to safety.

(21) Emergency plans should be established to deal effectively with accidents.

(22) If an accident occurs, the user should immediately inform the competent authority and communicate the information necessary for assessing the impact of that accident and for taking the appropriate action.

(23) It is appropriate for the Commission, in consultation with the Member States, to establish a procedure for the exchange of information on accidents and for the Commission to set up a register of such accidents.

(24) The contained use of GMMs throughout the Community should be monitored, and to this end Member States should supply certain information to the Commission.

(25) In order to be considered safe for human health and the environment, GMMs should meet the list of criteria as defined in Annex II, Part B. To take account of the pace at which biotechnology is advancing, the nature of the criteria to be developed and the limited scope of that list, it is appropriate for the Council to revise those criteria, which should, where necessary, be supplemented by guidance notes to facilitate their application.

(26) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [2].

(27) In particular, the Commission should be empowered to adopt the amendments necessary to adapt Annexes II, III, IV and V to technical progress, and to adapt Annex II, Part C. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(28) The new elements introduced into this Directive concern only the committee procedures. They therefore do not need to be transposed by the Member States.

[1] OJ L 262, 17.10.2000, p. 21.
[2] OJ L 184, 17.7.1999, p. 23.

(29) This Directive should be without prejudice to the obligations of the Member States relating to the time limits for transposition into national law of the Directives set out in Annex VI, Part B,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

This Directive lays down common measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment.

Article 2

For the purposes of this Directive the following definitions shall apply:

(a) 'micro-organism' means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, and animal and plant cells in culture;

(b) 'genetically modified micro-organism' (GMM) means a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination; within the terms of this definition:

(i) genetic modification occurs at least through the use of the techniques listed in Annex I, Part A;

(ii) the techniques listed in Annex I, Part B, are not considered to result in genetic modification;

(c) 'contained use' means 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, and to provide a high level of safety for, the general population and the environment;

(d) 'accident' means any incident involving a significant and unintended release of GMMs in the course of their contained use which could present an immediate or delayed hazard to human health or the environment;

(e) 'user' means any natural or legal person responsible for the contained use of GMMs;

(f) 'notification' means the presentation of the requisite information to the competent authorities of a Member State.

Article 3

1. Without prejudice to Article 4(1), this Directive shall not apply:

(a) where genetic modification is obtained through the use of the techniques/methods listed in Annex II, Part A; or

(b) for contained uses involving only types of GMMs meeting the criteria listed in Annex II, Part B which establish their safety for human health and the environment. These types of GMMs shall be listed in Annex II, Part C.

2. Article 4(3) and (6) and Articles 5 to 11 shall not apply to the transport of GMMs by road, rail, inland waterway, sea or air.

3. This Directive shall not apply to the storage, culture, transport, destruction, disposal or use of GMMs which have been placed on the market in accordance with Directive 2001/18/EC or pursuant to other Community legislation which provides for a specific environmental risk assessment similar to that laid down in that Directive, provided that the contained use is in accordance with the conditions, if any, of the consent for placing on the market.

Article 4

1. Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the contained use of GMMs.

2. To that end, the user shall carry out an assessment of the contained uses as regards the risks to human health and the environment that those contained uses may pose, using as a minimum the elements of assessment and the procedure set out in Annex III, Sections A and B.

3. The assessment referred to in paragraph 2 shall result in the final classification of the contained uses in four classes applying the procedure set out in Annex III, which will result in the assignment of containment levels in accordance with Article 5:

Class 1: activities of no or negligible risk, that is to say activities for which level 1 containment is appropriate to protect human health and the environment.

Class 2: activities of low risk, that is to say activities for which level 2 containment is appropriate to protect human health and the environment.

Class 3: activities of moderate risk, that is to say activities for which level 3 containment is appropriate to protect human health and the environment.

Class 4: activities of high risk, that is to say activities for which level 4 containment is appropriate to protect human health and the environment.

4. Where there is doubt as to which class is appropriate for the proposed contained use, the more stringent protective measures shall be applied unless, by agreement with the competent authority, there is sufficient evidence to justify the application of less stringent measures.

5. The assessment referred to in paragraph 2 shall especially take into account the question of disposal of waste and effluents. Where appropriate, the safety measures needed in order to protect human health and the environment shall be implemented.

6. A record of the assessment referred to in paragraph 2 shall be kept by the user and made available in an appropriate form to the competent authority as part of the notification pursuant to Articles 6, 8 and 9 or on request.

Article 5

1. Save to the extent that point 2 of Annex IV allows other measures to be applied, the user shall apply the general principles and the appropriate containment and other protective measures set out in Annex IV corresponding to the class of the contained use, so as to keep workplace and environmental exposure to any GMMs to the lowest reasonably practicable level, and so that a high level of safety is ensured.

2. The assessment referred to in Article 4(2) and the containment and other protective measures applied shall be reviewed periodically, and forthwith if:

(a) the containment measures applied are no longer adequate or the class assigned to the contained uses is no longer correct; or

(b) there is reason to suspect that the assessment is no longer appropriate judged in the light of new scientific or technical knowledge.

Article 6

When premises are to be used for the first time for contained uses, the user shall be required, before commencing such use, to submit to the competent authorities a notification containing at least the information listed in Annex V, Part A.

Article 7

Following the notification referred to in Article 6, subsequent class 1 contained use may proceed without further notification. Users of GMMs in class 1 contained uses shall be required to keep the record of each assessment referred to in Article 4(6), which shall be made available to the competent authority on request.

Article 8

1. For first and subsequent class 2 contained uses to be carried out in premises notified in accordance with Article 6, a notification containing the information listed in Annex V, Part B shall be submitted.

2. If the premises have been the subject of a previous notification to carry out class 2 or a higher class of contained uses and any associated consent requirements have been satisfied, the class 2 contained use may proceed immediately following the new notification.

However, the applicant may himself request from the competent authority a decision on the grant of a formal authorisation. The decision must be made within a maximum of 45 days from the notification.

3. If the premises have not been the subject of a previous notification to carry out class 2 or a higher class of contained uses, the class 2 contained use may, in the absence of any indication to the contrary from the competent authority, proceed 45 days after submission of the notification referred to in paragraph 1, or earlier with the agreement of the competent authority.

Article 9

1. For first and subsequent class 3 or class 4 contained uses to be carried out in premises notified in accordance with Article 6, a notification containing the information listed in Annex V, Part C shall be submitted.

2. A class 3 or higher class of contained use may not proceed without the prior consent of the competent authority, which shall communicate its decision in writing:

(a) at the latest 45 days after submission of the new notification, in the case of premises which have been the subject of a previous notification to carry out class 3 or a higher class of contained uses and where any associated consent requirements have been satisfied for the same or a higher class than the contained use with which it is intended to proceed;

(b) at the latest 90 days after submission of the notification, in other cases.

Article 10

1. Member States shall designate the authority or authorities competent to implement the measures which they adopt in application of this Directive and to receive and acknowledge the notifications referred to in Articles 6, 8 and 9.

2. The competent authorities shall examine the conformity of the notifications with the requirements of this Directive, the accuracy and completeness of the information given, the correctness of the assessment referred to in Article 4(2) and the class of contained uses and, where appropriate, the suitability of the containment and other protective measures, the waste management, and emergency response measures.

3. If necessary, the competent authority may:

(a) ask the user to provide further information or to modify the conditions of the proposed contained use or to amend the class assigned to the contained use(s). In this case the competent authority may require that the contained use, if proposed, should not begin, or, if in progress, should be suspended or terminated, until the competent authority has given its approval on the basis of the further information obtained or of the modified conditions of the contained use;

(b) limit the time for which the contained use should be permitted or subject it to certain specific conditions.

4. For the purpose of calculating the periods referred to in Articles 8 and 9, any period of time during which the competent authority:

(a) is awaiting any further information which it may have requested from the notifier in accordance with point (a) of paragraph 3; or

(b) is carrying out a public inquiry or consultation in accordance with Article 12;

shall not be taken into account.

Article 11

1. If the user becomes aware of relevant new information or modifies the contained use in a way which could have significant consequences in terms of the risks posed by it, the competent authority shall be informed as soon as possible and the notification pursuant to Articles 6, 8 and 9 shall be modified.

2. If information subsequently becomes available to the competent authority which could have significant consequences in terms of the risks posed by the contained use, the competent authority may require the user to modify the conditions of, or suspend or terminate, the contained use.

Article 12

Where a Member State considers it appropriate, it may provide that the public is to be consulted on aspects of the proposed contained use, without prejudice to Article 18.

Article 13

1. The competent authorities shall ensure that before a contained use commences:

(a) an emergency plan is drawn up for contained uses where failure of the containment measures could lead to serious danger, whether immediate or delayed, to humans outside the premises and/or to the environment, except where such an emergency plan has been drawn up under other Community legislation;

(b) information on such emergency plans, including the relevant safety measures to be applied, is supplied in an appropriate manner, and without their having to request it, to bodies and authorities liable to be affected by the accident. The information shall be updated at appropriate intervals. It shall also be made publicly available.

2. The Member States concerned shall at the same time make available to other Member States concerned, as a basis for all necessary consultation within the framework of their bilateral relations, the same information as that which is disseminated to their nationals.

Article 14

1. Member States shall take the necessary measures to ensure that, in the event of an accident, the user is required immediately to inform the competent authority specified in Article 10 and to provide the following information:

(a) the circumstances of the accident;

(b) the identity and quantities of the GMMs concerned;

(c) any information necessary to assess the effects of the accident on the health of the general population and the environment;

(d) the measures taken.

2. Where information is given pursuant to paragraph 1, the Member States shall be required to:

(a) ensure that any measures necessary are taken, and immediately alert any Member States which could be affected by the accident;

(b) collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit the effects thereof.

Article 15

1. Member States shall be required to:

(a) consult with other Member States likely to be affected in the event of an accident on the proposed implementation of emergency plans;

(b) inform the Commission as soon as possible of any accident within the scope of this Directive, giving details of the circumstances of the accident, the identity and quantities of the GMMs concerned, the response measures taken and their effectiveness and an analysis of the accident, including recommendations designed to limit its effects and to avoid similar accidents in the future.

2. The Commission, in consultation with the Member States, shall establish a procedure for the exchange of information pursuant to paragraph 1. It shall also set up and keep at the disposal of the Member States a register of accidents within the scope of this Directive, including an analysis of the causes of the accidents, experience gained and measures taken to avoid similar accidents in the future.

Article 16

Member States shall ensure that the competent authority organises inspections and other control measures to ensure that users comply with this Directive.

Article 17

1. Member States shall send to the Commission, at the end of each year, a summary report on class 3 and class 4 contained uses notified during that year pursuant to Article 9, including the description, purpose and risks of the contained use(s).

2. Every three years, and for the first time on 5 June 2003, Member States shall send the Commission a summary report on their experience with this Directive.

3. Every three years, and for the first time on 5 June 2004, the Commission shall publish a summary based on the reports referred to in paragraph 2.

4. The Commission may publish general statistical information on the implementation of this Directive and related matters, as long as it contains no information likely to cause harm to the competitive position of a user.

Article 18

1. Where its disclosure affects one or more of the items mentioned in Article 4(2) of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information [1], the notifier may indicate the information in the notifications submitted pursuant to this Directive that should be treated as confidential. Verifiable justification must be given in such cases.

The competent authority shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decision.

2. In no case may the following information, when submitted pursuant to Articles 6, 8 or 9, be kept confidential:

(a) the general characteristics of the GMMs, the name and address of the notifier, and the location of use;

(b) the class of contained use and the containment measures;

(c) the evaluation of foreseeable effects, in particular any harmful effects on human health and the environment.

3. The Commission and the competent authorities shall not divulge to third parties any information deemed to be confidential according to the second subparagraph of paragraph 1 and notified or otherwise provided pursuant to this Directive, and shall protect intellectual property rights relating to the data received.

4. If, for whatever reasons, the notifier withdraws the notification, the competent authority must respect the confidentiality of the information supplied.

Article 19

The measures designed to amend non-essential elements of this Directive relating to adapting Annexes II, III, IV and V to technical progress, and to adapting Annex II, Part C, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(2).

[1] OJ L 41, 14.2.2003, p. 26.

Article 20

1. The Commission shall be assisted by a committee.

2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

Article 21

Directive 90/219/EEC, as amended by the acts listed in Annex VI, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time limits for transposition into national law of the Directives set out in Annex VI, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VII.

Article 22

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 23

This Directive is addressed to the Member States.

Done at Strasbourg, 6 May 2009.

For the European Parliament	*For the Council*
The President	*The President*
H.-G. PÖTTERING	J. KOHOUT

ANNEX I

PART A

Techniques of genetic modification referred to in point (b)(i) of Article 2 are, inter alia:

1. Recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation.

2. Techniques involving the direct introduction into a micro-organism of heritable material prepared outside the micro-organism, including micro-injection, macro-injection and micro-encapsulation.

3. Cell fusion or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART B

Techniques referred to in point (b)(ii) of Article 2 which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs made by techniques/methods other than the techniques/methods excluded by Part A of Annex II:

1. *in vitro* fertilisation;

2. natural processes such as: conjugation, transduction, transformation;

3. polyploidy induction.

ANNEX II

PART A

Techniques or methods of genetic modification yielding micro-organisms to be excluded from this Directive on condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs other than those produced by one or more of the techniques/methods listed below:

1. Mutagenesis.

2. Cell fusion (including protoplast fusion) of prokaryotic species that exchange genetic material by known physiological processes.

3. Cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions.

4. Self-cloning consisting in the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent), with or without prior enzymic or mechanical steps, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by natural physiological processes where the resulting micro-organism is unlikely to cause disease to humans, animals or plants.

   Self-cloning may include the use of recombinant vectors with an extended history of safe use in the particular micro-organisms.

PART B

Criteria establishing the safety of GMMs for human health and the environment

This Annex describes in general terms the criteria to be met when establishing the safety of types of GMMs for human health and the environment and their suitability for inclusion in Part C. Technical guidance notes may be developed in accordance with the regulatory procedure referred to in Article 20(3) in order to facilitate the implementation and explanation of this Annex.

1. **Introduction**

   Types of GMMs listed in Part C in accordance with the regulatory procedure with scrutiny referred to in Article 20(2) are excluded from the scope of this Directive. GMMs will be added to the list on a case-by-case basis and exclusion will relate only to each clearly identified GMM. This exclusion applies only when the GMM is used under conditions of contained use as defined in point (c) of Article 2. It does not apply to the deliberate release of GMMs. For a GMM to be listed in Part C, it must be proved that it meets the criteria given below.

2. **General criteria**

   2.1. Strain verification/authentication

   Identity of the strain must be precisely established. Modification must be known and verified.

   2.2. Documented and established evidence of safety

   Documented evidence of the safety of the organism must be provided.

   2.3. Genetic stability

   Where any instability could adversely affect safety, evidence of stability is required.

3. **Specific criteria**

   3.1. Non-pathogenic

   The GMM should not be capable of causing disease or harm to a healthy human, plant or animal. Since pathogenicity includes both toxigenicity and allergenicity, the GMM should therefore be:

   3.1.1. Non-toxigenic

   The GMM should not produce increased toxigenicity as a result of the genetic modification nor be noted for its toxigenic properties.

3.1.2. Non-allergenic

The GMM should not produce increased allergenicity as a result of the genetic modification nor be a noted allergen, having, for example, allergenicity comparable in particular with that of the micro-organisms identified in Directive 2000/54/EC.

3.2. No harmful adventitious agents

The GMM should not harbour known harmful adventitious agents such as other micro-organisms, active or latent, existing alongside or inside the GMM, that could cause harm to human health and the environment.

3.3. Transfer of genetic material

The modified genetic material must not give rise to harm if transferred; nor should it be self-transmissible or transferable at a frequency greater than other genes of the recipient or parental micro-organism.

3.4. Safety for the environment in the event of a significant and unintended release

GMMs must not produce adverse effects on the environment, immediate or delayed, should any incident involving a significant and unintended release occur.

GMMs that do not meet the above criteria may not be included in Part C.

PART C

Types of GMMs which meet the criteria listed in Part B:

… (to be completed in accordance with the regulatory procedure with scrutiny referred to in Article 20(2))

ANNEX III

Principles to be followed for the assessment referred to in Article 4(2)

This Annex describes in general terms the elements to be considered and the procedure to be followed to perform the assessment referred to in Article 4(2). Technical guidance notes [1] may be developed in accordance with the regulatory procedure referred to in Article 20(3) in order to facilitate the implementation and explanation of this Annex, in particular as regards Section B.

A. **Elements of assessment**

1. The following should be considered as potentially harmful effects:

— disease to humans, including allergenic or toxic effects,

— disease to animals or plants,

— deleterious effects due to the impossibility of treating a disease or providing an effective prophylaxis,

— deleterious effects due to establishment or dissemination in the environment,

— deleterious effects due to the natural transfer of inserted genetic material to other organisms.

2. The assessment referred to in Article 4(2) should be based on the following:

(a) the identification of any potentially harmful effects, in particular those associated with:

(i) the recipient micro-organism;

(ii) the genetic material inserted (originating from the donor organism);

(iii) the vector;

(iv) the donor micro-organism (as long as the donor micro-organism is used during the operation);

(v) the resulting GMM;

(b) the characteristics of the activity;

(c) the severity of the potentially harmful effects;

(d) the likelihood of the potentially harmful effects being realised.

B. **Procedure**

3. The first stage in the assessment process should be to identify the harmful properties of the recipient and, where appropriate, the donor micro-organism, and any harmful properties associated with the vector or inserted material, including any alteration in the recipient's existing properties.

4. In general, only GMMs which show the following characteristics would be considered appropriate for inclusion in class 1 as defined in Article 4(3):

(i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants [2];

(ii) the nature of the vector and the insert is such that they do not endow the GMM with a phenotype likely to cause disease to humans, animals or plants [2], or likely to have deleterious effects on the environment;

(iii) the GMM is unlikely to cause disease to humans, animals or plants [2] and is unlikely to have deleterious effects on the environment.

[1] See Commission Decision 2000/608/EC of 27 September 2000 concerning the guidance notes for risk assessment outlined in Annex III to Directive 90/219/EEC on the contained use of genetically modified micro-organisms (OJ L 258, 12.10.2000, p. 43).

[2] This would only apply to animals and plants in the environment likely to be exposed.

5. In order to obtain the necessary information to implement this process the user may firstly take into account relevant Community legislation (in particular Directive 2000/54/EC). International or national classification schemes (e.g. World Health Organisation, National Institutes of Health) and their revisions due to new scientific knowledge and technical progress may also be considered.

   These schemes concern natural micro-organisms and as such are usually based on the ability of micro-organisms to cause disease to humans, animals or plants and on the severity and transmissibility of the disease likely to be caused. Directive 2000/54/EC classifies micro-organisms, as biological agents, into four classes of risk on the basis of potential effects on a healthy human adult. These classes of risk can be used as guidance for the purposes of categorisation of the contained use activities in the four classes of risk referred to in Article 4(3). The user may also take into consideration classification schemes referring to plant and animal pathogens (which are usually established on a national basis). The abovementioned classification schemes give only a provisional indication of the risk class of the activity and the corresponding set of containment and control measures.

6. The hazard identification process carried out in accordance with points 3 to 5 should lead to the identification of the level of risk associated with the GMM.

7. Selection of the containment and other protective measures should then be made on the basis of the level of risk associated with the GMMs together with consideration of:

   (i) the characteristics of the environment likely to be exposed (e.g. whether in the environment likely to be exposed to the GMMs there are known biota which can be adversely affected by the micro-organisms used in the contained use activity);

   (ii) the characteristics of the activity (e.g. its scale and/or nature);

   (iii) any non-standard operations (e.g. the inoculation of animals with GMMs; use of equipment likely to generate aerosols).

   Consideration of items (i) to (iii) for the particular activity may increase, reduce or leave unaltered the level of risk associated with the GMM as identified under point 6.

8. The analysis carried out as described above will finally lead to the assignment of the activity to one of the classes described in Article 4(3).

9. The final classification of the contained use should be confirmed by reviewing the completed assessment referred to in Article 4(2).

ANNEX IV

CONTAINMENT AND OTHER PROTECTIVE MEASURES

General principles

1. These tables present the normal minimum requirements and measures necessary for each level of containment.

Containment is also achieved through the use of good work practices, training, containment equipment and special installation design. For all activities involving GMMs the principles of good microbiological practice and the following principles of good occupational safety and hygiene shall apply:

(i) to keep workplace and environmental exposure to any GMM to the lowest practicable level;

(ii) to exercise engineering control measures at source and to supplement these with appropriate personal protective clothing and equipment when necessary;

(iii) to test adequately and maintain control measures and equipment;

(iv) to test, when necessary, for the presence of viable process organisms outside the primary physical containment;

(v) to provide appropriate training of personnel;

(vi) to establish biological safety committees or subcommittees, if required;

(vii) to formulate and implement local codes of practice for the safety of personnel, as required;

(viii) where appropriate, to display biohazard signs;

(ix) to provide washing and decontamination facilities for personnel;

(x) to keep adequate records;

(xi) to prohibit eating, drinking, smoking, applying cosmetics or the storing of food for human consumption in the work area;

(xii) to prohibit mouth pipetting;

(xiii) to provide written standard operating procedures where appropriate to ensure safety;

(xiv) to have effective disinfectants and specified disinfection procedures available in case of spillage of GMMs;

(xv) to provide safe storage for contaminated laboratory equipment and materials, when appropriate.

2. The titles of the tables are indicative:

Table I A presents minimum requirements for laboratory activities.

Table I B presents additions to and modifications of Table I A for glasshouse/growth-room activities involving GMMs.

Table I C presents additions to and modifications of Table I A for activities with animals involving GMMs.

Table II presents minimum requirements for activities other than laboratory activities.

In some particular cases, it might be necessary to apply a combination of measures, from Table I A and Table II, of the same level.

In some cases users may, with the agreement of the competent authority, not apply a specification under a particular containment level or combine specifications from two different levels.

In these tables 'optional' means that the user may apply these measures on a case-by-case basis, subject to the assessment referred to in Article 4(2).

3. In implementing this Annex, Member States may in addition incorporate in the following tables the general principles set out in points 1 and 2, with a view to clarifying the requirements.

Table I A

Containment and other protective measures for laboratory activities

Specifications		Containment levels			
		1	2	3	4
1	Laboratory suite: isolation (1)	Not required	Not required	Required	Required
2	Laboratory: sealable for fumigation	Not required	Not required	Required	Required
Equipment					
3	Surfaces resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents, and easy to clean	Required (bench)	Required (bench)	Required (bench, floor)	Required (bench, floor, ceiling, walls)
4	Entry to lab via airlock (2)	Not required	Not required	Optional	Required
5	Negative pressure relative to the pressure of the immediate environment	Not required	Not required	Required except for (3)	Required
6	Extract and input air from the laboratory should be HEPA (4)-filtered	Not required	Not required	Required (HEPA — extract air except for (3))	Required (HEPA— input and extract air (5))
7	Microbiological safety post	Not required	Optional	Required	Required
8	Autoclave	On site	In the building	En suite (6)	In lab = double-ended
System of work					
9	Restricted access	Not required	Required	Required	Required
10	Biohazard sign on the door	Not required	Required	Required	Required
11	Specific measures to control aerosol dissemination	Not required	Required minimise	Required prevent	Required prevent
13	Shower	Not required	Not required	Optional	Required
14	Protective clothing	Suitable protective clothing	Suitable protective clothing	Suitable protective clothing and (optional) footwear	Complete change of clothing and footwear before entry and exit

Specifications		Containment levels			
		1	2	3	4
15	Gloves	Not required	Optional	Required	Required
18	Efficient vector control (e.g. for rodents and insects)	Optional	Required	Required	Required
Waste					
19	Inactivation of GMMs in effluent from hand-washing sinks or drains and showers and similar effluents	Not required	Not required	Optional	Required
20	Inactivation of GMMs in contaminated material and waste	Optional	Required	Required	Required
Other measures					
21	Laboratory to contain its own equipment	Not required	Not required	Optional	Required
23	An observation window or alternative is to be present so that occupants can be seen	Optional	Optional	Optional	Required

(1) Isolation = the laboratory is separated from other areas in the same building or is in a separate building.
(2) Airlock = entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.
(3) Activities where transmission does not occur via airborne route.
(4) HEPA = High efficiency particulate air.
(5) Where viruses which are not retained by HEPA filters are used, extra requirements will be necessary for extract air.
(6) With validated procedures, allowing the safe transfer of material into an autoclave outside the lab, and providing an equivalent level of protection.

Table I B

Containment and other protective measures for glasshouses and growth-rooms

The terms 'glasshouse' and 'growth-room' refer to a structure with walls, a roof and a floor designed and used principally for growing plants in a controlled and protected environment.

All provisions of Table I A shall apply with the following additions/modifications:

Specifications		Containment levels			
		1	2	3	4
Building					
1	Glasshouse: permanent structure (1)	Not required	Required	Required	Required
Equipment					
3	Entry via a separate room with two interlocking doors	Not required	Optional	Optional	Required
4	Control of contaminated run-off water	Optional	Minimise (2) run-off	Prevent run-off	Prevent run-off

	Specifications	Containment levels			
		1	2	3	4
System of work					
6	Measures to control undesired species such as insects, rodents, arthropods	Required	Required	Required	Required
7	Procedures for transfer of living material between the glasshouse/growth-room, protective structure and laboratory shall control dissemination of GMMs	Minimise dissemination	Minimise dissemination	Prevent dissemination	Prevent dissemination

(1) The glasshouse shall consist of a permanent structure with a continuous waterproof covering, located on a site graded to prevent entry of surface-water run-off, and with self-closing lockable doors.
(2) Where transmission can occur through the ground.

Table I C

Containment and other protective measures for activities in animal units

All provisions of Table I A shall apply with the following additions/modifications:

	Specifications	Containment levels			
		1	2	3	4
Facilities					
1	Isolation of animal unit (1)	Optional	Required	Required	Required
2	Animal facilities (2) separated by lockable doors	Optional	Required	Required	Required
3	Animal facilities designed to facilitate decontamination (waterproof and easily washable material (cages, etc.))	Optional	Optional	Required	Required
4	Floor and/or walls easily washable	Optional	Required (floor)	Required (floor and walls)	Required (floor and walls)
5	Animals kept in appropriate containment facilities such as cages, pens or tanks	Optional	Optional	Optional	Optional
6	Filters on isolators or isolated room (3)	Not required	Optional	Required	Required

(1) Animal unit: a building or separate area within a building containing facilities and other areas such as changing rooms, showers, autoclaves, food storage areas, etc.
(2) Animal facility: a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures.
(3) Isolators: transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

Table II

Containment and other protective measures for other activities

Specifications		Containment levels			
		1	2	3	4
General					
1	Viable micro-organisms should be contained in a system which separates the process from the environment (closed system)	Optional	Required	Required	Required
2	Control of exhaust gases from the closed system	Not required	Required, minimise dissemination	Required, prevent dissemination	Required, prevent dissemination
3	Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	Optional	Required, minimise dissemination	Required, prevent dissemination	Required, prevent dissemination
4	Inactivation of bulk culture fluids before removal from the closed system	Optional	Required, by validated means	Required, by validated means	Required, by validated means
5	Seals should be designed so as to minimise or prevent release	No specific requirement	Minimise dissemination	Prevent dissemination	Prevent dissemination
6	The controlled area should be designed to contain spillage of the entire contents of the closed system	Optional	Optional	Required	Required
7	The controlled area should be sealable to permit fumigation	Not required	Optional	Optional	Required
Equipment					
8	Entry via airlock	Not required	Not required	Optional	Required
9	Surfaces resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents, and easy to clean	Required (bench if any)	Required (bench if any)	Required (bench if any, floor)	Required (bench, floor, ceiling, walls)
10	Specific measures to adequately ventilate the controlled area in order to minimise air contamination	Optional	Optional	Optional	Required
11	The controlled area should be maintained at an air pressure negative to the immediate surroundings	Not required	Not required	Optional	Required

Specifications		Containment levels			
		1	2	3	4
12	Extract and input air from the controlled area should be HEPA filtered	Not required	Not required	Required (extract air, optional for input air)	Required (input and extract air)
System of work					
13	Closed systems should be located within a controlled area	Not required	Optional	Required	Required
14	Access should be restricted to nominated personnel only	Not required	Required	Required	Required
15	Biohazard signs should be posted	Not required	Required	Required	Required
17	Personnel should shower before leaving the controlled area	Not required	Not required	Optional	Required
18	Personnel should wear protective clothing	Required (work clothing)	Required (work clothing)	Required	Complete change before exit and entry
Waste					
22	Inactivation of GMMs in effluent from hand-washing sinks and showers or similar effluents	Not required	Not required	Optional	Required
23	Inactivation of GMMs in contaminated material and waste, including those in process effluent before final discharge	Optional	Required, by validated means	Required, by validated means	Required, by validated means

ANNEX V

Information required for the notification referred to in Articles 6, 8 and 9

PART A

Information required for the notification referred to in Article 6:

— name of user(s), including those responsible for supervision and safety,

— information on the training and qualifications of the persons responsible for supervision and safety,

— details of any biological committees or subcommittees,

— address and general description of the premises,

— a description of the nature of the work which will be undertaken,

— the class of the contained uses,

— only for class 1 contained uses, a summary of the assessment referred to in Article 4(2) and information on waste management.

PART B

Information required for the notification referred to in Article 8:

— the date of submission of the notification referred to in Article 6,

— the names of the persons responsible for supervision and safety and information on their training and qualification,

— the recipient, donor and/or parental micro-organism(s) used and, where applicable, the host-vector system(s) used,

— the source(s) and the intended function(s) of the genetic material(s) involved in the modification(s),

— the identity and characteristics of the GMM,

— the purpose of the contained use, including the expected results,

— the approximate culture volumes to be used,

— a description of the containment and other protective measures to be applied, including information about waste management, including the wastes to be generated, their treatment, final form and destination,

— a summary of the assessment referred to in Article 4(2),

— the information necessary for the competent authority to evaluate any emergency response plans, if required under Article 13(1).

PART C

Information required for the notification referred to in Article 9:

(a) — the date of submission of the notification referred to in Article 6,

— the names of the persons responsible for supervision and safety and information on their training and qualification;

(b) — the recipient or parental micro-organism(s) to be used,

— the host-vector system(s) to be used (where applicable),

— the source(s) and intended function(s) of the genetic material(s) involved in the modification(s),

— the identity and characteristics of the GMM,

— the culture volumes to be used;

(c) — a description of the containment and other protective measures to be applied, including information about waste management, including the type and form of wastes to be generated, their treatment, final form and destination,

— the purpose of the contained use, including the expected results,

— a description of the parts of the installation;

(d) information about accident prevention and emergency response plans, if any:

— any specific hazards arising from the location of the installation,

— the preventive measures applied, such as safety equipment, alarm systems and containment methods,

— the procedures and plans for verifying the continuing effectiveness of the containment measures,

— a description of information provided to workers,

— the information necessary for the competent authority to evaluate any emergency response plans, if required under Article 13(1);

(e) a copy of the assessment referred to in Article 4(2).

ANNEX VI

PART A

Repealed Directive with list of its successive amendments

(referred to in Article 21)

Council Directive 90/219/EEC (OJ L 117, 8.5.1990, p. 1)	
Commission Directive 94/51/EC (OJ L 297, 18.11.1994, p. 29)	
Council Directive 98/81/EC (OJ L 330, 5.12.1998, p. 13)	
Council Decision 2001/204/EC (OJ L 73, 15.3.2001, p. 32)	
Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1)	Annex III, point 19, only

PART B

Time limits for transposition into national law

(referred to in Article 21)

Directive	Time limit for transposition
90/219/EEC	23 October 1991
94/51/EC	30 April 1995
98/81/EC	5 June 2000

ANNEX VII

CORRELATION TABLE

Directive 90/219/EEC	This Directive
Article 1	Article 1
Article 2	Article 2
Article 3, introductory wording	Article 3(1), introductory wording
Article 3, first indent	Article 3(1), point (a)
Article 3, second indent	Article 3(1), point (b)
Article 4, first paragraph	Article 3(2)
Article 4, second paragraph	Article 3(3)
Article 5	Article 4
Article 6	Article 5
Article 7	Article 6
Article 8	Article 7
Article 9	Article 8
Article 10	Article 9
Article 11(1), (2) and (3)	Article 10(1), (2) and (3)
Article 11(4), introductory wording	Article 10(4), introductory wording
Article 11(4), first indent	Article 10(4), point (a)
Article 11(4), second indent	Article 10(4), point (b)
Article 12, first paragraph	Article 11(1)
Article 12, second paragraph	Article 11(2)
Article 13	Article 12
Article 14, first paragraph	Article 13(1)
Article 14, second paragraph	Article 13(2)
Article 15(1), introductory wording	Article 14(1), introductory wording
Article 15(1), first indent	Article 14(1), point (a)
Article 15(1), second indent	Article 14(1), point (b)
Article 15(1), third indent	Article 14(1), point (c)
Article 15(1), fourth indent	Article 14(1), point (d)
Article 15(2), introductory wording	Article 14(2), introductory wording
Article 15(2), first indent	Article 14(2), point (a)
Article 15(2), second indent	Article 14(2), point (b)
Article 16	Article 15
Article 17	Article 16
Article 18	Article 17
Article 19(1)	Article 18(1), first subparagraph
Article 19(2)	Article 18(1), second subparagraph
Article 19(3), introductory wording	Article 18(2), introductory wording
Article 19(3), first indent	Article 18(2), point (a)
Article 19(3), second indent	Article 18(2), point (b)
Article 19(3), third indent	Article 18(2), point (c)
Article 19(4)	Article 18(3)
Article 19(5)	Article 18(4)
Article 20	Article 19

Directive 90/219/EEC	This Directive
Article 20a	—
Article 21(1)	Article 20(1)
Article 21(2), first subparagraph	Article 20(2) and (3), first subparagraph
Article 21(2), second subparagraph	Article 20(3), second subparagraph
Article 21(3)	—
Article 22	—
—	Article 21
—	Article 22
Article 23	Article 23
Annexes I-V	Annexes I-V
—	Annex VI
—	Annex VII