European Commission
Contract no. FIF.2004 0828:

Users Guide to European Regulation in Biotechnology

Final Report, Part I:

Complete text

USERS GUIDE TO EUROPEAN REGULATION IN BIOTECHNOLOGY

CONTENTS

GENERAL INTRODUCTION

Welcome to this easy-access tour of the European Union's biotechnology regulation. Created with industry in mind, the Guide aims to help companies identify routes to regulatory compliance for their products and processes. At the same time, it will help all EU citizens further their understanding of the way regulation balances the benefits, risks and ethical issues arising from biotechnology.

To get started now, go to our Route Planner to select your key topics. Then use the Route Planner and Sectional Maps to explore the areas you need to cover.

Each of the Guide's eight Sections is set out in a Question and Answer format. The Answers contain brief explanatory text, with links to legislation and related information.

The Guide begins by examining the Community's biotechnology strategy, then looks at the measures in place that help to inform citizens so that they can participate fully. Detailed Sections cover genetic modification (GM) in experimental, industrial and environmental contexts; the authorisation of agricultural biotech products, including those intended for use in the food chain; the consignment and international movement of genetically modified organisms (GMOs); medicinal products, and the advanced therapies which are now beginning to be recognised in Community law; and the Community's implementation of intellectual property (IP) arrangements that aim to promote innovation and deliver wider benefits.

From the Guide, you can access legislation, outlines of the main legislative requirements, official guidance, official bodies and contact points. Member State national legislation is not covered, but where possible, lists of national authorities are provided. Links to international agreements are provided if they are relevant to biotechnology regulation in the Community.

Acknowledgements

The *Users Guide to European Regulation in Biotechnology* was compiled and written by LGC Limited, London. LGC wishes to acknowledge contributions made by specialists from many parts of the European Commission (including Directorates-General Agriculture and Rural Development, Enterprise and Industry, Environment, Internal Market and Services, and Health and Consumer Protection, the Legal Service, and the Bureau of European Policy Advisers), the University of Bradford's Department of Peace Studies, the UK Government Biotechnology Portal (i-bio), the Dangerous Goods Advisory Service, the UK Biotechnology Regulatory Atlas, and The Design Clinic Ltd, London.

USERS GUIDE TO EUROPEAN REGULATION IN BIOTECHNOLOGY

EXECUTIVE SUMMARY

1. Introduction

1.1 Purpose

The *Users Guide to European Regulation in Biotechnology* aims to provide a basic overview of the Community regulatory system for biotechnology, and guidance as to how it operates from a user's perspective. It helps companies identify routes to regulatory compliance for their products and processes, reducing uncertainty as it clarifies which regulations are applicable and what the basic regulatory procedures are. This should reduce the costs of compliance. At the same time, the Guide promotes understanding of the way regulation balances the benefits, risks and ethical issues arising from biotechnology.

Key legislative requirements are indicated by the Guide, but the focus is on providing access to more specific Community sources of information. The Guide does not aim to interpret legal documents, and should not be read as legally binding. National (Member State) legislation is not covered, but, where relevant, lists of national authorities are provided.

1.2 Intended Audience

The Guide has been designed to assist users by clarifying how the Community regulatory system operates. It will, therefore, be useful for SMEs, other companies (including those from the developing world), and entrepreneurs working in the field of life sciences and biotechnology, who have limited access to expertise in the regulatory field. The Guide is also intended to be accessible to a broader audience of the interested public and is designed so that specialist scientific or legal knowledge is not required.

1.3 Structure

The Guide has eight Sections providing explanatory text and key information in the areas of:

- The Community strategy for biotechnology
- Access to information
- Contained use of genetically modified organisms (GMOs)
- Release and commercialisation of genetically modified organisms
- The GM feed and food chain
- Transportation and international (transboundary) movement of genetically modified organisms
- Medicinal products and healthcare
- Intellectual property.

2. Background

In 2002, following a public consultation, the European Commission published a *Strategy for Life Sciences and Biotechnology*[1]. Through implementation of the Strategy, the European Community and its Member States should be able to maximise the potential of biotechnology for increasing productivity and economic growth and at the same time ensure adequate governance. The Strategy recognised the importance of ensuring that businesses are aware of the comprehensive biotechnology regulatory system that is already in place, and supported public engagement with the Community's approach.

The Strategy incorporated an Action Plan; this Guide responds to Action 11:

> The Commission ... should aid applicants, especially from start up companies and SMEs, requesting approval through the regulatory process.
> The Commission will issue a guide to community regulation for users and for entrepreneurs who have limited staff expertise in the regulatory and legal fields. Such a guide should also benefit non-EU (e.g. developing world) applicants and the general public.

3. Main aims of the Community regulatory system

The aims of the Community regulatory system for biotechnology include:

- Safeguarding public health (e.g. effective regulation of medicines)
- Safeguarding the environment (e.g. environmental risk assessments for releases of GMOs)
- Protecting consumers' interests (e.g. labelling of GM feed and food)
- Promoting competitiveness (e.g. clarifying intellectual property rights).

Not all elements of biotechnology are regulated at the Community level; some are more appropriately regulated on a national basis. Community legislation is used only where it will be the most effective means of regulation.

4. Key instruments and major legislative areas

4.1 The Community strategy for biotechnology

Effective and coherent regulation forms an important part of the *Strategy for Life Sciences and Biotechnology*, particularly for the creation of a conducive environment for R & D investment. Since the launch of the Strategy, in 2002, there have been important advances in the Community regulatory frameworks for pharmaceuticals and for GMOs. There have also been improvements in national implementation of the GMO legislation and of Directive 98/44/EC *on*

[1] http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0027en01.pdf.

the legal protection of biotechnological inventions[2]. Annual progress reports on the Strategy have been published.[3]

4.2 Access to information

The importance of ensuring public confidence in Community legislation is recognised. In achieving this aim, the promotion of regulatory transparency and democratic accountability are important. They are particularly important in the area of biotechnology because there are a variety of ethical and social issues raised by advances in this area. In accordance with the UNECE Aarhus Convention[4], the Community is committed to promoting dialogue with the public and to ensuring that the public is involved in decision-making on genetically modified organisms.

Regulation (EC) No 1049/2001 *regarding public access to European Parliament, Council and Commission documents*[5] provides a general right of access to documentary information drawn up or received by European Union institutions. Limits on access are recognised in respect of certain public or private interests, as well as personal data.

Directive 2003/4/EC *on public access to environmental information*[6] guarantees and promotes access to such information held by or for public authorities at national, regional and local level. Directive 2003/4 applies to GMOs when they may:

- Affect and/or interact with biodiversity
- Affect other environmental elements (e.g. water, soil, land)
- Affect human health and safety through their environmental effects.

A wide range of legislative instruments relating to particular fields and applications of biotechnology contain more specific provisions enabling public access to information and participation in decision-making. Requirements include access to certain regulatory and supporting scientific documents, consultation of the public on scientific assessments, the keeping of public registers, and product traceability and labelling. Exemptions provide for specified information to be kept confidential.

4.3 Contained use of GMOs

---

[2] http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf.
[3] First Progress Report, COM(2003)96 Final, http://europa.eu.int/eur-lex/en/com/cnc/2003/com2003_0096en01.pdf.
Second Progress Report, COM(2004)250 Final, http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/com/2004/com2004_0250en01.pdf.
Third Progress Report, COM(2005)286 Final, http://europa.eu.int/comm/biotechnology/DOCS/COM(2005)286finalEN.pdf.
[4] http://europa.eu.int/comm/environment/aarhus/
[5] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32001R1049&model=guichett
[6] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_041/l_04120030214en00260032.pdf.

Containment of GMOs is required where human, animal or plant health would be put at risk by exposure to them. This may, for example, be during laboratory or industrial use. The key legislative instrument is the framework Directive 90/219/EEC *on the contained use of genetically modified micro-organisms*[7] . Containment measures vary according to the nature and degree of risk involved. But in all cases the Competent Authority of the Member State in which the contained use is intended to take place must be notified prior to the use commencing, and a risk assessment must be conducted prior to the notification. Two other principal instruments will apply in certain situations: Directive 2000/54/EC *on the protection of workers from risks related to exposure to biological agents at work*[8]; and certain provisions of Regulation 1946/2003 *on transboundary movements of genetically modified organisms*[9].

Apart from some provisions of Regulation 1946/2003 on transboundary movements (see 4.6 below), specific regulation of the contained use of GMOs other than genetically modified micro-organisms (GMMs) is at Member State level.

4.4 Release and commercialisation of GMOs

Release and commercialisation of GMOs are regulated by the Community in order to ensure the protection of human health and the environment, and to ensure fair practices in the internal market. The authorisation procedures for non-commercial releases (e.g. those carried out for research purposes) are different from those for commercial releases 'placing on the market'.

Parts A, B and D of the framework Directive 2001/18/EC *on the deliberate release into the environment of genetically modified organisms*[10] establish the authorisation procedures for all non-commercial releases, which take place at the national level and are restricted to the territory of the authorising Member State, except for clinical trials.

Parts A, C and D of the framework Directive 2001/18/EC establish the authorisation procedures for placing GMOs on the market. For commercial releases, authorisation decisions are usually made at the Community level, and authorisations are valid throughout the Community.

The Guide also covers related legislation on the marketing for any purpose of genetically modified seeds and plant propagating materials, and principles for the coexistence of genetically modified, conventional and organic agriculture.

4.5 The GM feed and food chain

---

7 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31990L0219&model=guichett.

8 http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_262/l_26220001017en00210045.pdf.

9 http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_287/l_28720031105en00010010.pdf.

10 http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf.

European regulation of feed and food safety is designed to protect human, animal and plant health, the environment and consumers' interests. For GM food and feed, this is achieved by a key Community Regulation – (EC) No 1829/2003 *on genetically modified food and feed*[11]. This Regulation puts in place a centralised, uniform and transparent EU procedure for all applications for placing on the market of GM food and feed, whether they concern the GMO itself or the food and feed products derived therefrom.

There are interdependencies between Regulation 1829/2003 and another important Regulation that was enacted alongside it, Regulation (EC) No 1830/2003 *concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC*[12].

Food or feed containing, consisting of, or produced from GMOs must not be placed on the market without authorisation. Marketing authorisation decisions are made at the Community level.

4.6 Transportation and international (transboundary) movement of GMOs

Two main regulatory regimes may apply to transportation and international movements of GMOs. First, legislation on the transport of dangerous goods applies where GMOs are considered to pose a risk to human, animal and plant health, or to the environment. Second, there is legislation covering exports and movements of GMOs outside of the Community market.

The key European legislation on the transport of dangerous goods includes Directive 94/55/EC *on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road*[13], and Directive 96/49/EC *on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail*[14].

Regulation (EC) No 1946/2003 *on transboundary movements of genetically modified organisms*[15] regulates transboundary movements of GMOs from the European Union to third countries, and implements certain other provisions of the international Cartagena Protocol on Biosafety[16], such as unintentional releases and information exchange.

4.7 Medicinal products and healthcare

European authorisation systems for medicinal products aim to protect public health by applying the fundamental criteria of quality, safety and efficacy. The key activities of the medicinal products sector are strictly regulated, including early development, clinical trials, manufacture, use, and feedback on product

[11] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf.
[12] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00240028.pdf.
[13] http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31994L0055:EN:HTML.
[14] http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31996L0049:EN:HTML.
[15] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_287/l_28720031105en00010010.pdf.
[16] http://www.biodiv.org/biosafety/protocol.asp.

performance. Regulation (EC) No 726/2004 *laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency*[17] details the centralised procedure under which most biotechnology medicinal products must be authorised for placing on the market.

A number of important existing and forthcoming legislative instruments may also apply to biotechnology medicinal products. For example:

- The Clinical Trials Directive (2001/20/EC)[18]
- The Human Tissues and Cells Directive (Directive 2004/23/EC)[19]
- Regulation (EC) No 141/2000 *on orphan medicinal products*[20]
- The SME Regulation - (EC) No 2049/2005[21]
- Proposed Regulation *on medicinal products for paediatric use*[22]
- Proposed Regulation *on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004*[23].

4.8 Intellectual property

The development of innovative biotechnological products and processes often requires significant funds, and the ability to protect intellectual property is an important incentive for investment.

Industrial inventions can be protected by patents if certain basic conditions are met. Systems of patent protection exist at the Member State, European and international levels. Patenting procedure is partially harmonised across countries participating in the European Patent Convention[24], but it is proposed that a system for unitary Community patents will be established in the future.

Directive 98/44/EC *on the legal protection of biotechnological inventions*[25] supplements general patent legislation by outlining which biotechnological inventions are eligible for protection. It takes into account the unique ethical and technical issues in this field, concerning for example genetic information and material derived from humans.

Plant varieties can be protected directly under Regulation (EC) No 2100/94 *on Community Plant Variety Rights*[26]. However, GMOs may be patentable, and plant varieties – including crops – derived from patented GMOs are themselves protected as a result. Community law aims for the clear and

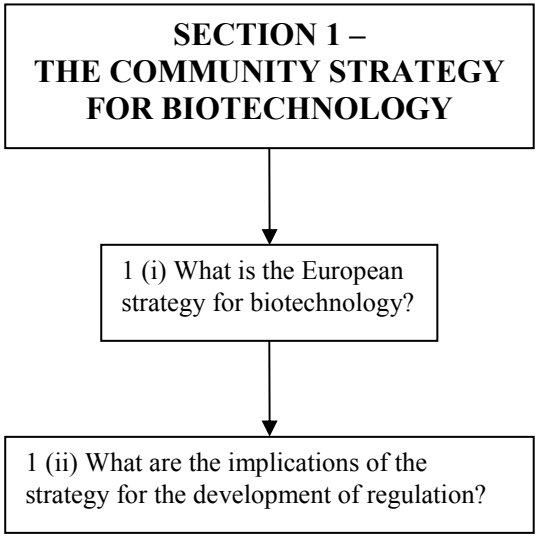
[17] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_136/l_13620040430en00010033.pdf.
[18] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_121/l_12120010501en00340044.pdf.
[19] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_102/l_10220040407en00480058.pdf.
[20] http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_018/l_01820000122en00010005.pdf.
[21] http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_329/l_32920051216en00040007.pdf.
[22] http://pharmacos.eudra.org/F2/Paediatrics/docs/_2004_09/EN.pdf.
[23] http://pharmacos.eudra.org/F2/advtherapies/index.htm.
[24] http://www.european-patent-office.org/legal/epc/e/ma1.html#CVN.
[25] http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf.
[26] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31994R2100&model=guichett.

consistent protection of intellectual property by enabling patents and plant variety rights to be cross-licensed.

5. Conclusion

The *Users Guide to European Regulation in Biotechnology* provides an overview of Community legislation and guidance for this key growth area. Much of the legislation is already highly developed. There is a strong regulatory system in place for the authorisation of GMOs for contained use, deliberate release, transboundary movement, and in food and feed. In the medicinal products area, the established legislation has been tailored to provide strict controls on biotechnology medicinal products throughout their life cycles. However, further regulations are under development that will clarify the applicability of current rules to areas such as emerging therapies. The Biotechnology Patents Directive (98/44/EC) provides a foundation for consistent exploitation of the benefits arising from innovation.

Public engagement - including access to information and participation in decision making - is a continuing priority for biotechnology. This Guide supports companies by clarifying the Community requirements with which they must comply, whilst offering a structured outline of European regulation in biotechnology for everyone interested.


SECTION 1 –
THE COMMUNITY STRATEGY
FOR BIOTECHNOLOGY
1 (i) What is the European strategy for biotechnology?
1 (ii) What are the implications of the strategy for the development of regulation?

SECTION 1 – THE COMMUNITY STRATEGY FOR BIOTECHNOLOGY

Biotechnology offers great potential for increasing productivity and economic growth in Europe. Maximising this potential requires the development of a coherent approach to policy and regulation. The European Commission has developed a strategy on life sciences and biotechnology which sets out major objectives, and is implementing an action plan of measures to achieve them.

1 (i) What is the European strategy for biotechnology?

The European Community's Lisbon Strategy of 2000 set the target of making the EU 'the most dynamic and competitive knowledge-based economy in the world' by 2010.[27] In a 'knowledge-based economy', knowledge, information and technology form the basis of productivity and economic growth. Developing a coherent European approach to meeting the challenges and opportunities of biotechnology is therefore a key element in achieving a successful knowledge-based economy. The European Commission published *Life Sciences and Biotechnology: A Strategy for Europe*[28] in January 2002, to guide the development of such an approach.

The pursuit of fragmentary policies in regard to certain aspects of biotechnology could damage Europe's competitiveness in this sector. This is a serious matter, as biotechnology will be an increasingly significant part of the global economy in decades to come. Uncertainty about regulatory approaches has resulted in insufficient resources being put into research and development (R & D). While it remains legitimate for Member States to pursue certain policies of their own in accordance with the 'subsidiarity principle'[29] – under which decisions are taken as closely as possible to the citizen – it is sensible for the Community to play a coordinating role, providing a degree of coherence to policies and legislation. The *Strategy for Europe* is key to this process, establishing a common vision and guiding principles and objectives. The Strategy is directed at EU institutions, Member States, and public and private bodies (including public authorities, academia and industry). It is intended only as the beginning of a process which will continue to develop up to 2010. The Commission is currently working on updating the Strategy in time for the Spring European Council in 2007.

The *Strategy for Europe* sets out key aims, followed by an action plan of practical measures to be used in achieving them. Because biotechnology has a wide range of applications and impacts, some aspects of its regulation fall within the European Community's competence (i.e. they are matters for which the Community has the authority to establish appropriate policies and legislation). For other aspects of biotechnology regulation, individual Member State actions, adapted to national needs and conditions, will be appropriate.

---

[27] http://europa.eu.int/growthandjobs/index_en.htm.
[28] http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0027en01.pdf.
[29] http://europa.eu.int/scadplus/glossary/subsidiarity_en.htm.

The Strategy

This sets out the reasons for establishing a strategy for Europe in the area of biotechnology, then outlines the key objectives. The objectives are focused around three main questions:

- How can Europe best attract the human, industrial and financial resources to develop and apply these technologies to meet society's needs and increase its competitiveness?
- How can Europe deliver effective, credible and responsible policies which enjoy the confidence and support of its citizens?
- How can Europe best respond to the global challenges [relating to competitiveness, the international regulatory framework, and issues of welfare, development and environmental protection], develop its domestic policies with a clear international perspective and act internationally to pursue its interests?

The Action Plan

The *Strategy for Europe's* Action Plan forms a framework identifying specific measures, both short and long-term, that can be used to achieve the objectives. There are 30 separate actions identified, some involving several elements. Each Action is allocated a time frame and is directed to one or more actors, e.g. the Commission, the Member States, academia, the private sector. The Plan covers:

- Education and training
- Support for research
- Management and legal services
- Exploitation of intellectual property
- Strengthening the capital base
- Networking of biotechnology communities
- Proactive role for public authorities
- Societal scrutiny and dialogue
- Developing life sciences and biotechnology in harmony with ethical values and societal goals
- Regulatory oversight
- International collaboration
- Responsibilities towards the developing world, and
- Implementation.

The final action point commits the Commission to report regularly on progress, and 'indicate possible specific proposals to ensure policy and legislative coherence'. Three reports have been produced so far. Each has been

accompanied by a detailed working paper[30] that charts progress made on specific actions.

The first progress report – COM(2003)96 Final[31]

The first progress report noted how well the *Strategy for Europe* had been received by various European institutions. It commended the early signs of progress in implementing the Strategy, but it also noted insufficient progress in certain areas. Particular concerns were a remaining lack of clarity in intellectual property protection, the need for increased financial resources and research, and a delay in implementing GMO legislation.

The second progress report – COM(2004)250 Final[32]

By the production of the second progress report, significant progress had been made on the reviews of Community pharmaceutical and GMO legislation. However, some important regulatory concerns remained. These included some Member States' delay in transposing and implementing key legislation, particularly Directive 98/44/EC *on the legal protection of biotechnological inventions*[33] and Directive 2001/18/EC *on the deliberate release into the environment of genetically modified organisms*[34]. Despite a major incentive provided by the EU's Research Framework Programme[35], an existing R & D funding gap was becoming a more immediate concern.

The third progress report – COM (2005)286 Final [36]

The third report notes that continuing progress has been made in implementing the Strategy, particularly in regard to regulation. The new pharmaceutical regulatory framework was adopted in 2004 and the Commission is continuing to produce implementing measures and guidance. Recent developments include proposed regulations on SMEs, medicinal products for paediatric use, and advanced therapies. Information on these proposed regulations can be found in Section 7 of this Guide.

The new regulatory framework for GMOs has been implemented, with nine decisions on placing on the market adopted by the Commission (as of January 2006) and several more in progress. For an updated state of play,

---

[30] Commission Staff Working Document SEC(2003)248, http://europa.eu.int/comm/biotechnology/pdf/sec2003-248_en.pdf.
Commission Staff Working Paper SEC(2004)438, http://europa.eu.int/comm/biotechnology/pdf/biotechrep2003stafwk.pdf.
Commission Staff Working Paper SEC(2005)850, http://europa.eu.int/comm/biotechnology/DOCS/SEC(2005)850.pdf.
[31] http://europa.eu.int/eur-lex/en/com/cnc/2003/com2003_0096en01.pdf.
[32] http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/com/2004/com2004_0250en01.pdf.
[33] http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf.
[34] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf.
[35] http://europa.eu.int/comm/research/fp6/index_en.html.
[36] http://europa.eu.int/comm/biotechnology/DOCS/COM(2005)286finalEN.pdf.

please refer to the webpages of DG Environment[37] and of DG Health and Consumer Protection[38]. In the third progress report the Commission has also stated that it 'expects more active cooperation from all Member States in ensuring the correct implementation of the new, more rigorous legislation governing GMOs'.

Twenty Member States have now transposed Directive 98/44/EC (the Biotechnology Patents Directive)[39] into their national legislation, and the Commission has started infringement procedures against the remaining Member States. The Commission has proposed two initiatives to help close the R & D funding gap in life sciences and biotechnology. These are: a €4.2 billion Competitiveness and Innovation Programme for 2007-2013[40]; and a new financing instrument, the 'risk-sharing finance facility'[41], as part of the 7th R & D Framework Programme.

For more on the *Strategy for Europe* and progress made, see the Commission's website[42].

1 (ii) What are the implications of the strategy for the development of regulation?

Effective and coherent regulation as a tool for governing biotechnology forms an important part of the European strategy. The framework document *Life Sciences and Biotechnology: A Strategy for Europe* emphasises responsible policy and regulatory oversight.

The Strategy recognises that clarification of the legislative environment will help to create an environment in which businesses are willing to take the risk of investing in expensive R & D. Uncertainty about intellectual property protection in the European Community has held back investment in biotechnology R & D[43]. Similarly, a lack of clarity on GMO legislation is believed to have contributed to a rapid decline in GMO field trials in Europe[44]. Responsible control of the new technologies should enhance both public and business confidence.

The *Strategy for Europe* specifically mentioned the need to develop a coherent regulatory framework on GMOs. Progress has been made through legislation introduced in 2003 and 2004 on GM food and feed, traceability and labelling, transboundary movements of GMOs, and coexistence of GMOs and environmental liability, details of which are provided in Sections 4, 5 and 6 of

[37] http://europa.eu.int/comm/environment/biotechnology/authorised_prod_2.htm.
[38] http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm.
[39] http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf.
[40] http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/com/2005/com2005_0121en01.pdf.
[41] http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/com/2005/com2005_0118en01.pdf.
[42] http://europa.eu.int/comm/biotechnology/introduction_en.html.
[43] Page 11, Life Sciences and Biotechnology: A Strategy for Europe, http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0027en01.pdf.
[44] Page 17, First Progress Report, COM(2003)96 Final, http://europa.eu.int/eur-lex/en/com/cnc/2003/com2003_0096en01.pdf.

this Guide. The Strategy also called for revision of the Community's pharmaceutical legislation. Regulation (EC) No 726/2004 *laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency* [45] is a significant development in the pharmaceutical sector. This Regulation and a number of complementary measures are outlined in Section 7 of this Guide.

Principles for biotechnology regulation

The *Strategy for Europe* introduces certain principles that should underlie all regulation of biotechnology, whether set at Community level or, in accordance with the subsidiarity principle, by the Member States. All biotechnology regulation should be science-based and people-centred and should respect human life, dignity, ethical values, and the fundamental values of the European Charter of Fundamental Rights[46]. The following four principles are outlined for use in Community legislation:

- Risk governance and product authorisation
- Safeguarding the internal market
- Proportionality and consumer choice
- Predictability, modernisation and impact assessment.

The principles are explained in more detail in the *Strategy for Europe*. Products must have a favourable risk assessment prior to authorisation; the precautionary principle should be used where there is scientific uncertainty. Regulation must be proportionate, coherent, efficient, feasible, and enforceable. It must also be regularly monitored, evaluated and updated in line with scientific and technological progress. Consumers must be able to make informed choices about GM products.

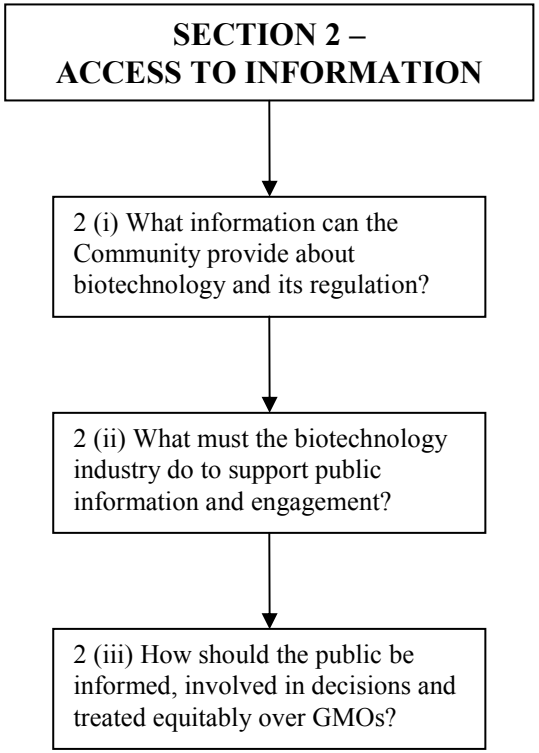
Since biotechnology is a global technology, with global impacts, regulation should also take into account the international context in which the Community is operating. The *Strategy for Europe* urges consideration both of Europe's competitiveness with developed economies, and its responsibility to ensure that developing countries can cope with any changes in regulation. Relevant international agreements to which the Community has consented are to be taken into account during the development of legislation. The EU will continue to play a significant role in the development of such agreements.

The *Strategy for Europe*'*s* Action Plan recognises that public support for European policy and legislation on biotechnology depends on widespread understanding of the approach being taken and the principles on which it is based. In particular, concepts such as scientific uncertainty, absence of zero risk, the precautionary principle, and risk analysis and management should be explained to the public.

---

[45] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_136/l_13620040430en00010033.pdf.
[46] http://www.europarl.eu.int/charter/default_en.htm.

In Action 11 of the Action Plan, the Commission committed itself to issuing a guide to Community biotechnology regulation 'for users and for entrepreneurs who have limited staff and expertise in the regulatory and legal fields', which would also be suitable for use by applicants from the developing world, and by the general public. This Guide aims to address the Action 11 commitment.


SECTION 2 –
ACCESS TO INFORMATION
2 (i) What information can the Community provide about biotechnology and its regulation?
2 (ii) What must the biotechnology industry do to support public information and engagement?
2 (iii) How should the public be informed, involved in decisions and treated equitably over GMOs?

SECTION 2 – ACCESS TO INFORMATION

In *Life Sciences and Biotechnology: A Strategy for Europe*, the Commission recognised the need for the public to be informed about the ethical and social issues raised by developments in the life sciences and biotechnology, and the way in which they are regulated at local, national, Community and international levels. The Community is committed to involving the public in decision-making on GMOs. This Section of the Guide outlines the responsibilities of the Community, Member States and industry for public access to information, and signposts Community resources for further guidance.

2 (i) What information can the Community provide about biotechnology and its regulation?

The Commission is committed to promoting dialogue with the public within the context of its *Strategy for Europe*[47] and its Science and Society programme[48]. Meaningful dialogue depends on a sharing of the information underpinning stakeholders' viewpoints. The Community provides direct electronic access to a great deal of general and case-specific information about biotechnology and its regulation. The main webpages are:

- *Life Sciences and Biotechnology: A Strategic Vision*[49]. For information on the Strategy for Europe, and related reports and working papers

- The Environment Directorate-General's *Biotechnology* page[50]. For links to legislation and documents on deliberate release, contained use, transboundary movement, and authorisations of GMOs

- The Health and Consumer Protection Directorate-General's *Biotechnology* pages[51]. For links to further pages providing information on GM food and feed, GM plants and seeds, traceability, labelling, coexistence, the Strategy for Europe, international regulation, and questions and answers

- The Joint Research Centre's *Biotechnology and GMOs Information Website – Deliberate releases and placing on the EU market of Genetically Modified Organisms (GMOs)*[52]. For links to notifications made under Directive 2001/18/EC *on the deliberate release into the environment*

[47] http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0027en01.pdf.
[48] http://europa.eu.int/comm/research/science-society/index_en.html.
[49] http://europa.eu.int/comm/biotechnology/introduction_en.html.
[50] http://europa.eu.int/comm/environment/biotechnology/index_en.htm.
[51] http://europa.eu.int/comm/food/food//biotechnology/index_en.htm.
[52] http://gmoinfo.jrc.it/default.asp.

of genetically modified organisms and repealing Council Directive 90/220/EEC[53]

- The *Community Register of GM Food and Feed*[54]. This provides comprehensive information on all authorised GM food, feed and seed for food and feed use, including a specific detection method for each authorised GM event

- The Enterprise Directorate-General's *Frequently Asked Questions – Biotechnology Industry* webpage[55]. For links to relevant legislation, publications, information about intellectual property and other Community websites

- Biosociety Research Online[56]. For information on European policy and research activities for researchers and the public

- European Group on Ethics in Science and New Technologies[57] (for links to opinions provided by the group to the Commission)

- JRC's webpage relating to international data sharing under Article 15 of Regulation 1946/2003 on transboundary movements of GMOs (under development).

It is also possible to access the official texts of European Community legislation through the Eur-Lex search engine[58].

Public authorities in the Member States respond to specific requests for information in accordance with Directive 2003/4/EC, which is discussed later in this Section of the Guide.

2 (ii) What must the biotechnology industry do to support public information and engagement?

European legislation relating to biotechnology contains specific provisions on making certain information publicly accessible. This includes:

- In Directive 90/219/EEC *on the contained use of genetically modified micro-organisms* as amended by Directive 98/81/EC[59], Articles 13 (public

[53] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf.
[54] http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm.
[55] http://europa.eu.int/comm/enterprise/faq/en/biotechnology_en.htm.
[56] http://europa.eu.int/comm/research/biosociety/index_en.htm.
[57] http://europa.eu.int/comm/european_group_ethics/index_en.htm.
[58] http://europa.eu.int/eur-lex/en/search/search_lif.html.

consultation), 14 (emergency plans), 15 (accidents) and 19 (confidentiality)

- In Directive 2001/18/EC *on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC*[60], in relation to both non-commercial releases in accordance with Parts A, B and D of the Directive, and commercial releases in accordance with Parts A, and C and D thereof. In relation to non-commercial releases, relevant provisions include Articles 7 (proposals for differentiated procedures), 8 (modifications and new information), 9 (all proposals for and instances of such releases, and information exchanged between authorities), 25 (confidentiality), 29 (ethics committee consultation), and 31 (public registers). In relation to commercial releases, relevant provisions include Articles 13 (proposals for derogations), 19 (consent), 20 (results of monitoring), 23 (emergency measures), 24 (notifications and assessment reports), 25 (confidentiality), 29 (ethics committee consultation), and 31 (public registers). Article 31 is applied by Decision 2004/204/EC *laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC of the European Parliament and of the Council*[61]. In many of its substantive provisions - including for information to the public - Directive 2001/18 is intended as a point of reference for GMOs as or in products authorised by other Community legislation. Such other legislation must make at least equivalent provision (Directive 2001/18, Articles 5(d) and 12)

- In Regulation (EC) No 1829/2003 *on genetically modified food and feed*[62], in relation to both food (Chapters I, II and IV) and feed (Chapters I, III and IV). In relation to food, relevant provisions include Articles 5 (summary of application dossier), 6 (EFSA opinion), 9 (monitoring reports), 10 (continued compliance), 12-14 (labelling), 28 (Community register), 29 (generic public access provision), 30 (confidentiality), 33 (ethics committee opinion), 47 (detection methods for traces of GM material), and 48 (report on implementation). In relation to feed, relevant provisions are largely parallel; they should clearly be consulted if appropriate

- The application summary submitted under Article 7 and EFSA opinion under Article 8 of Regulation (EC) No 1831/2003 *on additives for use in animal nutrition*[63]

---

59 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31998L0081&model=guichett

60 http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf.

61 http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_065/l_06520040303en00200022.pdf.

62 http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf.

63 http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00290043.pdf.

- Copies of the notification and decision on transboundary movements of GMOs under Regulation (EC) No 1946/2003 *on transboundary movements of genetically modified organisms*[64]. Certain information is subject to an international exchange mechanism under Article 15, and publicly accessible. Information is also to be supplied in documentation accompanying exports (Article 12). For further information on this Regulation, see Answer 6.2(ii).

In provisions to protect confidential information, the legislation also lists matters that must always be disclosed. For example, in Directive 90/219 as amended, Article 19(3) states that the following information from certain submissions may never be kept confidential:

- 'the general characteristics of the GMMs, name and address of the notifier, and location of use,

- class of contained use and measures of containment,

- the evaluation of foreseeable effects, in particular any harmful effects on human health and the environment.'

Under Regulation (EC) No 1830/2003 *concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC*[65], written information must accompany all products containing or consisting of GMOs. It must state that the product contains or consists of GMOs, and specify the GMOs involved with unique identifiers[66]. This procedure allows the products to be traced through all stages of the supply chain. Finally, labelling of the end product ensures the correct information is available to the end user, allowing consumers to make informed choices and facilitating public engagement in related aspects of biotechnology.

Participation of industry in open and inclusive dialogue with the public on the benefits of products will be important in enhancing public understanding of biotechnology and enabling informed viewpoints to gain wider acceptance. The *Strategy for Europe* therefore assigns industry 'a particular responsibility for active participation' in dialogue.

---

[64] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_287/l_28720031105en00010010.pdf.
[65] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00240028.pdf.
[66] "a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorised transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO." (Regulation 1830/2003, Article 3.4.)

2 (iii) How should the public be informed, involved in decisions and treated equitably over GMOs?

Access to Community documents

Regulation (EC) No 1049/2001 *regarding public access to European Parliament, Council and Commission documents*[67] provides a general right of access to documentary information drawn up or received by European Union institutions. Limits on access are recognised in respect of certain public or private interests, as well as personal data. Administrative procedures to enable access are laid down, and the provision of electronic information is promoted. In accordance with Article 13, many categories of documents must be published in the Official Journal of the European Union[68].

The Aarhus Convention

The European Community is a Party to the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters[69]. The principles and provisions of the Convention on access to information and access to justice were implemented for the Community in Directive 2003/4/EC *on public access to environmental information and repealing Council Directive 90/313/EEC*[70]. Both the Convention and the Directive apply to GMOs when they may:

- Affect and/or interact with biodiversity
- Affect other environmental elements (e.g. water, soil, land)
- Affect human health and safety through their environmental effects.

The Aarhus Convention and Directive 2003/4/EC assign responsibility for ensuring access to information to the public authorities of Member States, and not directly to private enterprises. However, Community legislation on GMOs requires certain information to be supplied by businesses during application, notification and reporting procedures, and some of this information will be made publicly available under the scope of Directive 2003/4/EC. For example, this will include information on the environmental risk assessment carried out as part of the authorisation procedure under Directive 2001/18/EC *on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC*[71].

---

67 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32001R1049&model=guichett

68 http://europa.eu.int/eur-lex/lex/JOIndex.do?ihmlang=en

69 http://www.unece.org/env/pp/documents/cep43e.pdf.

70 http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_041/l_04120030214en00260032.pdf.

71 http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf.

The Aarhus Convention also has provisions on allowing the public to take part in the decision-making of public authorities on environmental matters. The first meeting of the Parties to the Convention produced a document titled *Guidelines on Access to Information, Public Participation and Access to Justice With Respect to Genetically Modified Organisms*[72]. The second meeting of the Parties (held in Almaty in May 2005) adopted an amendment[73] to the Aarhus Convention, laying down additional provisions requiring States to implement national arrangements for public participation in decision-making on the deliberate release of GMOs. This includes arrangements for: provision of relevant information to the public on proposed releases; submission of comments on proposed releases by the public; taking due account of public opinion; and provision of the details of and reasons for decisions made.

Community legislation on GMOs contains provisions that allow the public to comment on applications for deliberate release and placing on the market. For deliberate releases for any other purpose than placing on the market, Part B of Directive 2001/18 provides specific requirements for public information and consultation on the application and the releases. Article 24 of Part C states the corresponding requirements for GMOs intended to be placed on the market under Directive 2001/18.

For applications for authorisation under Regulation (EC) No 1829/2003 *on genetically modified food and feed*[74], the public is given 30 days in which to comment on the opinions of the European Food Safety Authority. For this purpose, a consultation is opened by the Commission on the webpages of DG Health and Consumer Protection[75]. Moreover, the Regulation provides that full public access must be granted to the information submitted thereunder upon request, with the exception of information that might significantly harm the applicant's competitive position if disclosed.

More information on Regulation 1829/2003 can be found in Section 5 of this Guide – The GM Feed and Food Chain.

Requests for specific information under Directive 2003/4/EC

Under Directive 2003/4/EC, public authorities are expected to 'make available environmental information' at the request of any applicant, as soon as possible or, at the latest, within one month (in complex cases, this interval may be extended to two months if the applicant is notified promptly of the fact). The applicant is not obliged to state reasons for their application. The applicant can

[72] http://www.unece.org/env/pp/documents/gmoguidelinesenglish.pdf.
[73] http://www.unece.org/env/documents/2005/pp/ece/ece.mp.pp.2005.2.add.2.e.pdf.
[74] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf.
[75] http://europa.eu.int/comm/food/food/biotechnology/authorisation/public_comments_en.htm.

request that the information be provided in a particular format, and the authority should generally consent to this. Generally, a 'reasonable' charge may be made for providing the information.

There are certain conditions under which requests for environmental information may be refused:

- The information is not held
- The request is 'manifestly unreasonable' or too general
- The material is not yet completed
- The confidentiality of public authority proceedings, commercial or industrial information, or personal data would be adversely affected
- The course of justice, intellectual property rights or the protection of the environment would be adversely affected

(Article 4(1) and (2)).

At all times when refusal is considered, the following applies:

> The grounds for refusal…shall be interpreted in a restrictive way, taking into account for the particular case the public interest served by disclosure
> (Article 4(2)).

Notification of refusal must be sent to the applicant and contain information on the reasons for refusal. The applicant can challenge the public authority's refusal or response through review procedures established by Member States. Member States must also make provision for recourse by applicants to courts of law, where any final decisions will be binding on the public authority.

General requirements of Directive 2003/4/EC

Member States should ensure that lists of public authorities are publicly accessible. Lists or registers should be maintained of the environmental information that public authorities hold; access to these must be free of charge. Public authorities are expected to inform the public of their rights to access information.

Public authorities are also expected 'to ensure that…environmental information is progressively made available and disseminated to the public', particularly through the use of telecommunications technology (Article 1). Information to be included in national systems for dissemination of environmental information shall at a minimum include:

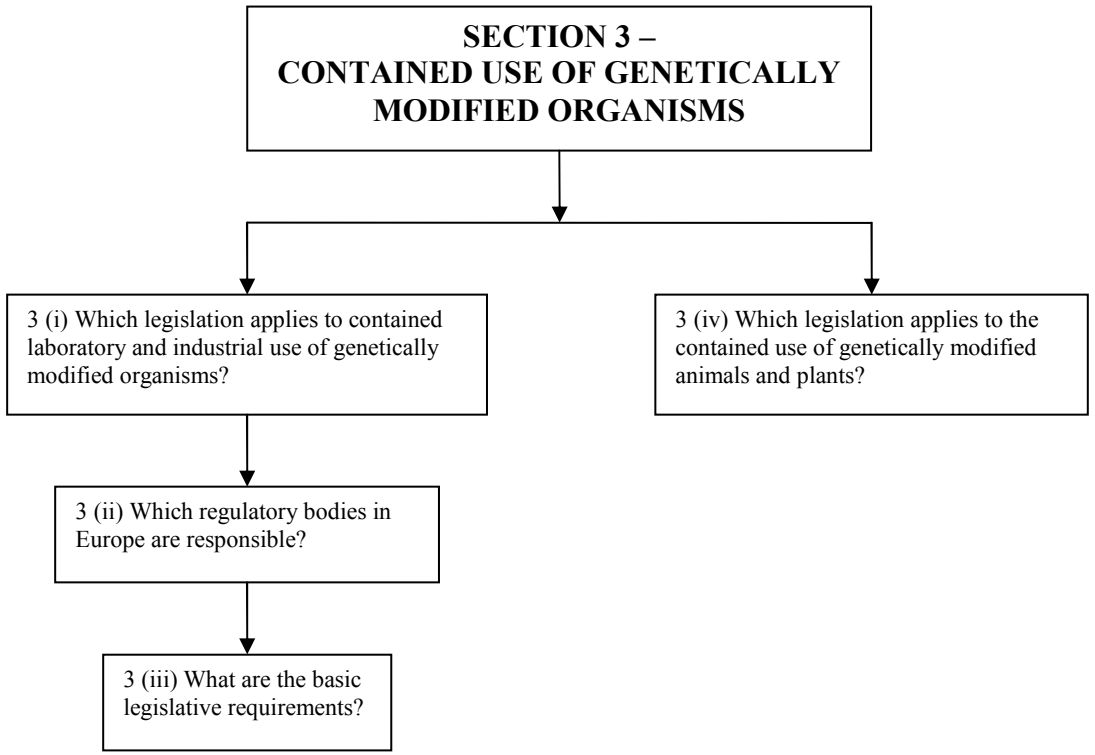
- Texts of international, regional, Community, national and local legislation or agreements related to the environment

- Policies, plans and programmes relating to the environment
- Progress reports on the implementation of legislation, policies, plans and programmes
- Data from monitoring activities that may affect the environment
- Authorisations with a significant impact on the environment
- Environmental impact studies and risk assessments

(Article 7).

Member States were required to transpose Directive 2003/4 into their national legislation by February 2005. They must report to the Commission on their experience in implementing the Directive by 2009.

In the event of an imminent threat to human health or the environment arising from any of the activities covered by the Directive, Member States must disclose all necessary information to the public to allow them to take measures to prevent or mitigate harm (Article 7(4)).


SECTION 3 –
CONTAINED USE OF GENETICALLY MODIFIED ORGANISMS
3 (i) Which legislation applies to contained laboratory and industrial use of genetically modified organisms?
3 (ii) Which regulatory bodies in Europe are responsible?
3 (iii) What are the basic legislative requirements?
3 (iv) Which legislation applies to the contained use of genetically modified animals and plants?

SECTION 3 – CONTAINED USE OF GENETICALLY MODIFIED ORGANISMS

Where human, animal or plant health, or the environment would be put at risk by exposure to GMOs, it is appropriate to have measures in place to ensure the GMOs are contained. In many laboratory and industrial situations, containment measures incorporating physical barriers are feasible. Necessary measures will vary according to the type and degree of risk involved. This Section of the Guide outlines Community legislation on the contained use of GMMs and GMOs.

3 (i) Which legislation applies to contained laboratory and industrial use of genetically modified organisms?

The main legislation of relevance is the framework Directive 90/219/EEC *on the contained use of genetically modified micro-organisms*[76]. This Directive has been amended and supplemented by several directives and decisions including:

- Decision 91/448/EEC *concerning the guidelines for classification referred to in Article 4 of Directive 90/219/EEC*[77]
- Directive 98/81/EC *amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms*[78]
- Decision 2001/204/EC *supplementing Directive 90/219/EEC as regards the criteria for establishing the safety, for human health and the environment, of types of genetically modified micro-organisms*[79]
- Decision 2000/608/EC *concerning the guidance notes for risk assessment outlined in Annex III of Directive 90/219/EEC on the contained use of genetically modified micro-organisms*[80]
- Decision 2005/174/EC *establishing guidance notes supplementing part B of Annex II to Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms*[81].

An unofficial, consolidated version of Directive 90/219/EEC as amended is available[82]. The most substantial amendment was through Directive 98/81/EC[83].

---

[76] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31990L0219&model=guichett.

[77] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31991D0448&model=guichett.

[78] http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_330/l_33019981205en00130031.pdf.

[79] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_073/l_07320010315en00320034.pdf.

[80] http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_258/l_25820001012en00430048.pdf.

[81] http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_059/l_05920050305en00200026.pdf.

[82] http://europa.eu.int/eur-lex/en/consleg/pdf/1990/en_1990L0219_do_001.pdf.

Where contained use will involve exposure to biological agents, Directive 2000/54/EC *on the protection of workers from risks related to exposure to biological agents at work*[84] will apply. Where GMOs for contained use are imported or exported, or are unintentionally released, certain provisions of Regulation (EC) No 1946/2003 *on transboundary movements of genetically modified organisms*[85] may apply. Regulation 1946/2003 also requires the exchange of information on certain domestic uses through the mechanisms established under the Cartagena Protocol on Biosafety – for further details, see Subsection 6.2 of this Guide.

A structured summary of EU legislation on contained use of genetically modified micro-organisms can be found on Scadplus[86].

3 (ii) Which regulatory bodies in Europe are responsible?

The Environment Directorate-General is responsible for the development and implementation of legislation on the contained use of GMOs. It has a biotechnology webpage with links to relevant legislation and reports[87].

National competent authorities have been established to oversee the implementation, administration and enforcement at Member State level of Directive 90/219/EEC and Directive 2000/54/EC. List 3.1, at the end of this Section, contains a list of competent authorities for contained use. Designated Member State competent authorities and national focal points, responsible for liaising with the Secretariat of the Cartagena Protocol on Biosafety, have also been established by Regulation 1946/2003 - see Section 6.2 of this Guide for details.

3 (iii) What are the basic legislative requirements?

The aim of the contained use legislation is to protect human health and the environment by minimising the risk of exposure to genetically modified micro-organisms.

Basic legislative requirements of Directive 90/219/EEC as amended

---

[83] Directive 98/81/EC *amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms*, http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_330/l_33019981205en00130031.pdf

[84] http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_262/l_26220001017en00210045.pdf.

[85] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_287/l_28720031105en00010010.pdf.

[86] Contained use of genetically modified micro-organisms, http://europa.eu.int/scadplus/leg/en/lvb/l21157.htm.

[87] http://europa.eu.int/comm/environment/biotechnology/index_en.htm.

Scope

The scope of Directive 90/219/EEC is limited to micro-organisms.

Techniques including the following, outlined in Annex I Part A to Directive 90/219 as amended, are viewed as resulting in genetic modification:

> 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.[88]

A complementary list of techniques that are not considered to result in genetic modification is given in Annex I Part B of Directive 90/219 as amended.

Articles 3 and 4 of Directive 90/219 as amended detail some exemptions from the requirements of Directive 90/219 for certain types of genetic modification and certain types of genetically modified micro-organisms. Article 3 exempts genetic modification achieved solely through certain specified methods or techniques, which are listed in Annex II Part A of Directive 90/219 as amended; and any genetically modified micro-organisms that meet the generic safety criteria of Annex II Part B (which will be listed in Annex II Part C). The methods and techniques listed in Annex II Part A include mutagenesis; cell fusion in the circumstances specified; and self-cloning. The requirements for exemption are quite specific and the full text of Directive 90/219, as amended, should be read. There have been differences in the transposition of Directive 90/219 between Member States and applicants should clarify requirements with the competent authority of the Member State in which they are intending to carry out contained use.

[88] Annex I, Part A, Directive 98/81/EC *amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms*, http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_330/l_33019981205en00130031.pdf

Risk assessment and notification

The individual intending to carry out a contained use operation (the 'user') must conduct an assessment of risks to human health and the environment. The assessment must at a minimum comply with the provisions of Annex III, Parts A and B of Directive 90/219/EEC as amended. A significant part of the risk assessment involves the classification of the contained use of the GMM into one of four risk classes to which corresponding containment levels (and therefore particular levels of control) apply. The classifications are:

- Class 1: activities of no or negligible risk, that is to say activities for which level 1 containment is appropriate to protect human health as well as the environment
- Class 2: activities of low risk, that is to say activities for which level 2 containment is appropriate to protect human health as well as the environment
- Class 3: activities of moderate risk, that is to say activities for which level 3 containment is appropriate to protect human health as well as the environment
- Class 4: activities of high risk, that is to say activities for which level 4 containment is appropriate to protect human health as well as the environment[89].

Users must notify the Member State competent authority of their intention to use a premises for a contained use purpose prior to its first use and the notification must include a copy of the risk assessment report. Annex V, Part A to Directive 90/219 as amended outlines the other information that is required for this notification. Notification requirements for subsequent uses vary according to which class of contained use applies (see Articles 8-10, Directive 90/219 as amended). Class 1 uses may proceed immediately following notification; Class 2 uses may proceed if no response has been given within 45 days of notification; and Class 3 and 4 uses may proceed only with the prior written consent of the competent authority. Competent authorities are to ensure that emergency plans are in place prior to the contained use operation taking place.

Decision 2001/204/EC[90] *supplementing Directive 90/219/EEC as regards the criteria for establishing the safety, for human health and the environment, of types of genetically modified micro-organisms* replaced Annex II, Part B of Directive 90/219/EEC covering those criteria. Guidance notes on risk assessments were provided in Decision 2000/608/EC *concerning the guidance notes for risk assessment outlined in Annex III of Directive 90/219/EEC*[91].

[89] Article 5, Directive 98/81/EC *amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms*, http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_330/l_33019981205en00130031.pdf

[90] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_073/l_07320010315en00320034.pdf.

[91] http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_258/l_25820001012en00430048.pdf.

During contained use

Throughout contained use operations the user is obliged to apply the necessary measures to ensure the health and safety of workers and to maintain the appropriate containment level. Annex IV of Directive 98/81/EC details the minimum requirements for each containment level.

If an accident occurs, the user must notify the competent authority immediately. The Member State concerned must report the notified accident to the Commission and to any potentially affected Member State.

Member States should provide annual reports on Class 3 and 4 contained use activities, and a report every three years on experience with implementation of Directive 90/219/EEC. The Commission will publish a summary based on those reports every three years[92].

The definition of contained use at Article 2(c) of Directive 90/219 as amended includes activities in which GMMs are transported. Article 4 disapplies many specific requirements under other articles of the Directive from the transport of GMMs by any mode (road, rail, inland waterway, sea or air). However, certain requirements of Article 5 (including a structured risk assessment) and the more general provisions of Article 13 onwards (covering emergency plans and accidents among other things) do apply to transport.

Basic legislative requirements of Directive 2000/54/EC

Scope

Directive 2000/54/EC *on the protection of workers from risks related to exposure to biological agents at work*[93] defines biological agents as:

> micro-organisms, including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity.[94]

[92] Summary Report from the Commission based on the reports of Member States concerning their experiences with Directive 90/219/EEC, as amended by Directive 98/81/EC, on the contained use of genetically modified micro-organisms for the period 1999 – 2003, http://europa.eu.int/comm/environment/biotechnology/pdf/summary_report_final_en.pdf.

[93] http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_262/l_26220001017en00210045.pdf.

[94] Article 2, Directive 2000/54/EC *on the protection of workers from risks related to exposure to biological agents at work,* http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_262/l_26220001017en00210045.pdf

Classification by risk

Biological agents should be classified into one of four risk groups:

- Group 1 – agents unlikely to cause human disease
- Group 2 – agents that can cause human disease, that may be a hazard to workers, but are unlikely to spread to the community and for which there is usually effective prophylaxis or treatment available
- Group 3 – agents that can cause severe human disease and present a serious hazard to workers, that may present a risk of spreading to the community and for which there is usually effective prophylaxis or treatment available
- Group 4 – agents that cause severe human disease and are a serious hazard to workers, that present a high risk of spreading to the community and for which there is usually no effective prophylaxis or treatment available.[95]
  (Directive 2000/54/EC, Article 2.)

The Community has already classified a number of biological agents, and these are listed in Annex III to Directive 2000/54. Member States are to provisionally classify other agents prior to their Community classification using the definitions from Article 2 of the Directive[96].

Risk assessment and management

Risks to workers' health and safety from exposure to biological agents must be assessed and managed. Along with the classification of the biological agent the assessment should take into account recommendations from a competent authority; information on diseases which may be contracted as a result of the work; and potential allergenic or toxigenic effects[97]. Many of the Directive's provisions do not need to be applied to group 1 biological agents. First use of any group 2, 3, or 4 agent must be notified to the competent authorities. There are slightly different notification requirements for subsequent uses depending on the classification and intended use (see Article 13). The results of risk assessments are to be made available on request to competent authorities, and 'any accident or incident which may have resulted in the release of a biological

[95] Article 2, Directive 2000/54/EC *on the protection of workers from risks related to exposure to biological agents at work,* http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_262/l_26220001017en00210045.pdf
[96] http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_262/l_26220001017en00210045.pdf.
[97] Article 3, Directive 2000/54/EC *on the protection of workers from risks related to exposure to biological agents at work,* http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_262/l_26220001017en00210045.pdf

agent and which could cause severe human infection and/or illness'[98] must be reported to them.

Article 6 suggests a range of control measures employers may use to protect workers' health and safety. Certain generally required measures are listed in Article 8. Further information on containment levels and corresponding measures is provided in Annexes V and VI to the Directive. Workers should be given appropriate training and information. A record must be kept for at least ten years of any exposure of workers to a group 3 or 4 agent (for certain agents this may be extended to forty years – see Article 11). Where appropriate, the health of workers should be monitored, and records kept for the same periods. Annex IV to the Directive provides more details on health surveillance of workers.

Additional provisions for health and veterinary care facilities, industrial processes, laboratories and animal rooms are outlined in Articles 15 and 16.

Basic legislative requirements of Regulation (EC) No 1946/2003

Regulation (EC) No 1946/2003 *on transboundary movements of genetically modified organisms*[99] implements certain provisions of the Cartagena Protocol on Biosafety[100], in particular as regards exports to third countries and information exchange. For the purposes of this Regulation, the term 'contained use' can apply in relation to any organism, not just a micro-organism. The term 'transboundary movement' relates to international movement of a GMO (i.e. movement involving a state, business or power outside the Community), and is more fully defined in the Regulation itself. Regulation 1946/2003 applies generally to all GMOs except pharmaceuticals for human use (see Article 2 thereof), and requires that explicit written consent is obtained from the state of import prior to the first transboundary movement of a particular GMO to be commercialised or released into the environment of that state. Decisions on whether to allow a transboundary movement are based on scientific assessments of the risks to biological diversity and human health.

Certain provisions of Regulation 1946/2003, as specified by Article 11, do not apply to GMOs intended for contained use 'where such transboundary movements are undertaken in accordance with the standards of the Party or non-Party of import.' Any GMO that is exported must be clearly identified. Specific identification requirements vary according to whether the exported GMO is intended for contained use or otherwise (Article 12). See also Section 6.2 of this Guide.

---

[98] Article 7, Directive 2000/54/EC *on the protection of workers from risks related to exposure to biological agents at work,* http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_262/l_26220001017en00210045.pdf

[99] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_287/l_28720031105en00010010.pdf.

[100] http://www.biodiv.org/biosafety/protocol.asp.

3 (iv) Which legislation applies to the contained use of genetically modified animals and plants?

There is currently no Community legislation on the contained use, in the Community, of genetically modified animals and plants. The *Annex to the Summary Report from the Commission based on the reports of Member States Concerning their experiences with Directive 90/219/EEC, as amended by Directive 98/81/EC, on the contained use of genetically modified micro-organisms*[101], describes features of the implementation of Directive 90/219/EEC into national law by each of the Member States. In most cases (e.g. UK), implementing legislation extends to the contained use of genetically modified animals and plants. Member State competent authorities designated by Directive 90/219/EEC may be able to provide more information on national controls in this area. A list of Member State competent authorities may be found at the end of this Section of the Guide.

[101] http://europa.eu.int/comm/environment/biotechnology/pdf/annex_summary_report.pdf.

LIST 3.1 – COMPETENT AUTHORITIES FOR CONTAINED USE

AUSTRIA

Federal Ministry of Education, Science and Culture, Dept. BrGt
Rosengasse 2-6
A-1010 Vienna
+43 (1) 53120-7114
+43 (1) 53120-6205
alois.haslinger@bmbwk.gv.at

Federal Ministry for Social Security and Generations
Radetzkystraße 2
A-1030 Wien
+43 (1) 71100 4845
+43 (1) 715 24 05
michel.haas@bmgf.gv.at

BELGIUM

Service of Biosafety and Biotechology (SBB) Dpt of Microbiology. Scientific Institute of Public Health
Rue Juliette Wytsmanstraat, 14
B-1050 Brussels
contained.use@sbb.ihe.be

Service of Biosafety and Biotechnology (SBB). Dpt. of Microbiology. Scientific Institute of Public Health
Rue Juliette Wytsmanstraat, 14
B-1050 Brussels
+32-2/642 52 93
+32-2/642 52 92
wmoens@sbb.ihe.be

CYPRUS

Ministry of Labour and Social Insurance. Dpt of Labour Inspection
12 Apellis Street
CY- 1493 Lefkosia (Nicosia)
Cyprus
+35-7 22 405650
+35-7 22 663 788

pdemetriades@dli.mlsi.gov.cy

CZECH REPUBLIC

Ministry of the Environment
Department of Environmental Risks,
Vrsovicka 65
100 10 Prague 10
Czech Republic
+42 0 26712 2922
+42 0 26731 0013
doubkova@env.cz

DENMARK

The Danish Forest and Nature Agency
Haraldsgade 53
DK-2100 Copenhagen Ø
fwb@sns.dk

National Working Environment Authority; The
Landskronagade, 33
DK - 2100 Copenhagen Ø
doh@arbejdstilsynet.dk

The Danish Forest and Nature Agency
Haraldsgade 53
DK-2100 Copenhagen Ø
bpc@sns.dk

ESTONIA

Ministry of the Environment - Labour Inspection
Teguri, 37
EE-50107 Tartu
Estonia
+37 2 7366 191
+37 2 7366 188
silja.soon@ti.ee

FINLAND

Ministry of Social Affairs and Health - Board for Gene Technology
Kirkkokatu, 14
P.O. Box 33
FI-00023 Government, Finland
+35 8 (9) 160 74124
+35 8 (9) 160 73876
hannele.leiwo@stm.vn.fi

FRANCE

CA FR
Ministère de l'Ecologie et du Développement Durable
BBIAA - SEI - DPPR
20, avenue de Ségur
F-75302 Paris
+33 (1) 42 19 14 67
biotech-bbiaa@environnement.gouv.fr

biotech-bbiaa@ecologie.gouv.fr

Commission de Génie Génétique, Ministry of Research
francoise.guillet@recherche.gouv.fr

GERMANY

Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft
Referat 222
Rochustrasse 1
DE-53123 Bonn
+49 228 529 3356
+49 228 529 3743
222@bmvel.bund.de

Staatliches Gewerbeaufsichtsamt Braunschweig
Petzvalstraße 18
38104 Braunschweig
Germany
+49 531 / 484 - 1640
+49 531 / 484 - 1699
Birgit.Corell@gaa-bs.niedersachsen.de

heino.niebel@bug.hamburg.de

hans-georg.starck@umin.landsh.de

GREECE

Ministère de l'Environnement, Aménagement du Territoire et Travaux Publics
Direction Environnement
PATISSION STREET, 147
GR-112 51 ATHENS
+30 (210) 69 17 620
+30 (210) 69 18 487
a.vlandou@dpers.minenv.gr

HUNGARY

Ministry of Environment and Water
Department of International Treaties for Nature Conservation
H-1121 Budapest, Költo u. 21
Hungary
+36 (1) 3911778
+36 (1) 2754505
homoki@mail2.ktm.hu

Ministry of Agriculture and Rural Development
Agricultural Department
Kossuth Square 11.
1055 Budapest
Hungary
+36 (1) 301 4445
+36 (1) 301 4668
gevbtitk@ommi.hu

IRELAND

EPA
P.O. Box 3000
Johnstown Castle Estate, Co. Wexford
Ireland
a.boland@epa.ie

EPA
P.O. Box 3000
Johnstown Castle Estate, Co. Wexford
Ireland
+35 3 (53) 60617
+35 3 (53) 60699
t.mcloughlin@epa.ie

EPA
P.O. Box 3000
Johnstown Castle Estate, Co. Wexford
Ireland
b.murray@epa.ie

ITALY

Ministry of Health - Prevention Dpt Office X°
Via della Sierra Nevada 60
IT- 00144 Roma
+39 (06) 5994 4209
+39 (06) 5994 4249
n.sarti@sanita.it

LATVIA

Ministry of Health - Latvian Food Center
Kr.Valdemara iela 38
LV-1010 Riga
Latvia
+37 1 7021576
+37 1 7021755
sarma.sleze@lpc.gov.lv

LITHUANIA

Ministry of Environment - Nature Protection Dpt
A. Jakšto St 4/9
LT-2600 Vilnius
LITHUANIA
+37 0 52 615 339
+37 0 52 663 663

g.merkeviciute@am.lt

LUXEMBOURG

Ministry of Health
Allée Marconi
L-2102 LUXEMBOURG
+35 2 478 55 91
+35 2 26 20 0147
marcel.bruch@ms.etat.lu

MALTA

Malta Environment and Planning Authority
Biosafety Co-ordinating Committee
Nature Protection Unit
Environment Protection Directorate
St. Francis Ravelin
MT-Valletta CMR01
Malta
+35 6 (2290) 6009
+35 6 (2290) 1585
bcc.notifications@mepa.org.mt

THE NETHERLANDS

Piet.deWildt@minvrom.nl

Janpiet.tijssen@minvrom.nl

NORWAY

Directorate for Health and Social Affairs
P.O. Box 7000
St Olavs Plass
N-0130 Oslo
Norway
+47 2416 3168
rolf.dalseg@shdir.no

tel@hd.dep.no

POLAND

Ministry of the Environment
Department of Nature Conservation
52/54 Wawelska Street
00 - 922 Warsaw
Poland
+48 (22) 57 92 538
+48 (22) 57 92 555
agnieszka.dalbiak@mos.gov.pl

Ministry of The Enviroment
Unit of GMO
52/54 Wawelska Street
00 - 922 Warsaw
Poland
+48 (22) 57 92 723
+48 (22) 57 92 555
malgorzata.wozniak@mos.gov.pl

PORTUGAL

Instituto do Ambiente - IA
Rua da Murgueira - Zambujal
Apartado 7585 - Alfragide
PT-2721-865 Amadora - Portugal
+35 1 (21) 4728341 (direct line)
+35 1 (21) 4719074
jorge.fernandes@iambiente.pt

SLOVAKIA

Ministry of the Environment of the Slovak Republic
Nam. Ludovita Stura 1
SK-812 35 Bratislava
Slovak Republic
+42 1 2 5956 2715
+42 1 2 5956 2533

holubova.diana@enviro.gov.sk

SLOVENIA

Ministry of Health
Sector for Food Safety and Health Suitability
Stefanova 5
SI-1000 LJUBLJANA
Slovenia
+38 6 1 478 68 51
+38 6 1 478 68 56
marusa.paveie@gov.si

Ministry of the Environment, Spatial Planning and Energy. Environmental Dept.
Sector for biotechnology
Dunajska 48
SI-1000 LJUBLJANA
Slovenia
+38 6 1 478 74 02
+38 6 1 478 74 25
martin.batic@gov.si

SPAIN

alba.rios@sgiapr.mma.es

Ministry of the Environment - General Direction of Quality and Environmental Risk
Plaza de San Juan de la Cruz
ES-28071 Madrid
+34 (91) 597 64 23
+34 (91) 597 58 16
AFresno@mma.es

SWEDEN

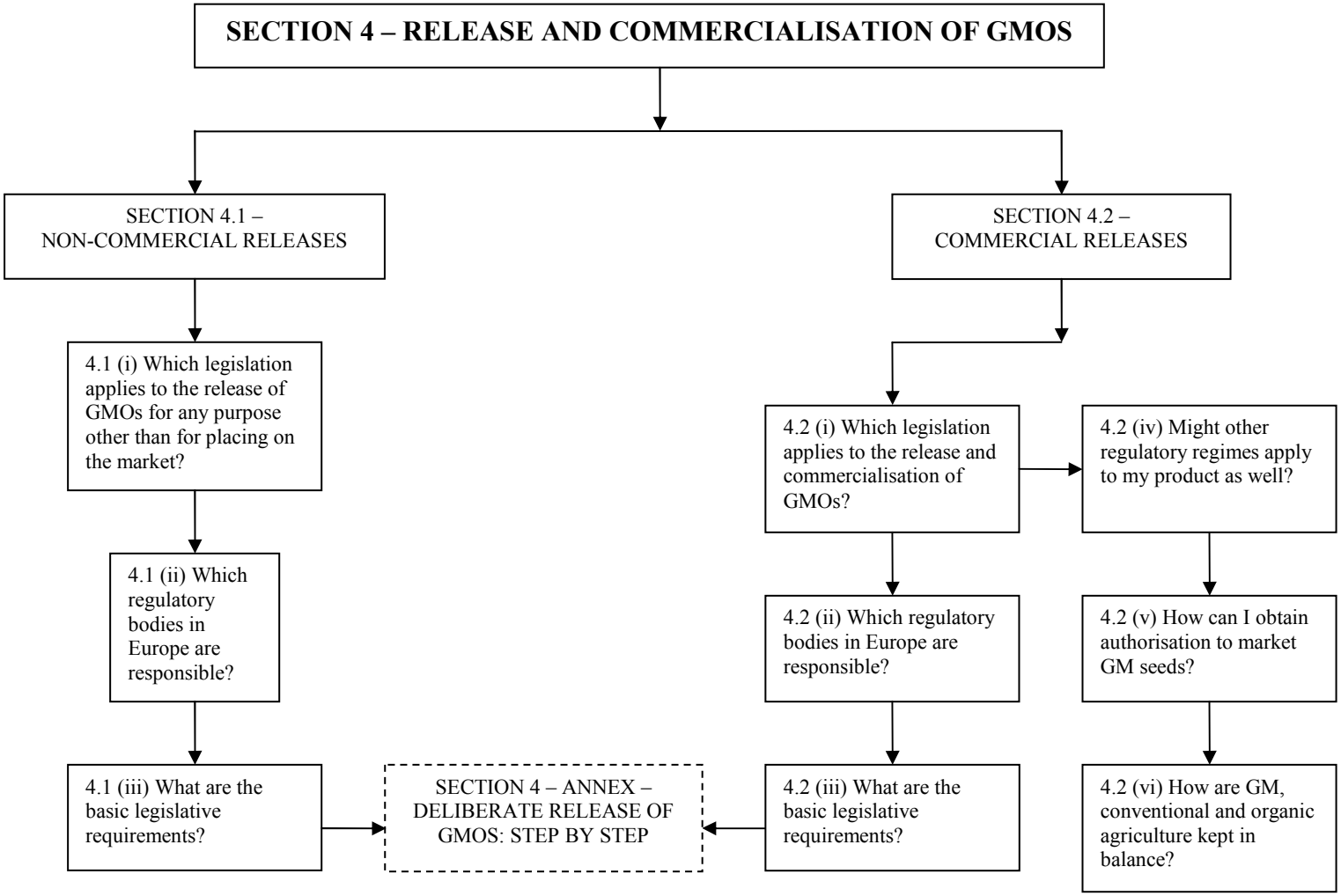
Swedish Work Environment Authority
Sweden
anna.malm@av.se

UNITED KINGDOM

+44 (0) 20 7717 6234
delyth.dyne@hse.gsi.gov.uk

paul.logan@hse.gsi.gov.uk

Biological Agents and GMOs Section. Hazards and Technical Policy Division.
Health and Safety Executive
6NW, Rose Court
2 Southwark Bridge
London SE1 9HS
+44 (0) 20 7717 6230
+44 (0) 20 7717 6199
jim.neilson@hse.gsi.gov.uk


SECTION 4 – RELEASE AND COMMERCIALISATION OF GMOS
SECTION 4.1 – NON-COMMERCIAL RELEASES
SECTION 4.2 – COMMERCIAL RELEASES
4.1 (i) Which legislation applies to the release of GMOs for any purpose other than for placing on the market?
4.1 (ii) Which regulatory bodies in Europe are responsible?
4.1 (iii) What are the basic legislative requirements?
SECTION 4 – ANNEX – DELIBERATE RELEASE OF GMOS: STEP BY STEP
4.2 (i) Which legislation applies to the release and commercialisation of GMOs?
4.2 (ii) Which regulatory bodies in Europe are responsible?
4.2 (iii) What are the basic legislative requirements?
4.2 (iv) Might other regulatory regimes apply to my product as well?
4.2 (v) How can I obtain authorisation to market GM seeds?
4.2 (vi) How are GM, conventional and organic agriculture kept in balance?

SECTION 4 – RELEASE AND COMMERCIALISATION OF GMOS

The release and commercialisation of GMOs is regulated by the Community in order to ensure the protection of human health and the environment, as well as fair practices in the internal market (the particular legal basis being Article 95 of the Treaty establishing the European Community[102]).

Non-commercial releases ('releases for any other purpose than placing on the market') of GMOs require authorisation at a national level, and are restricted to the territory of the Member State in which authorisation is granted. Commercial release ('placing on the market') authorisations are valid throughout the Community. This Section outlines the legislation applying to each of these categories. It also covers related legislation on the marketing of GM seeds and plant propagating materials, and the issue of coexistence of GM, conventional and organic agriculture.

The relevant EU legislation defines an organism as 'any biological entity capable of replication or of transferring genetic material'[103]. A dead cell or processed products are not GMOs, and therefore are not covered by Directive 2001/18/EC.

It is to be noted that for GMOs for food and feed use as well as for food and feed containing, consisting of or produced from GMOs, the procedure for its placing on the market shall be covered by Regulation (EC) No 1829/*2003 on genetically modified food and feed*[104]. In the case of a GMO that may be used as food or feed, Directive 2001/18 only applies as far as relevant general obligations under parts A and D are concerned, or for procedures for deliberate releases for any other purposes than placing on the market. Section 5 of this Guide covers GM food and feed.

4.1 NON-COMMERCIAL RELEASES

This Subsection provides information on the legislative requirements for deliberate releases of GMOs for any other purpose than placing on the market. These, for example, include releases made for research or development purposes.

4.1 (i) Which legislation applies to the release of GMOs for any purpose other than for placing on the market?

[102] http://europa.eu.int/eur-lex/lex/en/treaties/dat/12002E/htm/12002E.html
[103] Article 2(1) of Directive 2001/18/EC *on the deliberate release into the environment of genetically modified organisms and repealing Directive 90/220/EEC*, http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf.
[104] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf

Directive 2001/18/EC *on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC*[105] is the only legislation for this area, except for medicinal substances and compounds for human use. Parts A and D of the Directive contain general provisions for both commercial and non-commercial releases; Part B is specific for the procedures for releases for any purpose other than placing on the market. Supplementary guidance has been provided on the methodology for environmental risk assessments (Decision 2002/623/EC[106]); on the summary notification information format (Decision 2002/813/EC[107]); and on the format for presenting results of the deliberate release (Decision 2003/701/EC[108]).

4.1 (ii) Which regulatory bodies in Europe are responsible?

The Environment Directorate-General[109] has general responsibility for regulation of the release and commercialisation of GMOs under Directive 2001/18/EC. Release of GMOs for feed and food can also be authorised under Regulation (EC) No 1829/2003 *on genetically modified food and feed*[110], for which the Health and Consumer Protection Directorate-General is responsible under the 'one door, one key' principle of joined-up regulation. Further information on the release and commercialisation of GMOs for food and feed can be found in Section 5 of this Guide.

Non-commercial authorisation decisions under Directive 2001/18 are made on a national basis by the competent authority of the territory in which the release will take place. List 4.1, at the end of this Section, contains a list of competent authorities for this Directive.

The Joint Research Centre of the European Commission (on behalf of the Environment Directorate-General) publishes short summaries of the notifications received from competent authorities under Directive 2001/18/EC[111].

4.1 (iii) What are the basic legislative requirements?

Directive 2001/18/EC

[105] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf.
[106] http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_200/l_20020020730en00220033.pdf.
[107] http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_280/l_28020021018en00620083.pdf.
[108] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_254/l_25420031008en00210028.pdf.
[109] http://europa.eu.int/comm/environment/index_en.htm.
[110] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf.
[111] Deliberate Releases and Placing on the EU Market of Genetically Modified Organisms (GMOs), http://gmoinfo.jrc.it/.

The general objective of Directive 2001/18/EC is to ensure the protection of human health and the environment when deliberate releases of GMOs take place. Before a deliberate release can take place a notification must be sent to the national competent authority of the territory. The notification forms an application for consent. The notification must include a dossier of information, the requirements for which are outlined in Article 6 and Annex III of the Directive, and include the provision of information on:

- The GMO
- The receiving environment
- Interactions between the GMO and the receiving environment
- Conditions of release, and
- Monitoring, control, waste treatment and emergency response plans.

As well as the dossier of information, in accordance with Article 6 the notification must include the environmental risk assessment and the conclusions required in Annex II of the Directive, together with any bibliographic reference and indications of the methods used.

According to the standard procedure, the competent authority is expected to respond within 90 days after all the information requested has been received, with its decision on whether to authorise the deliberate release, and under which conditions. The notifier may not proceed with the release until written consent has been received from the competent authority, and has to comply with the conditions set in the consent. Member States are to ensure that the public are consulted on releases.

Certain GMOs, for which a competent authority has gained experience of their release into a particular environment, may be authorised through a 'differentiated procedure', under which certain parts of the Annex III dossier information will not be required. Design and use of a differentiated procedure is at the request of the competent authority. It is up to the Commission, after consultation with scientific committees and all the competent authorities, to decide on what the information requirements will be in these cases. Written consent will anyway be required prior to the deliberate release taking place.

If any changes are made to the deliberate release following consent that could affect human health and the environment, the notifier must inform the competent authority and take appropriate protective measures. The competent authority may decide to amend the conditions of, suspend or terminate the release. Notifiers are expected to report on the results of the deliberate release (in regard to human health and the environment) to the competent authority following completion of the release and subsequently 'at any intervals laid down in the consent' (Article 10, Directive 2001/18/EC[112]).

[112] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf.

Article 11 of Directive 2001/18/EC gave responsibility to the Commission to establish a system for exchange of information on notifications, decisions of the competent authorities and the results reported under Article 10 of the Directive. Some of this information is publicly available through the European Commission's Biotechnology and GMOs website[113].

In accordance with Article 31 of Directive 2001/18, Member States must establish public registers in which the location of the release of GMOs for any other purpose than placing on the market is recorded.

Supplementary legislation

Decision 2002/623/EC *establishing guidance notes supplementing Annex II to Directive 2001/18/EC*[114] gives guidance on the objectives, general principles and methodology of environmental risk assessments. The assessments are expected to be scientifically sound, to be made on a case-by-case basis and to consider both short and long-term effects. The methodology follows six steps:

1. Identification of characteristics which may cause adverse effects
2. Evaluation of the potential consequences of each adverse effect, if it occurs
3. Evaluation of the likelihood of the occurrence of each identified potential adverse effect
4. Estimation of the risk posed by each identified characteristic
5. Application of management strategies for risks from the deliberate release or marketing of GMOs
6. Determination of the overall risk of the GMOs

(Annex, Decision 2002/623/EC).

Decision 2002/813/EC[115] establishes the format to be used by competent authorities when they provide summaries of notifications to the Commission under Article 11 of Directive 2001/18/EC.

Decision 2003/701/EC[116] establishes the format to be used by notifiers in the reporting of results of the deliberate release to the competent authorities, as required by Article 10 of Directive 2001/18/EC. Reports are to include details of the notification and consent, details of the release, risk management measures, monitoring measures, and a conclusion on the results of the release in regard to human health and the environment.

---

[113] Deliberate Releases and Placing on the EU Market of Genetically Modified Organisms (GMOs), http://gmoinfo.jrc.it/

[114] http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_200/l_20020020730en00220033.pdf.

[115] http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_280/l_28020021018en00620083.pdf.

[116] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_254/l_25420031008en00210028.pdf.

Pre-commercial clinical trials and gene therapy experiments of medicinal substances and compounds for human use are addressed in Directive 2001/20/EC *on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use*[117]. See Answer 7.1 (iii) for further information on Directive 2001/20.

4.2 COMMERCIAL RELEASES

This Subsection provides information on the legislative requirements for commercial releases of GMOs. These are releases made in order to place products on the market.

If a GMO is to be used commercially in connection with food or feed, please refer to Section 5 of this Guide regarding the requirements for authorisation for placing on the market under Regulation (EC) No 1829/2003 *on genetically modified food and feed*, which is overseen by the Directorate-General for Health and Consumer Protection.

If a GMO is to be used as a medicinal product for human or veterinary use, see Section 7 of the Guide regarding the requirements for authorisation for placing on the market under Regulation (EC) No 726/2004.

4.2 (i) Which legislation applies to the release and commercialisation of GMOs?

The main EU legislation for this area is the framework Directive 2001/18/EC *on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC*[118]. Directive 2001/18/EC has been supplemented by the following legislation:

- Decision 2002/811/EC *establishing guidance notes supplementing Annex VII to Directive 2001/18/EC*[119]
- Decision 2002/812/EC *establishing pursuant to Directive 2001/18/EC the summary information format relating to the placing on the market of genetically modified organisms as or in products*[120]
- Decision 2002/623/EC *establishing guidance notes supplementing Annex II to Directive 2001/18/EC*[121], and

[117] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_121/l_12120010501en00340044.pdf.
[118] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf.
[119] http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_280/l_28020021018en00270036.pdf.
[120] http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_280/l_28020021018en00370061.pdf.
[121] http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_200/l_20020020730en00220033.pdf.

- Decision 2004/204/EC *laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC*[122]

Authorisation for the commercial release of GMOs can also be obtained under the 'one door, one key' regulatory principle via Regulation (EC) No 1829/2003 *on genetically modified food and feed*[123], the provisions of which are outlined in Section 5 of this Guide, and Regulation (EC) No 726/2004 *laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency*[124], the provisions of which are outlined in Section 7 of this Guide. An authorisation under Regulation 1829/2003 is required for the placing on the market of GMOs for food and feed use as well as for food and feed containing, consisting of or produced from GMOs. An authorisation under Regulation 726/2004 is required for the placing on the market of a GMO as medicinal product for human or veterinary use.

Traceability and labelling requirements for products consisting of, or containing, GMOs, and for food and feed produced from GMOs, are dealt with in more detail in Regulation (EC) No 1830/2003, which is covered in Section 5 of this Guide.

The European Commission has produced a detailed document, *Questions and Answers on the Regulation of GMOs in the European Union*[125], which provides further useful information on the legislation in this area. Relevant information is also provided about GM plants and seeds, labelling and coexistence, on the biotechnology webpages of the Directorate-General for Health and Consumer Protection[126].

4.2 (ii) Which regulatory bodies in Europe are responsible?

Authorisations for the commercial release of GMOs involve the competent authorities of the Member States established under Directive 2001/18 (see List 4.1 at the end of this Section) and the Environment Directorate-General of the European Commission. They may also require the involvement of the European Food Safety Authority[127], a regulatory committee (composed of Member States' representatives), and the Council of Ministers. The European Commission's Joint Research Centre, on behalf of the Environment Directorate-General, publishes information about decisions made and pending on commercial releases[128].

[122] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_065/l_06520040303en00200022.pdf.
[123] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf.
[124] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_136/l_13620040430en00010033.pdf.
[125] http://europa.eu.int/comm/food/food/biotechnology/gmfood/qanda_en.pdf.
[126] http://europa.eu.int/comm/food/food/biotechnology/index_en.htm.
[127] http://www.efsa.eu.int/.
[128] http://gmoinfo.jrc.it/.

Other European Commission DGs (for example Health and Consumer Protection) have responsibility for the scope and application of product-specific legislation which may supplement or replace the requirements of the legal framework covered in this Subsection of the Guide.

4.2 (iii) What are the basic legislative requirements?

Directive 2001/18/EC *on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC*[129] covers both commercial (placing on the market) and non-commercial releases of GMOs. Parts A and D of the framework Directive contain general provisions that apply to both types of release, and to the placing on the market of all types of GMOs. Part C contains the provisions specific to commercial release of a GMO or a combination of GMOs as or in products, and the detailed procedure for the placing on the market of GMOs that are not covered by other sectoral legislation.

Community authorisation procedure

Applications

Commercial releases of GMOs require Community-level approval, because once a release is authorised the product can be placed on the market throughout the EU. An environmental risk assessment (ERA), including assessment of the risks to human health, must be carried out before notifying the authorities of the intention to place a GMO on the market. The ERA should be carried out in compliance with Annexes II and III of Directive 2001/18/EC. A report on the ERA is to be included in the notification, along with other information specified in Annexes III, IV and VII, which includes, inter alia:

- The characteristics of the GMO
- Details of the release
- Interaction of the GMO with the environment
- Measures for control and waste treatment
- Emergency response plans
- Proposed commercial name
- Intended use, areas of use and categories of user
- Methods of detection and identification
- Proposed labelling, and
- Details of the monitoring plan.

[129] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf.

Decision 2002/623/EC[130] provides guidance notes on Annex II of Directive 2001/18/EC which concerns environmental risk assessment. Further information on this Decision can be found in Subsection 4.1 of this Guide.

A summary of the notification package ('dossier') is required in the format established by Decision 2002/812/EC[131], which includes:

- General information about the notification, notifier, product, regulatory status and proposed marketing and compliance activities
- Information on the organisms and the modification
- Information on environmental interactions
- Information on any previous releases, and
- Details of the monitoring plan.

Procedure for Community consent

The notification should be submitted to the competent authority of the territory in which it is intended that the first release will take place. The summary is immediately passed on to the other competent authorities and the Commission. The competent authority will produce an assessment report on the deliberate release, which will include its opinion on authorisation.

Whatever the opinion of the notified competent authority, all Member States and the Commission have an opportunity to examine the notification and assessment report. The notification and assessment report will also be made available to the public by the Commission, and members of the public have 30 days in which to make comments. In the case of a favourable assessment report, if after 60 days no objections have been raised by the Member States or the Commission, the competent authority to which the notification was submitted authorises the release. Conditions may be attached to the authorisation and its duration will be limited to a maximum of 10 years (this is renewable).

If the notified competent authority has decided that the GMO should not be placed on the market, the notification will be rejected and a statement of the reasons for the decision will be included. Rejection of such an application does not prevent its being submitted to another Member State. If objections are raised the Member States, the Commission and the notifier enter a conciliation phase. If the objections, based on environmental or health considerations, are maintained the Commission will request an opinion on the release from the European Food Safety Authority (EFSA) and, on receipt of this opinion, will draft a decision. EFSA's opinion is not binding for the Commission, but is taken into account in accordance with set procedures (see Answer 5(iii) of this Guide). The decision will be examined by a regulatory committee made up of Member States'

[130] http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_200/l_20020020730en00220033.pdf.
[131] http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_280/l_28020021018en00370061.pdf.

representatives. If the committee approves the decision by qualified majority, the Commission will adopt it; if not the decision is passed on to the Council of Ministers. If they do not respond within three months the Commission will adopt the decision.

If the Council of Ministers opposes the decision by qualified majority vote, the Commission re-examines it. The Commission may then submit an amended proposal to the Council, re-submit its proposal, or put forward legislation. Where no qualified majority is found in the Council, the Commission will take the final decision.

Releases must not take place until written consent has been received, and conditions of consents must be complied with. After authorisation the notifier must monitor the release and submit reports on it to the Commission and competent authorities at intervals specified in the consent. Decision 2002/811/EC[132] provides guidance notes on Annex VII of Directive 2001/18/EC, which concerns monitoring plans. These should be designed on a case-by-case basis, but Decision 2002/811/EC provides general guidance on objectives, principles, strategy, methodology, analysis, reporting and review.

Labelling

Under European legislation GMO products placed on the market (products consisting of or containing GMOs) must be clearly labelled as such. Specific labelling requirements are detailed in Annex IV to Directive 2001/18/EC[133] (the main requirement being that the label, or accompanying document, should state 'this product contains genetically modified organisms') and in Regulation (EC) No 1830/2003 *concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms*[134]. Regulation 1830/2003 is covered in Section 5 of this Guide.

The labelling requirements of Directive 2001/18/EC and Regulation 1830/2003 do not apply below set thresholds where the presence of authorised GMOs is 'adventitious or technically unavoidable'. For food and feed, the threshold of exemption from labelling requirements for the 'adventitious or technically unavoidable' presence of authorised GM material is 0.9% (the burden of proof being on the operator). The same threshold of 0.9% is inserted by Regulation 1830/2003 as Article 21(3) of Directive 2001/18 for products intended for direct processing. For the adventitious or technically unavoidable presence of GM seed in conventional seed no thresholds have yet been set.

[132] http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_280/l_28020021018en00270036.pdf.
[133] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf.
[134] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00240028.pdf.

Information management

Member States and the Commission will exchange information on their experience with Directive 2001/18/EC in accordance with Article 31 thereof. Registers have been established by the Commission for deliberate releases of GMOs, and Member States are also required to maintain publicly available registers, including registers of the locations of GMOs grown for placing on the market.

Decision 2004/204/EC[135] contains guidance on the registers to be established by the Commission under Article 31(2) of Directive 2001/18/EC, which are to contain certain information on genetic modifications and the corresponding detection methods. Decision 2004/204/EC specifies the information required, which includes the name and unique identifier[136] of the GMO, the nucleotide sequence of the insert, information on detection and identification, and the details of stored samples. While the registers are to be made publicly available, additional confidential information can be recorded separately with access limited to the Member States, the Commission and EFSA.

Member States and the Commission are also expected to provide information on the implementation and experience with Directive 2001/18/EC globally, through the information exchange mechanism of the Cartagena Protocol on Biosafety, in accordance with Regulation 1946/2003. For more about this information exchange mechanism, see Answer 6.2 (ii).

4.2 (iv) Might other regulatory regimes apply to my product?

Specific requirements for the marketing of GM seeds (see 4.2(v)) and for organic farming (see 4.2(vi)) will apply to some GM products. In addition the following regulatory regimes, covered in other Sections of this Guide, may apply:

- Exports of GMOs to third countries
- GMOs for food and feed
- Biotechnology medicinal products.

GMMs that are used with certain barriers in place to limit contact are generally subject to the Community's contained use legislation. However, under Article 4 of Directive 90/219 *on the contained use of genetically modified micro-organisms* as amended[137], GMMs are exempt from that Directive's requirements if they are

[135] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_065/l_06520040303en00200022.pdf.
[136] "a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorised transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO." (Regulation EC No1830/2003, Article 3.4).
[137] http://europa.eu.int/eur-lex/en/consleg/pdf/1990/en_1990L0219_do_001.pdf.

authorised for placing on the market - provided that the contained use is in accordance with the conditions of the consent for placing on the market.

Exports of GMOs

The main European legislation for this area, outlined in more detail in Section 6 of this Guide, is Regulation (EC) No 1946/2003 *on transboundary movements of genetically modified organisms*[138]. It applies to exports to non-EU states of most GMOs. Regulation 1946/2003 is also relevant to action required in the event of an unintentional release, and provides for public information to be made available to third countries on commercial uses of GMOs in the EU.

GM food and feed

The principal legislative instruments in the regulatory regime for commercial use of GM food and feed are:

- Regulation (EC) No 178/2002 *laying down the general principles and requirements of food law*[139]
- Regulation (EC) No 1829/2003 *on genetically modified food and feed*[140]
- and Regulation (EC) No 1830/2003 *concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC*[141].

Regulation 1829/2003 applied the general principles and requirements of Regulation 178/2002 to the area of genetically modified food and feed. Regulation 1830/2003 provides for certain information to be transmitted through the various stages of feed and food production, manufacture and processing , and also ensures that consumers receive full and reliable information on the final product. Section 5 of this Guide covers GM food and feed.

Biotechnology medicinal products

Medicinal products containing or consisting of GMOs are covered by the deliberate release legislation and legislation on the authorisation of medicinal products. Under Regulation (EC) No 726/2004 *laying down Community procedures for the authorisation and supervision of medicinal products for human*

[138] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_287/l_28720031105en00010010.pdf.
[139] http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf.
[140] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf.
[141] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00240028.pdf.

and veterinary use[142], copies of the technical dossier and the environmental risk assessment submitted, and the written consent received under Directive 2001/18/EC have to be included in applications for authorisation of biotechnology medicinal products. Section 7 of this Guide covers medicinal products and healthcare.

Other legislation

Plant protection products

In addition the following legislation on plant protection products may apply to some GMOs. Directive 91/414/EEC *concerning the placing of plant protection products on the market*[143] as amended (see unofficial consolidated text[144]) covers authorisation, placing on the market, use, and control of plant protection products, and plant protection products containing or consisting of GMOs are included in its coverage. These GMO products must have undergone environmental risk assessment in compliance with, and received a consent under, Directive 2001/18/EC before an application for authorisation can be granted under Directive 91/414. Plant protection products require prior authorisation from any Member State in which it is intended that they will be placed on the market. There are specific provisions on the labelling of products.

Plant health

Directive 2000/29/EC *on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community*[145] allows Member States to prohibit certain products, which pose significant risks to plant health, from entering their territory. However, GMOs approved for commercial use under Directive 2001/18/EC cannot be banned by Member States under Directive 2000/29/EC.

4.2 (v) How can I obtain authorisation to market GM seeds?

All GM seeds and plant propagating materials

Authorisation for commercial cultivation of GM seeds (registration in the catalogue of seed varieties) in consequence of their status as GMOs can only be

---

[142] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_136/l_13620040430en00010033.pdf.

[143] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31991L0414&model=guichett.

[144] http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/consleg/1991/L/01991L0414-20050601-en.pdf.

[145] http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_169/l_16920000710en00010112.pdf.

obtained after the procedures of Directive 2001/18/EC (see above) or Regulation 1829/2003 (see Section 5 – The GM Food and Feed Chain) have been complied with.

Seeds of the major agricultural and vegetable varieties

A marketing authorisation is to be obtained for all varieties of seeds of the major agricultural and vegetable varieties, whether or not they are genetically modified. This is a requirement under the following seed marketing directives as amended:

- Directive 66/401/EEC *on the marketing of fodder plant seed*[146]
- Directive 66/402/EEC *on the marketing of cereal seed*[147]
- Directive 2002/54/EC *on the marketing of beet seed*[148]
- Directive 2002/55/EC *on the marketing of vegetable seed*[149]
- Directive 2002/56/EC *on the marketing of seed potatoes*[150]
- Directive 2002/57/EC on *the marketing of seed of oil and fibre plants*[151].

The following Directives are also relevant to the authorisation of GM seeds:

- Directive 98/95/EC *amending, in respect of the consolidation of the internal market, genetically modified plant varieties and plant genetic resources, Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/457/EEC and 70/458/EEC on the marketing of beet seed, fodder plant seed, cereal seed, seed potatoes, seed of oil and fibre plants and vegetable seed and on the common catalogue of varieties of agricultural plant species*[152]
- Directive 2002/53/EC *on the common catalogue of varieties of agricultural plant species*[153].

Directive 98/95/EC amended several earlier Directives on the marketing of seed from important agricultural and vegetable crops. Directive 98/95/EC was partly a response to developments in the genetic modification of plants, and the relevant amendments are designed to ensure that when genetically modified seed is used, suitable risk assessment and management takes place, and appropriate

---

146 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31966L0401&model=guichett.

147 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31966L0402&model=guichett.

148 http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_193/l_19320020720en00120032.pdf.

149 http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_193/l_19320020720en00330059.pdf.

150 http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_193/l_19320020720en00600073.pdf.

151 http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_193/l_19320020720en00740097.pdf.

152 http://europa.eu.int/eur-lex/pri/en/oj/dat/1999/l_025/l_02519990201en00010026.pdf.

153 http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_193/l_19320020720en00010011.pdf.

labelling provisions apply. Quantities ('lots') of genetically modified seed must be labelled as such.

After inclusion in the Common Catalogue of Varieties of Agricultural Plant Species, seed of the major agricultural varieties should be freely marketable within the Community (Directive 2002/53/EC, Article 16(1)). Directive 2002/53 allows genetically modified varieties to be included in the Common Catalogue 'only if all appropriate measures have been taken to avoid adverse effects on human health and the environment'. An environmental risk assessment must have taken place in compliance with the requirements of Directive 2001/18/EC (Directive 2002/53/EC, Article 7). When genetically modified varieties are accepted for inclusion in the catalogue, they must be clearly identified as such.

Decision 2004/842/EC *concerning implementing rules whereby Member States may authorise the placing on the market of seed belonging to varieties for which an application for entry in the national catalogue of varieties of agricultural plant species or vegetable species has been submitted*[154] applies the general requirements for risk management, authorisation and labelling to a GM seed variety for which an application for entry into a national catalogue has been made, and which may be marketed under the provisions of this Decision and of Directive 98/95/EC (or of other relevant EU legislation on the marketing of plant propagating material).

Other species

Under Directive 1999/105/EC *on the marketing of forest reproductive material*[155], genetically modified forest reproductive material may not be placed on the market unless an environmental risk assessment has been conducted, and the approval of Member States has been granted. Directive 1999/105 includes provisions for traceability of the GM status of individual lots of reproductive material (Article 13), and labelling where it is derived from basic material which consists of a GMO (Article 14). National list entries must also state whether the basic material of the various species approved on the territory of the Member State in question is genetically modified (Article 10).

Under Directive 2002/11/EC *amending Directive 68/193/EEC on the marketing of material for the vegetative propagation of the vine and repealing Directive 74/649/EEC*[156], genetically modified vine varieties will not be authorised for placing on the market unless they have been subject to an environmental risk assessment in conformity with Directive 2001/18/EC, and comply with relevant

---

154 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32004D0842&model=guichett.

155 http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_011/l_01120000115en00170040.pdf.

156 http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_053/l_05320020223en00200027.pdf.

requirements equivalent to those of Directive 2001/18/EC, including those relating to risk management, labelling, monitoring and public information.

Thresholds for adventitious or technically unavoidable presence of GM seed in conventional seed

Article 21(2) of Directive 2001/18/EC provides that the Commission may adopt thresholds for the adventitious or technically unavoidable presence of GMOs in conventional products. Below such thresholds, products would not have to be labelled as genetically modified.

Above or in the absence of such thresholds, products containing adventitious presence of GMOs are subject to the labelling requirements established in Directive 2001/18/EC.

Enforcement

Recommendation 2004/787/EC *on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003*[157] is concerned with official control measures in the context of food and feed. It contains principles for official inspections, and guidance on the sampling and analytical testing of seeds and other propagating materials, as well as bulk agricultural commodities.

4.2 (vi) How are GM, conventional and organic agriculture kept in balance?

Organic agriculture

Regulation (EEC) No 2092/91 *on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs*[158] specifies the production requirements that must be met for a product to be labelled that it has been organically produced. With the amendment of the Community legislation on organic livestock production with Council Regulation (EC) No 1804/1999[159] there were added specific requirements that organic products must be 'produced without the use of genetically modified organisms and/or any products derived from such organisms' (Article 5(3)(h) of Regulation 2092/91 as

[157] http://europa.eu.int/comm/environment/biotechnology/pdf/recom2004_787.pdf.
[158] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31991R2092&model=guichett.
[159] http://europa.eu.int/eur-lex/pri/en/oj/dat/1999/l_222/l_22219990824en00010028.pdf.

amended[160]). However, veterinary products containing or produced from/with GMOs can be used in organic farming.

A temporary derogation from Article 6 of Regulation 2092/91 was extended for certain species by Regulation (EC) No 1452/2003[161] , which continues to allow Member States to 'authorise the use of seed or vegetative propagating material not obtained by the organic production method' (Article 1(1), Regulation 1452/2003) where such seed or propagating materials are not available through the organic production method, and still carry organic indications on the end product. This derogation does not apply to seed or propagating material produced with the use of GMOs or any products derived from such organisms (Regulation 1452/2003, Article 3); therefore such GMO-derived end products may not carry organic indications.
Regulation 2092/91 does not establish specific requirements with respect to adventitious or technically unavoidable presence of GMOs in organic end products and the labelling provisions of Regulation 1829/2003 therefore also apply to organic products, which therefore must be labelled as GM products if they contain more than 0.9% GMOs.

In accordance with Action 12 of the 2004 European Action Plan for Organic Food and Farming[162] as defended by the Commission, later fully shared by Council[163], the Commission is currently preparing a proposal for a new Council Regulation on Organic Farming which includes a ban on labelling a product as organic if the product has to be labelled as GM product according to Regulation 1829/2003. Article 13 of Regulation 2092/91 (as amended by Regulation 1804/1999)[164] provides that the Commission may adopt de minimis thresholds for the presence of GMOs in seeds and other inputs used in organic farming. So far, no such thresholds have been established.

Coexistence of conventional, GM and organic crops

While the environmental and health aspects of GMOs are covered by Directive 2001/18/EC, the economic aspects in relation to the segregation of GM from traditional crop production are dealt with by national legislation or non-legislative approaches in the Member States. Liability in case of economic damage resulting from the presence of GMOs in other products is covered by national civil law.

---

[160] http://europa.eu.int/eur-lex/en/consleg/pdf/1991/en_1991R2092_do_001.pdf.
[161] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_206/l_20620030815en00170021.pdf.
[162] Communication from the Commission to the Council and the European Parliament: European Action Plan for Organic Food and Farming (COM(2004) 415 final): http://europa.eu.int/comm/agriculture/qual/organic/plan/comm_en.pdf
[163] Council Conclusions of October 2004 on the Communication (2004) 415 final.
[164] Non-official, consolidated text of Regulation 2092/91: http://europa.eu.int/eur-lex/en/consleg/pdf/1991/en_1991R2092_do_001.pdf

Commission Recommendation 2003/556/EC *on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming*[165] aims to enable all types of farming to take place side by side. National strategies, adapted to local conditions, are required, but the Recommendation provides general guidance on principles to be taken into account in the Member States as well as on technical field measures for ensuring coexistence of GM and traditional crop production.

Under the provisions of paragraph 2.1.11 of Recommendation 2003/556/EC Member States should "inform the Commission about their national strategies for coexistence and the individual measures adopted"[166].

Further documents on coexistence of GMOs with conventional and organic agriculture have been provided by the Agriculture Directorate-General[167].

Liability for environmental damage

Directive 2004/35/CE [sic] *on environmental liability with regard to the prevention and remedying of environmental damage*[168] has been adopted to establish a framework based on the 'polluter pays' principle, and concerns the liability of companies for environmental damage caused by activities listed in Annex III to the Directive, which include the contained use and deliberate release of genetically modified organisms. Companies found liable for environmental damage, which is strictly defined in the Directive, will be made to clean up that damage, or otherwise bear the costs for the clean up. The Directive does not cover individual compensation for environmental damages and cannot directly be used by individuals. It does not therefore relate to coexistence. However, individuals may request that their Member State's competent authority makes use of the Directive's provisions in particular cases. Further information on environmental liability can be found in the press release *Questions and Answers Environmental Liability Directive*.[169].

[165] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_189/l_18920030729en00360047.pdf
[166] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_189/l_18920030729en00360047.pdf
[167] http://europa.eu.int/comm/agriculture/res/index_en.htm.
[168] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_143/l_14320040430en00560075.pdf.
[169] http://europa.eu.int/rapid/pressReleasesAction.do?reference=MEMO/04/78&format=HTML&aged=0&language=EN&guiLanguage=en.

SECTION 4 – ANNEX
DELIBERATE RELEASE OF GMOs: STEP BY STEP

PART A
Steps required to decide whether a product is in the scope of Directive 2001/18/EC *on the deliberate release into the environment of genetically modified organisms*[170]

(1) Does the product meet the definition of a GMO under Directive 2001/18/EC?

Directive 2001/18/EC defines a genetically modified organism as:

> an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Directive 2001/18/EC, Annex I A, Part 2 lists certain techniques which are not viewed as resulting in genetic modification. Directive 2001/18/EC, Annex I B lists some additional techniques that are exempt from the Directive's provisions. If your product meets this definition please go to question 2. If you are unsure please go to question 8.

(2) Is the GMO intended for contained use?

The contained use of GMOs (which requires specific containment measures) does not fall within the scope of Directive 2001/18/EC and the contained use of GMMs is instead subject to Directive 90/219/EEC *on the contained use of genetically modified micro-organisms*[171] and to the legislation of the Member States. Directive 90/219/EEC as amended[172] outlines the specific containment measures required in its Annex IV and defines contained use in its Article 2 as:

> 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.

---

[170] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf.

[171] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31990L0219&model=guichett.

[172] http://europa.eu.int/eur-lex/en/consleg/pdf/1990/en_1990L0219_do_001.pdf.

Information on Community legislation on the contained use of GMOs can be found in Section 3 of this Guide. If your product is not intended for contained use, please go to question 3.

(3) Is the GMO intended for commercial release (placing on the market)?

Article 2(3) of Directive 2001/18/EC defines deliberate release as:

> any intentional introduction into the environment of a GMO or a combination of GMOs for which no 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.

Article 2(4) defines placing on the market as:

> making available to third parties, whether in return for payment or free of charge ... .

Article 2(4) goes on to define operations that are not regarded as placing on the market, including making available:

- GMMs for activities regulated under Directive 90/219/EEC (see question 2 above), including culture collections
- Other GMOs to be used exclusively for activities applying the principles of containment laid down in Directive 90/219
- GMOs to be used exclusively for deliberate releases complying with the requirements laid down in Part B of Directive 2001/18.

GMOs for placing on the market fall within the scope of Part C of Directive 2001/18/EC. The authorisation procedure is outlined in Part C of this Annex, and further information on the Community legislation covering deliberate releases for the purpose of placing on the market can be found in Section 4.2 of this Guide. If you product is intended for commercial release please check questions 5 and 6 before proceeding to Part C of this Annex.

(4) Is the GMO intended for non-commercial deliberate release?

This applies to GMOs intended for deliberate release (as defined in Article 2(3) of Directive 2001/18/EC) but not for placing on the market (as defined in Article 2(4) thereof). Deliberate release of GMOs for non-commercial purposes (strictly

speaking, 'for any other purpose than for placing on the market') falls within the scope of Part B of Directive 2001/18. The authorisation procedure is outlined in Part B of this Annex, and further information on the Community legislation covering non-commercial deliberate releases can be found in Section 4.1 of this Guide. Please check question 5 before proceeding to Part B of this Annex.

(5) Is the GMO intended for use as a human or veterinary medicinal product?

(a) All medicinal products cannot be placed on the market under Directive 2001/18/EC and instead they must follow the centralised authorisation procedure outlined in Regulation (EC) No 726/2004 *laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicinal Agency*[173]. Copies of the notification dossier, environmental risk assessment and monitoring plan submitted under Part B of Directive 2001/18/EC, and of the written consent received, must accompany applications for authorisation under Regulation 726/2004. Information on Regulation 726/2004 can be found in Section 7 of this Guide.

(b) Medicinal substances and compounds for human use are not subject to authorisation in accordance with Part B of Directive 2001/18/EC provided that their deliberate release for any purpose other than that of being placed on the market is authorised by Community legislation meeting the conditions given in Article 5 thereof. Advice should be obtained from the appropriate authorities on compliance with Part B of Directive 2001/18 together with Directive 2001/20/EC *on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use*[174] (see also Answer 7.1 (iii) of this Guide).

(c) Biotechnology medicinal products for animal use must receive written consent for deliberate release into the environment for any other purposes than placing on the market under Part B of Directive 2001/18/EC.

Regulation 726/2004 defines biotechnology medicinal products as:

> Medicinal products developed by means of one of the following biotechnological processes:
> - recombinant DNA technology,
> - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells,
> - hybridoma and monoclonal antibody methods.

[173] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_136/l_13620040430en00010033.pdf.
[174] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_121/l_12120010501en00340044.pdf.

For information on Part B of Directive 2001/18/EC please see Part B of this Annex, and Section 4.1 of this Guide. If your product is not intended for use as a human or veterinary medicinal product please go to question 6.

(6) Is the GMO intended for commercial use as, or in, food or feed?

If so it shall in principle follow a single authorisation procedure for placing on the market and use as food or feed under Regulation (EC) No 1829/2003 *on genetically modified food and feed*[175]. An environmental risk assessment in line with the requirements of Directive 2001/18/EC must be conducted. If your product is intended for use as food or feed please refer to Section 5 of this Guide.

(7) Is the GMO intended to be exported and/or deliberately released in third countries (outside the Community)?

The definition of deliberate release - see Article 2(3) of Directive 2001/18/EC - does not exclude GMOs which are intended to be exported and/or deliberately released in third countries. Regulation (EC) No 1946/2003 *on transboundary movements of genetically modified organisms*[176] includes additional requirements regarding exports, and obligations to provide information about compliance with Directive 2001/18.

(8) How can I find out more about the scope of Directive 2001/18/EC?

If you remain unsure whether or not your product falls within the scope of Directive 2001/18/EC or other European legislation, please consult the competent authority for your Member State. Member State competent authorities should also be consulted for information on any differentiated procedures in operation under Article 7 of Directive 2001/18/EC which may ease the dossier requirements in clearly defined circumstances. List 4.1, at the end of this Section, contains a list of competent authorities for Directive 2001/18/EC.

Information is published on products that have already received or are pending authorisation. This may help to clarify issues relating to the scope of Community deliberate release legislation. Please see the following lists:

- *GMO Products Authorised Under Directive 2001/18/EC*[177]
- *GMO Products Approved Under Directive 90/220/EEC*[178]

[175] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf.
[176] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_287/l_28720031105en00010010.pdf.
[177] http://europa.eu.int/comm/environment/biotechnology/authorised_prod_2.htm.
[178] http://europa.eu.int/comm/environment/biotechnology/authorised_prod_1.htm.

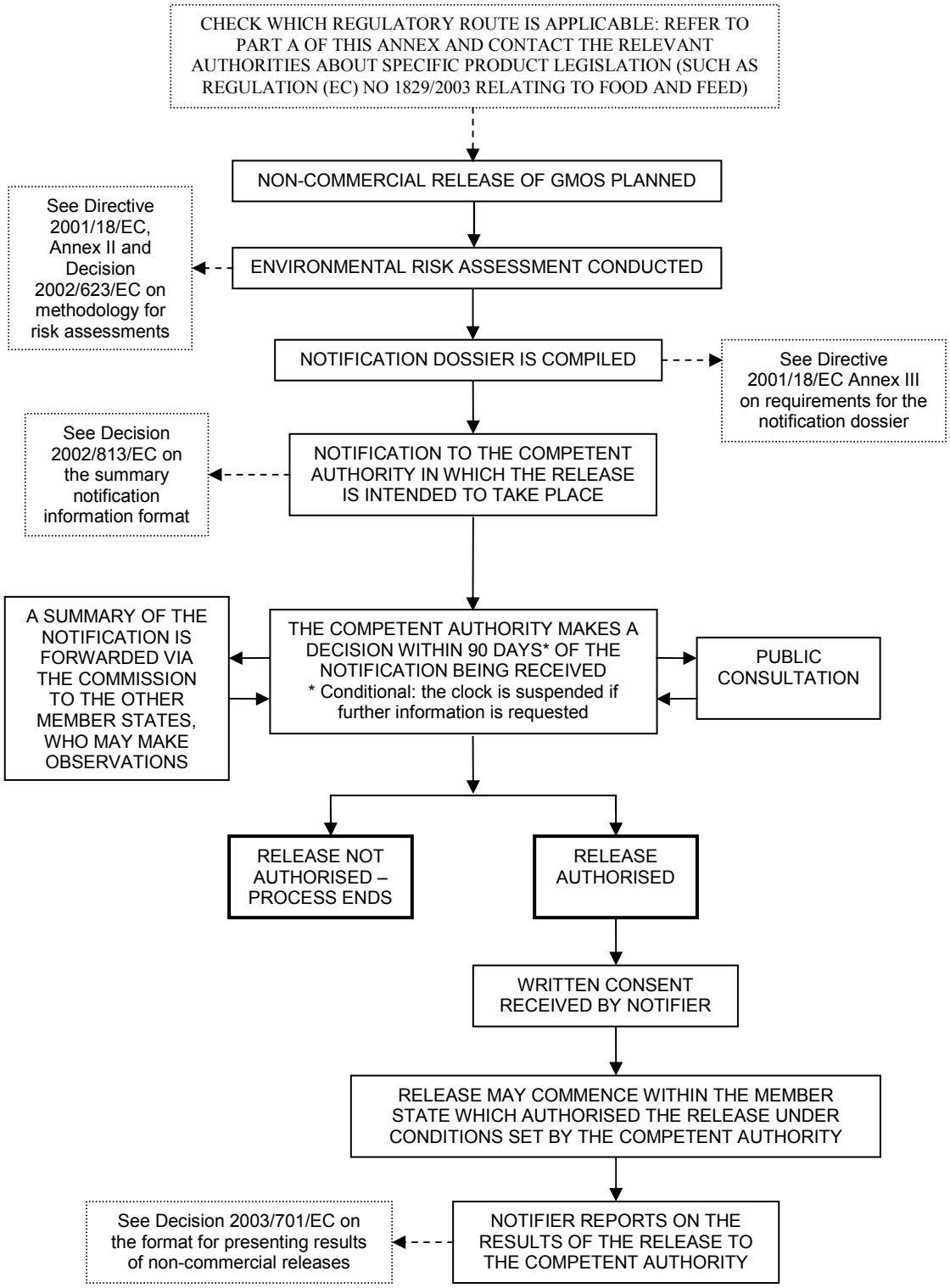
- *GMO Products – Pending Notifications Under Directive 2001/18/EC*[179].

The following lists may help to illustrate the complementary scope of Community legislation on GM food and feed:

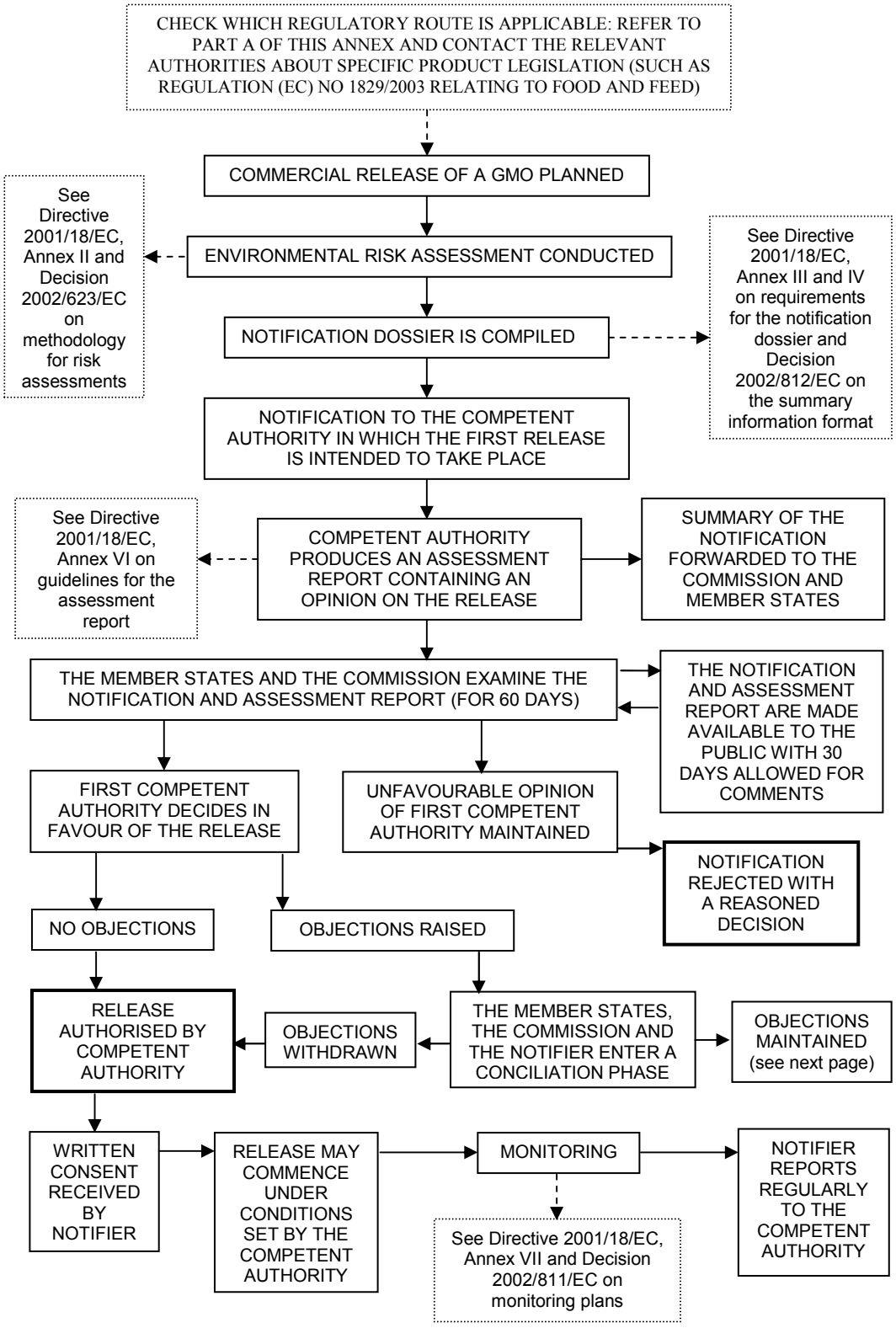
- *Community Register of GM Food and Feed*[180]
- *Applications under Regulation (EC) 1829/2003 on Genetically Modified Food and Feed*[181].

[179] http://europa.eu.int/comm/environment/biotechnology/pending_products.htm.
[180] http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm.
[181] http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html.

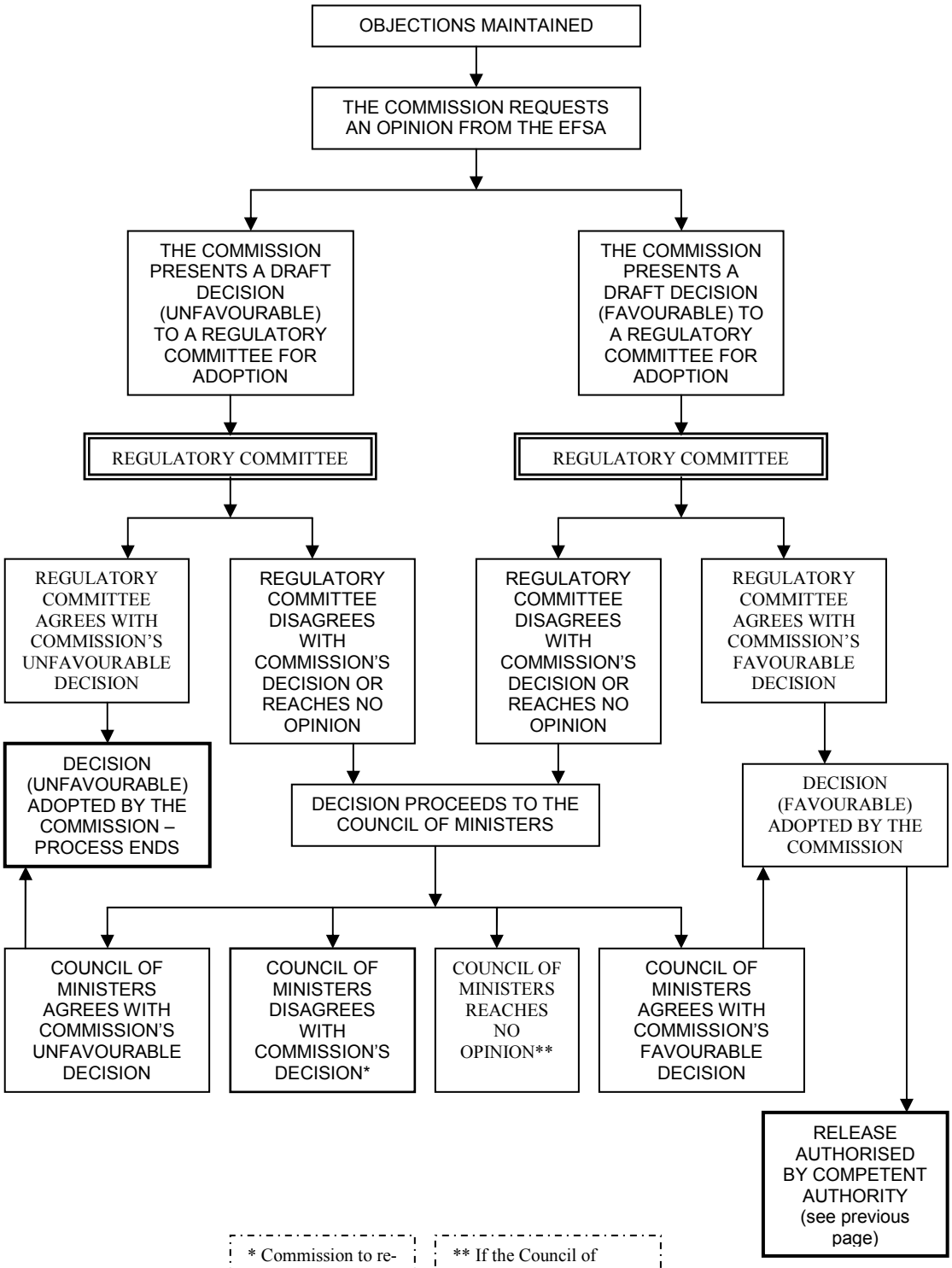
SECTION 4 – ANNEX – PART B
Procedure for obtaining authorisation for non-commercial deliberate releases of GMOs under Directive 2001/18/EC



SECTION 4 – ANNEX – PART C
Procedure for obtaining authorisation to place GMOs on the market under Directive 2001/18/EC



Procedure if objections are maintained:



LIST 4.1 – COMPETENT AUTHORITIES – DIRECTIVE 2001/18/EC

AUSTRIA

Michel Haas
Ministry of Health and Women - Dept IV/12
Radetzkystrasse 2
A-1030 Vienna
+43 (1) 711 004845
+43 (1) 715 24 05
michel.haas@bmgf.gv.at

Gertraud Fischinger
Perm. Rep. of Austria
30, Av. de Cortenbergh
BE-1040-Brussels
+32 2 2345 221
+32 2 2356 221
gertraud.fischinger@bmaa.gv.at

Eva Claudia Lang
Ministry for Health and Women
Department IV/B/12
Biotechnology & genetic engineering
Radetzkystr. 2
A-1030 Vienna
Austria
+43 (1) 71100 4450
+43 (1) 715 2405
eva.lang@bmgf.gv.at

Gabriele Satzinger
Ministry of Social Security and Generations
Radetzkystraße 2
AT-1030 Wien
+43 (1) 711 004826
+43 (1) 715 24 05
gabriele.satzinger@bmgf.gv.at

Alois Haslinger
Federal Ministry of Education, Science and Culture, Dept. BrGt
Rosengasse 2-6
A-1014 Vienna
+43 (1) 53120 7114
+43 (1) 53120 6205
alois.haslinger@bmbwk.gv.at

Manuela Wammerl
Bundestministerium für Gesundheit und Frauen
Radetzkystrasse 2
AT-1030 Wien
+43 (1) 71100 4844
+43 (1) 715 24 05
Manuela.Wammerl@bmgf.gv.at

Mag. Alice Schmatzberger
Umweltbundesamt GmbH
Abteilung Umweltfolgenabschätzung und Biologische Sicherheit
Spittelauer Lände 5
AT-1090 Wien
+43 (1) 31304 3125
+43 (1) 31304 3700
alice.schmatzberger@umweltbundesamt.at

BELGIUM

Myriam Sneyers
Institute of Public Health (IPH)
Federal Public Service (FPS) Health, Food Chain Security and Environment
Juliette Wytsmanstraat 14
B-1050 Brussels
Belgium
+32 2 642 52 93
+32 2 642 52 92
msneyers@sbb.ihe.be

Scientific Institute of Belgium
gmcropff@sbb.ihe.be

Martine Delanoy
FPS Health, Food Chain Safety and Environment
General direction Animals, Plants and Food
Division Raw materials and Plant protection
Place Victor Horta, 40 Boîte 10
Bloc II - 7° étage
1060 Bruxelles
+32 (2) 524 73 57
+32 (2) 524 73 99
martine.delanoy@health.fgov.be

CYPRUS

Elena Stylianopoulou
Ministry of Agriculture, Natural Resources and Environment
Department. Environment Service
Louki Akrita 1411, Nicosia
Cyprus
+35 7 22303865
+35 7 22774945
estylianopoulou@environment.moa.gov.cy

Nicos Georgiades
Ministry of Agriculture, Natural Resources and Environment
Environment Service
Blng. of the Cooperative Credit Society of Ayios Dhometios
4th floor
Gregoris Afxentiou str. Nos 10-12
CY-2360 Agios Dometios (Nicosia)
+35 7 22 303883
+35 7 22 774945
ngeorgiades@environment.moa.gov.cy

CZECH REPUBLIC

Zuzana Doubkova
Ministry of the Environment
Department of Environmental Risks,
Vrsovicka 65
100 10 Prague 10
Czech Republic
+42 0 (26712) 2922
+42 0 (26731) 0013

doubkova@env.cz

DENMARK

Mr Søren Søndergaard Kjær
Ministry of Environment
The Danish Forest and Nature Agency
Haraldsgade 53
DK-2100 Copenhagen ø
+45 (3947) 22 51
+45 (3947) 27 65
ssk@sns.dk

Gitte Silberg Poulsen
Ministry of the Environment
Danish Forest and Nature Agency
Agriculture and Biotechnology
Haraldsgade 53
DK-2100 Copenhagen Ø
+45 (39) 47 22 60 (direct)
+45 (39) 47 27 65
gsp@sns.dk

Lisbeth Overgaard Jensen
Ministry of Environment
The Danish Forest and Nature Agency
Haraldsgade 53
DK-2100 Copenhagen
+45 (39) 47 2252
+45 (39) 47 2765
loj@sns.dk

ESTONIA

Hardo Lilleväli
Ministry of Environment
Nature Protection Department
Narva mnt. 7A - 329
15172 Tallinn

Estonia
+37 2 6262 886
+37 2 6262 901
hardo.lillevali@envir.ee

Mati Koppel
The Jõgeva Plant Breeding Institute
Aamisepa 1
EE-alevik 48309, Jõgeva
Estonia
+37 2 7766 901
+37 2 7766 902
mati.koppel@jpbi.ee

FINLAND

Hannele Leiwo
Ministry of Social Affairs and Health - Board for Gene Technology
P.O. Box 33
Government
FI-00023 Helsinki, Finland
+35 8 (9) 160 74124
+35 8 (9) 160 73876
hannele.leiwo@stm.vn.fi

FRANCE

Eric Giry
Ministère de l'Agriculture, de l'alimentation, de la pêche et des affaires rurales
Direction générale de l'alimentation
251, rue de Vaugirard
FR-75732 PARIS Cedex 15
+33 (1) 49 55 59 28
+33 (1) 49 55 49 61
Eric.GIRY@agriculture.gouv.fr

Anne Grevet
Ministère de l'Agriculture
Direction Générale de l'Alimentation
251 rue Vaugirard
FR-75732 Paris Cedex 15
+33 (1) 49 55 59 12

+33 (1) 49 55 49 61
anne.grevet@agriculture.gouv.fr

Véronique Laborde
Ministère de l'Agriculture
Direction Générale de l'Alimentation
251 rue Vaugirard
FR-75732 Paris Cedex 15
+33 (1) 49 55 59 12
+33 (1) 49 55 49 61
veronique.laborde@agriculture.gouv.fr

Bérangère BASIN
Ministère de l'écologie et du développement durable
Bureau des Biotechnologies et des Installations agricoles et agro-alimentaires
Service de l'Environnement Industriel
Direction de la Prévention des Pollutions et des Risques
20, av de Ségur
FR-75302 Paris cedex 07
+33 (1) 42 19 14 83
+33 (1) 42 19 14 67
berangere.basin@ecologie.gouv.fr

Richard Smith
Ministère de l'écologie et du développement durable
DPPR/SEI
20, avenue de Ségur
FR-75302 PARIS 07 SP
+33 (1) 42 19 14 54
richard.smith@ecologie.gouv.fr

GERMANY

Hans-Jörg Buhk
Federal Office of Consumers Protection and Food Safety
Dept. of Genetic Engineering
Taubenstrasse 42 - 43
DE-10117 Berlin
+49 (0) 1888 413 3000
+49 (0) 1888 413 3060
Hans-Joerg.Buhk@bvl.bund.de

Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft
Referat 222
Rochustrasse 1
DE-53123 Bonn
+49 228 529 3356
+49 228 529 3743
222@bmvel.bund.de

GREECE

Ioannis Chondropoulos
Greek Ministry for the Environment
Nature Managment Unit, 2nd floor
Trikalon 36 & Messoghion
GR-Athens, 11526
+30 (210) 6918202
+30 (210) 6918487
biotech@minenv.gr

Dr Athena Mourmouri
Ministry of the Environment, Physical Planning and Public Works
Nature Management Unit
Trikalon 36 and Messoghion
GR-115 26 Athens
+30 (210) 6917620
+30 (210) 6918487
a.mourmouri@dpers.minenv.gr

HUNGARY

Mr Bertalan SZÉKELY
Ministry of Agriculture and Rural Development
Department for Agriculture
Kossuth L tér 11
HU-1055 Budapest
Hungary
+36 (1) 301 4111
+36 (1) 301 4668
bertalan.szekely@fvm.hu

Mrs Csabáné Vertes
Ministry of Agriculture and Rural Development

Budapest Kossuth square 11
HU-1055 Hungary
Hungary
+36 (1) 301 4617
+36 (1) 301 4668
VertesC@posta.fvm.hu

Ms Hajnalka Homoki
Ministry of Environment and Water
Department of International Treaties for Nature Conservation
H-1121 Budapest, Költo u. 21
Hungary
+36 (1) 391 1778
+36 (1) 275 4505
homoki@mail.kvvm.hu

IRELAND

Ronnie Devlin
Ministry - Department of the Environment, Heritage and Local Government
Environment Policy Section
Custom House
Dublin 1
Ireland
+35 3 (1) 888 2086
+35 3 (1) 888 2691
ronnie_devlin@environ.ie

Tom McLoughlin
EPA
P.O. Box 3000
Johnstown Castle Estate, Co. Wexford
Ireland
+35 3 (53) 60617
+35 3 (53) 60699
t.mcloughlin@epa.ie

ITALY

Clelia Boesi
Italian Representation
9, rue du Marteau

1000 Bruxelles
+32 (2) 220 04 84
+32 (2) 220 05 25
ambiente@rpue.it

Aldo Cosentino
Ministero dell'Ambiente e della Tutela del Territorio
Direzione per la Protezione della Natura
via Capitan Bavastro 174
IT-00154 Roma
+39 (06) 5722 8512
+39 (06) 5722 8707
scn-dg@minambiente.it

Giovanni Staiano
APAT - Agency for Environmental Protection
Nature Protection Dept
via V. Bancati 48
IT-0144 Roma
+39 (06) 4444 2620
+39 (06) 4444 2618
staiano@apat.it

Dr Silvio Vetrano
Ministero dell'Ambiente e della Tutela del Territorio
Dirigente Divisione VIII
via Capitan Bavastro 174
IT-00154 Roma
+39 (06) 5722 8260
+39 (06) 5722 8390
vetrano.silvio@minambiente.it

LATVIA

Baiba Holcmane
Ministry of Agriculture of Latvia
Republikas laukums 2
LV-1981 Riga
+37 1 (70) 27 404
+37 1 (70) 27 205
baiba.holcmane@zm.gov.lv

Ieva Klavinska
Ministry of Agriculture
Food Surveillance Department
Food & Veterinary Service
Republikas laukums 2
LV-1981 Riga
+37 1 (70) 27 483
ieva.klavinska@pvd.gov.lv

Gundega Micule
Permanent Representation of Latvia to the EU
+32 2 282 48 50
+32 2 282 03 69
gundega.micule@mfa.gov.lv

Uldis Armanis
Latvian Food Center
Kr.Valdemara Street 38
LV-1010, Riga
Latvia
+37 1 (7021713)
+37 1 (7021755)
uldis.armanis@lpc.gov.lv

Sarma Sleze
Latvian Food Center (Ministry of Health)
Kr. Valdemara iela 38
LV-1010 Riga
Latvia
+37 1 7021576
+37 1 7021755
sarma.sleze@lpc.gov.lv

LITHUANIA

Aleksandras Spruogis
Ministry of Environment
Jaksto 4/9
LT-2694 Vilnius
Lithuania
+37 0 (52) 66 34 85

+37 0 (52) 66 36 65
a.spruogis@am.lt

Ms Neringa Šarkauskiene
Ministry of the Environment
GMO division
Nature Protection Dpt
A. Jakšto St 4/9
LT-2600 Vilnius
+37 0 (52) 663 562
+37 0 (52) 663 663
n.sarkauskiene@am.lt

Danius Lygis
Ministry of Environment
Jaksto 4/9
LT-2694 Vilinius
Lithuania
+37 0 (52) 66 35 62
+37 0 (52) 66 36 68
d.lygis@am.lt

LUXEMBOURG

Sarah Blau
Représentation Permanente du Grand-Duché de Luxembourg auprès de l'Union européenne
75, Av. de Cortenbergh
B-1000 Bruxelles
+32 2 737 56 67
+32 2 737 5610
sarah.blau@rpue.etat.lu

Marcel Bruch
Ministry of Health
Allée Marconi
L-2102 LUXEMBOURG
+35 2 478 55 91
+35 2 26 20 0147
marcel.bruch@ms.etat.lu

MALTA

Nadia Lanzon
Malta Environment and Planning Authority
Biosafety Co-ordinating Committee
Nature Protection Unit
Environment Protection Directorate
St. Francis Ravelin,
Floriana
(P.O. Box 200)
MT-Valletta CMR01
Malta
+35 6 (2290) 6009
+35 6 (2290) 1585
bcc.notifications@mepa.org.mt

THE NETHERLANDS

Ir. Hinse J. Boonstra
Ministry of Housing, Spatial Planning and the Environment
Directorate-General for Environmental Protection
Directorate for Chemicals, Waste, Radiation Protection
Rijnstraat 8, P.O. Box 30945
NL-2500 GX The Hague
+31 (70) 3395389
+31 (70) 3391316
Hinse.Boonstra@minvrom.nl

Dr Boet Glandorf
National Institute of Public Health and the Environment
Bureau GGO
RIVM, CSR
Antonie van Leeuwenhoeklaan 9
NL-3721 MA BILTHOVEN
+31 (30) 2744176
Boet.Glandorf@rivm.nl

Dr Marco Gielkens
Company National Institute for Public Health and Environment
Dept GMO Office
PO box 1
(Antonie van Leeuwenhoeklaan 9)
NL-3720 (3721) BA Bilthoven

+31 (30) 2744179
+31 (30) 2744461
marco.gielkens@rivm.nl

Inge van der Leij
Ministry for Housing, Spatial Planning and the Environment
Directorate-General for Environmental protection
Directorate for Chemicals, Waste, Radiation Protection
Radiation Protection, Nuclear and Biosafety
Rijnstraat 8
P.O. BOX 30945
2500 GX The Hague
The Netherlands
+31 (70) 3394893
+31 (70) 3391316 (fax)
inge.vanderleij@minvrom.nl

POLAND

Izabela TANSKA
Chief Sanitary Inspectorate. Dept of food, nutrition and daily use objects hygiene
Dluga Str. 38/40
00-238 Warsaw, Poland
Poland
+48 (22) 536 13 16
+48 (22) 635 61 94
i.tanska@gis.gov.pl

Agnieszka Dalbiak
Ministry of the Environment
Department of Nature Conservation
52/54 Wawelska Street
00 - 922 Warsaw
POLAND
+48 (22) 57 92 538
+48 (22) 57 92 555
agnieszka.dalbiak@mos.gov.pl

Malgorzata Wozniak
Ministry of The Enviroment
Unit of GMO
52/54 Wawelska Street

00 - 922 Warsaw
POLAND
Poland
+48 (22) 57 92 723
+48 (22) 57 92 555
malgorzata.wozniak@mos.gov.pl

PORTUGAL

Maria do Carmo Palma
Instituto do Ambiente
Environmental Risks and Emergencies Unit
Rua da Murgueira 9/9A- Zambujal
Apartado 7585 - Alfragide
PT-2611-865 Amadora
+35 1 (21) 4728368
+35 1 (21) 4728231
carmo.figueira@iambiente.pt

SLOVAKIA

Mr Milan Pesko
Ministry of the Environment of the Slovak Republic
Biosafety Department
Námestie L. Stúra 1,
SK-812 35 Bratislava
+42 1 (2) 5956 2208
+42 1 (2) 5956 2533
pesko.milan@enviro.gov.sk

Mr Igor Ferencik
Ministry of Environment of SR
Biosafety Department
Nam. L. Stura 1
SK-812 35 Bratislava
Slovak Republic
+42 1 (2) 5956 2185
+42 1 (2) 5956 2533
ferencik.igor@enviro.gov.sk

Leopold Dugovic
Ministry of the Enviroment of the Slovak Republik

Biosafety Department
Namestie L.Stura 1
812 35 Bratislava
Slovakia
+42 1 (2) 5956 2716
+42 1 (2) 5956 2533
dugovic.leopold@enviro.gov.sk

Magdalena Rosinova
Ministru of Agriculture
+42 1 (2) 5926 6567/66
+42 1 (2) 5926 6562
magdalena.rosinova@land.gov.sk

SLOVENIA

Dr Martin Batic
Ministry of the Environment
Sector for Biotechnology, Office for the Environment
Spatial Planning and Energy
Dunajska 48
SI-1000 Ljubljana
+38 61 4787 402
+38 61 4787 420
martin.batic@gov.si

Dr. Darja Stanic-Racman
Ministry for the Environment, Spatial Planning and Energy
Sector for Environmental Policy
Dunajska cesta 48
SI-1000 Ljubljana
+38 61 4787 338
+38 61 4787 420
darja.stanic@gov.si

Ms Marusa Pavcic
Ministry of Health
Sector for Food Safety and Health Suitability
Stefanova 5
SI-1000 Ljubljana
+38 61 4786 851
+38 61 4786 856

marusa.pavcic@gov.si

SPAIN

Ana Fresno Ruiz
Ministerio de Medio Ambiente
DG de Calidad y Evaluacion Ambiental
Plaza San Juan de la Cruz s/n
ES-28071 Madrid
+34 (91) 453 53 62
+34 (91) 534 05 82
afresno@mma.es

SWEDEN

Kersti Gustafsson
National Chemicals Inspectorate
Kemikalieinspektionen
Box 2
S-172 13 Sundbyberg
Sweden
+46 8 519 41 195 direct
+46 8 735 76 98
Kersti.Gustafsson@kemi.se

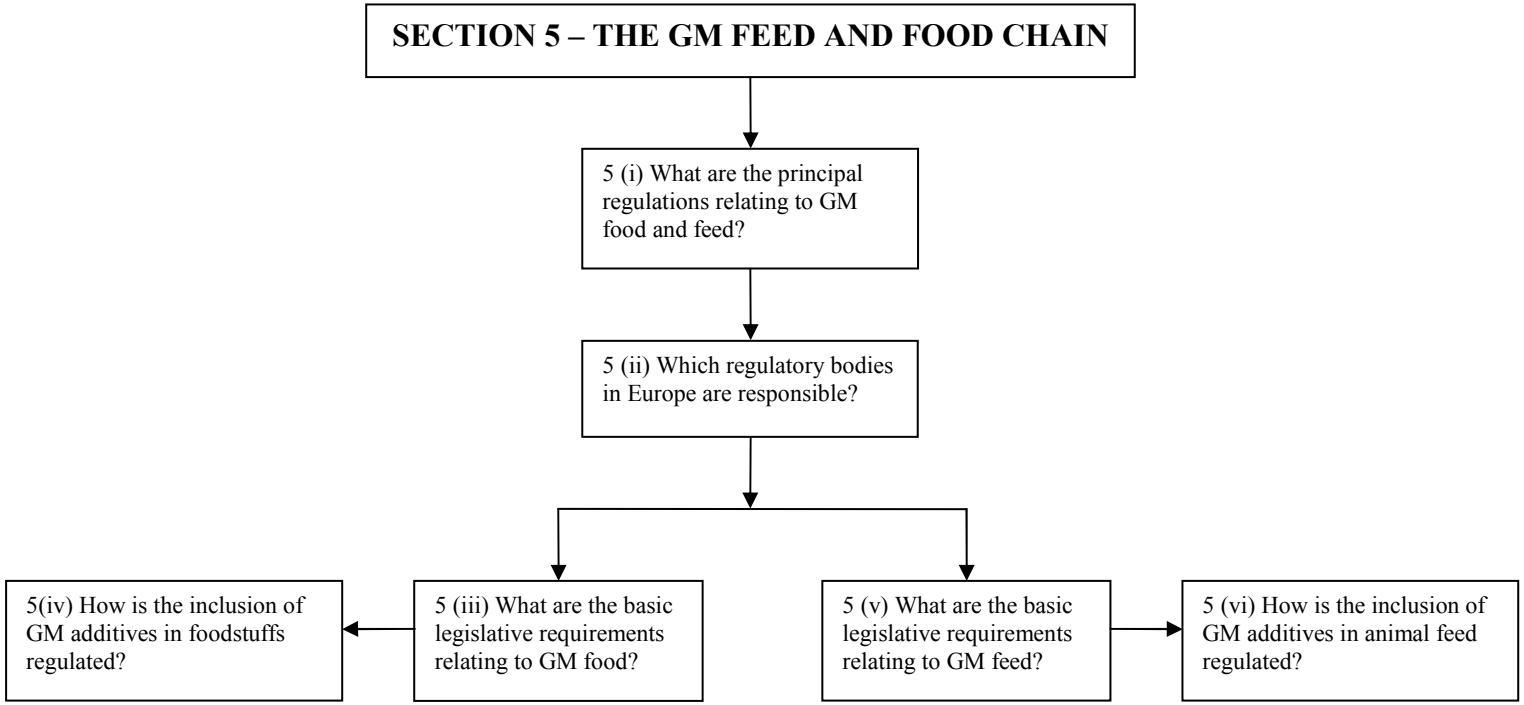
Staffan Eklöf
Swedish Board of Agriculture
Crop Production Division
Vallgatan 8
S-551 82, Jönköping
+46 (-36) -15 51 23
+46 (-36) -710517
staffan.eklof@sjv.se

UNITED KINGDOM

Louise Ball
DEFRA
GM controls
Chemical and GM Policy Division
Dpt for Environment, Food and Rural Affairs
Ashdown House

123 Victoria Street
UK-London SW1E 6DE
United Kingdom
+44 (207) 082 8116
+44 (207) 082 8123
Louise.ball@defra.gsi.gov.uk

Dr Androulla Gilliland
DEFRA
Department for Environment, Food and Rural Affairs
3/H10 Ashdown House
123 Victoria Street
UK -London SW1E 6DE
United Kingdom
+44 (207) 082 8118
+44 (207) 082 8123
androulla.gilliland@defra.gsi.gov.uk


SECTION 5 – THE GM FEED AND FOOD CHAIN
5 (i) What are the principal regulations relating to GM food and feed?
5 (ii) Which regulatory bodies in Europe are responsible?
5(iv) How is the inclusion of GM additives in foodstuffs regulated?
5 (iii) What are the basic legislative requirements relating to GM food?
5 (v) What are the basic legislative requirements relating to GM feed?
5 (vi) How is the inclusion of GM additives in animal feed regulated?

SECTION 5 – THE GM FEED AND FOOD CHAIN

In 2003, a key Community Regulation established dedicated marketing authorisation requirements covering the whole GM food and feed chain for the first time – the GM Food and Feed Regulation. These new procedures have since been clarified by a range of implementing legislation and guidance. Wider food and feed law complements the GM Food and Feed Regulation, in particular its sister Regulation on traceability and labelling.

If your product appears to be within scope of Section 5 of this Guide, please check with the relevant authorities whether all the approval requirements can be met by complying with this legislation in accordance with the regulatory 'one door, one key' principle.

GM seed which is part of the food chain (i.e. food, feed, or for food or feed use) falls within the scope of the GM Food and Feed Regulation. However, more generally, the marketing of any GM seed can be classified as the commercialisation of a GMO. For this reason, requirements applying to GM seed are outlined in Section 4 of this Guide. Please see Answer 4.2(v) for details. There may also be issues arising from the proximity of GM, conventional and organic crops, whether or not the GM crops are intended for use as or in food or feed. The coexistence of these different agricultural modes is therefore discussed in Section 4 - please see Answer 4.2(vi).

5 (i) What are the principal regulations relating to GM food and feed?

The principal regulations relating to GM food and feed are:

- Regulation (EC) No 178/2002 *laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*[182]
- Regulation (EC) No1829/2003 *on genetically modified food and feed*[183]
- Regulation (EC) No 641/2004 *on detailed rules for the implementation of Regulation (EC) No 1829/2003 as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation*[184]
- Regulation (EC) No 1830/2003 *concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed*

[182] http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf.
[183] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf.
[184] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_102/l_10220040407en00140025.pdf.

products produced from genetically modified organisms and amending Directive 2001/18/EC[185]

- Regulation (EC) No 65/2004 *establishing a system for the development and assignment of unique identifiers for genetically modified organisms*[186]
- Regulation (EC) No 1831/2003 *on additives for use in animal nutrition.*[187]

There are also several Directives that are relevant to the marketing of GM seed; see Section 4.2(v) of this Guide for details.

Authorisation procedures for placing GM food on the market were previously covered by Regulation (EC) No 258/97 *concerning novel foods and food ingredients*[188], which was amended by Regulation (EC) No 1829/2003 and no longer applies to foods or food ingredients containing, consisting of, or produced from GMOs. The European Commission document *Questions and answers on the regulation of GMOs in the European Union*[189] contains relevant information on much of this legislation.

5 (ii) Which regulatory bodies in Europe are responsible?

The Commission and the competent authorities of Member States established by Regulation 1829/2003 are the main players in the process of authorising GM food and feed products for placing on the market. In the case of deliberate release into the environment of GMOs for food and feed use as well as for food and feed containing or consisting of GMOs, the competent authorities of Member States established under Directive 2001/18/EC *on the deliberate release into the environment of genetically modified organisms*[190] are also involved. The Directorate-General for Health and Consumer Protection is responsible for coordinating policy, regulation and enforcement underpinning food chain safety, and a section of its food and feed safety website focuses on biotechnology[191].

The European Food Safety Authority (EFSA)[192] is *inter alia* responsible for conducting risk assessments and providing scientific advice on GM food and feed. EFSA is assisted by various scientific panels; its GMO Panel[193] provides scientific advice on questions relating to GMOs.

---

[185] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00240028.pdf.
[186] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_010/l_01020040116en00050010.pdf.
[187] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00290043.pdf.
[188] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31997R0258&model=guichett.
[189] http://europa.eu.int/comm/food/food/biotechnology/gmfood/qanda_en.pdf.
[190] http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32001L0018:EN:HTML.
[191] http://europa.eu.int/comm/food/food/biotechnology/index_en.htm.
[192] The European Food Safety Authority, http://www.efsa.eu.int/.
[193] http://www.efsa.eu.int/science/gmo/catindex_en.html.

5 (iii) What are the basic legislative requirements relating to GM food?

Requirements of Regulation (EC) No 178/2002

Regulation (EC) No 178/2002[194] outlines the general principles and requirements for European rules on food and feed safety. Its general aims are the protection of human, animal and plant health, the environment and consumers' interests. Important principles outlined in the Regulation include:

- Food law should be based on risk analysis, assessment and management which are to be scientific, independent, objective and transparent
- The public should be consulted during the development and revision of food law
- Labelling and packaging should not mislead consumers
- Operators should be responsible for traceability of food, and
- Only food/feed which is safe should be placed on the market.

Food will be regarded as unsafe if it is injurious to health or unfit for human consumption, and feed is to be regarded as unsafe if it has an adverse effect on human or animal health or if it makes the food derived from food-producing animals unsafe for human consumption.

Article 2 of Regulation 178/2002 defines food as: 'any substance or product, whether processed, partially processed, or unprocessed, intended to be or reasonably expected to be ingested by humans'.

Emergency measures may be taken under Regulation 178/2002 to prevent unsafe products from reaching the market, or to withdraw such products from the market. Such action was recently taken under Decision 2005/317/EC[195] to control imports of GM corn gluten feed and brewers grains from the US which have potentially been contaminated with a GM maize variety that was accidentally released into the environment during its development phase without being authorised for placing on the market.

Requirements of Regulation (EC) No 1829/2003

The principles and requirements of Regulation (EC) No 178/2002, and the framework marketing requirements of Directive 2001/18/EC, are given specific application to the area of genetically modified food and feed in Regulation (EC)

[194] http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf.
[195] Decision 2005/317/EC on emergency measures regarding the non-authorised genetically modified organism Bt10 in maize products, http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_101/l_10120050421en00140016.pdf.

No 1829/2003[196]. Genetically modified food is defined in Article 2(6) of Regulation 1829/2003 as 'food containing, consisting of or produced from GMOs.'

The term 'produced from GMOs' is defined in the Regulation as 'derived, in whole or in part, from GMOs, but not containing or consisting of GMOs.' It covers for example oil produced from GM oilseed rape or flour produced from GM maize. The term does not include products produced *with* GMOs, such as for example eggs or milk from animals fed with GMOs.

Specific provisions on genetically modified food are to be found in Chapter II of Regulation 1829/2003, whereas Chapter III deals with genetically modified feed.

Genetically modified food requires authorisation at the Community level to be placed on the market. GM food will not be authorised if it will:

> (a) have adverse effects on human health, animal health or the environment
> (b) mislead the consumer
> (c) differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer
> (Article 4(1), Regulation 1829/2003).

Article 47 of Regulation 1829/2003 (supplemented by Articles 18 and 19 of Regulation 641/2004) makes temporary allowance for the presence of material which has not yet been authorised and which contains, consists of or is produced from GMOs. Conditions include that such presence is adventitious or technically unavoidable (the burden of proof being on the operator), below a threshold of 0.5% and that the GMO has benefited from a favourable risk evaluation on behalf of the Community. An updated list of the genetically modified material which benefits from this exception is published by the Commission on the webpages of DG Health and Consumer Protection[197].

Applying for authorisation

Applications for authorisation should be submitted to the competent authority of the Member State in which the applicant is based. Information which is to accompany the application includes:

- The applicant's name and address
- Designation of the GMO and the transformation event
- Description of the production and manufacturing methods

[196] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf.
[197] http://europa.eu.int/comm/food/food/biotechnology/gmfood/tolerance_en.htm.

- Copies of studies which demonstrate compliance with Article 4 criteria (see above)
- If appropriate an analysis showing that the characteristics of the GMO are not different from its conventional counterpart
- A statement that the food does not give rise to ethical or religious concerns, or a proposal for specific labelling
- Any conditions for placing on the market
- Methods for detection, sampling and identification
- Details of samples and the location of reference material
- A proposal for post-market monitoring (if applicable)
- A summary of the above.

Additional information is required for GMOs and food containing or consisting of GMOs (but not for other food produced from GMOs):

- The technical dossier produced under Annexes III and IV or Directive 2001/18/EC
- The information and conclusions from the risk assessment conducted in accordance with the requirements of Directive 2001/18/EC
- The monitoring plan in conformity with Annex VII of Directive 2001/18/EC.

EFSA's GMO Panel has produced guidance on applications submitted under Regulation 1829/2003, *Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed*[198].

Where a single product is intended for use as both a food and a feed it need only be authorised for placing on the market through a single application under Regulation 1829/2003, as long as the intention to use the product for both food and feed is specified in the application.

Assessment and authorisation procedure

EFSA (simply called 'the Authority' in Regulation 1829/2003) is the independent body responsible at Community level for risk assessment and scientific advice in this field. Its role in providing opinions is clearly defined in the Regulation (particularly Article 6). The Authority's risk assessment responsibilities are distinct from the risk management functions carried out by the Commission and the regulatory authorities in the Member States.

The Member State competent authority should acknowledge receipt of the application within 14 days, and will forward the application and any supplementary information supplied by the applicant to EFSA. EFSA will make

[198] http://www.efsa.eu.int/science/gmo/gmo_guidance/660_en.html.

all this information available to the Commission and the other Member States, and will make the application summary available to the public.

EFSA should give an opinion on the application within six months, particularly having checked its compliance with Articles 4(1) and 5 of Regulation 1829/2003. The time limit can be extended if EFSA seeks supplementary information from the applicant. EFSA may delegate the food or feed safety assessment to the appropriate assessment body of a Member State in line with Article 36 of Regulation 178/2002[199]. The environmental risk assessment for food and feed consisting of or containing a GMO may be delegated to competent authorities designated under Directive 2001/18; this delegation is, however, mandatory for GMOs used as seeds or other plant propagating material. The Authority makes methods and samples available to the Community Reference Laboratory for GM Food and Feed[200], which validates the methods for detection, sampling and identification of the transformation event. Checks are also made to show that the characteristics of the food are not different from those of its conventional counterpart.

Annex I of Regulation (EC) No 641/2004[201] contains details on the requirements for method validation. These show what the minimum requirements are for a method to be validated by the CRL. The CRL has provided further guidelines including the documents *Explanatory Notes to Applicants*[202] and *Description of the CRL Validation Process*[203].

EFSA forwards its reasoned opinion, along with the assessment report, to the Commission, the Member States and the applicant. Article 6(5) of Regulation 1829/2003 details particulars that the opinion must include if it is in favour of authorising the food. The opinion is also made available to the public, who have 30 days to comment. To this end, a consultation is opened by the Commission on the webpages of DG Health and Consumer Protection[204].

Within three months the Commission will draft a decision and forward it to the Standing Committee on the Food Chain and Animal Health, taking into account the opinion of EFSA, any relevant provisions under Community law, and other legitimate factors. If this draft decision is not in accordance with EFSA's opinion, it will explain the differences. Ordinarily, the Committee gives an opinion on the Commission's decision. If the Committee's opinion accords with the Commission's decision, the Commission adopts its decision. If the Committee's opinion is not in accordance with the Commission's decision, or if the Committee does not deliver an opinion, the Commission submits a related proposal to the

[199] http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf.
[200] Community Reference Laboratory for GM Food and Feed, http://gmo-crl.jrc.it/.
[201] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_102/l_10220040407en00140025.pdf.
[202] http://gmo-crl.jrc.it/doc/Explanatory%20Note.pdf.
[203] http://gmo-crl.jrc.it/doc/Description%20CRL%20validation%20process.pdf.
[204] http://europa.eu.int/comm/food/food/biotechnology/authorisation/public_comments_en.htm.

Council of Ministers and informs the European Parliament. The Council acts by qualified majority vote on such a proposal. If the Council supports the Commission's proposal or if no qualified majority is found in the Council, the Commission adopts its proposal. The Commission informs the applicant of the outcome and publishes the decision in the Official Journal of the European Union. If the Council opposes the Commission's proposal by qualified majority, the Commission has to re-examine its proposal.

Authorisations are valid Community-wide for ten years and are renewable. Applications for renewal need to be submitted by the authorisation-holder to the competent authority at least one year before the authorisation expires. Requirements for renewal applications are outlined in Article 11 of Regulation 1829/2003.

The details of the authorised product are entered into the Community Register of Genetically Modified Food and Feed[205]. The Commission will also notify risk assessment summaries, all authorisations, changes to authorisations and renewals to the international Biosafety Clearing House (BCH) established by the Cartagena Protocol on Biosafety[206]. The BCH is an online mechanism used by states to exchange information about their decisions and regulation of GMOs, particularly in regard to whether the import of particular GMOs is authorised (for more, see Section 6.2 of this Guide).

Applications for authorisations of GM food shall in principle follow a single route under Regulation 1829/2003 for authorisation of deliberate release and of use in food, since the environmental risk assessment is integrated in the procedure under Regulation 1829/2003. A list of applications made under Regulation 1829/2003 is published on EFSA's website[207].

After authorisation

The authorisation holder must ensure compliance with the authorisation conditions, and is responsible for post-market monitoring (if applicable), for which reports should be submitted to the Commission.

Any holder wishing to change the terms of an authorisation must apply to the Commission. The Commission will forward the request to EFSA and Member States. EFSA can, on its own initiative, or at the request of the Commission or a Member State, give an opinion on whether the modified authorisation would still be compliant with the Regulation. This opinion will be forwarded to the

[205] Community Register of GM Food and Feed, http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm.
[206] http://www.biodiv.org/biosafety/bch.aspx.
[207] Applications under Regulation (EC) No 1829/2003 on genetically modified food and feed (GM Food Feed Applications), http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html.

Commission, the authorisation holder and the Member States. The Commission will take any appropriate measures, which may include modification, suspension or revocation of the authorisation.

Labelling requirements

GM foods must conform to labelling requirements that are outlined in Article 13 of Regulation 1829/2003. However, there are some exemptions to the labelling requirements where the presence of authorised GM material in a conventional food is 'adventitious or technically unavoidable' (the burden of proof being on the operator). The threshold for the application of this exemption is 0.9%.

Article 13 includes several labelling requirements to provide for the range of products on the market, including:

- For foods with more than one ingredient:

  The words 'genetically modified' or 'produced from genetically modified (name of the ingredient)' shall appear in the list of ingredients…in parentheses immediately following the ingredient concerned

- For items that have no list of ingredients:

  The words 'genetically modified' or 'produced from genetically modified (name of organism)' shall appear clearly on the labelling.

The authorisation may specify additional labelling requirements, particularly where a GM food is different from its conventional counterpart or 'may give rise to ethical or religious concerns'. Where there is no conventional counterpart the labelling should include information on the food's characteristics.

The Commission is expected to produce a report on implementation of Regulation 1829/2003 beginning 2006.

Requirements of Regulation (EC) No 641/2004

Regulation (EC) No 641/2004 provides some further details on what is required in the applications for authorisation of GM food and feed. It includes procedures for the transformation of requests or notifications made under previous legislation (including Regulation (EC) No 258/97, and Directives 2001/18/EC, 90/220/EEC and 82/471/EEC) into applications under Regulation 1829/2003. Generally for these products it will be necessary for the information under Article 5 (for food) or

Article 17 (for feed) of Regulation 1829/2003 to be compiled and forwarded to EFSA by a competent authority, and they will then be subject to the same procedures as other applications.

Articles 8 and 20 of Regulation 1829/2003 allow food and feed products respectively that were placed on the market before 18 April 2004 to continue being placed on the market as long as the Commission was notified, within 6 months of that date, in accordance with information requirements laid down by Regulation 641/2004. All such products (that met the necessary requirements) were entered in the *Community Register of GM Food and Feed*[208] by 18 October 2004. Renewal applications, as specified under Articles 11 (for food) and 23 (for feed) of Regulation 1829/2003, should be submitted, either within three years from the date of application of 1829/2003 (17 April 2004) for products that were lawfully placed on the market, but were not subject to an explicit authorisation, or, for products authorised by the legislation listed in the previous paragraph "Within nine years from the date on which the products… were first placed on the market, but in no case earlier than three years after the date of application of this Regulation" (Articles 8(4) and 20(4) Regulation 1829/2003).

Requirements of Regulation (EC) No 1830/2003

Regulation (EC) No 1830/2003 established a framework for traceability including labelling, monitoring and risk management, which applies to products consisting of, containing, and food/feed produced from GMOs. The provisions of this regulation do not apply where the presence of GM material is adventitious or technically unavoidable (the burden of proof being on the operator) and below the thresholds set in Regulation (EC) No 1829/2003 (outlined above) and Directive 2001/18/EC.

In order to maintain traceability for GMOs, operators involved in all stages of the supply chain are to ensure that certain information accompanies all products as they are transmitted from one operator to another. This information must include a statement that the product contains/consists of GMOs and provide unique identifiers of the GMOs. Traceability information is transmitted in writing between operators.

For GM food or feed products that contain or consist of a mixture of GMOs, provision of unique identifiers may be done through a declaration that GMOs have been used, 'accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture' (Article 4(3), Regulation 1830/2003). This list may include GMOs that are not present in the final mixture.

The assignment of unique identifiers is explained below. Operators should keep a record of this information for five years, along with details of the operators who

[208] http://europa.eu.int/comm/food//dyna/gm_register/index_en.cfm.

supplied them, and to which they have transferred the products. Operators are also responsible for ensuring that the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' appear either on the product label, or, if the product is not pre-packaged, on or by the display of the product.

For food and feed produced from GMOs (rather than containing or consisting of GMOs) the requirements are different. The information to be transmitted by operators is an indication of which ingredients, feed materials or additives are produced from GMOs – or where there is no list of ingredients, simply an indication that the product is produced from GMOs. In the case of processed products, the unique identifiers of the GMOs from which the products are derived are not required. This information must again be kept for five years.

Identification systems

Where Community legislation has provided for the use of lot numbering (or another specific identification system) to be used, the information transmitted by operators need not be kept as long as such information is 'clearly marked on the package and that information about lot numbers is held' for the same period of five years.

Regulation 1830/2003 instructed the Commission to establish 'a system for development and assignment of unique identifiers to GMOs'; this was done in Regulation (EC) No 65/2004[209]. The Regulation applies to all GMOs that are authorised for placing on the market under Community legislation. The unique identifiers are to follow a particular alphanumeric format which is set out in an Annex to Regulation 65/2004 and is based on the same identification system used globally and adopted by the OECD.

Enforcement

Member States are expected to put in place measures to ensure compliance with Regulation (EC) No 1830/2003 including inspection, and 'effective, proportionate, and dissuasive' penalties. The Commission has produced non-binding guidance on sampling and testing to assist in inspection and control measures, in Recommendation 2004/787/EC *on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003* [210]. The Commission will report on implementation of Regulation (EC) No 1830/2003.

[209] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_010/l_01020040116en00050010.pdf.
[210] http://europa.eu.int/comm/environment/biotechnology/pdf/recom2004_787.pdf.

Further information on the traceability and labelling of GMOs can be found on Scadplus[211,212] and in the European Commission document *Questions and Answers on the Regulation of GMOs in the European Union*[213].

5 (iv) How is the inclusion of GM additives in foodstuffs regulated?

Food additives are regulated under a framework Directive – 89/107/EEC *on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption*[214] – and three specific Directives. The specific Directives are:

- 94/36/EC *on colours for use in foodstuffs*[215]
- 94/35/EC *on sweeteners for use in foodstuffs*[216] (as amended)
- 95/2/EC *on food additives other than colours and sweeteners*[217] (as amended).

Each of the three Directives contains a list of approved additives. Only the additives on those lists 'may be used in the manufacture or preparation of foodstuffs' (Directive 89/107/EEC, Article 2).

Food additives containing, consisting of or produced from GMOs are also regulated by Regulation (EC) No 1829/2003 *on genetically modified food and feed*[218], under which they must be assessed for safety. The authorisation procedures of Regulation 1829/2003 are outlined in Section 5(iii) above. GM food additives still require a final authorisation under Directive 89/107/EEC. Details of the procedure for requesting authorisation of a food additive are outlined in *Administrative guidance for the request of authorisation of a food additive*[219]. Food additives which are 'borderline products' for authorisation under

---

[211] Scadplus – *New regulations concerning the traceability and labelling of genetically modified organisms*, http://europa.eu.int/scadplus/leg/en/lvb/l21170.htm.
[212] Scadplus – *New rules on genetically modified food and feed*, http://europa.eu.int/scadplus/leg/en/lvb/l21154.htm.
[213] http://europa.eu.int/comm/food/food/biotechnology/gmfood/qanda_en.pdf.
[214] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31989L0107&model=guichett.
[215] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31994L0036&model=guichett.
[216] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31994L0035&model=guichett.
[217] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31995L0002&model=guichett.
[218] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf.
[219] http://europa.eu.int/comm/food/food/chemicalsafety/additives/flav16_en.pdf.

Regulation 1829/2003, such as those produced with rather than from GMOs, must in any case be authorised in accordance with Directive 89/107/EEC.

General information on food additives can be found on the website of the DG Health and Consumer Protection[220].

GM food additives are also required to meet the traceability and labelling requirements of Regulation (EC) No 1830/2003 *concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC*[221] which are outlined in Section 5(iii) above.

5 (v) What are the basic legislative requirements relating to GM feed?

The GM food legislation outlined above also covers GM feed, and contains similar provisions for both.

Before the application of Regulation (EC) No 1829/2003, feed produced from GMOs was not regulated, and hence has been placed lawfully on the market and notified as such; and feed consisting or containing GMOs was authorised under Directive 90/220/EEC[222] and subsequently Directive 2001/18/EC[223]. Hence, GMOs notified prior to the application of Regulation 1829/2003, and authorised under these Directives, are also authorised for food uses when the application covered such uses. In accordance with Article 20 of Regulation 1829/2003, particulars relating to these products have been entered in the Community Register of GM Food and Feed[224].

Article 2(7) of Regulation 1829/2003 defines genetically modified feed as: 'feed containing, consisting of or produced from GMOs'. Article 3(4) of Regulation 178/2002 provides the supporting definition of feed: 'any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.'

Chapter III of Regulation 1829/2003 contains the provisions specific to GM feed, and also covers GMOs for feed use. GM feed is not to be placed on the market without authorisation. Criteria for authorisation are that the feed must not:

(a) have adverse effects on human health, animal health or the environment
(b) mislead the user

[220] http://europa.eu.int/comm/food/food/chemicalsafety/additives/index_en.htm.
[221] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00240028.pdf.
[222] http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31990L0220:EN:HTML.
[223] http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32001L0018:EN:HTML.
[224] http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm.

(c) harm or mislead the consumer by impairing the distinctive features of the animal products
(d) differ from the feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for animals or humans
(Article 16, Regulation 1829/2003).

The application procedures are similar to those for GM food. Application is through a Member State's competent authority, which forwards it to EFSA. EFSA produces an opinion which the Commission considers when drafting a decision on the authorisation. The draft decision is submitted to the Standing Committee on the Food Chain and Animal Health for approval. If authorisation is granted it will be valid Community-wide for a maximum of ten years, which is renewable.

The labelling requirements specific to GM feed are stated in Article 25 of Regulation 1829/2003. The wording of Article 25 differs from that of the legislation concerning GM food (Article 13). The specific requirements apply to each feed of which a particular feed is composed. The fact of being, or being produced from GM, and the name of the GMO, must appear in parentheses immediately following the specific name of the feed, or in a prominent footnote. Under Article 25 of the product authorisation, additional labelling requirements may apply, particularly where the feed differs from or lacks a conventional counterpart, or may give rise to ethical or religious concerns.

Regulation (EC) No 641/2004[225] supplemented Regulation 1829/2003, providing more detailed guidance on its implementation. The traceability requirements introduced by Regulation (EC) No 1830/2003 apply to GM feed as well as GM food. Relevant information on these Regulations is given under Question 5 (iii) above.

5 (vi) How is the inclusion of GM additives in animal feed regulated?

General information on feed additives can be found on the website of the Directorate-General for Health and Consumer Protection[226].

Regulation (EC) No 1831/2003[227] introduces a Community authorisation procedure for feed additives, which for GM-related products applies in addition to the authorisation procedure under Regulation (EC) No 1829/2003 since it has different objectives. Feed additives which are 'borderline products' for authorisation under Regulation 1829/2003, such as those produced with rather

[225] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_102/l_10220040407en00140025.pdf.
[226] Feed Additives, Basic Legislation, http://europa.eu.int/comm/food/food/animalnutrition/feedadditives/legisl_en.htm.
[227] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00290043.pdf.

than from GMOs, must in any case be authorised in accordance with Regulation 1831/2003.

Regulation 1831/2003 aims to protect human health, animal health and welfare, the environment and users' and consumers' interests. It generally does not apply to veterinary medicinal products, but does currently cover coccidiostats and histomonostats when used as feed additives (these being substances intended to kill or inhibit protozoa). No other antibiotics may be authorised as feed additives, and the use of coccidiostats and histomonostats is to be phased out.

Feed additives must not be placed on the market without prior authorisation from the Community, and the first placing on the market must be by the authorisation holder. Member States may authorise the use of additives for scientific purposes. Mixtures of authorised additives do not require an additional specific authorisation.

Criteria for authorisation

There are two main requirements to be met if a feed additive is to be authorised. The first is that it must not:

> (a) have an adverse effect on animal health, human health or the environment
> (b) be presented in a manner which may mislead the user
> (c) harm the consumer by impairing the distinctive features of animal products or mislead the consumer with regard to the distinctive features of animal products
> (Article 5(2), Regulation 1831/2003).

The second requirement is that the additive fulfils at least one of the following functions:

> (a) favourably affect the characteristics of feed
> (b) favourably affect the characteristics of animal products
> (c) favourably affect the colour of ornamental fish and birds
> (d) satisfy the nutritional needs of animals
> (e) favourably affect the environmental consequences of animal production
> (f) favourably affect animal production, performance or welfare…or
> (g) have a coccidiostatic or histomonostatic effect
> (Article 5(3), Regulation 1831/2003).

Applying for authorisation

For the application for authorisation, the feed additive is to be categorised in regard to its function, in one of the following additive groups:

- Technological additives
- Sensory additives
- Nutritional additives
- Zootechnical additives
- Coccidiostats and histomonostats

These terms are explained in Article 6 of Regulation 1831/2003. The feed additive should also be subcategorised into one of the functional groups listed in Annex I to the Regulation.

Applications for authorisation should be sent to the Commission, which will inform Member States of the application and forward it to EFSA. EFSA will acknowledge receipt to the applicant and will make the accompanying information available to the Commission and the Member States, and a summary of the information available to the public. The information to accompany the application includes:

- Applicant's name and address
- Identification and proposed classification of the feed additive
- Description of the product and its manufacturing method
- Intended use
- Copies of any studies that demonstrate compliance with the Article 5 criteria (see above)
- Proposed conditions for placing on the market (labelling, handling and use)
- A summary of the above
- And where the additive is covered by legislation on the marketing of products consisting of, containing or produced from GMOs, details of any authorisation granted under the applicable legislation, and a post-market monitoring plan.

Three samples of the additive are to be sent directly to the Community Reference Laboratory for Feed Additives Authorisation[228], which will store and maintain the samples submitted and will also validate the detection method.

Guidance for applicants is provided by EFSA[229] and the Community Reference Laboratory for Feed Additives Authorisation[230]. EFSA has a contact e-mail for

[228] http://www.irmm.jrc.be/html/crlfaa/.
[229] EFSA, Administrative Guidance for Applicants, http://www.efsa.eu.int/science/feedap/authorisations/519/authorise_01_guide_feedap_v3_en1.pdf.
[230] CRL for Feed Additives Authorisation, Guidance for Applicants, http://www.irmm.jrc.be/html/crlfaa/guidance_applicants/index.htm.

queries on the authorisation of feed additives – FEEDADDITIVES@efsa.eu.int. A table of applications under Regulation (EC) No 1831/2003 on additives for use in animal nutrition is available on the EFSA website[231].

Authorisation procedure

EFSA will give an opinion on the application within six months, which it will forward to the Commission, Member States and the applicant. The opinion will also be made available to the public. The Commission will draft a regulation within three months, to be adopted through the Standing Committee on the Food Chain and Animal Health. The regulation will include details of the additive's designation, classification, and post-authorisation conditions. Where the additive consists of, contains or is produced from GMOs, the name of the authorisation holder will also be given along with the GMO's unique identifier (where appropriate in accordance with Regulation (EC) No 1830/2003). Maximum residue limits will be set where necessary. The authorisation will be valid for ten years (this is renewable), and will be specific to a particular use. The authorised additive will be entered into a Community Register of Feed Additives, which will be made available to the public. The authorisation holder is responsible for ensuring compliance with the authorisation conditions, and particularly for post-market monitoring, which may require reports to be submitted to the Commission.

Under Article 3(3) of Regulation 1831/2003, for GM additives (those falling within the scope of Regulation 1829/2003), only the authorisation holder, his legal successors, or a person acting under his written authority may first place the product on the market.

Labelling

Article 16 of Regulation 1831/2003 details the labelling requirements that must be fulfilled prior to the additive being placed on the market. The information to be given includes:

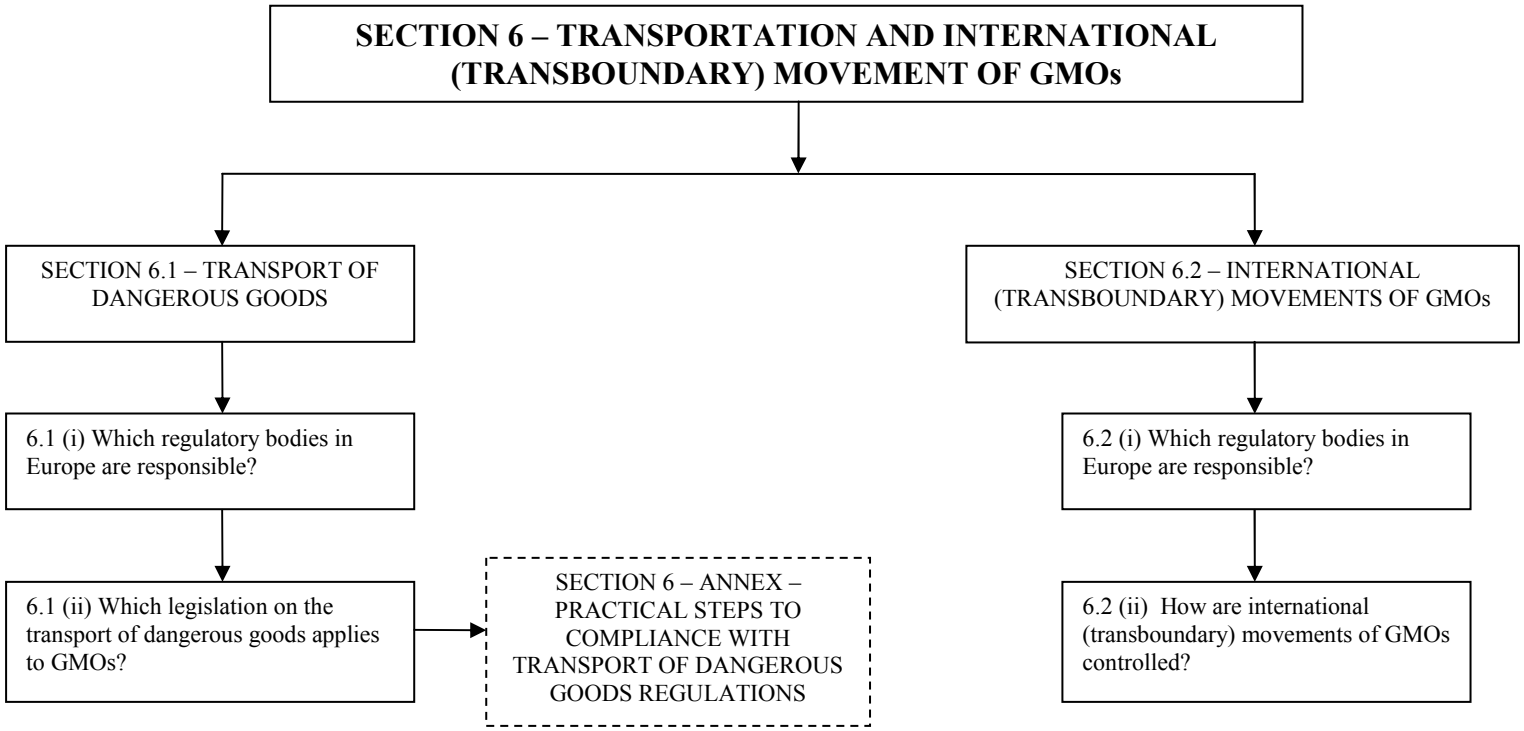
- Name of the product and its functional group
- Directions for use
- Safety recommendations
- Identification number
- Batch reference number and date of manufacture.

For some of the additive groups there are further specific labelling requirements listed in Annex III of the Regulation.

[231] http://www.efsa.eu.int/science/feedap/an_applications/catindex_en.html.

Scadplus also provides a summary of the legislation on the use of additives in animal nutrition[232].

[232] Scadplus, Animal Nutrition – Use of Additives, http://europa.eu.int/scadplus/leg/en/lvb/l112037d.htm.


SECTION 6 – TRANSPORTATION AND INTERNATIONAL (TRANSBOUNDARY) MOVEMENT OF GMOs
SECTION 6.1 – TRANSPORT OF DANGEROUS GOODS
SECTION 6.2 – INTERNATIONAL (TRANSBOUNDARY) MOVEMENTS OF GMOs
6.1 (i) Which regulatory bodies in Europe are responsible?
6.2 (i) Which regulatory bodies in Europe are responsible?
6.1 (ii) Which legislation on the transport of dangerous goods applies to GMOs?
SECTION 6 – ANNEX – PRACTICAL STEPS TO COMPLIANCE WITH TRANSPORT OF DANGEROUS GOODS REGULATIONS
6.2 (ii) How are international (transboundary) movements of GMOs controlled?

SECTION 6 – TRANSPORTATION AND INTERNATIONAL (TRANSBOUNDARY) MOVEMENT OF GMOS

There are three main sets of legislation that govern the transport and international movement of GMOs:

- First, GMOs may be considered to be dangerous goods for transport purposes if they pose a risk to human, animal or plant health, or to the environment. Community legislation covers the transport of dangerous goods by road and rail within and between Member States. Additionally, the international carriage of dangerous goods by all major transport modes is regulated by various international agreements. See Subsection 6.1 for details;

- Secondly, international (transboundary) movements of GMOs are regulated by an international agreement and Community legislation implements these obligations - see Subsection 6.2 for details;

- Thirdly, certain provisions of legislation on the contained use of GMMs may apply - see Answer 3 (iii) for details.

6.1 – TRANSPORT OF DANGEROUS GOODS

This Subsection of the Guide provides information on regulation of the transport of dangerous goods within the Community and at an international level. An Annex to this Section provides additional practical information on compliance with dangerous goods regulations.

6.1 (i) Which regulatory bodies in Europe are responsible?

The Directorate-General for Energy and Transport[233] is responsible for the transport of passengers and goods by road, rail, air, sea and inland waterway. This includes the transport of dangerous goods, for which there is specific legislation incorporating international agreements. The DG Energy and Transport provides some general information about the relevant legislation on the carriage of dangerous goods by road[234] and rail[235].

For the transport of dangerous goods by road and rail, European legislation implements the European Agreement Concerning the International Carriage of

[233] http://europa.eu.int/comm/transport/index_en.html.
[234] DG Transport, Road Safety - Carriage of Dangerous Goods http://europa.eu.int/comm/transport/road/roadsafety/danggoods/carriage/index_en.htm.
[235] DG Transport, Rail Transport and Interoperability - Transport of Dangerous Goods http://europa.eu.int/comm/transport/rail/legislation/dangerous_en.htm.

Dangerous Goods by Road (ADR) [236] and the Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID)[237]. The ADR is overseen by the United Nations Economic Commission for Europe[238]; the RID is overseen by the Intergovernmental Organisation for International Carriage by Rail (OTIF) [239]. These international agreements are based on the framework of the United Nations Model Regulations on the Transport of Dangerous Goods[240].

6.1 (ii) Which legislation on the transport of dangerous goods applies to GMOs?

By road

Directive 94/55/EC *on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road*[241] applies. It has been amended by several Directives which have updated the rules contained in its Annexes in line with technical progress. Most recently it has been adapted by Directive 2004/111/EC[242], which replaced Annexes A and B of Directive 94/55/EC with referral to Annexes A and B of the European Agreement on the International Carriage of Dangerous Goods by Road[243]. The Annexes to the ADR follow the same structure as the Annexes to Directive 94/55/EC did. The Annexes to the ADR are regularly updated; the most recent amendments entered into force on 1 January 2005.

Directive 94/55/EC applies 'to the transport of dangerous goods by road within or between Member States' (Article 1). Goods considered dangerous are listed in Annex A of the ADR. Transport by road of some of the goods is prohibited. Other goods on the list may be transported as long as they comply with the requirements of the Annexes on matters such as packaging, labelling and 'the construction, equipment and proper operation of the vehicle carrying the goods' (Article 3, Directive 94/55/EC).

By rail

---

[236] http://www.unece.org/trans/danger/publi/adr/adr2005/05ContentsE.html.
[237] GB Department for Transport, *Regulations Concerning the International Carriage of Dangerous Goods by Rail, 2003 Edition*, Norwich: Stationery Office, 2003.
[238] http://www.unece.org/.
[239] http://www.otif.org/.
[240] http://www.unece.org/trans/danger/publi/unrec/rev13/13files_e.html.
[241] http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31994L0055:EN:HTML.
[242] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32004L0111&model=guichett
[243] http://www.unece.org/trans/danger/publi/adr/adr2005/05ContentsE.html.

Directive 96/49/EC *on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail*[244] applies. This Directive has also been amended to adapt it to technical progress. The most recent amendment was in Directive 2004/110EC[245] which replaced the Annex to Directive 96/49/EC with a referral to the Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID). The Annex lists dangerous goods that are either prohibited from transport by rail or to which certain conditions, also outlined in the Annex, must be applied (Article 3, Directive 96/49/EC).

General requirements

The transport of dangerous goods must comply with the provisions of the international agreement which covers the relevant mode of transport. The consignor (person sending the goods) must complete a dangerous goods declaration form, identifying the goods and their classification. There is no specific authorisation procedure, and prior informed consent from the importing state is not required under the ADR and RID.

The transport of GMOs across national borders may require prior informed consent under Regulation (EC) No 1946/2003, which is covered in Section 6.2 of this Guide.

The international agreements, of themselves, apply only to the international transport of dangerous goods. Directives 94/55/EC and 96/49/EC apply the provisions of the international agreements to transport within Member States as well.

The ADR and RID are detailed agreements having largely parallel structures and containing similar carriage requirements. This Guide is intended to indicate key features, and references to the agreements are for illustrative purposes only. Readers intending to transport dangerous goods should always work to the current official versions of the agreements.

Classification and specific requirements

An early stage in using the international agreements is the classification of dangerous goods. Classification allows the sections of the agreements containing the applicable requirements for transport of a particular good to be identified. The Annex to this Section of the Guide provides some additional information on the classification of dangerous goods including GMOs, and use of

[244] http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31996L0049:EN:HTML.
[245] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32004L0110&model=guichett

the Dangerous Goods List which refers to specific carriage requirements for each classification.

Labelling

Dangerous goods are to be clearly marked and labelled; this should include the display of the UN number assigned to the particular class of good. The Annexes to the ADR and RID, in paragraph 5.2.2.2.2, provide specimen labels for each class. There may be additional labelling requirements for GMOs under other European legislation, particularly Regulation (EC) No 1830/2003 *concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC*[246]. Please see Section 5 of this Guide for more information on that legislation.

Documentation

Certain documentation, specific to each substance, is required to accompany the goods during transport; this is referred to as the transport document in the ADR and the consignment note in the RID. In accordance with ADR paragraph 5.4.1.1.1, information required in this documentation includes:

- UN number preceded by the letters "UN"
- The proper shipping name[247], supplemented when applicable with the technical name[248]
- Packing group[249] (where applicable)
- Number and a description of the packages
- Quantity or volume of the dangerous good
- Name and address of the consignor and consignee(s)
- A declaration as required by the terms of any special agreement

Under the ADR, written instructions to be followed in the event of an accident are to be provided for the driver. A particular format for these instructions is given in paragraph 5.4.3.8, and the required contents, specified in paragraph 5.4.3.1, include:

- Name, class and UN number

[246] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00240028.pdf.
[247] The proper shipping name is the name in the Dangerous Goods List that most accurately describes the good.
[248] The technical name is a generally recognised chemical, biological or other technical name used in scientific or technical documents.
[249] Dangerous goods may be assigned to one of three packing groups according to the level of danger they pose. Not all dangerous goods are assigned to a packing group.

- Nature of danger posed by the good
- Personal protection
- General actions to be taken by the driver
- Additional and/or special actions to be taken by the driver including protective equipment to be used

Provisions Concerning Transport Equipment and Transport Operations

Annex B of the ADR states the requirements for vehicle crews, equipment, operation and documentation, and the requirements concerning the construction and approval of vehicles.

Monitoring and enforcement

Member States' competent authorities may check on compliance with these dangerous goods regulations, prohibiting transport if the necessary requirements are not met. In accordance with Directive 95/50/EC *on uniform procedures for checks on the transport of dangerous goods by road*[250] (amended by Directive 2004/112/EC[251]), Member States should carry out random checks on a 'representative proportion' of vehicles transporting dangerous goods. In carrying out the checks they should use the checklist contained in Annex I to Directive 95/50/EC.

Undertakings involved in the transport of dangerous goods (including loading and unloading) are to appoint safety advisers, who, among other duties, must monitor compliance with relevant legislation. The role of safety advisers, and requirements for their training and qualification, are outlined in Directive 96/35/EC *on the appointment and vocational qualification of safety advisers for the transport of dangerous goods by road, rail and inland waterway*[252]. Minimum examination requirements for safety advisers to gain a certificate of training are outlined in Directive 2000/18/EC[253]. The Annex to this Section of the Guide provides further information on the functions of Dangerous Goods Safety Advisers.

---

250 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31995L0050&model=guichett.

251 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32004L0112&model=guichett

252 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31996L0035&model=guichett.

253 http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_118/l_11820000519en00410043.pdf.

Scadplus provides summaries of legislation on the transport of dangerous goods by road[254] and by rail[255], on checks on the transport of dangerous goods[256], and on the appointment and vocational qualification of safety advisers[257]. The United Nations Economic Commission for Europe has provided a list of competent authorities under the ADR on its website[258].

Transport by sea, air and inland waterway

Directive 2002/59/EC *establishing a Community vessel traffic monitoring and information system and repealing Council Directive 93/75/EEC*[259] contains provisions covering the transport of dangerous goods by sea. The shipper (the person for whom the goods are being carried) must provide a declaration of the goods to the person in charge of the ship. The person in charge of the ship, or their agent, is to submit a notification to the competent authority of the Member State from which they are departing, or, if arriving from outside the Community, to the Member State of destination. Alternatively the notification may be submitted to the relevant port authority, which must maintain access to the information by the competent authority at all times. The requirements for the notification are outlined in Annex I (3) to Directive 2002/59/EC. They include general information about the ship and its departure/arrival schedule; and information about the cargo, including its UN number and any hazard class designated by the International Maritime Dangerous Goods Code (IMDG Code)[260], its quantity and location.

The international regulations covering the transport of dangerous goods by air are the International Civil Aviation Organisation's Technical Instructions for the Safe Transport of Dangerous Goods by Air, but there is no EU legislation implementing their provisions.

The IMDG Code and the ICAO Technical Instructions are based on the framework of the UN Model Regulations on the Transport of Dangerous Goods, as are the Regulations for road and rail transport. They contain similar provisions to the other international agreements on the transport of dangerous goods, adapted to the particular mode of transport.

There is a European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterway (ADN)[261]. This agreement specifies that

[254] http://europa.eu.int/scadplus/leg/en/lvb/l24051.htm.
[255] http://europa.eu.int/scadplus/leg/en/lvb/l24061.htm.
[256] http://europa.eu.int/scadplus/leg/en/lvb/l24052.htm.
[257] http://europa.eu.int/scadplus/leg/en/lvb/l24053.htm.
[258] http://www.unece.org/trans/danger/publi/adr/comp.htm.
[259] http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_208/l_20820020805en00100027.pdf.
[260] http://www.imo.org/Safety/mainframe.asp?topic_id=158.
[261] http://www.unece.org/trans/danger/adn-agree.html.

Member States of the [United Nations] Economic Commission for Europe[262] may become Contracting Parties (Article 10), so it is not implemented by Community legislation.

[262] http://www.unece.org/oes/member_countries/member_countries.htm.

6.2 – INTERNATIONAL (TRANSBOUNDARY) MOVEMENTS OF GMOS

This Subsection of the Guide provides information on the Community legislation regulating the trade and transboundary movements of GMOs from the EU to third countries, which implements the international Cartagena Protocol on Biosafety. This legislation also regulates situations of unintentional release, including within the Community, and international information exchange mechanisms. With respect to intentional introduction or use within the Community, the Cartagena Protocol is implemented via the existing legislation, including inter alia Directive 2001/18/EC *on the deliberate release into the environment of genetically modified organisms*[263] (discussed in Section 4 of this Guide), Regulation (EC) No 1829/2003 *on genetically modified food and feed*[264](discussed in Section 5), and Regulation (EC) No 726/2004[265] (discussed in Section 7) in its application to veterinary medicinal products (transboundary movements of pharmaceuticals for humans are not covered by the Cartagena Protocol).

6.2 (i) Which regulatory bodies in Europe are responsible?

The Directorate-General for the Environment[266] has responsibility for the main objective of these instruments, i.e. protection of the environment (and human, animal and plant health) from GMOs, and this includes their movement across international borders.

The Secretariat of the Convention on Biological Diversity[267] oversees the international Cartagena Protocol on Biosafety[268], which is part of the framework, with trade rules, for European controls on transboundary movements of GMOs. Under Regulation (EC) No 1946/2003, the Commission and each Member State must designate a focal point and competent authorities for the purposes of the Protocol and Regulation. Competent authorities are assigned an administrative role in regard to implementing the Protocol's provisions. These essentially correspond to the competent authorities established by the legislation applicable for uses within the Community. Focal points are responsible for communication with the Convention on Biological Diversity Secretariat and the Biosafety Clearing House (discussed below). Contact lists for competent authorities[269] and focal points[270] can be found on the Biosafety Clearing House website. The competent

[263] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf.
[264] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf.
[265] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_136/l_13620040430en00010033.pdf.
[266] http://europa.eu.int/comm/environment/.
[267] http://www.biodiv.org/secretariat/default.asp.
[268] http://www.biodiv.org/biosafety/protocol.asp.
[269] http://bch.biodiv.org/Doc/BCH-CNA.pdf.
[270] http://bch.biodiv.org/Doc/CPB-FP.pdf.

authority and focal point for the European Community are both based in the DG Environment[271].

6.2 (ii) How are international (transboundary) movements of GMOs controlled?

The main Community legislation for this area is Regulation (EC) No 1946/2003 *on transboundary movements of genetically modified organisms*[272].

Regulation 1946/2003 implements for the Community the provisions of the Cartagena Protocol on Biosafety[273], establishing an 'advance informed agreement' system for prior consent by third countries to the import of GMOs exported from the Community.

As far as authorisations are concerned, Regulation 1946/2003 only applies to exports of GMOs from the Community to third countries. Imports of GMOs into the Community have to be approved at the Community level (for placing on the market) or at Member State level (for all other uses) under framework or product legislation described in other Sections of this Guide (listed in the introductory paragraph of this Subsection). Pharmaceuticals for humans that are addressed by other relevant international agreements or organisations are excluded from the Regulation's scope. Transboundary movement is defined in Article 3(14) of Regulation (EC) No 1946/2003 as:

> the intentional or unintentional movement of a GMO between one Party or non-Party and another Party or non-Party, excluding intentional movements between Parties within the Community.

In this context 'Party' means a State which has ratified (adhered or acceded to) the Cartagena Protocol on Biosafety; 'non-Party' means a State which has not done so. A list of Parties to the Protocol is available on the Protocol's website[274]. The Protocol has been ratified by the European Community in its own right and by all the individual Member States.

Chapter II of Regulation 1946/2003 has separate provisions for three types of GMO use. Section 1 of Chapter II of the Regulation covers GMOs for deliberate release into the environment; Section 2 covers GMOs for direct use as food or feed, or for processing; and Section 3 covers GMOs for contained use. Notification requirements for each of the three types of GMO use are outlined below under separate subheadings.

---

[271] Up-to-date contact details for the Community's competent authority and focal point can be found in the lists mentioned above.
[272] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_287/l_28720031105en00010010.pdf.
[273] http://www.biodiv.org/biosafety/protocol.asp.
[274] http://www.biodiv.org/biosafety/ratification.asp.

There are also general and specific provisions on documentation that must be provided by the exporter to accompany the transboundary movement, for each type of use. The documents must state 'that [the shipment] contains or consists of GMOs' (Article 12(1)) and give the unique identifier (where applicable). A registry of unique identifiers given to GMOs is available on the BCH website[275].

Provisions of Section 1, Regulation 1946/2003 (deliberate release):

The exporter should notify the competent authority of the importing state in writing before the first transboundary movement of a GMO for a specific use. The information required in the notification is specified in Annex I of Regulation 1946/2003; this includes:

- Name, address and contact details for the exporter and importer
- Name and identity of the GMO
- Intended date(s) of the transboundary movement
- Details of the recipient and/or parent organism including on centres of origin and centres of genetic diversity
- Details of the donor organism
- A 'Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the GMO'
- Details of the intended use
- Quantity or volume to be exported
- A risk assessment compliant with Annex II of Directive 2001/18/EC
- Information on safe handling, transport, storage and use
- Information on the 'Regulatory status of the GMO within the State of export'.

Exporters may keep certain information in the notifications confidential; however, this does not include contact details, the description of the GMO, the summary of the risk assessment, or emergency response plans.

The transboundary movement may not take place until written consent has been received from the importing state. The importing state should make its decision on import known to the exporter within 270 days, however the lack of a response during this time may not be construed as consent. The exporter is to maintain copies of the notification and decision for at least five years, and should also supply copies to the competent authority of the exporting state and to the Commission. The Commission will make the documents publicly available. Under Article 7 of Regulation 1946/2003, exporters may request that the importing state's decision be reviewed in light of new scientific or technical

[275] http://bch.biodiv.org/.

information, or other factors that may have changed the risk assessment submitted in the notification.

The Parties to the Cartagena Protocol may decide that a particular GMO does not present a risk to biodiversity, in which case the above provisions will not apply to it. Individual Parties to the Protocol may use its Biosafety Clearing House (BCH) mechanism to indicate that they have exempted certain GMOs from the 'advance informed agreement' procedure (i.e. the need for prior consent from the importing state). The BCH is an online facility designed to support the exchange of information on all uses and transboundary movements of GMOs. Under Article 5(4) of Regulation 1946/2003, States can also make agreements between themselves that allow certain transboundary movements to take place under alternative arrangements.

In addition to the general requirements of Regulation 1946/2003 concerning information accompanying a transboundary movement, information accompanying GMOs for deliberate release must include:

> (a) the identity and relevant traits and characteristics of the GMOs;
> (b) any requirements for the safe handling, storage, transport and use of these GMOs;
> (c) the contact point for further information and, as appropriate, the name and address of the importer and exporter;
> (d) a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter.
> (Article 12(4), Regulation 1946/2003.)

Provisions of Section 2, Regulation 1946/2003 (food, feed, processing):

Article 10(3) of Regulation 1946/2003 provides that a GMO for use in food or feed or in processing may not be exported unless it has Community authorisation 'or the competent authority of a third country has expressly agreed to the import as required under Article 12 of Regulation (EC) No 178/2002'.

Where the Commission or an individual Member State has made a decision on use 'of a GMO that may be subject to transboundary movements for direct use in food or feed or for processing' (with the exception of field trials) they should inform the BCH of this decision within 15 days. The minimum information to be included in this notification is specified in Annex II to Regulation 1946/2003; this includes:

- Name and contact details of the applicant for authorisation and the authority which made the decision
- Name, identity and where relevant the unique identifier of the GMO

- 'Description of the gene modification, the technique used, and the resulting characteristics of the GMO'
- Details of the recipient and/or parental organism, including information on centres of origin and centres of genetic diversity
- Details of the donor organism
- Approved uses
- A risk assessment in compliance with Annex II of Directive 2001/18/EC
- Information on safe handling, storage and use.

Importing states still have the right to make decisions on whether to import these GMOs. If the Party of import requires a consent, the GMO may not be exported before the consent has been granted.

Where the GMO is for direct use as food or feed or for processing this must be clearly indicated in documentation accompanying the transboundary movement, by stating that it is not intended for deliberate release into the environment and with a contact point for further information.

Provisions of Section 3, Regulation 1946/2003 (contained use):

For transboundary movements of GMOs intended for contained use, the requirements in Section 1 of Regulation 1946/2003 need not apply as long as the movement is 'undertaken in accordance with the standards of the Party or non-Party of import' (Article 11, Regulation 1946/2003). Certain provisions of Directive 90/219/EEC *on the contained use of genetically modified micro-organisms*[276] do not apply to GMMs being transported. Other provisions will still apply, for example the provisions on risk assessment, emergency plans and measures. For further information on Directive 90/219/EEC please see Section 3 of this publication.

In addition to the general information required in the documentation accompanying transboundary movements of GMOs for contained use, information must also be provided on safe handling, storage, transport and use, and the details of a contact point for further information must be given.

Other general provisions of Regulation 1946/2003:

Regulation 1946/2003 contains further provisions that are common to all transboundary movements of GMOs outside of the Community, and others that apply for all GMOs, irrespective of their export or not from the Community.

276 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31990L0219&model=guichett.

Where GMOs moving across borders will be in transit through another State outside of the Community, and where that State has indicated through the BCH that it wishes to regulate transit of GMOs, the exporter must ensure notification of transit.

Member States are to put in place measures to prevent unintentional transboundary movements, whether inside or outside the Community (the definition of transboundary movement covers unintentional movements inside the Community). If an unintentional movement does occur, with significant risks to biodiversity (or human health), the Member State must take appropriate measures, and inform the public, the Commission, the BCH, all Member States and any other potentially affected states (whether they are a Party to the Protocol or not).

The Member States and the Commission are also required to submit certain information on uses inside of the Community and transboundary movements of GMOs to the Biosafety Clearing House. Article 15 of Regulation 1946/2003 implements the Cartagena Protocol's provisions for the international sharing of information. The legal duties fall to the Member States and the European Commission, but with important consequences for businesses and other operators. Information that the Commission will submit to the BCH includes details of relevant Community legislation, decisions and guidance on commercial uses according to Community legislation, any bilateral or multilateral agreements on transboundary movements, and also summaries of risk assessments or environmental reviews conducted under Community procedures and details of related products. Member States must inform the BCH and the Commission about their relevant legislation, guidelines, decisions, and arrangements with other states; national contact points; urgent situations and measures; risk assessments, environmental reviews and related products. Article 15 should be consulted for full details of the categories of information that must be shared. The information held by the BCH is accessible to all users; however, only authorised users, including the designated Member State and Commission focal points, can submit information to it. This applies without prejudice to the protection of confidential information in accordance with the provisions of the Cartagena Protocol (particularly Article 21 thereof).

Further information on transboundary movements of GMOs can be found on Scadplus[277] and in the European Commission document *Questions and Answers on the Regulation of GMOs in the European Union*[278].

[277] http://europa.eu.int/scadplus/leg/en/lvb/l28119.htm.
[278] http://europa.eu.int/comm/food/food/biotechnology/gmfood/qanda_en.pdf.

SECTION 6 – ANNEX
PRACTICAL STEPS TO COMPLIANCE WITH TRANSPORT OF DANGEROUS GOODS REGULATIONS

1. Know when you need a professional adviser

The transport of dangerous goods requires access to certain specialist knowledge, depending on the range of goods involved. This Annex aims to help undertakings to evaluate the roles of the dangerous goods safety adviser (DGSA) and other specialists in this field, so that they can work constructively with advisers and make due provisions in their business plans for the tasks required.

In accordance with Directive 96/35/EC *on the appointment and vocational qualification of safety advisers for the transport of dangerous goods by road, rail and inland waterway*[279], undertakings involved in the transport of dangerous goods must employ a dangerous goods safety adviser. Directive 96/35/EC also outlines DGSA training and qualification requirements. Functions assigned to the DGSA under Directive 96/35/EC include ensuring activities relating to dangerous goods are conducted safely and in compliance with the relevant rules, monitoring compliance, advising on the transport of dangerous goods, ensuring suitable means of transport and equipment are used, training of employees, implementation of emergency responses and the investigation of accidents (Annex I, Directive 96/35/EC).

The DGSA ensures the preparation and provision to the employer of reports on any accident that affects the health or safety of any person or causes damage to the environment or property and that occurs during the loading, carriage or unloading of dangerous goods that are under the responsibility of the employer.

In any circumstances that are not covered by the DGSA in accordance with Directive 96/35/EC, the appropriate Member State competent authority is the primary contact point for guidance on the transport of dangerous goods. For specialised enquiries concerning the classification of dangerous goods and the specific carriage requirements applying to them, consult a DGSA or other professional adviser with suitable credentials. Any such adviser should be able to demonstrate familiarity with the relevant regulations, as well as having qualifications or experience in scientific or technical disciplines related to the goods involved.

2. Define the mode(s) of transport required

279 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31996L0035&model=guichett.

To identify the particular requirements applicable to goods under the dangerous goods legislation the relevant international agreements for the modes of transport used should be consulted.

- For transport by road – consult the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR)[280] and Directive 94/55/EC[281]
- For transport by rail – consult the Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID)[282] and Directive 96/49/EC[283]
- For transport by inland waterway – consult the European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN)[284]
- For transport by sea – consult the International Maritime Dangerous Goods Code[285]
- For transport by air – consult the ICAO's Technical Instructions for the Safe Transport of Dangerous Goods by Air.[286]

All of the agreements listed above are based on the UN Model Regulations on the Transport of Dangerous Goods, and use the same framework and principles, but specific provisions may vary where they have been adapted for the particular transport mode.

Carriage by more than one mode of transport

For dangerous goods being carried by more than one mode of transport, derogation from Directives 94/55/EC and 96/49/EC is allowed as long as the goods are 'classified, packed and labelled in accordance with international requirements for maritime or air transport whenever the transport involves a sea or air voyage'. The RID and ADR similarly allow dangerous goods that have been or will be transported by air or sea, which conform to the provisions of the IMDG Code or ICAO Technical Instructions, to be accepted for carriage (paragraph 1.1.4.2.1 ADR).

3. Know what to expect from an adviser

[280] http://www.unece.org/trans/danger/publi/adr/adr2005/05ContentsE.html.
[281] http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31994L0055:EN:HTML.
[282] GB Department for Transport, *Regulations Concerning the International Carriage of Dangerous Goods by Rail, 2003 Edition*, Norwich: Stationery Office, 2003.
[283] http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:31996L0049:EN:HTML.
[284] http://www.unece.org/trans/main/dgdb/adnconf/adnfdoc/e-accord.pdf.
[285] http://www.imo.org/Safety/mainframe.asp?topic_id=158.
[286] ICAO, Technical Instructions for the Safe Transport of Dangerous Goods by Air, 2005-2006 Edition, (Doc. 9284), November 2004.

A dangerous goods adviser should be able to demonstrate competence in correctly classifying the goods of interest, and deriving the specific carriage requirements applying to them. An outline covering the derivation of requirements for GMOs follows, and is intended to illustrate the required approach.

The class under which a particular good falls will determine which of the specific provisions of the international carriage agreements must be applied to that good. GMOs as dangerous goods will generally fall under:

- Class 6.2 – Infectious Substances; or
- Class 9 – Miscellaneous Dangerous Substances and Articles, Classification code M8 – Genetically modified micro-organisms and organisms.

Details of the various classifications that can apply to dangerous goods can be found in Part 2 of the agreements.

Class 6.2. Infectious substances are defined in Class 6.2 of the Annexes to the ADR and RID as 'substances which are known to contain or are reasonably expected to contain pathogens'. The class covers GMOs that meet this definition. Class 6.2 is subdivided into infectious substances affecting humans; infectious substances affecting animals only; clinical waste; and diagnostic specimens. Slightly different rules apply to each subdivision. Live animals may not be used to carry infectious agents unless there is no suitable alternative. Blood or blood components which have been collected for the purpose of transfusion or for the preparation of blood products to be used for transfusion or transplantation, and any tissues or organs intended for use in transplantation are not subject to the provisions of the agreements.

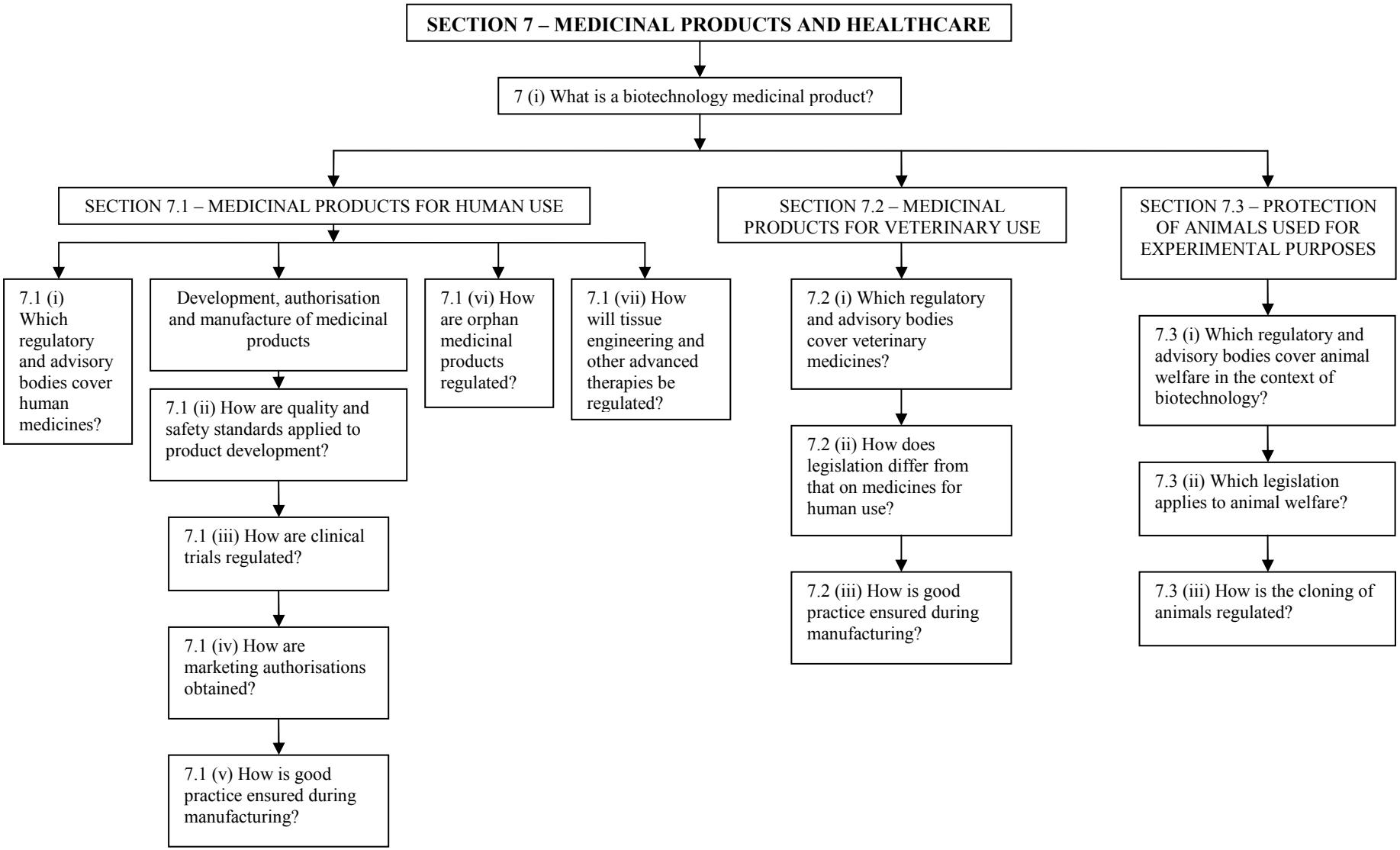
Class 9. GMOs are also covered by Classification code M8 of Class 9. They are included in this class if, while not an infectious substance under Class 6.2, they 'are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction' (paragraph 2.2.9.1.11, ADR). GMOs are not covered by Class 9 of the ADR if they have been authorised 'by the competent authorities of the countries of origin, transit and destination' (Note 2, 2.2.9.1.11, ADR). The ADR refers to the authorisation procedures of Part C of Directive 2001/18/EC in this context. A further provision, under paragraph 2.2.9.1.12 of the ADR, is that GMOs 'known or suspected to be dangerous to the environment shall be carried in accordance with conditions specified by the competent authority of the country of origin'.

Table A of Chapter 3.2 – generally known as the Dangerous Goods List[287] – contains references to the provisions that apply to each good or class of good in order of its assigned UN number. UN numbers are four digit codes, recognised

[287] http://www.unece.org/trans/danger/publi/adr/adr2005/English/Part3b-TableA.pdf.

internationally, used to identify hazardous articles and substances during transport. Infectious substances affecting humans are assigned UN 2814, infectious substances affecting animals only are assigned UN 2900, clinical waste is assigned UN 3291, diagnostic and clinical specimens are assigned UN 3373, and genetically modified organisms in Class 9 are assigned UN 3245. Against the UN number and the name of the goods, successive columns of the Dangerous Goods List contain codes referring to the applicable requirements, including the packing group, labels, special provisions, packaging, and provisions for loading, unloading and handling. The detailed requirements for the goods of interest are found elsewhere in the agreement. They are located by combining each reference code from the relevant row in the Dangerous Goods List with the chapter number located at the head of the corresponding column.

Aside from the specific provisions applicable to the particular good, employers must comply with the general provisions of the international carriage agreements. It is always appropriate to consult a Dangerous Goods Safety Adviser to ensure that no requirements have been missed.


SECTION 7 – MEDICINAL PRODUCTS AND HEALTHCARE
7 (i) What is a biotechnology medicinal product?
SECTION 7.1 – MEDICINAL PRODUCTS FOR HUMAN USE
SECTION 7.2 – MEDICINAL PRODUCTS FOR VETERINARY USE
SECTION 7.3 – PROTECTION OF ANIMALS USED FOR EXPERIMENTAL PURPOSES
7.1 (i) Which regulatory and advisory bodies cover human medicines?
Development, authorisation and manufacture of medicinal products
7.1 (ii) How are quality and safety standards applied to product development?
7.1 (iii) How are clinical trials regulated?
7.1 (iv) How are marketing authorisations obtained?
7.1 (v) How is good practice ensured during manufacturing?
7.1 (vi) How are orphan medicinal products regulated?
7.1 (vii) How will tissue engineering and other advanced therapies be regulated?
7.2 (i) Which regulatory and advisory bodies cover veterinary medicines?
7.2 (ii) How does legislation differ from that on medicines for human use?
7.2 (iii) How is good practice ensured during manufacturing?
7.3 (i) Which regulatory and advisory bodies cover animal welfare in the context of biotechnology?
7.3 (ii) Which legislation applies to animal welfare?
7.3 (iii) How is the cloning of animals regulated?

SECTION 7 – MEDICINAL PRODUCTS AND HEALTHCARE

Biotechnology has already played a significant part in developing novel medicinal products and therapies. It promises to reach out to highly specialised medical conditions, and to those which have until now been intractable.

This Section of the Guide consists of three Subsections. The first outlines Community legislation on medicinal products for human use. The second signposts the specific requirements relating to medicinal products for veterinary use. The third Subsection covers legislation that aims to protect the welfare of animals used for experimental and scientific purposes.

7 (i) What is a biotechnology medicinal product?

No general definition of a biotechnology medicinal product is set out in the EU legislation. However, Regulation (EC) No 726/2004 *laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency* [288] makes reference to:

> Medicinal products developed by means of one of the following biotechnological processes:
> - recombinant DNA technology,
> - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells,
> - hybridoma and monoclonal antibody methods.
> (Point 1, Annex to Regulation (EC) No 726/2004).

These products must receive marketing authorisation through the European Community's 'centralised procedure'.

A general definition of a biological medicinal product can be found in point 3.2.1.1 of Annex I to Directive 2001/83/EC *on the Community code relating to medicinal products for human use*[289], as amended by Directive 2003/63/EC[290]. The EMEA's Emerging Therapies and Technologies microsite[291] reflects the potential for applying biotechnology in medicine.

[288] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_136/l_13620040430en00010033.pdf.
[289] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_159/l_15920030627en00460094.pdf.
[290] http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32003L0063:EN:HTML.
[291] http://www.emea.eu.int/htms/human/itf/itfguide.htm.

7.1 – MEDICINAL PRODUCTS FOR HUMAN USE

European legislation and regulatory guidance are continually being developed to provide consistent and effective control of high-technology medicines, particularly biotechnology products. The authorisation system ensures that medicinal products marketed in the EU meet the fundamental criteria of quality, safety and efficacy. All the key processes are highly regulated, including early development, clinical trials, manufacture, use and post-authorisation vigilance (pharmacovigilance). The overall aim is the protection of public health.

7.1 (i) Which regulatory and advisory bodies cover human medicines?

Within the 'centralised procedure', which is mandatory for those biotechnology medicinal products which fall within the scope of the Annex to Regulation 726/2004, the body in charge of granting the marketing authorisations is the European Commission. The European Medicines Agency[292] (EMEA – previously known as the European Agency for the Evaluation of Medicinal Products) provides a scientific opinion on the quality, safety and efficacy of the products, prior to a decision on their marketing authorisation.

Detailed information on the EU regulatory framework, the applicable legislation and future initiatives can be found through the 'Enterprise and Industry' Directorate-General[293], in particular through its Pharmaceutical Unit and online *Pharmacos* system[294].

The main role of the EMEA is:

> the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use[295].

More specifically it oversees the European system for authorising biotechnology medicinal products, for the purposes of placing products on the market and for conducting clinical trials. The EMEA has four committees, with the following three being relevant to medicines for human use:

- the Committee for Medicinal Products for Human Use (CHMP)[296];
- the Committee on Orphan Medicinal Products (COMP)[297];

---

[292] European Medicines Agency Website, http://www.emea.eu.int.
[293] Home page of the Enterprise and Industry Directorate-General, http://europa.eu.int/comm/dgs/enterprise/index_en.htm.
[294] Home page of Pharmacos, the Pharmaceuticals Unit of the Enterprise and Industry Directorate-General, http://pharmacos.eudra.org/F2.
[295] EMEA, Overview, http://www.emea.eu.int/htms/aboutus/emeaoverview.htm.
[296] The Committee for Medicinal Products for Human Use, http://www.emea.eu.int/htms/general/contacts/CHMP.html.

- the Committee for Herbal Medicinal Products (HMPC)[298].

The CHMP has a Biologics Working Party (previously the Biotechnology Working Party) which produces advice, guidance and recommendations for the Committee on the quality of biotechnology medicinal products. Its 2005 Working Programme is available online[299] along with its guidelines and concept papers, which are located in the file Guidance Documents/Biologics in the Human Medicines section of the EMEA website[300].

The CHMP also has other working parties relevant to biotechnology medicinal products, such as:

- the Similar Biological Medicinal Products Working Party[301], which addresses issues related to 'biosimilars' ('biogenerics')
- the Cell-Based Products Working Party
- the Gene Therapy Working Party

Advice to users on the evaluation of human medicinal products before and after they are authorised can be found through the webpages of the respective EMEA management units:

Pre-Submission Unit[302]
Post-Authorisation Unit[303]

The European Group on Ethics in Science and New Technologies[304] (EGE) 'advises the European Commission on ethical aspects of science and new technologies in connection with the preparation and implementation of Community legislation or policies.' Several of the EGE's opinions have relevance to Community legislation and policy on medicinal products, particularly those involving advanced therapies. The EGE's mandate was renewed for the second time by the Commission in May 2005 in Decision 2005/383/EC *on the renewal of*

---

[297] The Committee on Orphan Medicinal Products, http://www.emea.eu.int/htms/general/contacts/COMP.html.
[298] The Committee for Herbal Medicinal Products, http://www.emea.eu.int/htms/general/contacts/HMPC.html.
[299] *CHMP Biotechnology Working Party (BWP) Work Programme 2005*, EMEA/CHMP/BWP/188963/2004, EMEA, London, 17 January 2005, http://www.emea.eu.int/pdfs/human/bwp/18896305en.pdf.
[300] File of Guidance Documents – Biotechnology in the Human Medicines Section of the EMEA website, http://www.emea.eu.int/index/indexh1.htm.
[301] *Mandate, Objectives and Rules of Procedure for the Working Party on Similar Biological Medicinal Products (BMWP)*, EMEA/CHMP/80650/2004, 18 March 2005, http://www.emea.eu.int/pdfs/human/biosimilar/8065005en.pdf.
[302] EMEA *Pre-Submission Guidance for Users of the Centralised Procedure,* EMEA-H-38179-1998, EMEA, London, November 1998, http://www.emea.eu.int/htms/human/presub/index.htm.
[303] EMEA *Post-Authorisation Guidance: Human Medicinal Products*, EMEA-H-19984/03rev3, EMEA, London, May 2004, http://www.emea.eu.int/htms/human/postguidance/index.htm.
[304] http://europa.eu.int/comm/european_group_ethics/index_en.htm.

the mandate of the European Group on Ethics in Science and New Technologies[305].

7.1 (ii) How are quality and safety standards applied to product development?

There are three main areas of European legislation applicable to quality and safety standards for product development; they all aim to achieve high levels of protection for human health.

- The first area is **good laboratory practice**. There are two relevant Directives: Directive 2004/9/EC *on the inspection and verification of good laboratory practice (GLP)*[306] and Directive 2004/10/EC *on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances*[307]. Directive 2004/9/EC defines Good Laboratory Practice (GLP) as that 'conducted in accordance with the principles set out in Directive 2004/10/EC.' It is the responsibility of Member States to verify and endorse compliance with GLP.

GLP applies to laboratories involved in:

> …the non-clinical testing…of all chemicals (e.g. cosmetics, industrial chemicals, medicinal products, food additives, animal feed additives, pesticides).
> (Article 1(1), Directive 2004/9/EC.)

Non-clinical testing laboratories are expected to comply with the *OECD Principles of Good Laboratory Practice* annexed in Directive 2004/10/EC. The main requirements of the OECD Principles are that non-clinical safety studies (tests) should: be well planned; use suitably qualified and experienced staff; take place in suitable facilities and with appropriate equipment; and be monitored for quality assurance purposes and to ensure GLP compliance. There should also be prompt and accurate recording of results, and an organisational structure that ensures responsible and effective oversight. Annex I of Directive 2004/9/EC provides detailed guidance for Member States on monitoring of and compliance with GLP.

- The second area concerns **human blood and blood components**, which are covered by Directive 2002/98/EC *setting standards of quality and safety for the collection, testing, processing, storage and distribution of human*

[305] http://europa.eu.int/comm/european_group_ethics/docs/mandate2005.pdf.
[306] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_050/l_05020040220en00280043.pdf.
[307] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_050/l_05020040220en00440059.pdf.

blood and blood components and amending Directive 2001/83/EC[308]*,* and Directive 2004/33/EC *implementing Directive 2002/98/EC as regards certain technical requirements for blood and blood components*[309]. Directive 2002/98/EC covers quality and safety standards for collection and testing of human blood and blood components for all uses; further standards for processing, storage and distribution apply only to those intended for transfusion. The Directive does not apply to blood stem cells, which are covered by Directive 2004/23/EC. Competent authorities established by Member States are responsible for oversight of implementation of the Directive. Blood establishments – a term defined in the Directive that covers a wide range of organisations – are responsible for quality management, traceability, notification of serious adverse events and testing, storage, transport and distribution of donations. Requirements for labelling and basic testing are outlined in Annexes III and IV to the Directive.

Directive 2004/33/EC establishes detailed requirements for the application and implementation of Directive 2002/98/EC, which are laid out in the Annexes and include: information required to be given to donors and obtained from them; eligibility criteria for donors of whole blood and blood components; storage, transport, and distribution conditions for blood and blood components; and quality and safety requirements for blood and blood components.

Directive 2002/98/EC has also been supplemented by Directive 2005/61/EC *implementing Directive 2002/98/EC as regards traceability requirements and notification of serious adverse reactions and events*[310], and Directive 2005/62/EC *implementing Directive 2002/98/EC as regards Community standards and specifications relating to a quality system for blood establishments*[311]*.*

More information on these Directives can be found on DG SANCO 'Blood' website[312].

- The third area concerns **human tissues and cells** and is framed by Directive 2004/23/EC *on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells*[313]. It includes products that have been derived from human tissues and cells (when intended for use for humans), but does not apply to tissues and cells for autologous graft, organs, or blood and blood components. Competent authorities in each Member State are responsible for implementing the Directive through measures such as supervision, licensing and inspections. The Directive has provisions on traceability, import/export, notification of serious

[308] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_033/l_03320030208en00300040.pdf.
[309] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_091/l_09120040330en00250039.pdf.
[310] http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_256/l_25620051001en00320040.pdf.
[311] http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_256/l_25620051001en00410048.pdf.
[312] http://europa.eu.int/comm/health/ph_threats/human_substance/blood_en.htm.
[313] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_102/l_10220040407en00480058.pdf.

adverse events/reactions, principles for donations, quality management, storage, labelling and distribution.

More information on these Directives can be found on DG SANCO 'Tissues and cells' website[314].

Scientific experimentation involving animals during product development is covered by European legislation on animal welfare. For further information see Section 7.3 – Animal Welfare.

7.1 (iii) How are clinical trials regulated?

Clinical trials are regulated by Directive 2001/20/EC *on the approximation of the laws, regulations, and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use*[315]. Its provisions include protection of subjects; use of ethics committees; conduct of trials; manufacture and import of investigational medicinal products; labelling; verification of compliance; notifications of adverse events and reactions; and exchange of information. Clinical trials must not commence until a favourable opinion is received from an ethics committee, which has been accepted by the Competent Authority for the territory in which the trial is to take place.

In accordance with Article 9 of Directive 2001/20, written authorisation is required before commencing clinical trials involving medicinal products for gene therapy, somatic cell therapy including xenogenic cell therapy and all medicinal products containing GMOs. No gene therapy trials may be carried out which result in modifications to the subject's germ line genetic identity. Such authorisation is without prejudice to the application of the framework GMO legislation covered by Sections 3 and 4 of this Guide. Advice on complementarity of the requirements should be obtained from the appropriate authorities.

Directive 2005/28/EC *laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products*[316] supplements Directive 2001/20/EC.

Further guidance produced by the Commission on the principles and guidelines of good clinical practice can be found through the EMEA's Good Clinical Practice

[314] http://europa.eu.int/comm/health/ph_threats/human_substance/tissues_en.htm.
[315] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_121/l_12120010501en00340044.pdf.
[316] http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_091/l_09120050409en00130019.pdf.

pages[317]. In Directive 2001/83/EC, Annex I provides information on the documentation required for clinical trials[318].

Investigational medicinal products for clinical trials must be manufactured to good manufacturing practice (GMP) guidelines. Further details on these guidelines are provided later on in this chapter, in answer to the Question 'How is good practice ensured during manufacturing?'

7.1 (iv) How are marketing authorisations obtained?

Biotechnology medicinal products falling within the scope of the Annex to Regulation (EC) No 726/2004 *laying down community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency*[319] have to follow the EU's 'centralised procedure' for marketing authorisation. Please note that Regulation (EC) No 726/2004 repealed Regulation (EEC) No 2309/93 as of 20 November 2005. Marketing authorisation is mandatory for biotechnology products listed in the Annex to Regulation (EC) No 726/2004 (as quoted at the beginning of this chapter).

Authorisation procedure

Applications for market authorisation are to be submitted to the European Medicines Agency (EMEA)[320]. Within the EMEA an opinion on the application will be drawn up by the Committee for Medicinal Products for Human Use (CHMP)[321]. Applications are expected to conform to Articles 8.3, 10, 11 and Annex I of Directive 2001/83/EC *on the Community code relating to medicinal products for human use*[322], as amended by Directive 2004/23/EC[323], which covers the details to be provided and the contents required in the dossier of accompanying documentation. There are some additional requirements for products that contain or consist of genetically modified organisms:

> (a) a copy of the competent authorities' written consent to the deliberate release into the environment of the genetically modified organisms for research and development purposes

---

[317] EMEA, Good Clinical Practice: Human Medicinal Products, http://www.emea.eu.int/Inspections/GCPgeneral.html.
[318] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_311/l_31120011128en00670128.pdf.
[319] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_136/l_13620040430en00010033.pdf.
[320] European Medicines Agency website, http://www.emea.eu.int/.
[321] The Committee for Medicinal Products for Human Use (CHMP), http://www.emea.eu.int/htms/general/contacts/CHMP.html.
[322] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_311/l_31120011128en00670128.pdf.
[323] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_102/l_10220040407en00480058.pdf.

where provided for in Part B of Directive 2001/18/EC or in Part B of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms;
(b) the complete technical dossier supplying the information required by Annexes III and IV to Directive 2001/18/EC;
(c) the environmental risk assessment in accordance with the principles set out in Annex II to Directive 2001/18/EC; and
(d) the results of any investigations performed for the purposes of research or development.
(Article 6(2), Regulation 726/2004.)[324]

The Committee's opinion should be reached within 210 days of the application being received. The Agency notifies the Commission and Member States of the Committee's final opinion. The Commission then has fifteen days to draft a decision on the application which it will forward to Member States and the applicant. If the application is refused then a Community-wide ban results; if accepted then it is valid throughout the Community. Authorisations are initially valid for five years and are generally renewable after five years for an indefinite period on re-evaluation by the Agency. More information can be found in the EMEA's *Pre-Submission Guidance for Users of the Centralised Procedure*[325]. In the *Rules Governing Medicinal Products for Human Use*[326], Volume 2 'Notice to Applicants'[327] provides detailed guidance on procedures for marketing authorisation (Volume 2A), the presentation and content of the application dossier (Volume 2B), and on regulatory guidelines (Volume 2C). Volume 3[328] 'Guidelines' provides testing guidelines for quality and biotechnology (Volume 3A), safety, environment and information on the medicinal product (Volume 3B), and clinical efficacy (Volume 3C).

Procedures for applying to make variations to marketing authorisation terms are outlined in Regulation (EC) No 1085/2003 *concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93*[329].

---

[324] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_136/l_13620040430en00010033.pdf.
[325] *EMEA Pre-Submission Guidance for Users of the Centralised Procedure*, EMEA-H-38179-1998, EMEA, London, November 1998, http://www.emea.eu.int/htms/human/presub/index.htm.
[326] Enterprise Directorate-General, Pharmaceuticals Unit, Eudralex: *The Rules Governing Medicinal Products in the European Union,* Volume 2, http://pharmacos.eudra.org/F2/eudralex/index.htm.
[327] *The Rules Governing Medicinal Products in the European Union,* Volume 2, http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm.
[328] *The Rules Governing Medicinal Products in the European Union,* Volume 3, http://pharmacos.eudra.org/F2/eudralex/vol-3/home.htm.
[329] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_159/l_15920030627en00240045.pdf.

Directive 2001/83/EC *on the Community code relating to medicinal products for human use* has been amended by Directive 2003/63/EC[330] and Directive 2004/27/EC[331]. These can be accessed separately or as a consolidated version[332]. Directive 2003/63/EC outlines the requirements for the authorisation dossier (the set of documents that must accompany the application). It includes a section with specific requirements for 'advanced therapy medicinal products', which include gene therapies, cell therapies and xenotransplantation. Directive 2004/27/EC modifies the definition of a medicinal product and, in concert with Regulation (EC) No 726/2004, the scope of the marketing authorisation procedures.

Biosimilar ('biogeneric') medicinal products

A generic medicinal product is one which is essentially similar to, and shares properties with, a reference product that has already received Community marketing authorisation. Community legislation recognises that making appropriate comparisons with the reference product may go some way towards compliance with the requirement to establish the quality, safety and efficacy of a generic product.

A biosimilar product - a biological medicinal product that is similar to a reference biological product - will generally not meet the conditions required to be considered generic, mainly due to manufacturing process characteristics, raw materials used, molecular characteristics and therapeutic modes of action. However, Community legislation contains provisions on data requirements for biosimilar products:

- Part II.4 of the replacement Annex I inserted into Directive 2001/83/EC by Directive 2003/63/EC[333] outlines the specific marketing authorisation requirements for biosimilars
- Directive 2004/27/EC *amending Directive 2001/83/EC on the Community code relating to medicinal products for human use*[334] states that supplementary data relating to pre-clinical and clinical tests, in line with the requirements of Annex I to Directive 2001/83/EC, will be required for biosimilar products

[330] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_159/l_15920030627en00460094.pdf.
[331] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_136/l_13620040430en00340057.pdf.
[332] *Consolidated Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use as amended by Directive 2002/98/EC, Directive 2004/24/EC and Directive 2004/27/EC,* http://pharmacos.eudra.org/F2/eudralex/vol-1/CONSOL_2004/Human%20Code.pdf.
[333] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_159/l_15920030627en00460094.pdf.
[334] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_136/l_13620040430en00340057.pdf.

- The EMEA has produced guidance relating to biosimilar products that can be accessed through the file Guidance Documents/Biosimilar Products on the Human Medicines section of its website[335].

Conditional marketing authorisations

Article 14(7) of Regulation 726/2004 states that provisions for granting conditional marketing authorisations are to be set out in an additional Regulation. The draft Regulation *on the conditional marketing authorisation for medicinal products falling within the scope of Regulation (EC) No 726/2004* can be found on Enterprise and Industry DG's Pharmacos website[336]. Conditional marketing authorisations may be granted for:

- Human medicinal products for the treatment, prevention, or diagnosis of chronically or seriously debilitating or life-threatening diseases
- Orphan human medicinal products
- Human medicinal products for emergency situations (recognised public health threats).

Applicants can request conditional marketing authorisation at the time of their marketing authorisation application under Regulation 726/2004. Applicants can seek advice from the EMEA as to the eligibility of their product before requesting a conditional marketing authorisation. The Regulation also covers: criteria for granting conditional marketing authorisations; evaluation procedures; renewal procedures and fees; information leaflets and packaging; and periodic safety reports.

Provisions for small and medium-sized enterprises

Article 70(2) of Regulation 726/2004 states that:

> Provisions shall be adopted…establishing the circumstances in which small and medium-size enterprises may pay reduced fees, defer payment of the fee, or receive administrative assistance.

These provisions have been adopted in Regulation (EC) No 2049/2005 *laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises*[337]. In accordance with Regulation 2049/2005,

---

[335] http://www.emea.eu.int/index/indexh1.htm.
[336] http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2004/nov/draft-regulation_13-10-2005.pdf.
[337] http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_329/l_32920051216en00040007.pdf.

EMEA has launched an SME Office[338] dedicated to addressing the particular needs of smaller companies.

Penalties

Article 83(4) of Regulation 726/2004 states that:

> At the Agency's request the Commission may impose financial penalties on the holders of marketing authorisations granted under this Regulation if they fail to observe certain obligations laid down in connection with the authorisations.

A draft Regulation *laying down the maximum amounts and the conditions and methods for the collection of penalties under Regulation (EC) No 726/2004*[339] was produced by the Commission in February 2005.

Medicinal products for paediatric use

Currently most medicines used to treat children have not been specifically tested or authorised for such use. A proposed Regulation *on medicinal products for paediatric use and amending Regulation (EEC) No 1708/92, Directive 2001/83/EC and Regulation (EC) No 726/2004*[340] aims to remedy this situation by integrating research and development of paediatric use into research and development programmes for medicinal products for adult use. The proposed Regulation was amended in November 2005[341]. The Regulation will require that paediatric investigations are conducted prior to applications for marketing authorisations, in line with an approved Paediatric Investigation Plan. Clinical trials on children must continue to comply with Directive 2001/20/EC *on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use*[342].

Applications for marketing authorisations will continue to follow the procedures outlined in Directive 2001/83/EC or Regulation 726/2004. Certain waivers and deferrals of this requirement will be allowed. The Regulation will establish a Paediatric Committee within the EMEA, which will be responsible for the approval of Paediatric Investigation Plans and waivers and deferrals. The Committee will be central to the operation of the Regulation. Post-authorisation monitoring of

---

[338] http://www.emea.eu.int/SME/SMEoverview.htm.
[339] http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/02_05/Penalties%20-%20Public%20consultation%2002%202005.pdf.
[340] http://pharmacos.eudra.org/F2/Paediatrics/index.htm.
[341] http://pharmacos.eudra.org/F2/Paediatrics/docs/COM_2005_0577_EN.PDF.
[342] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_121/l_12120010501en00340044.pdf.

efficacy and adverse reactions of paediatric use will be required. Further information on the proposed Regulation can be found in the document *Regulation on medicines for children: frequently asked questions*[343].

7.1 (v) How is good practice ensured during manufacturing?

The European Commission has produced principles and guidelines for good manufacturing practice (GMP) and these are outlined in Directive 2003/94/EC *laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use*[344], which is supplemented by Volume 4 of Eudralex, *Medicinal Products for Human and Veterinary Use: Good Manufacturing Practice*[345]. The GMP principles and guidelines include the implementation of effective systems for: quality assurance; quality control; review of complaints; recall of products; and accurate documentation of manufacture, in particular allowing the history of each batch to be traced[346].

Inspections to assess compliance with GMP are carried out in accordance with Article 111(1) of Directive 2001/83/EC[347] and Article 15(1) of Directive 2001/20/EC[348]. It is the responsibility of manufacturers and importers to ensure that manufacturing operations conform to GMP, or in the case of imports, 'standards which are at least equivalent' (Article 4(2)). The inspections section of the EMEA website provides further information on GMP[349]. Directive 2003/94/EC repealed Directive 91/356/EEC, and references to the latter in other legislation should now be taken as referring to the former.

7.1 (vi) How are orphan medicinal products regulated?

An orphan medicinal product must meet the following criteria:

> A medicinal product shall be designated as an orphan medicinal product if its sponsor can establish:
> (a) that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the Community when the application is made, or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating

[343] http://pharmacos.eudra.org/F2/Paediatrics/docs/Paeds%20Q&A%20October%2028.pdf.
[344] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_262/l_26220031014en00220026.pdf.
[345] Eudralex Volume 4: *Medicinal Products for Human and Veterinary Use: Good Manufacturing Practice*, http://dg3.eudra.org/F2/eudralex/vol-4/home.htm.
[346] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_262/l_26220031014en00220026.pdf.
[347] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_311/l_31120011128en00670128.pdf.
[348] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_121/l_12120010501en00340044.pdf.
[349] EMEA: *Good Manufacturing Practice – General*, http://www.emea.eu.int/Inpsections/GMPhome.html.

> or serious and chronic condition in the Community and that without incentives it is unlikely that the marketing of the medicinal product in the Community would generate sufficient return to justify the necessary investment; and
> (b) that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition.
> (Article 3(1), Regulation (EC) No 141/2000)[350]

The Community procedure for designation of orphan medicinal products is outlined in Regulation (EC) No 141/2000 *on orphan medicinal products* [351]. This Regulation also outlines measures for providing market exclusivity for orphan medicinal products and how marketing authorisations take place. Medicinal products designated as orphan medicinal products can take the centralised marketing authorisation route outlined in Regulation (EC) No 726/2004[352]. Please note that Regulation (EEC) No 2309/93 referred to in Regulation (EC) No 141/2000 has been repealed. These references should now be read as references to Regulation (EC) No 726/2004. Regulation (EC) No 141/2000 established the Committee on Orphan Medicinal Products (COMP)[353] under the European Medicines Agency. The COMP has produced a leaflet on *Orphan Medicinal Product Designation in the European Union* which outlines the designation procedure and the incentives provided[354]. The Pharmaceuticals Unit of the Enterprise and Industry Directorate-General provides links to relevant studies, documents and legislation for orphan medicinal products.[355]

7.1 (vii) How will tissue engineering and other advanced therapies be regulated?

Advanced therapy products require different regulatory treatment from conventional medicinal products because they are developed and used in different ways, and require the application of different standards. Directive 2003/63/EC, discussed under point 7.1 (iv), introduced some specific requirements for the authorisation dossiers for advanced therapies. Meanwhile, a dedicated Regulation *on advanced therapy medicinal products and amending*

---

[350] http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_018/l_01820000122en00010005.pdf.
[351] http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_018/l_01820000122en00010005.pdf.
[352] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_136/l_13620040430en00010033.pdf.
[353] The Committee on Orphan Medicinal Products, http://www.emea.eu.int/htms/general/contacts/COMP.html.
[354] *Orphan Medicinal Product Designation in the European Union*, EMEA, London, http://www.emea.eu.int/pdfs/human/comp/leaflet/661801En.pdf.
[355] *Pharmaceuticals: Orphan Medicinal Products*, Pharmaceuticals Unit, Enterprise Directorate-General, http://pharmacos.eudra.org/F2/orphanmp/index.htm.

Directive 2001/83/EC and Regulation (EC) No 726/2004[356], which covers human tissue engineering, gene therapy and (somatic) cell therapy, has been developed and published in draft. The proposed Regulation aims to harmonise market access, foster competitiveness and provide legal certainty, while maintaining high standards of health protection.

In accordance with the draft Regulation, advanced therapy medicinal products would have to follow the EU's centralised procedure for marketing authorisation, and would, generally, be subject to the provisions of Regulation 726/2004 in this regard. Other proposed provisions include: a new scientific advisory and product assessment body, the Committee for Advanced Therapies; a commitment to developing technical requirements for quality, safety and efficacy; risk management and traceability requirements; a centralised scientific advice system; harmonised data protection (10 years); and special incentives for SMEs. Member States will remain responsible for deciding whether human embryonic stem cells may be used in their respective territories.

More information on the proposed legislation on tissue engineering can be found in the advanced therapies section of the Pharmaceuticals Unit website[357]. The EMEA also has an Emerging Therapies and Technologies section on its website[358].

[356] http://pharmacos.eudra.org/F2/advtherapies/docs/COM_2005_567_EN.pdf.
[357] http://pharmacos.eudra.org/F2/advtherapies/index.htm.
[358] http://www.emea.eu.int/htms/human/itf/itfintro.htm.

7.2 – MEDICINAL PRODUCTS FOR VETERINARY USE

Commercial use of veterinary biotechnology medicinal products is covered by the EU's centralised authorisation procedure for their placing on the market, which aims to ensure that they all meet the same high standards of quality, safety and efficacy. These products are regulated throughout their development, manufacture and application with the primary aim of safeguarding public health.

7.2 (i) Which regulatory and advisory bodies cover veterinary medicines?

The European Medicines Agency (EMEA)[359] covers veterinary medicines[360] and is responsible for:

> the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use[361].

The EMEA oversees the European system for authorising veterinary medicines, and is assisted in this role by the Committee for Medicinal Products for Veterinary Use (CVMP)[362].

The regulation of veterinary medicines is also covered by the Enterprise Directorate-General[363], and relevant advice can be found through the website of its Pharmaceutical Unit[364], particularly in Volumes 4-9 of *The Rules Governing Medicinal Products in the European Union*[365].

7.2 (ii) How does legislation differ from that on medicines for human use?

---

[359] European Medicines Agency Website, http://www.emea.eu.int.
[360] EMEA's veterinary medicines pages, http://www.emea.eu.int/index/indexv1.htm.
[361] EMEA, Overview, http://www.emea.eu.int/htms/aboutus/emeaoverview.htm.
[362] The Committee for Medicinal Products for Veterinary Use, http://www.emea.eu.int/htms/general/contacts/CVMP.html.
[363] Home page of the Enterprise Directorate-General, http://europa.eu.int/comm/dgs/enterprise/index_en.htm.
[364] Home page of Pharmacos, the Pharmaceuticals Unit of the Enterprise Directorate-General, http://pharmacos.eudra.org.
[365] Volume 4 – Good Manufacturing Practice – Medicinal Products for Human and Veterinary Use, http://pharmacos.eudra.org/F2/eudralex/vol-4/home.htm; Volume 5 – Pharmaceutical Legislation – Veterinary Medicinal Products http://pharmacos.eudra.org/F2/eudralex/vol-5/home.htm; Volume 6 – Notice to Applicants – Veterinary Medicinal Products http://pharmacos.eudra.org/F2/eudralex/vol-6/home.htm; Volume 7 – Guidelines – Veterinary Medicinal Products, http://pharmacos.eudra.org/F2/eudralex/vol-7/home.htm; Volume 8 – Maximum Residue Limits – Veterinary Medicinal Products, http://pharmacos.eudra.org/F2/eudralex/vol-8/home.htm; Pharmacovigilance – Medicinal Products for Human and Veterinary Use, http://pharmacos.eudra.org/F2/eudralex/vol-9/home.htm.

Regulation (EC) No 726/2004 *laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency*[366] sets out the European centralised procedure for marketing authorisations which must be used for biotechnology medicinal products and others listed in the Regulation's Annex. This Regulation contains similar provisions for human and veterinary medicinal products. Title III of Regulation (EC) No 726/2004 details the provisions specific to the authorisation and supervision of veterinary medicinal products. Title III also establishes the Committee for Medicinal Products for Veterinary Use (CVMP) in a role similar to that of the CHMP.

For further information on Regulation (EC) No 726/2004 see Section 7.1 – Medicinal Products for Human Use.

Directive 2001/82/EC *on the Community code relating to veterinary medicinal products*[367] (amended by Directive 2004/28/EC[368]) outlines marketing authorisation procedures for products not covered by Regulation 726/2004. This Directive also covers authorisation of manufacture and distribution of veterinary medicinal products and their components, and has very similar provisions to Directive 2001/83/EC *on the Community code relating to medicinal products for human use* [369], which covers human medicinal products, except that Directive 2001/82 does not cover advertising or have specific provisions on blood products. Further guidance on the authorisation procedures can be found in Volume 7 (Guidelines) of *The Rules Governing Medicinal Products in the European Union*[370], and in the *Pre-Submission Guidance for the Central Authorisation Procedure for Veterinary Medicinal Products*[371].

Veterinary medicinal products, in contrast to those for human use, are subject to Regulation (EC) No 1946/2003 *on transboundary movements of genetically modified organisms*[372] (see Subsection 6.2 of this Guide). The application of Directive 2001/18/EC[373] regarding the Part B authorisation procedure for deliberate release of GMOs for any other purpose than for placing on the market also differs depending on whether a medicinal product is for veterinary or human use (see Section 4 of this Guide).

Information on the rules governing the use of animals in clinical trials and other scientific procedures can be found under Section 7.3 – Animal Welfare.

---

[366] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_136/l_13620040430en00010033.pdf.
[367] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_311/l_31120011128en00010066.pdf
[368] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_136/l_13620040430en00580084.pdf
[369] http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_311/l_31120011128en00670128.pdf.
[370] Eudralex, Volume 7 – Guidelines – Veterinary Medicinal Products, http://pharmacos.eudra.org/F2/eudralex/vol-7/home.htm
[371] Pre-Submission Guidance for the Central Authorisation Procedure for Veterinary Medicinal Products, http://www.emea.eu.int/hmts/vet/presub/index.htm.
[372] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_287/l_28720031105en00010010.pdf.
[373] http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32001L0018:EN:HTML.

7.2 (iii) How is good practice ensured during manufacturing?

There is a growing international consensus on the principles of good manufacturing practice (GMP). For veterinary medicines manufactured in the Community, key features of GMP include implementation of an effective quality assurance and control system (incorporating self-inspection) and having: sufficient, qualified and trained personnel; suitable and properly maintained premises and equipment; a system for documentation that allows the history of each batch to be traced; pre-established and validated manufacturing instructions and procedures; and systems for reviewing complaints and recalling products[374].

According to Directive 91/412/EEC *laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products*[375], GMP should ensure 'that products are consistently produced and controlled to the quality standards appropriate to their intended use.' (Article 2, Directive 91/412/EEC). This Directive is supplemented by Volume 4 (Medicinal Products for Human and Veterinary Use – Good Manufacturing Practice) of *The Rules Governing Medicinal Products in the European Union*[376].

Member States ensure compliance with GMP through inspections carried out in accordance with Directive 2001/82/EC[377] Article 80. Directive 2001/82/EC repealed Directive 81/851/EEC, and references to the latter in Directive 91/412/EEC should now be read as referring to 2001/82/EC. The inspections section of the EMEA website provides further information on good manufacturing practice[378].

---

374 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31991L0412&model=guichett.

375 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31991L0412&model=guichett.

376 Volume 4 – Good Manufacturing Practice – Medicinal Products for Human and Veterinary Use, http://pharmacos.eudra.org/F2/eudralex/vol-4/home.htm

377 http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_311/l_31120011128en00010066.pdf

378 EMEA: *Good Manufacturing Practice – General*, http://www.emea.eu.int/Inspections/GMPhome.html.

7.3 – PROTECTION OF ANIMALS USED FOR EXPERIMENTAL PURPOSES

To facilitate the functioning of the common market, animal welfare laws are harmonised across the EU. A wide range of experimental and other scientific procedures - including medicinal product development - are subject to special animal welfare rules.

7.3 (i) Which regulatory and advisory bodies cover animal welfare in the context of biotechnology?

The welfare of animals used for scientific purposes is covered by the Environment Directorate-General[379].

The Health and Consumer Protection Directorate-General[380] and the European Food Safety Authority[381] cover animal welfare - mainly in regard to food producing animals - on farms, during transport and at time of slaughter. Readers should be aware that these regulatory areas exist because they may become more relevant as animal biotechnology progresses.

7.3 (ii) Which legislation applies to animal welfare?

The principal European legislation is Directive 86/609/EEC *on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes*[382]as amended by Directive 2003/65/EC[383]. Directive 86/609/EEC details the reasons for which experimentation on animals may take place, sets limits for its use and conditions for the treatment of animals used in or bred for experiments, and specifies the personnel who may conduct the experiments and care for animals. The Commission is currently considering a revision of Directive 86/609/EEC with particular regard to new scientific techniques[384].

Wider animal welfare requirements are framed by a Protocol on Protection and Welfare of Animals[385], which requires that:

---

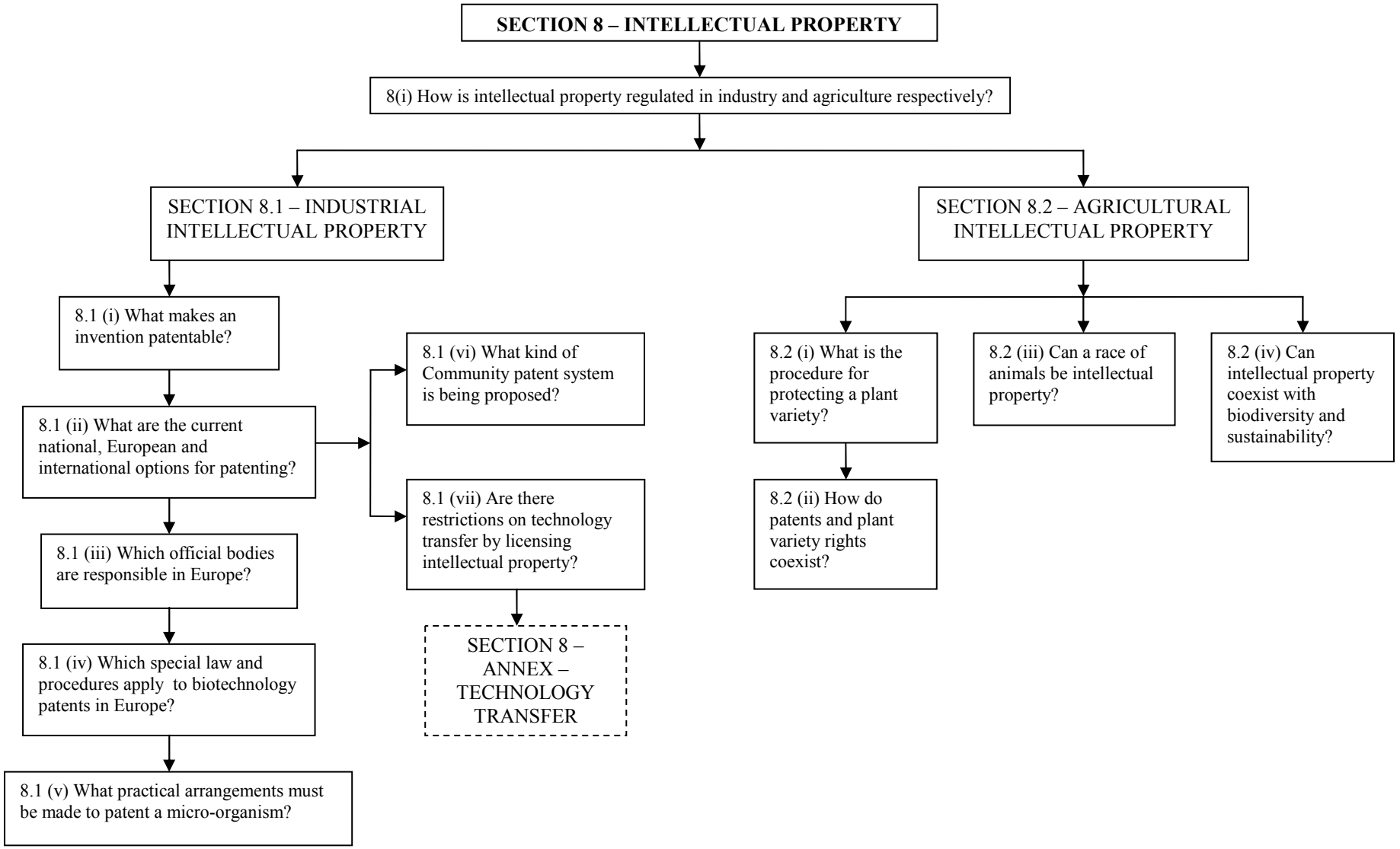
[379] http://europa.eu.int/comm/environment/chemicals/lab_animals/index_en.htm.
[380] http://europa.eu.int/comm/food/animal/index_en.htm.
[381] EFSA, Panel on Animal Health and Welfare, http://www.efsa.eu.int/science/ahaw/catindex_en.html.
[382] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31986L0609&model=guichett
[383] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_230/l_23020030916en00320033.pdf.
[384] Revision of Directive 86/609/EEC on the protection of Animals used for experimental and other scientific purposes, http://europa.eu.int/comm/environment/chemicals/lab_animals/revision_en.htm.
[385] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=11997D/PRO/10&model=guichett

> In formulating and implementing the Community's agriculture, transport, internal market and research policies, the Community and the Member States shall pay full regard to the welfare requirements of animals…
> (Annex to the 1997 Treaty of Amsterdam.)

7.3 (iii) How is cloning of animals regulated?

There is, as yet, no European legislation specific to the cloning of animals. Directive 86/609/EEC (see above) currently applies to animals used in cloning for experimental and scientific purposes. An overview of a study on 'Mammalian Cloning in Europe: Prospects and Public Policy' can be found in the European Commission's report on *Ethical, Legal and Socio-Economic Aspects of Food Biotechnology – An Overview of Research Activities 1994-2002*[386].

[386] http://europa.eu.int/comm/research/biosociety/pdf/agrofood.pdf.


SECTION 8 – INTELLECTUAL PROPERTY
8(i) How is intellectual property regulated in industry and agriculture respectively?
SECTION 8.1 – INDUSTRIAL INTELLECTUAL PROPERTY
SECTION 8.2 – AGRICULTURAL INTELLECTUAL PROPERTY
8.1 (i) What makes an invention patentable?
8.1 (ii) What are the current national, European and international options for patenting?
8.1 (iii) Which official bodies are responsible in Europe?
8.1 (iv) Which special law and procedures apply to biotechnology patents in Europe?
8.1 (v) What practical arrangements must be made to patent a micro-organism?
8.1 (vi) What kind of Community patent system is being proposed?
8.1 (vii) Are there restrictions on technology transfer by licensing intellectual property?
SECTION 8 – ANNEX – TECHNOLOGY TRANSFER
8.2 (i) What is the procedure for protecting a plant variety?
8.2 (ii) How do patents and plant variety rights coexist?
8.2 (iii) Can a race of animals be intellectual property?
8.2 (iv) Can intellectual property coexist with biodiversity and sustainability?

SECTION 8 – INTELLECTUAL PROPERTY

The development of innovative biotechnological products and processes often requires significant investment, and the ability to protect intellectual property is an important stimulus to such investment. Protection may be sought for both industrial and agricultural innovations. Industrial inventions can be protected by patent rights if certain basic conditions are met. Systems of patent protection exist at the Member State, European and international levels. There is also Community legislation laying down principles for the protection of biotechnological inventions. The major form of agricultural property protection at the Community level is a system of plant variety rights.

8 (i) How is intellectual property regulated in industry and agriculture respectively?

Industrial intellectual property regarding innovative products and processes is protected by a system of patent rights. In Europe patents can be granted on a national basis by individual Member States, on a European basis for two or more Member States where they are members of the European Patent Organisation, or on an international basis for two or more designated states which are party to the Patent Cooperation Treaty. There have been efforts to harmonise patent rules internationally, particularly with the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organisation. Information on these systems of patent protection can be found in part 8.1 of this Guide.

Agricultural intellectual property is primarily given protection through systems of plant variety rights. Under the TRIPS Agreement, countries may choose to protect plant varieties with patent rights, but the European Community has opted for a system of Community Plant Variety Rights that excludes the option of patenting plant varieties as such. Animal varieties cannot be patented, but certain inventions involving animals may be patentable. Part 8.2 of this Guide provides further information on the protection of agricultural intellectual property.

8.1 – INDUSTRIAL INTELLECTUAL PROPERTY

This Subsection of the Guide outlines the European, national and international options for protecting industrial inventions through patenting, and the Community legislation relating to the protection of biotechnological inventions.

8.1 (i) What makes an invention patentable?

Article 52 of the European Patent Convention[387] outlines the factors that make an invention patentable:

> European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

The Article then goes on to outline ideas and products that are not considered to be inventions, and items excluded from patentability are detailed in Article 53. Articles 54, 56 and 57 explain the meanings of the terms novelty, inventive step and industrial application.

8.1 (ii) What are the current national, European and international options for patenting?

Patents were originally granted on a national basis and can still be applied for in this way, but there are now European and international routes that can be followed when applying for patents in more than one territory. Most Member States have national systems for patent applications; the procedures and requirements for applications vary. Further details can be obtained through national patent offices. List 8.1, at the end of this Section, contains a list of national intellectual property offices.

At the European level, a patent system is run by the European Patent Office[388] (EPO) and governed by the European Patent Convention (EPC)[389]. Through the European patent system, inventors can use a single, centralised procedure to apply for a patent in all or a selection of the EPO's member states. Use of such a procedure is said by the EPO to be cost-effective where a patent is desired in three or more EPO states[390]. The EPO is not an institution of the European Union, however most EU Member States are also members of the EPO (excluding Malta).

At the international level, the Patent Cooperation Treaty[391] of the World Intellectual Property Organisation[392] has a similar centralised procedure allowing inventors to specify the countries in which they wish to apply for patents. The PCT, with 124 contracting states, has a wider membership than the EPO and so can provide a broader coverage if this is required.

---

[387] http://www.european-patent-office.org/legal/epc/e/ar52.html
[388] http://www.european-patent-office.org/epo_general.htm
[389] http://www.european-patent-office.org/legal/epc/index.html
[390] See: http://www.european-patent-office.org/epo/pubs/brochure/europat/pdf/europat_e_20040708.pdf.
[391] http://www.wipo.int/pct/en/texts/articles/atoc.htm
[392] http://www.wipo.int/

Applications for the European patent system are made directly to the EPO. Applications made under the PCT are submitted to the national patent office of the country in which the applicant is based (referred to in the PCT as the 'receiving office'). The European Patent can also be applied for through the PCT system[393]. Guidance may be available on international, European and national applications from the patent offices of Member States (e.g. the UK Patent Office[394]).

8.1 (iii) Which official bodies are responsible in Europe?

The European Patent Office[395] is responsible for the European patent system.

The Directorate-General Internal Market and Services[396] is responsible for industrial property issues within the Community and oversees Directive 98/44/EC *on the legal protection of biotechnological inventions*[397]. A section of its website focuses on biotechnological inventions[398]. The Directorate-General for Trade[399] is responsible for the promotion, implementation and enforcement of intellectual property rights at the international level. The Directorate-General for Enterprise[400] oversees policy on innovation and technology transfer.

A list of Member State and other European national IP offices is provided at the end of this Section.

The World Intellectual Property Organisation provides a global directory of national intellectual property offices[401] which includes their contact details.

8.1 (iv) Which special law and procedures apply to biotechnology patents in Europe?

There is one piece of European legislation that specifically deals with biotechnology patents – Directive 98/44/EC o*n the legal protection of biotechnological inventions*[402]. This Directive outlines which biotechnological inventions are eligible for patenting and which are not (Articles 4-11). So for example 'Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal

---

[393] http://www.european-patent-office.org/epo/pubs/brochure/europat/html/europat3_e.htm.
[394] The Patent Office, December 2004, *Patents: Essential Reading*, http://www.patent.gov.uk.
[395] http://www.european-patent-office.org/epo_general.htm.
[396] http://europa.eu.int/comm/internal_market/index_en.htm.
[397] http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf
[398] http://europa.eu.int/comm/internal_market/en/indprop/invent/index.htm.
[399] http://europa.eu.int/comm/trade/index_en.htm
[400] http://europa.eu.int/comm/enterprise/innovation/index_en.htm.
[401] http://www.wipo.int/directory/en/urls.jsp.
[402] http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf

variety.' However, plant and animal varieties are not patentable. The Directive also outlines the extent of the protection of biological material, or processes for producing biological material, for example the protection extends to material derived from the patented material and which possesses the same, specific characteristics (Articles 8-11). There are also provisions on compulsory licensing (Article 12) and the need to deposit biological material for patent applications (see later Questions).

Further information can be found in the Scadplus guide *Legal Protection: Biotechnological Inventions*[403], in two reports of the European Commission on the operation of the Directive – *Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering* (2002 Report[404] and 2005 Report[405]), and in the document *Legal protection of biotechnological inventions: Frequently Asked Questions on scope and objectives of the EU Directive (98/44)*[406]. The European Patent Office has a section on biotechnology applications in its *Guide for Applicants*[407].

The World Trade Organisation's Agreement on Trade Related Aspects of Intellectual Property Rights has provisions specific to biotechnological innovations in Article 27.3. The current Article reads[408]:

> Members may also exclude from patentability…
> plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO agreement.

The review of the Article began in 1999 and is ongoing. Details can be found on the WTO website[409].

---

[403] http://europa.eu.int/scadplus/leg/en/lvb/l26026.htm
[404] European Commission, *Report from the Commission to the European Parliament and the Council: Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*, COM(2002)545 Final, http://europa.eu.int/eur-lex/pri/en/dpi/rpt/doc/2002/com2002_0545en01.doc.
[405] European Commission, *Report from the Commission to the European Parliament and the Council: Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*, COM(2005)312 Final, http://europa.eu.int/comm/internal_market/en/indprop/invent/com_2005_312final_en.pdf.
[406] http://europa.eu.int/comm/internal_market/en/indprop/invent/2k-39.htm.
[407] EPO, *Guide for Applicants – Biotechnology applications*, http://www.european-patent-office.org/legal/guiapp1/e/ga_c_ii_5.htm.
[408] WTO, *Annex 1C – Agreement on Trade Related Aspects of Intellectual Property Rights*, http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.
[409] WTO, *TRIPS: Reviews, Article 27.3 (b) and Related Issues*, http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm.

Supplementary protection certificates

Medicinal products can be granted commercial protections in addition to those granted by patent rights. Regulation (EEC) No 1768/92 *concerning the creation of a supplementary protection certificate for medicinal products*[410] details a certification scheme that can extend commercial protections for medicinal products beyond the period of patent protection, and can be applied in circumstances where there has been a gap between the patent and the marketing authorisation being granted (for details on marketing authorisations for medicinal products see Section 7). This extended time period gives a maximum of fifteen years' protection from the time of authorisation. The certificate has the same effect as the patent did during its validity (see Article 5, Regulation (EEC) No 1768/92).

A similar system of extended protection exists for plant protection products under Regulation (EC) No 1610/96 *concerning the creation of a supplementary protection certificate for plant protection products*[411]. Again this is for when there has been a gap between the patent and the marketing authorisation being granted.

Under both of the Regulations, applications for the certificates should be made within 6 months of the granting of either the marketing authorisation or the patent, whichever was later (see Article 7 in both Regulations). The details of the application procedure are outlined in Articles 8-11 of both Regulations.

8.1 (v) What practical arrangements must be made to patent a micro-organism?

Directive 98/44/EC[412] explains that biological material may need to be deposited in order to obtain a patent for a biotechnological invention. A patent application must contain sufficient information about an invention for an appropriately skilled person to be able to duplicate it. This is usually achieved through the inclusion of a description and diagrams in the patent application, but these may not be sufficient where biological material is involved. Such material can be deposited with an international depositary authority through procedures detailed in the *Budapest Treaty on the International Deposit of Microorganisms for the Purpose of Patent Procedure*[413]. 'Deposit' in the context of the Budapest Treaty refers to

410 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31992R1768&model=guichett.

411 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31996R1610&model=guichett

412 http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf.

413 http://www.wipo.int/treaties/en/registration/budapest/trtdocs_wo002.html.

the transmission of a sample of a micro-organism and its subsequent receipt and storage by a depositary authority. The World Intellectual Property Organisation provides a list of international depositary authorities[414]; some accept all micro-organisms, others are limited to particular types.

8.1 (vi) What kind of Community patent system is being proposed?

The European Patent Convention system provides inventors with a single process that enables them to make single applications for patents in all or a selection of EPO states, and thus provides a single route for applying for patents in the EU Member States (apart from Malta which is not an EPO member). The proposed Community patent system would go further than this, allowing applications to be made for unitary Community patents. These would be granted or refused for the Community as a whole and would be valid throughout the Community when granted. Application would be through the EPO, which would amend the EPC accordingly.

Negotiations in the EU on the creation of the Community patent system have been in progress for several years, and as yet an agreement has not been reached. A proposed regulation was drafted in 2000 (COM(2000)412 Final[415]). Further details on the proposed system can be found in a green paper *Community Patent and the Patent System in Europe*[416], on Scadplus[417] and on the EPO's website[418]. The rights conferred by the Community patent would be the same as those conferred by European patents, and they would similarly be valid for twenty years. A necessary part of the system would be the establishment of a Community intellectual property court to rule on infringements and invalidity claims.

8.1 (vii) Are there restrictions on technology transfer by licensing intellectual property?

Article 81(1) of the EC Treaty[419] prohibited the formation of certain types of agreements between undertakings, which would negatively affect competition in the common market. Certain exemptions known as 'block exemptions' to Article 81 are permitted, and rules on their use are detailed in Regulation (EC) No

---

[414] List of International Depositary Authorities for the Budapest Treaty, http://www.wipo.int/treaties/en/registration/budapest/idalist.doc.
[415] *Proposal for a Council Regulation on the Community Patent*, COM (2000) 412 Final, http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/ce337/ce33720001128en02780290.pdf.
[416] *Community Patent and the Patent System in Europe: Green Paper (1997)*, http://europa.eu.int/scadplus/leg/en/lvb/l26051.htm.
[417] Scadplus – Community Patent, http://europa.eu.int/scadplus/leg/en/lvb/l26056.htm.
[418] EPO, The Community Patent, http://www.european-patent-office.org/epo/pubs/brochure/general/e/communitypat_e.htm.
[419] http://europa.eu.int/comm/competition/legislation/treaties/ec/art81_en.html.

1/2003 *on the implementation of the rules on competition*[420]. Such exemptions can be withdrawn where particular cases do not comply with Article 81(3).

Regulation (EC) No 772/2004 *on the application of Article 81(3) of the Treaty to categories of technology transfer agreements*[421] details exemptions to Article 81(1) in regard to technology transfer agreements and the conditions which must be met for such exemptions to apply. The main condition is that the market share, i.e. 'the presence of the licensed technology on the relevant product market(s)' (Article 3, Regulation 772/2004), of the two undertakings party to the agreement must not exceed 20% for competing undertakings or 30% for non-competing undertakings. Article 8 of Regulation 772/2004 explains how market share is to be calculated. Article 4 outlines some further conditions on the nature of the technology transfer agreement, such as that it must not restrict research and development, or limit output of the product.

8.2 – AGRICULTURAL INTELLECTUAL PROPERTY

This Subsection of the Guide outlines European legislation on the protection of agricultural intellectual property, including the Community plant variety rights system. It also explains the interdependency of Community commitments to intellectual property protection, biodiversity and sustainability.

8.2 (i) What is the procedure for protecting a plant variety?

Community plant variety rights

At the Community level, plant varieties *per se* cannot be patented (see Question 8.2 (ii) for more on the role of patents in this area). Instead, they can be protected by plant variety rights, which are a *sui generis* category of intellectual property.

Alongside national procedures for granting these rights (which may vary), Regulation (EC) No 2100/94 *on Community plant variety rights*[422] established a central procedure. Community plant variety rights are granted or refused for the whole Community and are valid throughout the Community. Community plant variety rights are issued by the Community Plant Variety Office (CPVO)[423]. To qualify for protection the plant variety must be "(a) distinct; (b) uniform; (c) stable;

---

[420] http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_001/l_00120030104en00010025.pdf.
[421] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_123/l_12320040427en00110017.pdf.
[422] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31994R2100&model=guichett.
[423] Community Plant Variety Office, http://www.cpvo.eu.int.

and (d) new" (Article 6). Each of those terms is defined in more detail in the Regulation (Articles 7-10). The breeder, the person who discovered and developed the variety, or their successor in title are entitled to claim plant variety rights. The content of the rights granted is covered in Articles 13-18.

A structured list of legislation in force on Community plant variety rights is available from the CPVO[424]. List 8.2, at the end of this Section, contains a list of national plant variety right offices.

Applications

Applications for Community plant variety rights should be made directly to the Community Plant Variety Office, or to a sub-office or national agency on condition that the Community office is notified within two weeks (Regulation 2100/94, Article 49). Article 50 details the required contents for applications. Right of priority can be claimed if the application is made within 12 months of an application in an EU Member State or a member state of the International Union for the Protection of New Varieties of Plants (Article 52). The International Union was created by the International Convention for the Protection of New Varieties of Plants (UPOV Convention)[425], which covers similar rights (it refers to these as breeder's rights). UPOV provides a list of plant variety protection offices[426], including contact details, of its members.

An application for a Community plant variety right undergoes three types of examination: formal; substantive; and technical. The formal examination assesses whether the application meets the administrative requirements of Regulation 2100/94; the substantive examination assesses whether the variety is new and whether the applicant is entitled to make the claim, and examines the proposed variety denomination; and the technical examination assesses compliance with Articles 7, 8 and 9 (distinctness, uniformity and stability). These examinations are outlined in Articles 53-55. The office maintains two registers: one for applications and one for granted rights (Article 87). A variety that is the subject of a Community plant variety right may not be patented or protected by national plant variety rights (in EU Member States).

Regulation (EC) No 1239/95 e*stablishing implementing rules for the application of Council Regulation (EC) No 2100/94 as regards proceedings before the Community Plant Variety Office*[427] includes further details of the application procedure (see Chapter I – Application for a Community Plant Variety Right).

---

[424] http://www.cpvo.eu.int/default.php?res=1&w=1024&h=604&lang=en&page=droit/legislation.htm.
[425] http://www.upov.int/en/about/upov_convention.htm.
[426] Addresses of Plant Variety Protection Offices in UPOV Member States, http://www.upov.int/en/about/members/pvp_offices.htm.
[427] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31995R1239&model=guichett.

Regulation (EC) No 1239/95[428] was amended by Regulation (EC) No 2181/2002, which replaced Article 27. Article 27 includes provisions on the status of examination reports from various official sources.

8.2 (ii) How do patents and plant variety rights coexist?

At the Community level and under the European Patent Convention, plant varieties cannot be protected using patents, but can be covered by *sui generis* plant variety rights. However, GMOs are patentable, and varieties - including crops - derived from patented GMOs are themselves protected as a result. Legislation has established a basis for coexistence of the two forms of IP.

In the Community, where a plant variety right cannot be exploited without infringing a patent or vice versa, Article 12 of Directive 98/44/EC[429] allows cross-licensing; this can be on a compulsory basis if the holders have not been able to reach a contractual agreement. Regulation (EC) No 2100/94 *on Community plant variety rights* was amended by Regulation 873/2004[430] which replaced Article 29 on compulsory exploitation rights with an article on compulsory licensing. The new article outlines the conditions which must be met for a compulsory licence to be granted, and the procedures for granting and review of the licence. Point 5a of the new article gives the terms under which compulsory cross-licensing in line with Article 12 of Directive 98/44/EC may take place.

8.2 (iii) Can a race of animals be intellectual property?

Directive 98/44/EC *on the legal protection of biotechnological inventions*[431] excludes animal varieties from patentability, along with 'essentially biological processes' for their production. However: 'Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety' (Article 4).

Article 6 excludes certain processes from patentability 'where their commercial exploitation would be contrary to ordre public or morality', including 'processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.'

---

[428] Commission Regulation (EC) No. 2181/2002 amending Regulation (EC) No. 1239/95 establishing implementing rules for the application of Council Regulation (EC) No. 2100/94 as regards proceedings before the Community Plant Variety Office, http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_331/l_33120021207en00140015.pdf.

[429] http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf.

[430] Council Regulation (EC) No. 873/2004 *amending Regulation (EC) No. 2100/94 on Community plant variety rights,* http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_162/l_16220040430en00380039.pdf.

[431] http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf.

A Commission report relevant to this Question, *Development and implications of patent law in the field of biotechnology and genetic engineering, COM(2002)545 Final*[432], is available online, and is summarised in a Scadplus webpage[433].

8.2 (iv) Can intellectual property coexist with biodiversity and sustainability?

Community law and international agreements together determine how intellectual property rights can coexist with biodiversity and sustainability. The balance between the relevant acts and conventions helps to ensure that intellectual property protection does not have negative impacts on biodiversity and its sustainable use. Maintenance of biodiversity is important to sustainable development, which is in turn important for IP in agricultural production.

In its 1998 *Communication on a European Community Biodiversity Strategy, COM(98)42*[434], the Commission indicated that intellectual property rights can encourage innovation and assist in the development and transfer of technologies for the conservation and sustainable use of biodiversity. Whilst 'an adequate legal and economic framework, including intellectual property regimes, is necessary in order to facilitate technology cooperation and transfer', 'it is necessary to consider removing incentives which have a negative impact. This includes reviewing certain systems of property use and rights'[435].

The countries party to the international Convention on Biological Diversity[436], which include the European Community and its Member States, also view intellectual property rights as potentially beneficial for the protection of biodiversity. This is because intellectual property rights can promote access to genetic resources, assist in the sharing of benefits from their use, and contribute to the protection of traditional knowledge[437].

Plant genetic resources

Regulation (EC) No 870/2004 *establishing a Community programme on the conservation, characterisation, collection and utilisation of genetic resources in*

---

[432] http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=COMfinal&an_doc=2002&nu_doc=545.

[433] http://europa.eu.int/scadplus/leg/en/lvb/l26026a.htm.

[434] *Communication of the European Commission to the Council and to the Parliament on a European Community Biodiversity Strategy*, http://europa.eu.int/comm/environment/docum/pdf/9842en.pdf.

[435] *Communication of the European Commission to the Council and to the Parliament on a European Community Biodiversity Strategy*, http://europa.eu.int/comm/environment/docum/pdf/9842en.pdf.

[436] http://www.biodiv.org/welcome.aspx.

[437] CBD Secretariat, Economics, Trade and Incentive Measures – Biodiversity and International Trade, http://www.biodiv.org/programmes/socio-eco/incentives/int-trade.asp.

agriculture and repealing Regulation (EC) No 1467/94[438] gives details of a Community programme for 2004-2006 that helps to implement international commitments on biodiversity and the equitable sharing of benefits derived from genetic resources.

The European Community and its Member States are also signatories to the International Treaty on Plant Genetic Resources for Food and Agriculture[439]. This Treaty established a Multilateral System through which states, international institutions and collection centres grant access to their plant genetic resources, with a particular focus on major food and forage crops. Certain restrictions are placed on the granting of intellectual property rights for the resources in the Multilateral System:

> Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System (Article 12.3(d)).

However, there are also several provisions which make it clear that access to genetic resources, and transfers of materials and technologies in terms of benefit sharing should be done with respect to the protection of intellectual property rights, for example:

> Access to plant genetic resources for food and agriculture protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws (Article 12.3(f)).

[438] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_162/l_16220040430en00180028.pdf.
[439] ftp://ext-ftp.fao.org/ag/cgrfa/it/ITPGRe.pdf.

SECTION 8 – ANNEX –TECHNOLOGY TRANSFER

What is technology transfer?

Technology transfer involves the transfer of research, knowledge or technology from the owner to a user. For example, this will often be from academia to industry. The transferor usually receives something in return for the transfer, often in the form of financial remuneration.

Why are technology transfer agreements used?

Where an innovation is subject to intellectual property protection e.g. through patent rights, then technology transfer agreements enable that innovation to be used by others under conditions set by the right-holder. The right-holder receives reward for the innovation and the knowledge is disseminated, which can promote further technological advances. Use of new technologies can increase productivity and contribute to industrial development and economic growth.

What forms can technology transfer agreements take?

Technology transfer agreements generally take the form of a contract between the owner of the knowledge or technology and the enterprise that wants to use that knowledge. An example would be a licensing agreement between a patent-holder and an enterprise that wishes to use, manufacture or sell the patented product or process. The agreement will set out what remuneration is due to the transferor and any conditions which apply to the use of the knowledge.

Regulation (EC) No 772/2004 *on the application of Article 81(3) of the Treaty to categories of technology transfer agreements*[440] provides the following definition:

> 'technology transfer agreement' means a patent licensing agreement, a know-how licensing agreement, a software copyright licensing agreement or a mixed patent, know-how or software copyright licensing agreement, including any such agreement containing provisions which relate to the sale and purchase of products or which relate to the licensing of other intellectual property rights or the assignment of intellectual property rights, provided that those provisions do not constitute the primary object of the agreement and are directly related to the production of the contract products; assignments of patents, know-how, software copyright or a combination thereof where

[440] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_123/l_12320040427en00110017.pdf.

> part of the risk associated with the exploitation of the technology remains with the assignor, in particular where the sum payable in consideration of the assignment is dependent on the turnover obtained by the assignee in respect of products produced with the assigned technology, the quantity of such products produced or the number of operations carried out employing the technology, shall also be deemed to be technology transfer agreements;

Information on some of the different forms that technology transfer agreements can take is provided in Chapter 3 of the World Intellectual Property Organisation's *Intellectual Property Handbook: Policy, Law and Use*[441].

Is there any guidance on setting up a technology transfer agreement?

The Intellectual Property Rights Helpdesk[442] of the Enterprise Directorate-General provides advice to current and potential EU Research, Technology and Development contractors. More general sources of guidance on technology transfer agreements include national intellectual property offices (listed in Section 8), the PATLIB network of the European Patent Organisation[443] and the World Intellectual Property Organisation[444]. It is particularly worth consulting the Small and Medium-Sized Enterprises section of WIPO's website[445] which includes an *Overview of Contractual Agreements for the Transfer of Technology*[446] and a helpline service[447]. Further sources of information include the European University Association[448] and the European Association of Research and Technology Organisations[449].

How is the use of technology transfer agreements regulated?

Technology transfer is encouraged by the Community as a stimulus to economic development, but there are also rules designed to ensure that technology transfer agreements do not disrupt the working of the internal market by allowing businesses to gain dominance of particular product markets. Regulation (EC) No 772/2004 *on the application of Article 81(3) of the Treaty to categories of technology transfer agreements*[450] is outlined in Section 8 of this Guide.

---

441 http://www.wipo.int/about-ip/en/iprm/pdf/ch3.pdf.
442 http://www.ipr-helpdesk.org/index.htm.
443 http://patlib.european-patent-office.org/welcome/whatis/index.en.php.
444 http://www.wipo.int/portal/index.html.en.
445 http://www.wipo.int/sme/en.
446 http://www.wipo.int/sme/en/documents/pdf/technology_transfer.pdf.
447 http://www.wipo.int/sme/en/helpline.html.
448 http://www.unige.ch/eua.
449 http://www.earto.org.
450 http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_123/l_12320040427en00110017.pdf.

Member State governments are likely to have different policies on technology transfer, adapted to their own economic needs, and national law on technology transfer agreements will vary. National intellectual property offices (listed in Section 8) or departments responsible for innovation policy should be consulted for information on national rules.

Must technology transfer comply with other requirements?

Technology which is of a dual-use nature, i.e. it has both civilian and military uses, may be subject to the provisions of Regulation (EC) No 1334/2000 *setting up a Community regime for the control of exports of dual-use items and technology*[451]. The definition of 'export' in Regulation 1334/2000 includes 'transmission of software or technology by electronic media, fax or telephone'. The Regulation's provisions on technology transfer do not apply to:

- Information in the public domain
- Basic scientific research
- The minimum information necessary for patent applications.

(Annex I, Regulation 1334/2000.)

The Regulation also does not apply to the transmission of technology where it involves the cross-border movement of natural persons.

Export of dual-use items and technology listed in Annex I to Regulation 1334/2000 must be authorised by the competent authority[452] of the Member State in which the exporter is based. Dual-use items not listed in Annex I may still require authorisation under certain circumstances, including:

- If a Member State competent authority indicates that the items may be intended for use in the development, production, handling, operation, maintenance, storage, detection, identification or dissemination of chemical, biological or nuclear weapons
- If the destination country is subject to an arms embargo and the items may be intended for a military end-use
- If required by the Member State in which the exporter is based for reasons of public security or human rights considerations.

(Articles 4 and 5, Regulation 1334/2000.)

The Annexes to Regulation 1334/2000 have been updated and replaced by the Annexes to Regulation (EC) No 1504/2004[453].

[451] http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_159/l_15920000630en00010215.pdf.
[452] EU Member States' Authorities in Charge of Export Control Applications and Commission Services in Charge of Export Controls, http://trade-info.cec.eu.int/doclib/docs/2005/may/tradoc_114154.pdf.
[453] http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_281/l_28120040831en00010225.pdf.

LIST 8.1 – INTELLECTUAL PROPERTY OFFICES

AUSTRIA / AUTRICHE	
Ministère fédéral pour le transport, l'innovation et la technologie Office autrichien des brevets Austrian Patent Office Österreichisches Patentamt Dresdner Straße 87 A-1200 Wien	Tel. (43-1) 53424 0 Fax. (43-1) e-mail: info@patent.bmvit.gv.at website: http://www.patentamt.at/
BELGIUM / BELGIQUE	
Service public fédéral économie, P.M.E., Classes moyenne & energie Office de la Propriété Intellectuelle Ministry of Economic Affairs Administration of Trade Policy Industrial Property Office Rue du Progrès, 50 B-1210 BRUSSELS	Tel. (32-2) 277 5111 Fax. (32-2) 277 5107 e-mail: info.eco@mineco.fgov.be. website: http://mineco.fgov.be/
CYPRUS / CHYPRE	
Direction de l'enregistrement des sociétés et des recettes Department of Registrar of Companies and Official Receiver Corner Makarios Av. and Karpenissiou str. CY-1427 Nicosia	Tel. (357 22) 404 301/2, 404 433, 404 4367 Fax. (357 22) 304 887 e-mail : deptcomp@rcor.gov.cy; eterion@drcor.mcit.gov.cy website: http://www.mcit.gov.cy/
CZECH REPUBLIC / RÉPUBLIQUE TCHÈQUE	
Office de la propriété industrielle de la République tchèque Industrial Property Office of the Czech Republic Antonína Cermáka 2a 160 68 Praha 6 - Bubenec	Tel. (420 2) 24 311 555 / 24 383 111 Fax. (420-2) 243 24 718 e-mail: posta@upv.cz website: http://isdvapl.upv.cz/
DENMARK / DANEMARK	
Ministère de commerce et de l'industrie Office danois des brevets et des marques Ministry of Trade and Industry Danish Patent and Trademark Office Patent-og Varemaerkestyrelsen Helgeshøj Allé 81 DK-2630 Taastrup	Tel. (45) 4350 8000 Fax. (45) 4350 8001 e-mail: pvs@dkpto.dk website: http://www.dkpto.dk
ESTONIA / ESTONIE	
Office des brevets de l'Estonie The Estonian Patent Office	Tel. (372) 627 79 00 Fax (372) 645 13 42

Toompuiestee 7 15041 Tallinn	e-mail: Patendiamet@epa.ee website: http://www.epa.ee/
FINLAND / FINLANDE	
Office national des brevets et de l'enregistrement de la Finlande National Board of Patents and Registration of Finland Arkadiankatu 6 A P.O. Box 1140 FIN-00101 Helsinki	Tel. (358-9) 6939 500 Fax. (358-9) 6939 5328 e-mail: website: http://www.prh.fi
FRANCE	
Institut national de la propriété industrielle National Institute of Industrial Property 26bis rue de St.-Pétersbourg F-75800 Paris Cedex 08	Tel. (33-1) 53 04 53 04 Fax. (33-1) 53 04 45 24 website: http://www.inpi.fr
GERMANY / ALLEMAGNE	
Office allemand des brevets et des marques Deutsches Patent- und Markenamt D-80297 Munich	Tel. (49-89) 21 95 0 Fax. (49-89) 21 95 22 21 e-mail: info@dpma.de website: http://www.dpma.de
GREECE / GRECE	
Organisation de la propriété industrielle (OBI) Industrial Property Organization (OBI) 5 Pantanassis St. Paradissos Amaroussiou GR-151 25 Athens	Tel. 210 618 3500 Fax. 210 681 9231 e-mail : info@obi.gr website: http://www.obi.gr
HUNGARY / HONGRIE	
Office hongrois des brevets Hungarian Patent Office Magyar Szabadalmi Hivatal Garibaldi-utca 2 - B.P. 552 H-1370 Budapest	Tel. (36-1) 312 44 00 Fax. (36-1) 331 25 96 e-mail: mszh@hpo.hu website: http://www.hpo.hu
IRELAND / IRLANDE	
Ministère de l'entreprise, du commerce et de l'emploi - Office des brevets Department of Enterprise, Trade and Employment - Patent Office Government Buildings Hebron Road Kilkenny	Tel. (353-56) 7720111 Fax. (353-56) 7720100 e-mail: patlib@entemp.ie website: http://www.patentsoffice.ie
ITALY / ITALIE	
Ministère des activités productives	Tel. (39-6) 4705 5654

Direction générale de la production industrielle - Office italien des brevets et des marques Ministry of Production Activities Directorate General of Industrial Production Italian Patent and Trademark Office 19, via Molise I-00187 Roma	Fax. (39-6) 4705 3035 e-mail: info@uibm.gov.it website: http://www.uibm.gov.it/
LATVIA / LETTONIE	
Office des brevets de Lettonie Patent Office of the Republic of Latvia Citadeles iela 7/70 LV-1010 Riga	Tel. (+371) 7027 676 Fax (+371) 7027 690 e-mail: valde@lrpv.lv website: http://www.lrpv.lv
LITHUANIA / LITUANIE	
Bureau national des brevets de la républic de Lithuanie State Patent Bureau of the Republic of Lithuania Kalvariju str. 3 LT-2600 Vilnius	Tel. (370 5) 278 0250, 278 0290 Fax (370 5) 275 0723, 275 0733 e-mail: spb@vpb.lt; info@vpb.gov.lt Website: http://www.vpb.lt
LUXEMBOURG	
Ministère de l'économie Direction de la propriété intellectuelle Ministry of Economy Intellectual Property Office 19-21 Boulevard Royal L-2449 Luxembourg	Tel. (352) 478 4156 Fax. (352) 22 26 60 e-mail : dpi@eco.etat.lu website: http://www.eco.public.lu/
MALTA / MALTE	
Ministère de finance et des affaires économiques Division du commerce Ministry of Finance and Economic Affairs Commerce Division Lascaris Valletta CMR 02	Tel. (356) 25 69 03 04 Fax. (356) 21 23 19 19 e-mail : info@foi.org.mt website: http://www.foi.org.mt
THE NETHERLANDS / PAYS-BAS	
Office néerlandais de la propriété industrielle Netherlands Industrial Property Office Patentlaan 2 NL-2288 EE Rijswijk Bureau voor de Industriële Eigendom P.O. Box 5820	Tel. (31 70) 398 6655, 398 6699 Fax. (31 70) 390 0190, 398 6606 e-mail: publicksvoorlichting@bie.minez.nl Website: http://www.bie.minez.nl

NL-2280 HV Rijswijk	
POLAND / POLOGNE	
Office des brevets de la République de Pologne Patent Office of the Republic of Poland P.O. Box 203 00-950 Warsaw	Tel. (48 22) 825 80 01 Fax. (48 22) 875 06 80 e-mail: informacja@uprp.pl website: http://www.uprp.pl/
PORTUGAL	
Institut national de la propriété industrielle National Institute of Industrial Property Campo das Cebolas 1114-035 Lisboa	Tel. (351-21) Fax. (351-21) e-mail: cadm@inpi.pt website: http://www.inpi.pt
SLOVAKIA / SLOVAQUIE	
Office de la propriété industrielle de la République slovaque Industrial Property Office of the Slovak Republic ul. Jána Svermu 43 P.O. Box 7 974 04 Banská Bystrica 4	Tel. (421 48) 430 0111, 413 2572 Fax. (421 48) 413 2563, 413 5037 e-mail: upv@indprop.gov.sk Website: http://www.indprop.gov.sk/
SLOVENIA / SLOVÉNIE	
Office slovène de la propriété intellectuelle Slovenian Intellectual Property Office (SIPO) Kotnikova 6 SI-1000 Ljubljana	Tel. (386-1) 478 31 54 Fax. (386-1) 478 31 10 e-mail: info@uil-sipo.si Website: http://www.uil-sipo.si/
SPAIN / ESPAGNE	
Office espagnol des brevets et des marques Oficina Española de Patentes y Marcas Panamà 1 28071 Madrid	Tel. (34) 902 157 530 Fax. (34 91) 349 5597 e-mail: informacion@oepm.es Website: http://www.oepm.es
SWEDEN / SUÈDE	
Office suédois des brevets et de l'enregistrement Swedish Patent and Registration Office (SPRO) Patent department Box 5055 S-102 42 Stockholm Designs and Trademarks department Box 530	Tel. (46-8) 782 25 00, 782 25 00 Fax. (46-8) 666 02 86, 270-173 51 e-mail: prv.patent@prv.se; prv.varumarke@prv.se Website: http://www.prv.se

S-826 27 Söderhamn	
UNITED KINGDOM / ROYAUME-UNI	
Office des brevets The Patent Office Concept House Cardiff Road Newport, South Wales NP10 8QQ	Tel. (44) 1633 813930 Fax. (44) 1633 813600 e-mail: enquiries@patent.gov.uk website: http://www.patent.gov.uk

Non EC

BULGARIA / BULGARIE	
Office des brevets de la République de Bulgarie Patent Office of the Republic of Bulgaria 52 B, Dr. G.M. Dimitrov Blvd. 1040 Sofia	Tel. (359 2) 970 11 75 / 873 51 71/ 853 51 72 Fax. (359 2) 870 83 25 / 873 51 78 e-mail: bpo@bpo.bg website: http://www.bpo.bg
CROATIA / CROATIE	
Office national de la propriété intellectuelle de la République de Croatie State Intellectual Property Office of the Republic of Croatia Ulica grada Vukovara 78 10000 Zagreb	Tel. (385 1) 61 06 436 / 61 06 100 Fax. (385 1) 61 12 017 e-mail: website:
NORWAY / NORVÈGE	
Office norvégien des brevets Norwegian Patent Office Københavngaten 10 Postboks 8160 Dep. N-0033 Oslo	Tel. (47) 22 38 73 00 Fax. (47) 22 38 73 01 e-mail : mail@patentstyret.no Website: http://www.patentstyret.no
ROMANIA / ROUMANIE	
Office de l'Etat pour les Inventions et les Marques State Office for Inventions and Trademarks (OSIM) 5, Ion Ghica Str., Sector 3 P.O. Box 52 70018 Bucharest	Tel. (40-1) 315 90 66 Fax. (373-2) 312 38 19 e-mail: office@osim.ro website: http://www.osim.ro

LIST 8.2 –PLANT VARIETY RIGHT OFFICES

AUSTRIA / AUTRICHE	
Bundesamt für Ernährungssicherheit Institut für Sortenwesen Postfach 400 Spargelfeldstrasse 191 A-1226 Wien	Tel. (43-1) 732 16 40 00 Fax. (43-1) 732 16 42 11 e-mail: sortenwesen@ages.at website: http://www.lwvie.ages.at
BELGIUM / BELGIQUE	
Service public fédéral économie, P.M.E., Classes moyenne & energie Office de la Propriété Intellectuelle North Gate III – 5ème étage 16, bd du Roi Albert II B-1000 Bruxelles	Tel. (32-2) 206 5158 Fax. (32-2) 206 5750 e-mail: camille.vanslembrouck@mineco.fgov.be website: http://mineco.fgov.be/opri-die.htm
CYPRUS / CHYPRE	
No national authority	
CZECH REPUBLIC / RÉPUBLIQUE TCHÈQUE	
Central Institute for Supervising and Testing in Agriculture Department of Plant Variety Rights Za Opravnou 4 150 06 Praha 5 – Motol	Tel. (420-2) 572 11755 Fax. (420-2) 572 11752 e-mail: motol@ooz.zeus.cz website: http://www.ukzuz.cz/en/index.php
DENMARK / DANEMARK	
Minsitry of Food, Agriculture and Fisheries Danish Institute of Agricultural Sciences Department of Variety Testing Teglværksvej 10 Tystofte DK-4230 Skælskør	Tel. (45) 5816 06 00 Fax. (45) 5816 06 06 e-mail: afs.djf@agrsci.dk website: http://eng.agrsci.dk http://www.agrsci.org/
ESTONIA / ESTONIE	
Plant Production Inspectorate Variety Control Department Vabaduse plats 4	Tel./Fax (+372) 433 4650 e-mail: pille.ardel@plant.agri.ee website: http://www.plant.agri.ee

71020 Viljandi	
FINLAND / FINLANDE	
Plant Variety Board Plant Variety Rights Office Ministry of Agriculture and Forestry Hallituskatu 3a, Helsinki Box 30 FIN-00023 GOVERNMENT	Tel. (358-9) 160 3316 Fax. (358-9) 88663 e-mail: arto.vuori@mmm.fi website: http://www.mmm.fi
FRANCE	
Comité de la protection des obtentions végétales 11, rue Jean Nicot F-75007 Paris	Tel. (33-1) 42 75 93 14 Telex 250 648 Fax. (33-1) 42 75 94 25 website: http://www.geves.fr
GERMANY / ALLEMAGNE	
Bundessortenamt Postfach 61 04 40 D-30604 Hannover	Tel. (49-511) 9566-5 Fax. (49-511) 563362 e-mail: bsa@bundessortenamt.de website: http://www.bundessortenamt.de
GREECE / GRECE	
No national authority	
HUNGARY / HONGRIE	
Hungarian Patent Office Magyar Szabadalmi Hivatal Garibaldi-u.2 - B.P. 552 H-1370 Budapest	Tel. (36-1) 312 44 00, 331 3992 Fax. (36-1) 311 48 41, 331 25 96 e-mail: mszh@hungary.com website: http://www.hpo.hu
IRELAND / IRLANDE	
Controller of Plant Breeders' Rights Department of Agriculture and Food Backweston Leixlip Co. Kildare	Tel. (353) 1-628 0608 Fax. (353) 1-628 0634 e-mail: backwest@agriculture.gov.ie website: http://www.gov.ie/daff
ITALY / ITALIE	
Ufficio Italiano Brevetti e Marchi Ministero delle attività produttive 19, via Molise I-00187 Roma	Tel. (39-06) 47 05 1, 488 43 54 (Div. IV) Fax. (39-06) 47 05 30 35 e-mail: segreteria.dgspc@minindustria.it website: http://www.minindustria.it
LATVIA / LETTONIE	
Plant Variety Testing	Tel. (+371) 7365567

Department State Plant Protection Service Lubānas ielā, 49 1073 Riga	Fax (+371) 7365571 e-mail: info@vaad.gov.lv, assd@vaad.gov.lv website: http://www.vaad.gov.lv
LITHUANIA / LITUANIE	
Lithuanian State Plant Varieties Testing Centre Smelio st. 8 LT-2055 Vilnius Lithuania	Tel. (370 5) 234 3647 Fax (370 5) 234 1862 e-mail: sigitaavtc@takas.lt Website: http://www.avtc.lt
LUXEMBOURG	
No national authority	
MALTA / MALTE	
No national authority	
POLAND / POLOGNE	
Research Center for Cultivar Testing (COBORU) 63-022 Slupia Wielka	Tel. (48-61) 285 23 41 Fax. (48-61) 285 35 58 e-mail: coboru@bptnet.pl website: http://www.coboru.pl
PORTUGAL	
Centro Nacional de Registo de Variedades Protegidas (CENARVE) Edificio II da DGPC Tapada da Ajuda P-1300 Lisboa	Tel. (351-213) 613 216 Fax. (351-213) 613 222 e-mail: info@dgpc.min-agricultura.pt website: http://www.dgpc.min-agricultura.pt
SLOVAKIA / SLOVAQUIE	
Ministry of Agriculture Dobrovicova 12 812 66 Bratislava	Tel. (421-7) 306 62 90 Fax. (421-7) 306 62 94 e-mail: tlacove@land.gov.sk Website: http://www.mpsr.sk/english/index.htm http://www.uksup.sk/
SLOVENIA / SLOVÉNIE	
Phytosanitary Administration of the Republic of Slovenia Ministry of Agriculture, Forestry and Food (MAFF) Einspielerjeva 6 1000 Ljubljana	Tel. (386-1) 3094 396 Fax. (386-1) 3094 335 e-mail: furs.mkgp@gov.si Website: http://www.furs.si
SPAIN / ESPAGNE	
Oficina Española de Variedades Vegetales (OEVV)	Tel. (34) 91 347 65 93 Fax. (34) 91 347 67 03 Website: http://www.mapya.es

Ministerio de Agricultura, Pesca y Alimentación Av. Ciudad de Barcelona N° 6 Madrid 28007	
SWEDEN / SUÈDE	
Statens växtsortnämnd National Plant Variety Board Box 1247 S-171 24 Solna	Tel. (46-8) 783 12 60, 783 12 61 Fax. (46-8) 83 31 70 e-mail: info@vaxtsortnamnden.se Website: http://www.vaxtsortnamnden.se http://www.svn.se/
THE NETHERLANDS / PAYS-BAS	
Raad voor het Kwekersrecht *(Board for Plant Breeders' Rights)* Postbus 27 NL-6710 BA Ede	Tel. (31-318) 82 25 80 Fax. (31-318) 82 25 89 e-mail: raad.kwekersrecht@rkr.agro.nl Website: http://www.kwekersrecht.nl
UNITED KINGDOM / ROYAUME-UNI	
Department for Environment, Food & Rural Affairs (DEFRA) The Plant Variety Rights Office and Seeds Division White House Lane Huntingdon Road Cambridge CB3 0LF	Tel. (44-1223) 34 23 81 Telex 817 422 pvscam g Fax. (44-1223) 34 23 86 e-mail: mike.wray@defra.gsi.gov.uk website: www.defra.gov.uk/planth/pvs/default.htm

Non EC

BULGARIA / BULGARIE	
State Patent Office of the Republic of Bulgaria 52 B, Dr. G.M. Dimitrov Blvd. BG-1040 Sofia Central Office "Variety Testing" Executive Agency for Variety Testing, Field Inspection and Seed Control (IASAS) 125 Tzarigradsko shose Blvd. Block 1 1113 Sofia	Tel. (359-2) 873 51 75 Fax. (359-2) 873 51 78 e-mail: bpo@bg.net website: http://www.bpo.bg Tel. (359-2) 700 375 Fax. (359-2) 71 36 35
CROATIA / CROATIE	
Institute for Seed and Seedlings Vinkovacka cesta 63c 31000 Osijek	Tel. (385-31) 275 206 Fax. (385-31) 275 193 e-mail: r.ore@zsr.hr website: http://www.zsr.hr/main.htm
NORWAY / NORVÈGE	
Plantesortsnemnda *(The Plant Variety Board)* P.O. Box 3 N-1431 Ås	Tel. (47) 64 94 44 00 Fax. (47) 64 94 44 10 Website: http://odin.dep.no/ld
ROMANIA / ROUMANIE	
State Office for Inventions and Trademarks (OSIM) 5, Ion Ghica Str., Sector 3 P.O. Box 52 70018 Bucharest	Tel. (40-1) 315 90 66 Fax. (373-2) 312 38 19 e-mail: office@osim.ro website: http://www.osim.ro

Glossary

Where glossary entries are quoted directly from key biotechnology legislation, the legal instrument is referenced at the end of the entry. Definitions may differ between legal instruments. Always refer to the definitions contained in legislation relating to your own area of interest.

Absence of zero risk

The commonly held belief that no technology or product carries a zero risk (for instance, to human health or the environment). Risks can be assessed, and then minimised by risk management. A regulatory decision on whether to accept the managed risk may take into account any accompanying benefits, costs and ethical considerations.

Autologous graft
"tissues removed and transplanted back to the same individual“
(Directive 2004/23/EC, preamble, paragraph 8).

Biological diversity

“the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.”
(Convention on Biological Diversity, Article 2).

Biosafety Clearing House

Part of the clearing house mechanism under the Convention on Biological Diversity, established in accordance with Article 20 of the Cartagena Protocol on Biosafety to:

"(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small

island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity".

Cell fusion

The formation of a hybrid cell produced by fusing two different cells. (European Commission's Biosociety Research Online, Bio-glossary).

(Somatic) Cell therapy

"use in humans of autologous (emanating from the patient himself), allogenic (coming from another human being), or xenogenic (coming from animals) somatic living cells, the biological characteristics of which have been substantially altered as a result of their manipulation to obtain a therapeutic, diagnostic or preventive effect through metabolic, pharmacological and immunological means." (Directive 2003/63/EC, Annex, Point 2).

Centres of origin and genetic diversity

Geographic area in which a particular species of plant first developed (centre of origin), or in which there is a high level of genetic diversity within a plant species (centre of genetic diversity).

Commission

"The European Commission is a politically independent collegial institution which embodies and defends the general interests of the European Union. Its virtually exclusive right of initiative in the field of legislation makes it the driving force of European integration. It prepares and then implements the legislative instruments adopted by the Council and the European Parliament in connection with Community policies.

The Commission also has powers of implementation, management and control. It is responsible for planning and implementing common policies, executing the budget and managing Community programmes. As 'guardian of the Treaties', it also ensures that European law is applied."
(Scadplus - Glossary, http://europa.eu.int/scadplus/glossary/european_commission_en.htm).

Community legal instruments

- “regulations: these are binding in their entirety and directly applicable in all Member States;
- directives: these bind the Member States as to the results to be achieved; they have to be transposed into the national legal framework and thus leave a margin for manoeuvre as to the form and means of implementation;
- decisions: these are fully binding on those to whom they are addressed;
- recommendations and opinions: these are non-binding, declaratory instruments.”

(Scadplus – Glossary – http://europa.eu.int/scadplus/glossary/community_legal_instruments_en.htm).

Competent authority

Competent authorities are bodies established by particular regulations or directives to perform administrative functions.

Contained use

"any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with the general population and the environment"
(Directive 90/219/EEC as amended, Article 2).

Council of Ministers

“The Council of the European Union (the ‘Council of Ministers’ or the ‘Council’) is the Union’s main decision-making institution. It is composed of the ministers of the Member States and thus constitutes the EU institution in which the governments of the Member States are represented.”
(Scadplus – Glossary – http://europa.eu.int/scadplus/glossary/eu_council_en.htm).

Decision

see ‘Community legal instruments’.

Deliberate release

“any intentional introduction into the environment of a GMO or a combination of GMOs for which no 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.”
(Directive 2001/18/EC, Article 2.3).

Directive

see ‘Community legal instruments’.

Directorate-General

An organisational unit within the Commission, generally focused on a particular policy area.

Environmental risk assessment

“the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose”
(Directive 2001/18/EC, Article 2.8).

Feed additive

“substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3)”, such as having a favourable effect on animal production, performance or welfare, or the characteristics of feed or animal products.
(Regulation (EC) No 1831/2003, Article 2.2(a)).

Genetically modified micro-organism

“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 following techniques:

"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."

(ii) the following techniques 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 techniques/methods excluded by Annex II, Part A of Directive 90/219/EEC as amended:

"(1) in vitro fertilisation;

(2) natural processes such as: conjugation, transduction, transformation;

(3) polyploidy induction."

(Directive 90/219/EEC as amended, Article 2 and Annex I).

Genetically modified organism

“an organism, with the exception of human beings, 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,

(a) genetic modification occurs at least through the use of the following techniques:

"(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 an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

(3) cell fusion (including protoplast 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."

(b) the following techniques are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Annex I B of Directive 2001/18/EC:

"(1) in vitro fertilisation,

(2) natural processes such as: conjugation, transduction, transformation,

(3) polyploidy induction."

(Directive 2001/18/EC, Article 2 and Annex I A).

Gene therapy

“uses purified preparations of a gene or a fraction of a gene to treat a disease. This can be done either by correcting the functioning of a cell in which a single gene does not work properly from birth or sometimes by killing a cell which is out of control.”
(Gene Therapy: The Great Debate, 2nd Edition, 1996, http://europa.eu.int/comm/research/biomed/therapy.pdf).

A gene therapy product is defined in Annex I to Directive 2001/83/EC as “a product obtained through a set of manufacturing processes aimed at the transfer, to be performed either in vivo or ex vivo, of a prophylactic, diagnostic or therapeutic gene (i.e. a piece of nucleic acid), to human/animal cells and its subsequent expression in vivo.

Gene therapy may be redefined under forthcoming legislation. Related approaches such as RNA interference (RNAi) technology are emerging, and may in the future be applied therapeutically.

Genetically modified food

“food containing, consisting of or produced from GMOs”
(Regulation (EC) No 1829/2003, Article 2.6).

Genetically modified feed

“feed containing, consisting of or produced from GMOs”
(Regulation (EC) No 1829/2003, Article 2.7).

Insert

The genetic material inserted into an organism during genetic modification.

Lot numbering

A form of identification system allowing tracing of food and feed.

Maximum residue limit

“the maximum concentration of residue resulting from the use of an additive in animal nutrition which may be accepted by the Community as being legally permitted or recognised as acceptable in or on food.” (Regulation (EC) No 1831/2003, Article 2.2 (l)).

Mutagenesis

The causing of mutations (genetic changes) which are stable and can be inherited.

Nucleotide sequence

The order of occurrence of chemical residues, known as nucleotides or bases, in DNA or RNA.

Official Journal

The *Official Journal of the European Communities* is a publication in which all Regulations and Directives must be published.

Packing group (for dangerous goods)

Dangerous goods may be assigned to one of three packing groups according to the level of danger they pose (I - high; II - medium; III - low). Not all dangerous goods are assigned to a packing group.

'Party' in the context of transboundary movements

"any country or regional economic integration organisation being Party to the Protocol." That is the Cartagena Protocol on Biosafety.
(Regulation (EC) No 1946/2003, Article 3.5).

Placing on the market

"making available to third parties, whether in return for payment or free of charge."
(Directive 2001/18/EC, Article 2.4; other legal instruments contain differing definitions of placing on the market).

Precautionary principle

"Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."
(1992 Rio Declaration on Environment and Development, Principle 15, http://www.unep.org/Documents.Multilingual/Default.asp?ArticleID=1163&DocumentID=78&l=en). Other versions of the precautionary principle have emerged, for instance in relation to risks to human health.

Recommendation

see 'Community legal instruments'.

Regulation

see 'Community legal instruments'.

Risk assessment

"a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation" (Regulation (EC) No 178/2002, Article 3).

Risk management

"the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options"
(Regulation (EC) No 178/2002, Article 3).

Scadplus

Scadplus is the name of a European Union website that provides summaries of European legislation. It can be found at: http://europa.eu.int/scadplus/.

Scientific uncertainty

“Scientific uncertainty results usually from five characteristics of the scientific method: the variable chosen, the measurements made, the samples drawn, the models used and the causal relationship employed. Scientific uncertainty may also arise from a controversy on existing data or lack of some relevant data. Uncertainty may relate to qualitative or quantitative elements of the analysis.” (Communication from the Commission on the Precautionary Principle, COM(2000)1, Brussels, 02/02/2000, http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf).

Self-cloning

Self-cloning means “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.”
(Directive 98/81/EC, Annex II, Part A).

Shipping name (for dangerous goods)

The shipping name is the name in the Dangerous Goods List that most accurately describes the good while it is being transported.

Somatic cell

Cells other than sperm or egg cells, which are not naturally involved in conceiving children.

Specific identification system

A system which allows goods to be easily traced.

Technical name (for dangerous goods)

The technical name is a generally recognised chemical, biological or other technical name used in scientific or technical documents.

Threshold for adventitious or technically unavoidable presence of GMOs

The threshold below which the presence of authorised GMOs does not trigger labelling and traceability requirements, provided that appropriate steps have been taken to avoid the presence of such materials (Regulation (EC) No 1829/2003, Articles 12 and 24). The burden of proof is on the operator.

Traceability

“the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.”
(Regulation (EC) No 178/2002, Article 3.15).

Transboundary movement

"the intentional or unintentional movement of a GMO between one Party or non-Party and another Party or non-Party, excluding intentional movements betwen Parties within the Community."
(Regulation EC No 1946/2003, Article 3.14).

Unique identifier

“a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorised transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO.” (Regulation EC No 1830/2003, Article 3.4).

UN Number

Four digit code, recognised internationally, used to identify hazardous articles and substances during transport.

Xenogenic cell

"a biological cell derived from a different biological species (in the context of cell therapy)"
(UK Biotechnology Regulatory Atlas)

Xenotransplantation

“The use of living, non-human animal organs, tissues or cells in human patients” (Research Projects – Xenotransplantation: ethical, social, economical and legal aspects, http://europa.eu.int/comm/research/biosociety/research_projects/xenotransplantation_en.htm).

Abbreviations

ADN – European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterway (ADN)

ADR – European Agreement concerning the International Carriage of Dangerous Goods by Road

BCH – Biosafety Clearing House

CHMP – Committee for Medicinal Products for Human Use

COMP – Committee for Orphan Medicinal Products

CPVO – Community Plant Variety Office

CRL – Community Reference Laboratory

CVMP – Committee for Medicinal Products for Veterinary Use

DG – Directorate-General

DG Agri – Directorate-General Agriculture

DG Entr – Directorate-General Enterprise and Industry

DG Env – Directorate-General Environment

DG Markt – Directorate-General Internal Market

DG SANCO – Directorate-General Health and Consumer Protection

DGSA – Dangerous Goods Safety Adviser

EFSA – European Food Safety Authority

EMEA – European Medicines Agency

EPO – European Patent Office

ERA – Environmental Risk Assessment

Eur-Lex – Portal to European law

GLP – Good Laboratory Practice

GM – Genetically modified

GMM – Genetically modified micro-organism

GMO – Genetically modified organism

GMP – Good Manufacturing Practice

HMPC – Committee for Herbal Medicinal Products

ICAO – International Civil Aviation Organisation

IMDG Code – International Maritime Dangerous Goods Code

IP – Intellectual property

JRC – Joint Research Centre of the European Commission

OECD – Organisation for Economic Cooperation and Development

PCT – Patent Cooperation Treaty

R & D – Research and development

RID – Regulations Concerning the International Carriage of Dangerous Goods by Rail

TRIPS – Agreement on Trade Related Aspects of Intellectual Property Rights

UNECE – United Nations Economic Commission for Europe

UPOV – International Convention for the Protection of New Varieties of Plants

WIPO – World Intellectual Property Organisation

WTO – World Trade Organisation

COMMUNITY LEVEL CONTACT POINTS

BIOTECHNOLOGY INDUSTRY

Directorate-General Enterprise and Industry:

Biotechnology – Unit F5:

Biotechnology – Unit F5
Enterprise Directorate-General
European Commission
B-1049 Brussels
Belgium
Tel: + 32 2 299 9665
Fax: + 32 2 295 7637
E-mail: ec-biotechnology@cec.eu.int
Biotechnology industry webpage:
http://europa.eu.int/comm/enterprise/faq/en/biotechnology_en.htm

COEXISTENCE OF GM, CONVENTIONAL AND ORGANIC AGRICULTURE

Directorate-General Agriculture and Rural Development:

Unit F1 – Environment, GMO and Genetic Resources:

Mr. Leo Maier, Head of Unit
Tel: +32 2 299 8195
E-mail: leo.maier@cec.eu.int

Mr. Andreas Gumbert. Coexistence of GM crop production with organic and conventional agriculture.
Tel: +32 2 296 9916
E-mail: Andreas.gumbert@cec.eu.int

Mrs. Caroline Raes. Coexistence of GM crop production with organic and conventional agriculture.
Tel: +32 2 296 6694
E-mail: caroline.raes@cec.eu.int

ETHICS

European Group on Ethics

Secretariat of the EGE
European Commission
BERL 8/261
B-1049 Brussels
Belgium
Tel: + 32 2 295 4565
E-mail: BEPA-ETHICS-GROUP@cec.eu.int
Website: http://europa.eu.int/comm/european_group_ethics/index_en.htm

Head of the EGE Secretariat, Michael D. Rogers, Michael.Rogers@cec.eu.int,
Tel: + 32 2 295 0641

GM FOOD/FEED

Community Register of GM Food/Feed:
http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm

European Food Safety Authority:

General:

European Food Safety Authority
Largo N. Palli 5/A
I-43100 Parma
Italy
Tel: + 39 0521 036111
Fax: + 39 0521 036110
E-mail: info@efsa.eu.int
Website: http://www.efsa.eu.int/

Animal Health and Welfare:

Head of Team, Jordi Serratosa Vilageliu, Tel: + 39 0521 036238,
Jordi.Serratosa@efsa.eu.int

Secretary, Silvie Mateljan, Tel: +39 0521 036220, Silvie.Mateljan@efsa.eu.int

Secretary, Norma-Maria Sanchez Alvarez, Tel: + 39 0521 036284

Secretary, Elizabeth Moore, Tel: + 39 0521 036412,
Elizabeth.Moore@efsa.eu.int

Unit on additives and products or substances used in animal feed (FEEDAP):

Head of Team, Liisa Vahteristo, Tel: + 39 0521 036227,
Liisa.Vahteristo@efsa.eu.int

Secretary, Dominique Byron, Tel: + 39 0521 036252,
Dominique.Byron@efsa.eu.int

Secretary, Sandra Ziakas, Tel: + 39 0521 036296, Sandra.Ziakis@efsa.eu.int

Secretary, Caroline Baltus, Tel: + 39 0521 036455, Caroline.Baltus@efsa.eu.int

Feed additives query contact e-mail FEEDADDITIVES@efsa.eu.int

Unit on genetically modified organisms (GMO):

Head of Team, Suzy Renckens, Tel: + 39 0521 036223,
Suzy.Renckens@efsa.eu.int

Secretary GMO Panel, Susan Parker, Tel: + 39 0521 036265,
Susan.Parker@efsa.eu.int

Secretary GM food/feed applications, Jane Quist, Tel: + 39 0521 036246,
Jane.Quist@efsa.eu.int

Secretary, Claudine Ziegelmeyer, Tel: + 39 0521 036496,
Claudine.Ziegelmeyer@efsa.eu.int

GMO Panel website: http://www.efsa.eu.int/science/gmo/catindex_en.html

Community Reference Laboratory - GM food and feed:

Guy Van den Eede
Head of Biotechnology and GMOs Unit
European Commission
Directorate-General Joint Research Centre
21020 Ispra
Italy
Fax: + 39 0332 785483
E-mail: JRC-BGMO@cec.eu.int
Website: http://gmo-crl.jrc.it/

Community Reference Laboratory - Feed Additives Authorisation:

Dr. Christoph von Holst
Operating Manager
Community Reference Laboratory – Feed Additives Authorisation
European Commission

Directorate-General Joint Research Centre
Institute for Reference Materials and Measurements
Retieseweg 111
B-2440 Geel
Belgium
Tel: + 32 1 457 1211
Fax: + 32 1 457 1787
E-mail: christoph.von-holst@cec.eu.int

Mrs Machteld De Smet
European Commission
Directorate-General Joint Research Centre
Institute for Reference Materials and Measurements
Retieseweg 111
B-2440 Geel
Belgium
Tel: + 32 1 457 1691
Fax: + 32 1 457 1787
E-mail: jrc-irmm-fsq-crl@cec.eu.int

Website: http://www.irmm.jrc.be/html/crlfaa

Directorate-General Health and Consumer Protection:

European Commission
DG Health and Consumer Protection
B-1049 Brussels
Belgium

Biotechnology website:
http://europa.eu.int/comm/food/food/biotechnology/index_en.htm

GMOs: CONTAINED USE, DELIBERATE RELEASE, AND TRANSBOUNDARY MOVEMENT

Directorate-General Environment

Unit B4 – Biotechnology and Pesticides :

Mr Hervé Martin, Head of Unit
Tel: +32 2 296 5444
E-mail: herve.martin@cec.eu.int

Ms Aurélie André, Policy Officer. Implementation of the Directive on the deliberate release of genetically modified organisms, technical aspects of the Cartagena Protocol on Biosafety.
Tel: +32 2 295 5831
E-mail: aurelie.andre@cec.eu.int

Policy Officer - Horizontal legal aspects. Implementation of the Cartagena Protocol on Biosafety in Community legislation. GMO aspects of the Aarhus Convention. Evaluation of national measures on coexistence. Infringement and speech writing correspondent. Comitology.
Appointment pending.

Ms Kathryn Tierney, Policy Officer - Implementation of Directive 2001/18/EC on the deliberate release into the environment of GMOs
Tel: +32 2 296 8118
E-mail: kathryn.tierney@cec.eu.int

Mr Andrew Tommey, Policy Officer - development and legislation concerning the deliberate release into the environment and contained use of genetically modified organisms (GMOs) and micro-organisms (GMMs).
Tel: +32 2 299 2482
E-mail: andrew.tommey@cec.eu.int

Mr Werner Bosmans, Policy Officer - Technical expert on the implementation of the Directives on the contained use of genetically modified micro-organisms and the deliberate release of genetically modified organisms.
Tel: +32 2 296 7282
E-mail: Werner.bosmans@cec.eu.int

Ms Bénédicte Vroye, Administrative Assistant, Circulation of part C of Directive 2001/18/EC, IT Correspondent
Tel: +32 2 295 3196
E-mail: benedicte.vroye@cec.eu.int

E-mail for notifications from Part C of Directive 2001/18/EC :
env-dir-2001-18-notifications-part-c@cec.eu.int

Webpage : http://europa.eu.int/comm/environment/biotechnology/index_en.htm

Unit E2 - Environmental Agreements and Trade:

Mr Matthias Buck, General coordination of Commission relations with the Convention on Biological Diversity, in particular : The Cartagena Protocol on Biosafety, Legal issues, Access and Benefit Sharing, Traditional Knowledge and

Indigenous people.
Tel: +32 2 295 8264
E-mail: matthias.buck@cec.eu.int

HEALTH AND SAFETY AT WORK

Directorate-General Employment, Social Affairs and Equal Opportunities:

Unit D4: Health, Safety and Hygiene at Work
Head of Unit: Jose Biosca de Sagastuy, jose.biosca-de-sagastuy@cec.eu.int,
Tel: + 35 24301 34988

European Agency for Health and Safety at Work:

Website: http://europe.osha.eu.int

INTELLECTUAL PROPERTY RIGHTS

European Patent Office:

European Patent Office
Erhardtstrasse 27
D-80298 Munich
Germany
Tel: +49 89 2399 0
Fax: +49 89 2399 4560 (Administration)
Fax: +49 89 2399 4465 (Patent)
Website: http://www.european-patent-office.org/epo/

Community Plant Variety Office:

Community Plant Variety Office
P.O. Box 2141
F-49021 Angers Cedex
02
France
Tel: +33 2 4125 6432
Fax: +33 2 4125 6410
Website: www.cpvo.eu.int

Directorate-General Enterprise and Industry:

Intellectual Property Rights Helpdesk:

Project Management Office
IPR-Helpdesk
Germán Benácer Building
Universidad de Alicante
Po Box 99
03088 Alicante
Spain
Tel: + 34 965 909 798
Fax: + 34 965 909 715
E-mail: ipr-helpdesk@ua.es

Representative Office
IPR-Helpdesk
98, Rue du Trône
B-1050 Brussels
Belgium
Tel: + 32 2 213 4163
Fax: + 32 2 213 4169
E-mail: ipr-helpdesk@ua.es
Website: http://www.ipr-helpdesk.org/index.htm

Directorate-General Internal Market:

European Commission
Directorate-General for the Internal Market and Services
B-1049 Brussels
Belgium

Directorate D – Knowledge-Based Economy:

Unit D2 - Industrial Property
Erik Nooteboom, Deputy Mirjam Soderholm.

Internal Market information mailbox website:
http://europa.eu.int/comm/internal_market/contact/contact-info_en.htm

Contacts website:
http://europa.eu.int/comm/internal_market/contact/index_en.htm

Directorate-General Trade:

Trade Unit A2 Information
European Commission
200, Rue de la Loi
(CHAR 7/116)

B-1049 Brussels
Belgium
Tel: + 32 2 295 2888
Fax: + 32 2 296 9854
Website: http://trade-info.cec.eu.int/inforequest/index.cfm

LEGISLATION/LEGISLATIVE GUIDES

Eur-Lex
Website: http://europa.eu.int/eur-lex/lex/index.htm

Official Journal of the European Union:
Website: http://europa.eu.int/eur-lex/lex/JOIndex.do?ihmlang=en

Scadplus:
Website: http://europa.eu.int/scadplus/scad_en.htm

MEDICINAL PRODUCTS

Directorate-General Enterprise and Industry:

Pharmaceuticals – Unit F2:

Pharmaceuticals – Unit F2
Enterprise Directorate-General
European Commission
BREY 10/114
B-1049 Brussels
Belgium
Tel: + 32 2 295 9072
Fax: + 32 2 299 8046
E-mail: entr-pharmaceutic-regul@cec.eu.int
Website: http://pharmacos.eudra.org/F2/home.html

European Medicines Agency:

European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
UK

Tel: + 44 20 74 188 400
Fax: +44 20 74 188 416
General e-mail: mail@emea.eu.int
Information request e-mail: info@emea.eu.int
Website: http://www.emea.eu.int

Pharmacovigilance – Human Use:

Panos Tsintis
Tel: + 44 20 75 237 108
E-mail: Panos.tsintis@emea.eu.int

Pharmacovigilance – Veterinary Use:

Kornelia Grein
Tel: + 44 20 74 188 432
E-mail: vet-phv@emea.eu.int

Enquiries on certificates for centrally authorised medicines:

Tel: + 44 20 75 237 181
E-mail: certificate@emea.eu.int

Documentation Service:

Tel: + 44 20 74 188 582
Fax: + 44 20 74 188 670
E-mail: emearequests@emea.eu.int

European Experts List:

Tel: + 44 20 74 188 584
E-mail: europeanexperts@emea.eu.int

Integrated Quality Management:

Marijke Korteweg
Tel: + 44 20 72 188 556
E-mail: iqmanagement@emea.eu.int

Emerging Therapies:

Dr. Marisa Papaluca-Arnati, Tel: +44 20 74 188 436
Dr. Constantinos Ziogas, Tel: +44 20 74 188 463
E-mail: ITFsecretariat@emea.eu.int
Website: http://www.emea.eu.int/htms/human/itf/itfsupport.htm

SME Office

E-mail: smeoffice@emea.eu.int
EMEA Pre-Submission Unit:

Contact for guidance on pre-submission meetings:
Tony Humphreys, Head of Sector, Regulatory Affairs and Organisational Support,
Tel: + 44 20 74 188 583
Fax: + 44 20 75 237 051
E-mail: anthony.humphreys@emea.eu.int
Website: http://www.emea.eu.int/htms/human/presub/index.htm

EMEA Post-Authorisation Unit:
Website: http://www.emea.eu.int/htms/human/postguidance/index.htm

Committee on Human Medicinal Products:

Members contact addresses can be found at:
http://www.emea.eu.int/htms/general/contacts/CHMP.html

Committee on Veterinary Medicinal Products:

Members contact addresses can be found at:
http://www.emea.eu.int/htms/general/contacts/CVMP.html

Committee on Orphan Medicinal Products:

Members contact addresses can be found at:
http://www.emea.eu.int/htms/general/contacts/COMP.html

Committee on Herbal Medicinal Products:

Members contact addresses can be found at:
http://www.emea.eu.int/htms/general/contacts/HMPC.html

RESEARCH

Joint Research Centre:

European Commission
DG Joint Research Centre
Public Relations Unit
SDME 10/78

B-1049 Brussels
Belgium
Tel: + 32 2 295 7624
Fax: + 32 2 299 6322
E-mail: jrc-info@cec.eu.int
GMO Information website: http://gmoinfo.jrc.it/default.asp

Research Directorate-General:

Head of Unit E1, "Biotechnology, Agriculture and Food – Strategy and Policy Aspects", Manuel.Hallen@cec.eu.int

Policy aspects and scientific support to GMO legislation, Mark.Cantley@cec.eu.int, Maurice.Lex@cec.eu.int

EC life sciences and biotechnology strategy, Line-Gertrud.Matthiessen-Guyader@cec.eu.int, Elena.Sachez@cec.eu.int

International relations and the European Group on Life Sciences, Elisabetta.Balzi@cec.eu.int

Socio-economics and Communication, Alessio.Vassarotti@cec.eu.int

General matters, Marta.Iglesias@cec.eu.int, Jean-Francois.Maljean@cec.eu.int

Biosociety Research e-mail: Rtd-biosociety@cec.eu.int
Biosociety Research website:
http://europa.eu.int/comm/research/biosociety/index_en.htm

SCIENCE AND SOCIETY

Science and Society Programme:

Research Directorate-General
Directorate for Science and Society
Jean-Michel Baer, Director
Office SDME 7/66
B-1049 Brussels
Belgium
Fax: + 32 2 296 6020
rtd-sciencesociety@cec.eu.int
http://europa.eu.int/comm/research /science_society/index_en.html

General list of contacts within the Directorate for Science and Society:
http://europa.eu.int/comm/research/science-society/contacts_en.html.

SMEs

SME Envoy (Directorate-General Enterprise and Industry):

Fax: + 32 2 299 4143
E-mail: entr-sme-envoy@cec.eu.int

Innovation and SMEs (Directorate-General Research):

E-mail: Waldemar.Kutt@cec.eu.int

EMEA SME Office:

E-mail: smeoffice@emea.eu.int

STRATEGY

Biotechnology Strategy:

Biotechnology
European Commission – BEPA
(BERL 13/230)
Rue de la Loi, 200, Wetstraat
B-1049 Brussels
Belgium
Tel: + 32 2 295 9186
Fax: + 32 2 299 2223
http://europa.eu.int/comm/biotechnology/index.html

TRANSPORT OF DANGEROUS GOODS

Directorate-General Energy and Transport:

Website: http://europa.eu.int/comm/transport/index_en.html
See also entry on GMOs (transboundary movement).