Study – Means to improve the consistency and efficiency of the legislative framework in the field of biotechnology Article 31 (7a, 7b and 7d) of Directive 2001/18/EC

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EXECUTIVE SUMMARY

1. Introduction

Directive 2001/18/EC updates European Union (EU) law on the deliberate release into the environment of genetically modified organisms (GMOs). It replaces former Directive 90/220/EEC and entered fully into force on 17 October 2002.

Under Article 31(7) of the Directive, the Commission is to submit a report to the European Parliament and the Council on the operation of Part B and Part C of the Directive. This study will assist with the preparation of the report to the European Parliament and the Council, which will provide an assessment of the feasibility of various options for further improving the consistency and efficiency of the framework set out in the Directive. It also has to provide an evaluation of the implications and consequences of deliberate releases and placing on the market of GMOs in the EU.

This report is specifically concerned with Directive 2001/18/EC and the deliberate release of GMOs, although the wider framework is also considered. The vast majority of GMOs that have been developed to date for deliberate release are transgenic crop plants, modified to be tolerant to certain herbicides or resistant to certain insect pests. Consequently, much of the available information and experience relates to GM crops although, more recently, GM vaccines have also been trialled under the deliberate release regulations.

The Deliberate Release Directive is based on two regulatory regimes. Part B covers releases for research and development, and Part C covers placing on the market in the EU. In both cases, notification is made to the competent authority in the Member State where the release is to take place or where the GMO is to be placed on the market. If a Part C application is recommended for approval by the relevant Member State, then an EU-wide procedure allows for objections, which are to be resolved by voting if necessary. Final approval will then apply to all Member States. As a result, national legislation only covers certain aspects of the Part C approvals process. In contrast, decision-making on Part B releases is at the Member State level, and requires full implementation in national legislation.

The new Directive, adopted in February 2001, should have been fully implemented by 17 October 2002. To date, seven Member States have transposed the Directive into national legislation: Sweden, Denmark, UK, Portugal, Italy, the Republic of Ireland and Spain. The remaining countries have been taken to court by the Commission for non-transposition.

2. Operation of Part B

The number of Part B applications depends largely on the potential for obtaining Part C consents. Thus whilst uncertainty remains on the

authorisation process for Part C releases, there will be a related impact on Part B applications. In addition, the relatively recent transposition of Directive 2001/18/EC in some countries, and the failure of other Member States to transpose the Directive, means that there is little experience of the new Directive in practice and stakeholders are faced with different approaches across the EU. However, there is evidence to suggest that countries which have not yet transposed the Directive still process a number of Part B applications, thus any inconsistencies experienced by industry are more likely to be related to the political situation than to the regulatory situation.

The revision of Directive 90/220/EEC in the form of Directive 2001/18/EC aimed to address certain aspects of the authorisation process for Part B releases. Increased requirements for the environmental risk assessment (ERA) appear to be assisting a move towards harmonisation across the EU and to address the possible longer term, direct, indirect, delayed and cumulative effects on the environment and wildlife of releasing and using GMOs. However, issues of definition still remain; most significantly, acceptable risk remains undefined. Whilst some stakeholders consider it important that Member States should be able to make decisions according to national ethical principles, variations in interpretation of this term may lead to major differences amongst Member States and further uncertainty for industry. In this situation it is unlikely that Member States will take decisions about GMO releases on a consistent basis.

Consultation with the public on experimental releases of GMOs and information to the public on the release of all GMOs is seen as a key change in the new Directive. Whilst public interest groups welcome the formalisation of consultation processes, there is frustration that socio-economic and ethical objections appear to have no place in the decision-making process. Furthermore, where GMO releases may be regulated under different legislation, for example gene therapy trials, the potential for public consultation may be reduced. As experience increases it may be necessary to consider improvements to the provisions for public information and consultation in the Directive.

3. Operation of Part C

Practical experience with the operation of Part C has been limited as Directive 2001/18/EC only came into force on 17 October 2002 and, as would be expected, the number of Part C applications is generally less than Part B applications. Although the absence of regulations on traceability and labelling were cited as the main problem under Directive 90/220/EEC, the recent adoption of Regulation (EC) No 1830/2003 concerning the traceability and labelling of GMOs and the traceability of genetically modified food and feed products may not be enough to ease the current uncertainty in the approvals process. Further issues related to coexistence and liability, although issues of subsidiarity and, thus, to be dealt with by individual Member States, may need to be resolved to increase the acceptability of commercial releases of GMOs for certain stakeholders. As they are to be largely addressed on the basis of

subsidiarity, such issues perhaps relate more to the uptake of the technology than the smooth functioning of the Directive. As such, while coexistence and liability issues may present obstacles to the process, this is a matter for arrangements at Member State level rather than Commission level.

However, the overall number of applications for Part C authorisations under Directive 2001/18/EC is likely to be reduced in the near future as GM crops can be authorised under Regulation (EC) No 1829/2003 on genetically modified food and feed and GM medicines under Regulation 2309/93. Thus the authorisation of GMOs under alternative regulations raises questions about the effectiveness of central authorization bodies to effectively assess the environmental impacts of the GMOs, particularly at a regional level.

Furthermore, significant differences in Member States' current approaches to post-market monitoring may result in uncertainty for industry, which may favour certain countries. Further clarification is required to ensure a more harmonised approach across the EU, but the need for flexibility to consider different ecosystems and regional situations is likely to limit the degree to which this can be achieved.

4. Improving the Consistency and Efficiency of Directive 2001/18/EC

Although many stakeholders believe that Directive 2001/18/EC, and the associated framework, will assist with removing uncertainty in the decision-making process, a number of outstanding issues remain, including:

- national implementation of Directive 2001/18/EC;
- the coexistence measures and liability issues to be addressed on the basis of subsidiarity (and so not within the remit of the Directive); and
- the need for clearer guidance in a number of areas for all stakeholders.

There is still uncertainty in the authorisation procedures, and the need for clearer guidance for both Competent Authorities and industry and research organisations was identified in relation to the environmental risk assessment, post-market monitoring, and the use of antibiotic resistance markers (ARMs). In addition, the whole process (i.e. forms and guidance) is directed towards GM plants. Specific guidance should be developed on the authorisation of non-plant GMOs, both for Competent Authorities and for industry and research organisations.

In order to assist innovation it may be necessary to have a flexible approach towards the ten year limit for Part C consents, with respect to other authorisations which also have to be obtained at the same time, so that unnecessary delays that reduce the ten year limit are avoided. This would, however, require an amendment of the Directive. Furthermore, industry suggests that research material developed as a contained use in the EU, but exported for experimental deliberate release should be exempted from the

Advance Informed Agreement (AIA) procedure, in order not to block exchange of research material with non-EU countries.

Directive 2001/18/EC provides for public information and national procedures for consultation. As more experience is gained, improvement of the Directive may need to be considered. A clear procedure is needed for how public comments should be taken into account, including those to do with ethical and socio-economic principles, so that all stakeholders are aware of the process. In addition, clearer guidance on the timeframe for consultation is needed.

Furthermore, the final decision-making by the Commission on applications under Directive 2001/18/EC, Regulation (EC) 1829/2003 and Regulation (EEC) 2309/93 should transparently explain how comments and objections received from CAs and other parties have been considered.

The introduction of Regulation (EC) 1830/2003 on traceability and labelling assists with ensuring consumer choice. However, further guidance and consideration is needed on:

- the development of homogenous traceability systems and sampling methods;
- the verification of labelling of food and feed produced from GMOs but containing no GM material;
- the traceability requirements for farm-saved seed; and
- thresholds for the adventitious presence of GMOs not authorised in the EU and not having benefited from a favourable risk evaluation by the Community Scientific Committees or EFSA before the date of application of the new Regulation 1829/2003.

Areas which were identified as lacking data and information include rates of gene flow and introgression, the efficacy of measures to limit pollen flow and information on the environmental impact of different methods of conventional farming against which to compare the findings from GM crop monitoring.

Industry stakeholders generally advocated the establishment of a centralised EU approval procedure. It was also suggested that GMO authorisation procedures should be modelled after the authorisation procedure followed by the European Agency for the evaluation of Medicinal Products (EMEA). This centralised procedure, in relation to GM medicines, has been criticised by COGEM (2003) for lacking transparency and expert consideration of environmental risk assessments.

Some stakeholders have requested further guidance on the interaction between different pieces of legislation and how these will work in practice. It is therefore necessary to provide a detailed description of the decision-making process under Directive 2001/18/EC, Regulation (EC) No 1829/2003 and Regulation (EEC) 2309/93 on the websites of the JRC, EFSA and EMEA.

Although a number of outstanding issues remain, it is noted that the Commission is already taking action to address some of the issues, for

example in relation to the provision of location details of trials, the establishment of a Working Groups on ARMs and post-market monitoring, and development of guidance on sampling and testing in the context of Regulation 1830/2003.

CONTENTS

1. INTRODUCTION

1.1 Background

Directive 2001/18/EC updates European Union (EU) law on the deliberate release into the environment of genetically modified organisms (GMOs). It replaces former Directive 90/220/EEC and entered fully into force on 17 October 2002.

Under Article 31(7) of the Directive, the Commission is to submit a report to the European Parliament and the Council on the operation of Part B and Part C of the Directive. This study will assist with the preparation of the report to the European Parliament and the Council, which will provide an assessment of the feasibility of various options for further improving the consistency and efficiency of the framework set out in the Directive. It also has to provide an evaluation of the implications and consequences of deliberate releases and placing on the market of GMOs in the EU.

1.2 Objectives of the Study

The objectives of this study are:

- to prepare an overview and an analysis of available data on existing Community legislation in the field of biotechnology;
- to describe experiences with the implementation of Part B and Part C before and after 17 October 2002, including the different implications of the operation of Part B and Part C;
- to analyse and evaluate the environmental and socio-economic implications of deliberate releases and placing on the market of GMOs;
- to present the identification of data and knowledge gaps as well as bottlenecks and how to overcome these gaps and bottlenecks; and
- to recommend - if necessary - how to strengthen the consistency and efficiency of the legislative framework.

The Project Specification is reproduced in Annex I.

1.3 Approach to Study

A start-up meeting was held in Brussels on 10 September 2003. This is reported in more detail in the first interim report, which was submitted to the Commission on 7 October 2003. A further meeting was held with the Commission on 3 December 2003 following submission of the second interim report.

Four target groups of stakeholders were identified, in agreement with the Commission:

- Competent Authorities;
- industry and research organisations;
- public interest groups; and
- farmers' organisations.

Questionnaires were produced for each of the target groups and were distributed to stakeholders during October 2003. These questionnaires are reproduced in Annex II, and a list of consultees is provided in Annex III. Table 1.1 shows the number of questionnaires distributed and the number of responses received. In some cases the respondent did not complete the questionnaire; instead telephone or face-to-face interviews were held, following the format of the questionnaire.

Table 1.1: Overview of Questionnaire Consultation

Stakeholder Group	Number of Questionnaires Distributed[1]	Number of Completed Questionnaires Received	Number of Other Responses Received
Competent Authorities	18	12	1
Industry and Research	50	12	7
Public Interest Groups	30	6	5
Farmers Organisations	11	0	1
Total	**109**	**29**	**14**

[1] These figures have been adjusted from those presented in the interim reports. These figures represent the number of different organisations contacted, rather than national offices within each organisation, and are more representative since GMO-related issues are more often dealt with at a European level.

Responses were received from Competent Authorities in 13 Member States: Austria, Belgium, Finland, France, Denmark, Germany, Ireland, Italy, the Netherlands, Portugal, Spain, Sweden and the UK. However, the Competent Authority for Finland indicated that it did not have enough experience with Directive 2001/18/EC to provide an informed response to the questionnaire. No responses were received from Greece and Luxembourg. Detailed follow-up interviews were held with the Competent Authorities in Austria, France, Germany, the Netherlands, Spain and the UK.

In addition to the completed questionnaires, a number of responses were received from industry and research organisations which indicated that respondents had no experience of Directive 2001/18/EC, either because they are discouraged from submitting applications by the general political environment or because their national government has not yet implemented the relevant legislation. Such responses indicate a general dissatisfaction with the current situation.

Similarly, responses from some public interest groups indicated that their experience is with the broader implications of GMOs rather than the legislative framework per se and they were thus unable to provide a considered response. In addition, the relatively recent adoption of new regulations, the lack of applications in some Member States and/or the lack of national transposition has reduced experience with Directive 2001/18/EC. It is

likely that a number of other public interest groups and farmers' organisations contacted, which did not provide any response, are in a similar position.

1.4 Organisation of Report

This report follows the format required by the Project Specification, with:

- a critical overview of European legislation in the field of biotechnology provided in Section 2, with further detail in Annex IV;
- Section 3 evaluates the operation of Part B of Directive 2001/18/EC;
- Part C of Directive 2001/18/EC is evaluated in Section 4; and
- recommendations for improving the consistency and efficiency of Directive 2001/18/EC are given in Section 5.

2. OVERVIEW OF THE LEGISLATIVE FRAMEWORK

2.1 Introduction

A Genetically Modified Organism (GMO) is defined in Directive 2001/18/EC 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*".

Whether released into the environment in small amounts for experimental purposes or in large amounts as commercial products, GMOs have the potential to produce unintended effects. Since problems arising from the release of GMOs may cross national boundaries (particularly when products are traded widely), it has been important to have common EU rules ensuring that all risks are properly assessed and controlled.

Since 1990, the European Community has had a legislative framework governing the release of GMOs, in order to protect human health and the environment. This consists of a number of specific sectoral measures and a series of horizontal Directives, including:

- Directive 90/219/EEC on the contained use of genetically modified micro-organisms in research and industrial facilities, most recently amended by Directive 98/81/EC (the "Contained Use Directive");
- Directive 90/220/EEC on the deliberate release into the environment of GMOs, later repealed by Directive 2001/18/EC (the "Deliberate Release Directive"); and
- a range of EU-wide guidance and additional regulations to address specific issues, including Regulation (EC) No 1829/2003 on genetically modified food and feed and Regulation (EC) No 1830/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products produced.

This report is specifically concerned with Directive 2001/18/EC and the deliberate release of GMOs, although the wider framework is also considered. Table 2.1 provides an overview of the types of GMOs covered by the main deliberate release regulations; further supporting information on the wider framework is provided in Annex IV. The vast majority of GMOs that have been developed to date for deliberate release are transgenic crop plants, modified to be tolerant to certain herbicides or resistant to certain insect pests. Consequently, much of the available information and experience relates to GM crops although, more recently, GM vaccines have also been trialled under the deliberate release regulations.

Table 2.1: Scope of Legislative Framework according to Type of Genetically Modified Organism				
Type of Release	**Type of GMO Regulated**	**Directive 2001/18/EC**	**Regulation (EC) No 1829/2003 on genetically modified food and feed**	**Regulation (EC) No 1830/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs**
Part B – Deliberate release into the environment of GMOs for any other purpose than placing on the market	GM plants	Yes	No	No
	GM animals	Yes	No	No
	Medicinal substances and compounds for human use consisting of, or containing, a GMO or combination of GMOs	No[1]	No	No
	GM micro-organisms (other than those used for as medicinal substances and compounds)	Yes	No	No
Part C – Placing on the market of GMOs, as or in products within the Community	GM plants for human consumption	Yes	Yes	Yes
	GM plants for animal consumption	Yes	Yes	Yes
	GM plants not for consumption	Yes	No	Yes
	GM animals for human consumption	Yes	Yes	Yes
	GM animals not for consumption	Yes	No	Yes
	Animals for human consumption fed with GM food	No	No	No
	Animals for human consumption treated with GM medicinal products	No	No	No
	Food containing or consisting of GMOs	No	Yes	Yes
	Food produced from or containing ingredients produced from GMOs	No	Yes	Yes
	Feed containing or consisting of GMOs	No	Yes	Yes
	Feed produced from GMOs	No	Yes	Yes
	GM micro-organisms used for medicinal products	No	No	No
	GM micro-organisms not used for medicinal products	Yes	No	Yes
	GM imported products	Yes, if otherwise covered by scope of Directive	Yes	Yes

[1] Provided that the deliberate release is authorised by Community legislation which provides: for a specific environmental risk assessment in line with Directive 2001/18/EC; for explicit consent prior to release; for a monitoring plan in accordance with Directive 2001/18/EC; and requirements relating to treatment of new items of information, information to the public, information on the results of releases, and exchanges of information.

2.2 The Deliberate Release Directive

2.2.1 Basic Principles of the Deliberate Release Directive

The Deliberate Release Directive applies to the release and marketing of all GMOs, except the marketing of products (e.g. novel foods, or human and veterinary medicines) covered by separate EU legislation. Its objective is *to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment* (Art 1).

The Deliberate Release Directive is based on two regulatory regimes. Part B covers releases for research and development, and Part C covers placing on the market in the EU. In both cases, notification is made to the Competent Authority in the Member State where the release is to take place or where the GMO is to be placed on the market. If a Part C application is recommended for approval by the relevant Member State, then an EU-wide procedure allows for objections, which are to be resolved by voting if necessary. Final approval will then apply to all Member States. As a result, national legislation only covers certain aspects of the Part C approval process. In contrast, decision-making on Part B releases is at the Member State level, and requires full implementation in national legislation.

A crucial feature of the Deliberate Release Directive is the application of a precautionary approach (STOA, 1998). The Deliberate Release Directive sets out:

- common principles for decisions by individual Member States on proposed research and development releases of GMOs in their own territories;
- a single procedure enabling GMO products proposed for placing on the market in one Member State to be cleared for use on the whole EU market;
- common information requirements for notifications of proposed Part B and C releases focused on the assessment of risks to human health and the environment;
- common procedures for the exchange of risk assessments and other information between Member States, particularly as regards proposed Part C releases; and
- a centralised procedure for resolving differences between Member States on Part C notifications and for reaching collective decisions on matters such as guidance.

2.2.2 Implementation and Operation of Directive 90/220/EEC

Whilst the aim of Directive 90/220/EEC was to harmonise regulatory frameworks among Member States, a number of differences in interpretation arose. These included:

- **the interpretation on the scope of the Directive**. For instance, whereas countries such as France, the UK and Denmark focused on issues of environmental and human health safety, Austria interpreted the scope of the Directive more broadly and also included biodiversity (aspects of biological farming) and agronomic effects, such as effects on the use of pesticides, to determine the acceptability of products (STOA, 1998);

- **the approach to risk assessment**. The UK authorities, for instance, compared the risks of GM crops with the risks of the related non-modified crop. The Belgian Competent Authority, on the other hand, placed the risks of genetically modified organisms in the context of the general biological risks from living organisms (STOA, 1998); and

- **the definition of a number of terms**, including:

  → Directive 90/220/EEC noted that the introduction of GMOs into the environment should be carried out according to a 'step by step' principle. The Directive did not, however, define what counts as a **step**, and its interpretation was left open to the Member States;
  → the Directive did not define **'evidence for safety'**, nor **'environmental harm'**, rather, the Directive established flexible procedures for defining these terms in practice;
  → the concept of **'adverse effects on human health and the environment'** was also left open for interpretation by the Member States;
  → the Directive contained an annex with guidelines for what information could inform a risk assessment procedure. However, **the concept of risk** itself was not defined by the Directive; and
  → the Directive did not provide regulators with strict criteria to judge the **acceptability of the environmental impacts of releases**. Competent Authorities were thus forced to interpret the concept, causing variation between Member State responses and decision-making on this issue.

In the course of its operation, further issues arose concerning the interaction of Directive 90/220/EEC and the various pieces of vertical product sector legislation that were also in effect (or came into effect). The full extent of these issues was not realised until the first applications for Part C marketing releases in the mid-1990s. An early example of this concerned the interaction of Directive 90/220/EEC and Directive 91/414/EEC on Plant Protection Products and marketing releases for herbicide tolerant crops. Some Member States believed that secondary effects of herbicide tolerant crops, i.e. associated changes in pest management and applications of herbicides, should also be assessed under Directive 90/220/EEC. In contrast, the Commission stated that issues of plant protection should be considered under Directive 91/414/EEC.

In December 1996 the Commission issued a report on the review of Directive 90/220/EEC (COM (96) 630) and its decision to amend Directive 90/220/EEC during 1997. Also in December 1996, approval was granted for the

commercial planting of Bt-176 maize. Austria, Luxembourg and Italy promptly invoked the Article 16 safeguard clause and banned the use and sale of the crop on their territories. The issue was then referred to three Scientific Committees and, on the basis of their Opinions, the Commission determined that the appeal to Article 16 was not justified (as announced in September 1997 (CEC, 1997)). Although Austria and Luxembourg maintained their positions, Italy immediately lifted its ban.

In the meantime, applications under Directive 90/220/EEC continued. However, dissatisfaction with the process and public and government concerns over food safety issues in general raised further problems, particularly with the consideration of health effects and the issue of where and how secondary effects should be considered. The French government subsequently reversed its decision to authorise GM maize. The UK imposed additional monitoring and testing requirements and began a process of managed development under the Farm-scale Evaluations, accompanied by a three year voluntary agreement with industry not to commercially grow GM crops. Other Member States, including Germany, pursued a similar line and from March/April 1998 onwards the EU approval procedure under Directive 90/220/EEC was brought to a near halt. In June 1999, the Environment Council announced the declarations from a number of Member States which effectively suspended the decision-making process for new GMO authorisations for commercial release in the EU until a stricter and more transparent framework was in place (Environment Council, 1999).

2.2.3 Directive 2001/18/EC on the Deliberate Release of GMOs

Four years of intensive and wide-ranging negotiations on proposals concluded in 2001 with the adoption by Member States of Directive 2001/18/EC. The principles and basic procedures for the approval of GMO releases in Directive 90/220/EEC remain in the new Directive. Directive 2001/18/EC is still firmly based on the scientific assessment of environmental risk and the precautionary approach still follows the 'step by step' principle. However, clarification, improvement and strengthening of several aspects of the approvals process were required. Box 2.1 summarises the key features and revisions in the new Directive.

Box 2.1: Key Features of Directive 2001/18/EC

Environmental Risk Assessment: Article 2.8 and Annex II set out a harmonised approach to risk assessment based on best practice in Member States. The new Annex stresses the need for an approach that evaluates risks to human health and the environment "whether direct or indirect, immediate or delayed". Detailed implementation of the provisions for risk evaluation is informed by a guidance note supplementing the Directive's Annex II that was published on 3 October 2002.

Post-market Monitoring: Each application for a Part C consent must include a proposed monitoring plan to be carried out after the marketing consent has been granted. This confirms whether the assumptions made in the original risk assessment are valid and any adverse effects are identified and acted upon. On 3 October 2002 a guidance note on post-marketing was published to supplement the Directive's Annex VII.

Box 2.1: Key Features of Directive 2001/18/EC

Antibiotic Resistance Markers: The new Directive sets target dates of 31 December 2004 for Part C applications and 31 December 2008 for Part B applications, for the phasing out of antibiotic resistance markers in GMOs which may have adverse effects.

Traceability and Labelling: The Directive requires Member States to take measures to ensure 'traceability' at all stages of the placing on the market of GMOs authorised under Part C. It also requires that the words "This product contains genetically modified organisms" must be included on a label or in a document accompanying any GMO product.

Consultation with the Public: Directive 90/220/EEC contained optional provisions for consultation with members of the public on releases of GMOs under Part B provisions. The new Directive introduces a mandatory requirement for Member States to consult the public or groups on proposed releases under Part B of the Directive. The precise form of consultation is a matter for individual Member States. The new Directive also contains other specific requirements for seeking views from the public.

Information to the Public: The new Directive enhances the public information principles and procedures that all Member States must respect. It also requires the Commission to make available certain information centrally.

Predictability and Transparency of Decision-making: The regime under Directive 90/220/EEC had the potential for delays and a lack of transparency in decision-making by not having clear deadlines within which decisions must be reached and communicated. Directive 2001/18/EC provides for a more predictable and transparent regulatory process by setting deadlines for each stage.

Differentiated and 'Simplified' Procedures: There has been concern that the simplified procedure under Part B of Directive 90/220/EEC was inadequate in terms of information to the public. In particular, the 15 day period of notice of intention to plant a GMO is not regarded as sufficient by some stakeholders. Directive 2001/18/EC retains the simplified procedure but its use is optional. One of the new features in the revised Directive is the proposal of 'differentiated procedures' for certain categories of GMOs under Part B. This provides the possibility of retaining the option of different procedures for appropriate programmes of development work but only after giving due consideration to how the interests of the public can best be protected.

Time Limited Consents: Part C consents shall be given for a maximum period of 10 years starting from the date on which the consent is issued.

Ethical and Socio-economic Issues: The new Directive does not include ethical or socio-economic issues as specific factors to be taken into account when deciding applications to release or market GMOs. However, it does include provision for consulting ethical committees on matters of a general nature and for periodic reporting on the socio-economic implications of deliberate releases and the placing on the market of GMOs.

The new Directive, adopted in February 2001, should have been fully implemented by 17 October 2002. To date, seven Member States have transposed the Directive into national legislation: Sweden, Denmark, UK, Portugal, Italy, the Republic of Ireland and, most recently, Spain. The remaining Member States have been taken to court by the Commission for non-transposition. The progress of all Member States (as of 10 February 2004) is given in Table 2.2. It should be noted that, for the remainder of this report, Spain is treated as a Member State which has not transposed the Directive, as was the case when the research for this report was undertaken.

Table 2.2: Progress of Member States in Implementing Directive 2001/18/EC (as of 10 February 2004)	
Country	**Current Status**
Belgium	Draft legislation submitted to Commission in June 2003. Not yet transposed due to a change of government. Aiming for implementation by 18/04/04
Denmark	Complete
Germany	Draft being negotiated between ministries. Due to be implemented in early 2004.
Greece	Draft legislation has apparently been prepared but not yet submitted to Commission.
Spain	Directive has been transposed by the Law 9/2003 of 25/05/03 and the Royal Decree 178/2004 of 31 January 2004.
France	The implementing regulation for 90/220/EEC was very similar to the requirements for 2000/18/EC. More work is needed to implement the remainder of 2000/18/EC and this is being discussed at inter-ministerial level. Due to be adopted by Parliament early 2004.
Ireland	Transposed by legislation S.I.N°500 of 2003, received by Commission on 24/10/03.
Italy	Transposed on 08/07/03, enforced from 06/09/03. Competent authority is being transferred from the Ministry of Health to the Ministry of the Environment.
Luxembourg	Only partial transposition of Directive by Loi du 13/1/2004 modifiant la loi du 13/1/1977 relative au contrôle de l'utilisation et de la dissemination des organismes génétiquement modifies. Ref: MEMORIAL A n°. 5 du 23/1/2004 p.22.
Netherlands	Draft legislation under review at the Court of Advisement.
Austria	Not yet transposed, national implementation measures at the stage of a first draft.
Portugal	Complete. Implemented by Decreto Lei 72/2003 of 10 April 2003.
Sweden	Complete as of 17/01/03
Finland	Act recently finalised, will go to Parliament early in 2004.
UK	Complete as of 18/10/2002 for England and from 19/03/03 for Scotland, Wales and Northern Ireland.

Sections 3 and 4 of this Report provide a more detailed examination of the operation of Part B and Part C procedures respectively (under Directive 2001/18/EC).

2.3 The Wider Framework

2.3.1 Regulation (EC) 1829/2003 on GM Food and Feed

Regulation (EC) 1829/2003 on GM food and feed entered into force on 7 November 2003 and will have to be applied from April 2004. It replaces the GM part of Regulation (EC) 258/97 of 27 January 1997 on novel foods and novel food ingredients. In contrast to (the GM part of) the Novel Foods Regulation, the new Regulation on GM food and feed governs the use of GMOs both for food and for feed.

Key elements of the new Regulation include:

- a harmonised and centralised 'one door – one key' Community procedure for the scientific safety risk assessment to be carried out by the European Food Safety Authority (EFSA), covering both the environmental and human and animal health safety assessment;
- a single risk management process, involving the Commission and the Member States through a regulatory committee procedure;
- making a summary of the application and the opinion of the EFSA available to the public, which may make comments to the Commission within thirty days;
- granting of authorisation for a period of ten years and, if appropriate, subject to a post-market monitoring plan. After ten years the applicant may apply for renewal of the authorisation; and
- entering of authorised products into a register, including product specific information, studies on the safety of the product and the sampling, identification and detection methods as well as samples of the GM food and feed (reference materials), which have to be provided by the applicants.

The Regulation on GM food and feed gives the applicant the choice either of applying for an authorisation under Part C of Directive 2001/18/EC, or requesting the environmental risk assessment to be carried out at the same time as the food and feed safety assessment under this Regulation. Where the GMOs are seeds or other plant propagating material, however, the environmental risk assessment must be delegated to a national Competent Authority for Directive 2001/18/EC.

Industry stakeholders welcome the central role of EFSA in the authorisation procedure for GM food and feed (SBC, 2003a). However, both industry and CAs consider there is a need to clarify EFSA's obligation to consult advisory bodies and CAs of Member States, particularly with a view to the environmental risk assessment (ERA) as foreseen by Directive 2001/18/EC. Industry is concerned about lack of clarity over the data package applicants should submit. This makes it likely that the 'procedural clock' will be stopped, because the EFSA and/or national CAs require additional information from the applicant. Consequently, the authorisation procedure under the new Regulation is not considered as predictable by industry (SBCa, 2003).

Furthermore, CAs consider that there are some uncertainties in the texts concerning their role in the GM Food and Feed Regulation, and they believe it is important that the CAs under Directive 2001/18/EC are properly consulted on the ERA. The wording of the Regulation suggests that they only 'may' be consulted (apart from in the case of GM seeds). There is some concern that the EFSA may not have the expertise to comprehensively assess the environmental risks, especially concerning regional factors.

2.3.2 Regulation (EC) 1830/2003 on the Traceability and Labelling of GMOs and the Traceability of GM Food and Feed

Regulation (EC) 1830/2003 on traceability and labelling also entered into force on 7 November 2003. The Regulation views traceability as a tool for facilitating:

- post-market monitoring of GMOs and GM food and feed and targeted withdrawal if unforeseen adverse effects on human health or the environment occur; and
- control and verification of labelling claims.

For that purpose all operators in the food and feed production chain shall transmit and retain specified information on the GMOs. As a means to specify the identity of GMOs, a system of 'unique identifiers' has been developed (Regulation (EC) No 65/2004 of 14 January establishing a system for the development and assignment of unique identifiers for GMOs).

Although Regulation 1830/2003 applies to all GMOs falling under Directive 2001/18/EC, more detailed consideration has been given by most stakeholders to its application to GM food and feed. The Regulation introduces labelling of GM food and feed irrespective of the detectability in the final product of DNA or protein resulting from the genetic modification. Under the former EU legislation, labelling of a GM food or GM food ingredient (under Regulation (EC) 1139/98, Regulation (EC) 49/2000 and Regulation (EC) 50/2000), was essentially triggered by the presence of DNA or protein resulting from the genetic modification. The new Regulations therefore impose labelling requirements for two new categories of GM products: 1) GM food produced from GMOs, and; 2) GM food produced from GMOs but containing no GM material. Products obtained from animals fed with GM feed or treated with GM medicinal products are not subject to mandatory labelling.

SBC (2003a) reports that industry stakeholders do not expect that labelling of food or feed produced from GMOs, in particular for imports of food or feed with 'non-detectable' ingredients from non-EU countries, will be workable. Because it is impossible to control the origin of highly processed ingredients with analytic methods, downstream operators in the chain could only rely on paper trail systems for verification. On the other hand, retailers welcomed labelling of food and feed produced from GMOs but containing no GM material, as this would give more legal certainty to non-GM supply chains that have so far been set up for (some of) their own brand products. European and national consumer organisations also welcomed the switch to labelling of food and feed produced from GMOs but containing no GM material. Despite differences in views, downstream and upstream stakeholders agree that an absolute prerequisite for labelling for food and feed produced from GMOs was the establishment of an international accreditation body, in order to audit and verify labelling claims in relation to GM and non-GM supply chains world-wide.

Under former EU legislation the labelling threshold was set at 1% for the presence of modified DNA or protein in conventional foods. The new Regulation introduces a threshold of 0.9 % for the adventitious or technically unavoidable presence of authorised GM material in non-GM food and feed. The Regulation further provides an amendment of Directive 2001/18/EC, which in essence allows Member States to take appropriate measures for coexistence of GM, conventional (non-GM), and organic crops (i.e. the issue is to be addressed on the basis of subsidiarity).

In January 2002, the Commission made its first proposal for a Directive to amend the existing seed Directives. The proposal sought to establish conditions and requirements for thresholds for the adventitious or technically unavoidable presence of GM seeds in seed lots of conventional, non-genetically modified plant varieties, below which no labelling would be required. More recently it has been decided that a Commission proposal for the thresholds of GM seeds in lots of non-GM seeds will be finalised under Directive 2001/18/EC. Identical thresholds will then be adopted under the seed Directives. Some stakeholders believe that the proposed labelling thresholds for adventitious presence of GMOs in non-GM seeds, in order to meet the labelling threshold of 0.9 % for non-GM food and feed, may be difficult to achieve when GM crops are commercially grown in the EU.

The new Regulation effectively shifts responsibility for traceability measures to the operators. Some of the Competent Authorities consulted for this study believe that the approach adopted on traceability and labelling is feasible, whilst others question the workability of the system. As it has not yet been put into practice there is no practical experience on the new Regulation.

However, many of the requirements for seeds are already met through industry voluntary programmes and commercial practices. In some Member States (e.g. UK and the Netherlands) seed companies already have well-established systems for the segregation and labelling of conventional seed under the certification scheme. The information required for meeting GMO labelling requirements could be added to these. A Regulatory Impact Assessment of implementing Directive 2001/18/EC, prepared for the UK Department for the Environment, Food and Rural Affairs, indicated that the majority of notifiers in the UK believed that the requirements for traceability and labelling were necessary and that the cost was negligible (RPA, 2002).

Beyond the farm, the complexity of traceability and labelling of GMOs increases significantly. Farmers will be responsible for providing operators in the next stage with information about ‘events’ in their harvest and segregation of GM crops and non-GM crops. In addition, the legislative framework has not yet addressed traceability requirements for farm saved seeds of GM plant varieties. SBC (2003a) suggests that it may be difficult to control the traceability of farm saved GM seeds.

Most notifiers consulted for this study commented that the labelling threshold of 0.9 % for the adventitious presence of (EU-authorised) GM materials in GM food and feed was too low and would generate additional costs for

industry. In addition, SBC (2003a) reports that industry stakeholders suggest labelling thresholds for the adventitious presence of GMOs in non-GM food and feed should take into account that several non-EU countries have set such thresholds at 2% to 5%. Structural impacts on the biotechnology industry, seed industry, grain trade and food and feed industry are also possible and likely, as the added costs may be too high for small and medium-sized enterprises.

SBC (2003a) also found that most industry stakeholders believe that the labelling thresholds for the adventitious presence of GMOs in lots of non-GM seeds should be laid down by the seed directives, as this would increase legal certainty with a view to liability claims. However, the specific technical measures to avoid the presence of GMOs in non-GM seeds below a certain threshold should not be laid down in the (proposed) amendments of the seed Directives but should be left to the operators.

Public interests groups view the labelling threshold of 0.9 % as too high and have expressed concern that industry would interpret this as a threshold for *any* presence of GMOs in conventional products, whereas the threshold is meant for the *adventitious* presence of GMOs. A European coalition of public interest groups has campaigned for much lower labelling-thresholds (of 0.1 %), so as to 'save our seeds'.

There are some concerns about the detectability of GMOs at the proposed thresholds and Competent Authorities have requested further guidance on the development of homogenous traceability systems and sampling methods. It is understood that guidance on sampling and testing is currently being developed. However, it should be noted that in several countries, including Sweden, Portugal and Ireland, the verification of traceability and labelling of GM food and feed does not fall under the responsibility of the CAs for Directive 2001/18/EC. Thus, labelling requirements and thresholds for the adventitious presence of GMOs in non-GMO products are rather fragmented by various pieces of legislation and national administrations. One CA is concerned that this could lead to difficulties in understanding and a lack of transparency for users and consumers in the EU.

Neither the (proposed) amendments of the seed directives, nor Directive 2001/18/EC, allow the adventitious presence of GMOs not authorised in the EU and not having benefited from a favourable risk evaluation by the Community Scientific Committees or EFSA before the date of application of the new Regulation 1829/2003 in lots of conventional seed. These 'non-EU authorised GMOs' include GMOs authorised under Part B of Directive 2001/18/EC, GMOs not yet authorised pending approval under Part C and GMOs authorised by non-EU countries. Some CAs and most notifiers argued that there was an urgent need to establish a threshold for the adventitious presence of non-EU authorised GMOs and further provisions or requirements have to be developed under the Cartagena Biosafety Protocol. According to SBC (2003a), the present situation seriously jeopardises imports of conventional, non-GM seeds from non-EU countries into the EU. Because of the rapidly growing acreage for commercially cultivation of non-EU-

authorised GM crops and GM seed multiplication in other continents, globally operating seed companies are facing increasing difficulties to avoid the presence of 'non-EU-authorised' GM seeds in conventional seed lots. Sales of conventional seeds of certain crop species and conventional breeding programs have therefore already come to a stop in Europe out of liability considerations.

2.3.3 Other Regulations and Guidance

Regulation EC 1946/2003 on the transboundary movement of GMOs was adopted on 15 July 2003. In essence, this Regulation is linked to the ratification by the European Community of the Cartagena Protocol on Biosafety and governs the exports of GMOs intended for deliberate release into the environment to non-EU countries. The Regulation also sets rules for the exports of GMOs intended to be used as food, feed or for processing. The main elements of the Regulation are:

- the obligation to notify exports of GMOs intended for deliberate release into the environment and secure express consent prior to a first transboundary movement;
- provisions for identifying GMOs for export;
- a set of rules for the exports of GMOs intended to be used as food, feed or for processing, and;
- the obligation to provide information to the public and international partners on EU practices, legislation and decisions on GMOs, as well as on unintentional or illegal transboundary movements of GMOs.

Directive 2002/53/EC requires the Commission to inscribe in the Common Catalogue of agricultural plant species any plant varieties, which have been added to national catalogues. In the case of a GM plant variety the GMO (event), on which the GM plant variety is based, must be authorised under Directive 2001/18/EC for its use in cultivation and the GM material must be authorised for food and feed use under the Regulation on GM food and feed.

So far no single GM plant variety has been included in the EU's Common Catalogue, while several Member States have already registered a number of GM plant varieties on their national list. According to the relevant legislation, all varieties (GM or non-GM) are included in the Common Catalogue via a simple notification procedure, which is separate from the assessment procedure under Directive 2001/18/EC. However, SBC (2003a) reports that, in practice, some industry stakeholders believe that the uncertainty in the approvals process under Directive 2001/18/EC has affected the placing of GM plant varieties on the Common Catalogue.

In addition, at a national level, Member States have different approaches to placing GM varieties on national lists. For example, there are different views on whether GM variety-approval trials may be started under Directive 2001/18, Part B, or whether the event, on which the GM variety is based, should first obtain a full Part C authorisation. In theory, Directive 2001/18/EC allows for either approach but obligations to meet strict requirements for Part

B consents (e.g. isolation distances, specific requirements for waste disposal, etc.) may constrain the opportunity for variety-registration trials of GM varieties which do not have Part C authorisation.

On 23 July 2003 the Commission issued a Recommendation on guidelines for the development of national strategies and best practices for the coexistence of genetically modified crops with conventional and organic farming. Whilst the Commission did thus not propose legally binding rules for coexistence, Article 26a of Regulation (EC) 1829/2003 amends Directive 2001/18/EC with a view to coexistence. As a subsidiarity issue, Member States may now take measures to avoid the unintended presence of GMOs in other products. Previously under Directive 2001/18/EC (containment) measures were only allowed in the interest of the protection of human health and the environment.

Furthermore, in January 2002 the European Commission made its first proposal for a Directive on environmental liability. Annex 1 of the proposed Directive lists the risky and potentially risky activities, which would fall within the scope of this Directive. The proposal regarded deliberate release of GMOs into the environment as defined and within the scope of Directive 2001/18/EC as an Annex 1 activity.

Finally, prior to adoption the EU regulatory framework on the use of GMOs from farm to fork has been notified to the Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements of the World Trade Organisation (WTO), so as to ensure conformity with these agreements.

3. OPERATION OF PART B

3.1 Introduction

Part B covers releases for research and development and applications are made to the Competent Authority of the Member State where the release is to take place. All Member States had national legislation under Directive 90/220/EEC. Those countries which have transposed Directive 2001/18/EC (Denmark, Ireland, Italy, Portugal, Sweden and the UK)[1] are highlighted in grey in the following analysis, although all countries should now be applying the requirements of Directive 2001/18/EC regardless of national implementation. The remaining countries are in the process of transposing the Directive, thus they have been able to provide details of the requirements but are uncertain of the operation of these new regulations in practice due to a lack of experience.

3.2 General Implications

3.2.1 Authorisation under Different Directives

The scope of Directive 2001/18/EC in relation to type of GMO is illustrated in Table 2.1. The majority of GMOs authorised to date have been transgenic crop plants; these are clearly deliberate releases, which fall under Directive 2001/18/EC. Likewise, laboratory trials of GM micro-organisms are clearly contained uses, regulated by Directive 90/219/EEC[2]. However, research suggests that clinical trials of 'gene therapy' applications to humans may be regulated differently between Member States, as shown in Table 3.1 (based on SBC, 2003b) and more than one set of regulations may apply.

Table 3.1: Approach to Regulating Clinical Trials of Gene Therapy Applications

Approach	Country			
	DE	FR	GB	NL
Regulated as a 'contained use'			Determined on a case-by-case, contained or deliberate	
Regulated as a 'deliberate release'	Approval according to deliberate release laws is **not** required	Covered by deliberate release laws	Determined on a case-by-case, contained or deliberate	Covered by deliberate release laws
Regulated in another way	Other medical laws may apply	Specific law developed for novel types of therapeutics	General legislation on clinical trials	Medical research involving humans falls under a separate law

[1] As discussed in Section 2.2.3, although Spain has recently transposed Directive 2001/18/EC into national law (as of 31 January 2004), the research for this study was undertaken before the transposition and thus, for the purpose of this study, Spain is treated as a country which has not transposed the Directive.

[2] Although the scope of Directive 90/219/EEC is limited to GM micro-organisms, most Member States regulate 'contained use' trials with GM plants and GM animals in a similar way.

Article 5 of Directive 2001/18/EC excludes medicinal substances and compounds for human use consisting of, or containing, a GMO or combination of GMOs from regulation under the Directive, provided that their deliberate release is authorised by other Community legislation which requires:

- a specific environmental risk assessment;
- an explicit consent prior to release;
- a monitoring plan with a view to detecting the effects of the GMO or GMOs on human health or the environment; and
- has appropriate requirements relating to treatment of new items of information, information to the public, information on the results of releases, and exchanges of information at least equivalent to those contained in Directive 2001/18/EC.

Thus whilst it is not necessary for clinical gene therapy trials to be regulated under more than one set of regulations it appears that this may be the case in some countries where the existing regulations on clinical trials do not adequately address the requirements of Directive 2001/18/EC.

These differences in approach may, in practice, have implications for:

- public information and consultation;
- the extent of the environmental risk assessment; and
- the administrative burden for industry and research organisations.

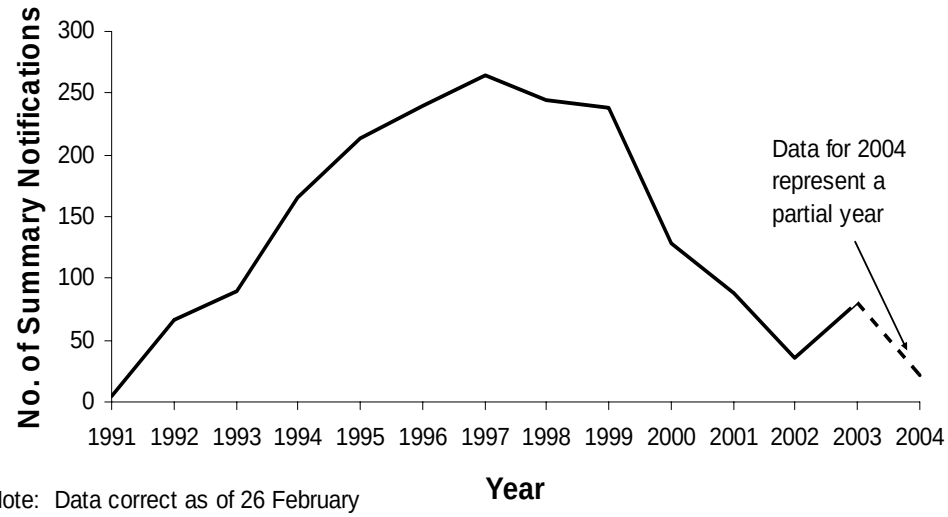
These issues are discussed in more detail below, under the relevant sections.

3.2.2 Number of applications

The effect of the uncertainty in the approvals process can be seen in Figure 3.1, showing the growth in notifications from the adoption of Directive 90/220/EEC until 1998 and the dramatic decline since. Despite the fact that it has been the process for Part C approvals which has been uncertain, the effect has been a slow-down in the whole process (including notifications for Part B consents).

The adoption of Directive 2001/18/EC seems to have been accompanied by a slight increase in the total number of summary notifications. It should be noted that data presented in Figure 3.1 only account for two months of 2004, but already 19 Part B applications have been made (equal to 24% of the total number of Part B applications in 2003). However, this increase in applications has only been experienced in Germany (increasing from 7 notifications in 2002 to 9 in 2003), the UK (increasing from 5 in 2002 to 8 in 2003), France (increasing from 3 in 2002 to 17 in 2003) and Spain (increasing from 17 notifications in 2002 to 40 in 2003). In all other countries there has been a reduction or no change in the number of summary notifications.

Figure 3.1: Number of Summary Notifications in the EU



Note: Data correct as of 26 February 2004. Does not include data for Austria, Finland and Sweden prior to their EU Membership in 1995.

Table 3.2 (overleaf) highlights the fact that most experience with Part B applications has been with the authorisation of GM plants. Although a number of non-plant GMOs were authorised under Directive 90/220/EEC, only five have been authorised since Directive 2001/18/EC came into force. Furthermore, only 13% of Part B applications have been made in countries which have fully transposed the Directive (UK, Italy and Sweden). This limits the extent of comparable national experience with the operation of Directive 2001/18/EC. Germany, Spain and France have received the majority of applications which suggests that the number of applications may be more dependent on the political situation in a Member State than the regulatory situation.

There is uncertainty over the impact that Directive 2001/18/EC will have on Part B applications. Particular issues which need to be resolved to facilitate Part B applications include:

- removing the uncertainty in the decision-making process for Part C applications;
- the provision of location details (related to the potential for vandalism);
- the threshold levels for GM contamination in marketed seeds; and
- liability issues relating to field trials.

Uncertainty over these issues may discourage industry and research organisations from applying for Part B authorisations. This is in contrast to the other issues discussed below that affect the effectiveness of the authorisation procedure, although the overall administrative burden of the process may also discourage applications.

Table 3.2: Number of Part B Applications (by Type of GMO) under Directive 90/220/EEC and Directive 2001/18/EC															
Type of Part B Application	**Member State**														
	AT	**BE**	**DE**	**DK**	**ES**	**FI**	**FR**	**GB**	**GR**	**IE**	**IT**	**NL**	**PT**	**SE**	**EU**
Directive 90/220/EEC															
Plants	3	119	119	39	181	18	501	211	19	4	273	136	12	64	1699
Other organisms	0	7	2	1	23	2	9	11	0	1	16	4	0	0	76
Total	*3*	*126*	*121*	*40*	*204*	*20*	*510*	*222*	*19*	*5*	*289*	*140*	*12*	*64*	*1775*
Since 17 October 2002 (Directive 2001/18/EC)															
Plants	0	1	15	0	47	1	17	4	0	0	2	3	0	4	94
Other organisms	0	0	0	0	1	0	0	3	0	0	0	1	0	0	5
Total	*0*	*1*	*15*	*0*	*48*	*1*	*17*	*7*	*0*	*0*	*2*	*4*	*0*	*4*	*99*
Total under both Directives															
Plants	**3**	**120**	**129**	**39**	**219**	**18**	**518**	**215**	**19**	**4**	**275**	**138**	**12**	**65**	**1774**
Other organisms	**0**	**7**	**2**	**1**	**24**	**2**	**9**	**14**	**0**	**1**	**16**	**5**	**0**	**0**	**81**
Total	***3***	***127***	***131***	***40***	***243***	***20***	***527***	***229***	***19***	***5***	***291***	***143***	***12***	***65***	***1855***

3.2.3 Pre-application Discussions

Responses from CAs suggest that Member States have different approaches towards applications for Part B consents. A significant difference concerns the opportunity for discussions between the notifier and the CA prior to the submission of an application, as shown in Table 3.3. It should be noted that Directive 2001/18/EC neither provides for, nor prohibits, pre-application discussions and, as such, this is a national issue.

Table 3.3: Member State Approaches to Pre-application Discussions												
Approach	**Member States responding to question**											
	AT	**BE**	**DE**	**DK**	**ES**	**FR**	**GB**	**IE**	**IT**	**NL**	**PT**	**SE**
No discussion						X						
Some discussion	X										X	X
Full discussion		X	X	X	X		X	X	X	X		X

These differences in approach may have implications for:

- the clarity of guidance provided to industry;
- the length of time required to provide a decision on the notification; and
- the administrative burden for CAs and for industry and research organisations.

Responses from CAs which allow for a full discussion of applications before the submission of the formal notification suggest that, in some cases, this may reduce the need to request further information from the notifier and thus reduce the time and resources required to process the application. Industry responses also support this approach, as it allows the CA to clarify its requirements and thus provides industry with greater predictability.

3.2.4 Changes in the Part B Authorisation Process

The key changes in national legislation between Directive 90/220/EEC and Directive 2001/18/EC relate to public information and consultation, whether it is the introduction or the formalisation of such processes. However, a number of additional changes, unique to individual Member States, highlight the degree of variation under Directive 90/220/EEC and suggest a move towards harmonisation under Directive 2001/18/EC. These changes are shown in Table 3.4.

Table 3.4: Key Changes in National Regulations between Directive 90/220/EEC and Directive 2001/18/EC

Key changes	Member States responding to question										
	AT	BE	DE	DK	ES	FR	GB	IT	NL	PT	SE
Formal requirement for public consultation		X		X	X	X	X	X		X	X
Extended timeframe due to public consultation	X										
Reduced timeframe for decision-making									X		
Requirement for public information					X					X	
Exemptions for pharmaceutical products		X									
Scope of risk assessment						X					
Requirement for monitoring		X								X	
Increased administrative requirement			X								
Inclusion of additional official bodies in process										X	
Establishment of fees					X						
Nomination of new Competent Authority								X			

3.2.5 Causes of Delays in the Authorisation Process

Some CAs report that delays are caused when additional information is required from the notifier (as foreseen by Article 6), and that the frequency with which this occurs has not changed from Directive 90/220/EEC to Directive 2001/18/EC. Responses from industry also support this as a cause for delays; it may result in part from different national interpretations and a lack of clear guidance. Pre-application discussions may help to reduce these delays.

CAs also suggest that public consultation and consultation of bodies that only convene occasionally may result in delays. However, CAs considered that delays caused by requesting further information and by consultation are necessary, given the importance of the risk assessment and consultation process. Two CAs specifically reported that they are still able to address the cause of the delay without exceeding the 90 day period.

3.2.6 Environmental Risk Assessment and Guidance

Under Directive 90/220/EEC, Member States had different requirements for the Environmental Risk Assessment (ERA). In the countries that had stricter requirements, Directive 2001/18/EC has not led to any significant changes. However, a number of countries have increased their requirements for the ERA, as shown in Table 3.5, particularly in relation to indirect and delayed effects which may not have been covered under Directive 90/220/EEC. This suggests that Directive 2001/18/EC has, or will, lead to a greater degree of harmonisation. However, there is insufficient experience at this stage for industry to assess the degree of consistency between Member States with regard to the requirements of the ERA.

Table 3.5: Change in Requirements for Environmental Risk Assessment under Directive 2001/18/EC (compared to Directive 90/220/EEC)

Change in requirements	Member States responding to question											
	AT	**BE**	**DE**	**DK**	**ES**	**FR**	**GB**	**IE**	**IT**	**NL**	**PT**	**SE**
Increased requirement for direct effects					X			X	X			
Increased requirement for indirect effects	X	X			X	X		X	X			
Increased requirements for immediate effects	X				X			X	X			
Increased requirements for delayed effects	X	X			X	X		X	X		X	
No impact on requirements			X	X			X			X		X

Increased, but harmonised, requirements for the ERA may result in:

- higher costs for notifiers;
- increased predictability of decision-making;
- reduced regulatory uncertainty for notifiers.

Responses from CAs are divided between the need for a flexible approach to the ERA, which allows the assessment of applications on a case-by-case basis, and the need to provide clearer guidance on, for example, common end-points and the standardisation of tests. Although there is general agreement that the Commission has provided clear guidance on the requirements of the ERA, further clarification is sought by CAs and industry on:

- what are considered acceptable and unacceptable risks;
- the baseline for evaluating the potential effects of GMOs;
- application of the precautionary principle; and
- specific guidance for non-plant GMOs.

Most of the responding CAs suggest that the clarified requirements of the ERA under Directive 2001/18/EC have had or will have no impact on the overall length of time required to gain approval; this is supported by industry responses. As reported above, CAs still need to request additional information

from applicants under the new Directive and this enables the procedural clock to be stopped. However, this response is provided in the context of little experience and/or little change to the requirements under Directive 90/220/EEC.

Public interest groups have expressed concern that the ERAs are evaluated mainly on the basis of data submitted by the notifier and that there are very few independent studies.

SBC (2003a) further reports that differences in interpretation of the provision allowing Member States to take ethical aspects into consideration in decision-making have the potential to reduce the predictability of the authorisation procedure. This is considered below in relation to public consultation.

Additional concerns reported by industry in SBC (2003a) are that the export of GM plant material developed in the EU under the Contained Use Directive, but intended for an experimental deliberate in a non-EU country might be subject to a full environmental risk assessment (e.g. under Part C). This is in contrast to GM plant material developed under contained use conditions and exported for contained use, which may not require a full environmental risk assessment, depending on the specific use. When GM plant material is only at the first stages of development it is not possible to conduct a full environmental risk assessment. Industry therefore argues that research material should be exempted from the Advance Informed Agreement (AIA) procedure, in order not to block exchange of research material with non-EU countries.

3.2.7 Public Information and Consultation

Directive 2001/18/EC contains similar provisions to Directive 90/220/EEC on the type of information which should be made public but, in contrast to Directive 90/220/EEC, the new Directive requires mandatory public consultation on each Part B application. Article 9 of Directive 2001/18/EC requires Member States to consult the public and, where appropriate, groups on the proposed deliberate release. The Directive allows for subsidiarity on this issue, stating only that Member States shall lay down arrangements for this consultation, including a reasonable time-period, in order to give the public or groups the opportunity to express an opinion, thus the specific arrangement are made at the national level. The exact methods (and timeframe) of public consultation under Directives 90/220/EEC and 2001/18/EC are summarised in Table 3.6, where available.

Increased public information and consultation may have the following results:

- increased public involvement in decision-making, and therefore increased acceptance of GMOs;
- increased vandalism of field trials, increasing R&D costs for industry or discouraging investment at all; and/or
- greater requirement for public relations personnel within industry and research organisations, increasing costs for notifiers.

Table 3.6: Member State Approaches to Consultation under Directive 90/220/EEC and Directive 2001/18/EC												
Approach	**Member States responding to question**											
	AT	**BE**	**DE**	**DK**	**ES**	**FR**	**GB**	**IE**	**IT**	**NL**	**PT**	**SE**
Directive 90/220/EEC												
Were there legal provisions for public consultation?	Y	N	Y	Y	N	N	Y	Y	Y	Y	N	N
Were the public involved?	Y	Y	Y	Y	N	N	Y	Y	Y	Y	N	Y
Directive 2001/18/EC												
Information available on CA website?	N	NA	NA	Y	Y	NA	Y		Y		Y	NA
Notification placed in a newspaper(s)?	Y			Y	N		Y	Y		Y	Y	
Full (F) or Summary (S) of notification available?	F			S	S		S			F		
Time period for consultation (days)	21			30	30		48	28		28	<60	
Public hearing	Y			Y			N		Y	N		

SBC (2003b) notes that public interest organisations or individual citizens in the Netherlands and France can legally appeal against an authorisation of a field trial, while in Germany only citizens whose interests might be affected can legally challenge an authorisation. No such appeal system exists in the UK. In the Netherlands, a number of public interest organisations and citizens have lodged appeals at the highest administrative court against almost every permit issued for field trials. These appeals have also led to a high administrative burden for the CA. Similarly, in Austria, the results of public hearings under Directive 90/220/EEC have led to the withdrawal of three applications.

In addition, in contrast to the advisory committees of the Netherlands and the UK CAs, the advisory committees of the French and German CAs include not only scientific experts but also representatives of public interest groups.

In the Netherlands and the UK, gene therapy clinical trials are generally considered as a Part B deliberate release. Consequently, the same provisions for public information and consultation are applicable as for a Part B release of a GM crop. In Germany, gene therapy clinical trials are covered by other legislation and, as a consequence, the public is not formally consulted. However, public input is obtained by another mechanism, as ethics committees have to include one or more laypeople to ensure public input.

As a first step, CAs must make certain information available to the public. Research suggests that, in some cases, stakeholders are uncertain where to find this information, or believe that they require more information to develop an informed opinion. Increased experience will facilitate stakeholders' ability to utilise the information available, but it is also possible that as more experience is gained with public consultation, improvement of Directive 2001/18/EC may need to be considered.

All stakeholders (CAs, industry and public interest groups) suggest that the content of the consultation responses and the subsequent consideration of these responses by CAs may not be sufficient. For example, public interest groups and individuals may tend to object to applications on the basis of socio-economic and ethical principles. However, the Directive does not provide the mechanisms for CAs to take account of these non-scientific implications in reviewing an application. Therefore, public stakeholders are increasingly frustrated when they believe that their objections are 'ignored' by CAs.

Obviously the content of responses cannot be addressed directly by the Directive but better, non-technical, guidance may increase the public's understanding of the overall process and how they may respond to the consultation more effectively. In addition, CAs could provide evidence of their consideration of public responses, which is currently lacking in many Member States. Again, as experience increases, it may be necessary to consider improving the Directive, so as to enable socio-economic and ethical issues to be incorporated in the decision-making process.

3.2.8 Antibiotic Resistance Markers

Article 4.2 of Directive 2001/18/EC states that Member States and the Commission shall ensure that GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment are taken into particular consideration when carrying out an environmental risk assessment, with a view to identifying and phasing out antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment. This phasing out shall take place by 31 December 2008 in the case of GMOs authorised under Part B.

CAs and industry both express a general dissatisfaction with the lack of guidance from the Commission on which ARMs are to be phased out. Industry notes that the lack of guidance, and the political rejection of ARMs, has made it impossible to develop ARM-containing products in the EU. One CA suggests that it may be difficult to identify which ARMs are likely to have harmful effects and that harmonised criteria are needed to avoid any inconsistencies.

This general view is supported by public interest groups, which suggest that there are no clear and transparent criteria available to assess whether a specific ARM is to be considered harmful and there is no procedure through which public interest groups can comment on this matter. The issue of mechanisms to ensure that the relevant GMOs are withdrawn from the environment following the ban was also raised.

Some CAs have allowed antibiotic resistance markers in Part B releases, provided that they do not endanger the use of the corresponding antibiotic in human or veterinary health care, while other CAs do not allow any ARM in Part B releases. For example, the Danish statutory order states that "experimental release or placing on the market of genetically modified organisms that transfer genes conferring resistance to antibiotics used in

human or veterinary medicine shall not be granted approval". In the Netherlands, the Government's White Paper of 2000 allows for the presence of NPTII and HPT ARMs in GM crops only in small-scale, confined field trials. In large-scale, unconfined field trials and commercial cultivation the presence of ARMs in GM crops is not allowed for precautionary reasons. Furthermore, in France, there is concern that an approved long-term (10 year) trial would need to be aborted if the particular ARM employed was to be placed on the prohibited list.

Although these CAs, and others, have acknowledged the current work being undertaken by the Commission on this subject, and have suggested that they will ensure consistency with the results of this work, companies conducting field trials with GM crops in several Member States are currently faced with divergent national policies on Part B releases of GM crops with ARMs. However, it is important to note that, besides the phasing out of specific ARMs, the case-by-case risk assessment will still apply.

Although some notifiers are using ARMs, the organisations involved do not expect these to be covered by the phase-out. Further development of non-plant GMOs, e.g. GM vaccines, may increase the use of ARMs, especially where they are needed to fulfil the monitoring requirements for field trials. Alternative methods to detecting the presence of, for example, GM vaccines in the environment may be prohibitively expensive. Although a few major biotechnology companies may now be phasing out the use of ARMs, smaller plant breeding firms and academic research institutions seem to have fewer (financial) resources to develop and use alternative markers.

There is also concern over the continued use of ARMs in non-EU countries. Respondents suggest that discussions with non-EU countries are undertaken at the earliest opportunity to achieve agreement on the accepted use and risks associated with ARMs. One CA suggests that this common position should take account of the precautionary principle. Agreement and clear guidance at the EU level would obviously assist these discussions and the results of the Working Group on ARMs are awaited.

3.2.9 Predictability and Transparency of Decision-making

As shown in Table 3.7, the majority of CAs believe that the changes introduced by Directive 2001/18/EC have resulted, or will result, in a more transparent and predictable regime. This is related to the increased requirements for the risk assessment and public consultation.

Table 3.7: Perceived Overall Improvements Resulting from Directive 2001/18/EC

Improvement	Competent Authorities			Industry & Research		
	Yes	No	D/K	Yes	No	D/K
More transparent?	8	2	2	1	6	0
More predictable?	6	4	2	1	6	0
Increased regulatory certainty?	2	5	5	3	3	1
More predictable time frame?	8	3	1	3	3	1

In contrast, industry respondents do not believe that Directive 2001/18/EC has provided for a more transparent and predictable regime, due to:

- uncertain monitoring guidance;
- lack of definition of acceptable and unacceptable risks;
- uncertain timelines; and
- the unpredictability of questions raised by the Competent Authorities on applications and the impact of public consultation.

There is general agreement among CAs that Directive 2001/18/EC establishes a more predictable time frame for decision-making, but this is not supported by responses from industry. Industry stakeholders suggest that the political climate increases uncertainty and unpredictability of time frames. In particular, one industry respondent suggests that unpredictable time frames have planning and cost impacts for trials conducted in consecutive years. Any delays in the review and approval process by the competent authority could lead to missing vital planting dates or deferring of trials for an entire year. This can have significant cost implications for the industry, and may affect investment in the EU.

3.3 Implications for the Diversity of European Ecosystems

Most CAs indicate that, after the end of a field trial with GM crops, consent holders have to send a report to the CA on observations of any risk for human health or the environment. The general observations are that nothing unusual has been observed and/or there is nothing to suggest any risks. Only some CAs make these reports accessible to the public.

Depending on the outcome of the risk evaluation of a field trial with a GM crop, CAs have imposed risk management measures such as the prevention of flowering, border rows and/or isolation distances to limit pollen flow. If deemed necessary, control of GM volunteer plants for one or more years after the end of the release has also been required. However, the efficacy of the risk management measures has never been routinely monitored in any of these Member States. Furthermore, in some cases where the risk evaluation had not identified potential risks to human health and the environment, consents for field trials have been given without imposing isolation measures. For example, the potential transfer of ARMs or herbicide-tolerance genes from GM crops to weedy or wild relatives is not regarded as a risk by most of the CAs, as this would not confer a selective advantage to recipient plants in natural ecosystems.

In most countries, national enforcement bodies regularly monitor whether consent holders comply with the imposed risk management measures, but only in a few Member States do the enforcement bodies make their findings publicly available. So far there have only been a few cases where consent holders have been found to be violating the conditions for risk management laid down in the consent. However, in none of these cases has this been reported to have resulted in harm to the environment.

Given this information, it could be argued that the field trials with GM crops conducted so far have had little impact on the diversity of European ecosystems. On the other hand, the efficacy of measures to limit pollen flow has not been systematically evaluated and in many cases field trials have been conducted with few isolation measures. Thus it could equally be argued that gene flow from GM crops to weedy and wild relatives in natural ecosystems might have taken place. Information is lacking as to whether this potential route for introgression actually results in the establishment of genes from GM crops in the gene pool of weedy and wild relatives in natural ecosystems. It is also uncertain whether the addition of a gene-construct from a GM crop to the species' gene-pool will enrich or affect the genetic diversity of that plant species in European ecosystems.

3.4 Socio-economic Implications

3.4.1 Industry Stakeholders

From 1998 to 2001 there has been a steep decline in the annual number of Part B applications for field trials with GM crops in the EU, and few industry responses suggest that the number of Part B applications will increase in the near future. Some argue that the burden of providing additional information for the environmental risk assessment and location details, which may lead to destruction of field trials, will reduce the number of Part B applications. Others suggest that the new Directive has no effect, because the major issue is the lack of industry confidence in the overall framework rather than the Directive itself. As few Member States have implemented Directive 2001/18/EC, companies have not yet experienced differences between national legislation, which may lead them to seek approval in one country as opposed to another. However, there is a strong expectation that differences will occur, influenced by political rather than scientific opinions.

All deliberate releases of GMOs into the environment raise issues of coexistence and liability. For example, one CA suggested that the Commission should have clarified the text of Directive 2001/18/EC to ensure that pollen flow or outcrossing from field trials with GM crops to neighbouring fields with non-GM crops is an accepted consequence of approval. Otherwise it would be illogical that crops from neighbouring fields do not need approval for placing on the market. The consultee indicated that, in some regions, conditions were attached to the consent for field trials with GM crops concerning whether neighbouring crops (or seeds in the case of neighbouring seed production fields) could be placed on the market. As a result of this regulatory uncertainty, liability in case of GM contamination was also unclear. Consequently, the number of field trials decreased.

These issues, relating to the economic impact on both the biotechnology companies and non-GM farmers, are discussed in more detail in relation to Part C releases.

Many industry respondents believe that the publication of information on Part B releases by the CAs has enabled activists in some countries to locate and destroy field trials. Several industry responses further suggest that public consultation activities significantly increase the costs of field trials with GM crops compared to conventional crop trials. In addition, academic research institutions in particular might not have sufficient (financial) resources for public communication.

So, in general, industry does not believe it will immediately benefit from the new requirements for public consultation in case of Part B releases, but rather expects an increase in costs for public communication and an increased potential for destruction of field trials by activists.

3.4.2 Non-industry Stakeholders

Directive 2001/18/EC acknowledges the particular importance of respect for ethical principles in Member States and accepts that ethical considerations may be taken into consideration when GMOs are placed on the market. It authorises the European Commission to take advice on general ethical issues from a specific Ethical Committee and the Commission is obliged to make an annual report to the European Parliament on ethical issues it has considered, accompanied if appropriate by a proposal to amend the Directive (AEBC, 2001).

However, this stated importance of ethical principles is not considered in the public consultation process. AEBC (2001) notes that there is a scientific, case by case risk assessment of GMO releases, although the decision to be made by Ministers and Governments on whether to allow deliberate release is not, and cannot be, a wholly scientific judgement. However, AEBC (2001) acknowledges that, in the absence of unacceptable adverse effects on human health or the environment, there is no regulatory barrier to the deliberate release of a GMO or, ultimately, to the marketing of a GM crop or product.

Under Directive 90/220/EEC, a minority of Member States formally or informally provided public interest groups and/or the general public the opportunity to comment on (proposed) Part B releases. However, environmental and consumer organisations generally feel that these CAs have so far not properly taken their concerns into account. In a few countries, there were also legal provisions enabling the public or affected individuals to challenge the consent granted by the CA before a court of law. In these cases, the organisations' experience is that decision-making is reviewed by the court of law mainly on administrative grounds, while scientific controversies over the official risk assessment are usually not addressed. It should be noted that these differences in national approaches to consultation, and the provision to allow an application to be challenged in a court of law, is due to the subsidiarity of Article 9.

There is possibly some confusion as to what the term consultation means for the public. It does not mean public consent, and only comments on matters within the scope of the defined risk assessment procedure are considered

relevant. This has not been addressed by Directive 2001/18/EC, which increases the potential for public consultation but does not expand on the range of relevant issues. Most significantly, broader socio-economic impacts are still excluded from this process. Some stakeholders are concerned that the decision-making framework, based on a risk assessment approach, addresses only a narrow interpretation of risk (AEBC, 2001).

Whilst a few CAs do not expect substantial changes of national legal provisions for public consultation under Directive 2001/18/EEC, most regard the new public consultation requirements as one of the major changes for their regulatory practices. So far, Member States appear to be implementing different practices for public consultation across the EU, as is allowed for under Article 9. In the view of many environmental and consumer organisations, the requirements for public consultation under Directive 2001/18/EC might lead to an improvement of legal provisions for public consultation on (proposed) Part B releases in their country. Having access to the full application file, including the data submitted, the full risk assessment and the advice of advisory bodies, is seen as a prerequisite for developing an informed opinion. On the other hand, many respondents from national environmental and consumer organisations indicate that their experience is with the broader, societal implications of GMOs rather than the legislative framework *per se*. The same applies to many traditional and organic growers associations, although the latter in particular are showing an increasing interest in GM crop releases, out of concern for GM contamination of their non-GM produce.

Directive 2001/18/EC thus formalises the legal provisions for public consultation on Part B releases but does not expand on the range of issues to be addressed in the decision-making process. Therefore legitimate concerns of the public appear to be ignored because the process does not provide for consideration of socio-economic or ethical issues and this undermines any attempts to increase public consultation. Furthermore, public interest groups experience financial difficulties in responding to every application. It is likely that frustration with the perceived lack of consideration of the wider issues causes public interest groups to focus their resources on campaigning on the broader issues, rather than providing targeted responses to individual cases.

3.5 Use of Differentiated Procedures

Article 7 of Directive 2001/18/EC allows Member States to utilise either differentiated or simplified procedures for certain GMOs for which sufficient experience has been gained. Countries are divided in their use of, or preference for, simplified and differentiated procedures. Those that regularly used simplified procedures under Directive 90/220/EEC have retained their use under Directive 2001/18/EC. However, most CAs have allowed for both simplified and differentiated procedures under national legislation, as shown in Table 3.8.

Table 3.8: Use of Simplified and Differentiated Procedures												
	Member States responding to question											
	AT	BE	DE	DK	ES	FR	GB	IE	IT	NL	PT	SE
Use of Simplified Procedures under Directive 90/220/EEC												
Never	X			X				X		X	X	X
Less than 5 times												
Between 5 and 10 times												
More than 10 times		X	X		X	X	X		X			
Favoured Approach under Directive 2001/18/EC												
Retained use of simplified procedures	X		X	NA	X	X	X		X	NA		NA
Moved to use of differentiated procedures	X	X	X		X		X	X	X		X	

Two CAs consider that the information requirements for the differentiated procedures for proposed Part B releases will be similar to those for the standard procedure. However, simplified procedures are generally considered to reduce the information burden.

Industry responses agree that the use of simplified procedures under Directive 90/220/EEC were important or very important. These reduced the time and resources required and thus provided cost savings. One notifier from industry argued that, under Directive 2001/18/EC, simplified procedures should be developed for GMOs used for food, feed and processing in order to be consistent with the Cartagena Biosafety Protocol. Simplified procedures are also suggested for 'stacks' of previously authorised GM products, combined by traditional breeding. However, there is currently limited experience with differentiated procedures and there is insufficient experience for industry to assess the impact of any shift towards differentiated procedures by Member States.

3.6 Conclusions on the Operation of Part B

The number of Part B applications depends largely on the potential for obtaining Part C consents. Thus whilst uncertainty remains on the authorisation process for Part C releases, there will be a related impact on Part B applications. In addition, the relatively recent transposition of Directive 2001/18/EC in some countries, and the failure of other Member States to transpose the Directive, means that there is little experience of the new Directive in practice and stakeholders are faced with different approaches across the EU. However, there is evidence to suggest that countries which have not yet transposed the Directive still process a number of Part B applications, thus any inconsistencies experienced by industry are more likely to be related to the political situation than to the regulatory situation.

The revision of Directive 90/220/EEC in the form of Directive 2001/18/EC aimed to address certain aspects of the authorisation process for Part B releases. Increased requirements for the ERA appear to be assisting a move towards harmonisation across the EU and to address the possible longer term,

direct, indirect, delayed and cumulative effects on the environment and wildlife of releasing and using GMOs. However, issues of definition still remain; most significantly, acceptable risk remains undefined. Whilst some stakeholders consider it important that Member States should be able to make decisions according to national ethical principles, variations in interpretation of this term may lead to major differences between Member States and further uncertainty for industry. In this situation it is unlikely that Member States will take decisions about GMO releases on a consistent basis.

Consultation with the public on experimental releases of GMOs and information to the public on the release of all GMOs is seen as a key change in the new Directive. Whilst public interest groups welcome the formalisation of consultation processes, there is frustration that socio-economic and ethical objections appear to have no place in the decision-making process. Furthermore, where GMO releases may be regulated under different legislation, for example gene therapy trials, the potential for public consultation may be reduced. As experience increases it may be necessary to consider improvements to the provisions for public information and consultation in the Directive.

Although a number of outstanding issues remain, and are discussed further in Section 5, it is noted that the Commission is already taking action to address some of the issues, for example in relation to the provision of location details of trials and the establishment of a Working Group on ARMs.

4. OPERATION OF PART C

4.1 Introduction

Part C covers commercial releases. Once a consent is given under this procedure for a GMO to be placed on the market in the EU, it extends to all Member States. All Member States had national legislation under Directive 90/220/EEC. As in the previous Section, those countries which have transposed Directive 2001/18/EC (Denmark, Ireland, Italy, Portugal, Sweden and the UK) [3] are highlighted in grey in the following analysis, although all countries should now be applying the requirements of Directive 2001/18/EC regardless of national implementation. The remaining countries are in the process of transposing the Directive, thus they have been able to provide details of the requirements but are uncertain of the operation of these new regulations in practice due to a lack of experience.

4.2 General Implications

4.2.1 Authorisation under Different Regulations

In some cases, CAs report to be uncertain when considering whether a GMO is a contained use or a deliberate release. This is particularly an issue for transgenic animals and one CA raised the case of GM luminous fish. Although it can be argued that a fish in a tank is a contained use, in order to effectively market such GMOs, it is necessary to regulate them under the Deliberate Release Directive to avoid the need for authorisation of every use (i.e. individual consumers). Thus the application of regulations is related to practical issues as well as definitions. Comparable requirements between the contained use and deliberate release regulations should not lead to significant differences in the approach to regulation, but this may depend on national implementation.

In addition, one industry consultee highlighted uncertainty for the marketing of GM vaccines. As Part B applications have been regulated by both Directive 2001/18/EC and the relevant clinical trials procedures, it might be assumed that notifiers have to submit an application under both Directive 2001/18/EC and Regulation 2309/93. Although Article 12 of Directive 2001/18/EC states that the Deliberate Release Directive will not apply to GMOs authorised by Regulation 2309/93, this appears to be a source of uncertainty for industry which may arise in the future as the development of GM vaccines progresses.

Industry and CA stakeholders have requested further guidance on the interaction between the different pieces of legislation, including Regulation 1829/2003 on GM food and feed, and how these will work in practice.

[3] As discussed in Section 2.2.3, although Spain has recently transposed Directive 2001/18/EC into national law (as of 31 January 2004), the research for this study was undertaken before the transposition and thus, for the purpose of this study, Spain is treated as a country which has not transposed the Directive.

Although the requirements of the different pieces of legislation are essentially the same, the choice of regulations for the authorisation of GMOs for marketing may have implications for:

- the environmental risk assessment;
- public information and consultation; and
- the administrative burden for industry and research organisations.

These are discussed in more detail in the relevant sections below.

4.2.2 Number of Part C Applications

There are currently 23 Part C applications at various stages of the authorisation process, as shown in Table 4.1. Although Part C of Directive 2001/18/EC covers all commercial releases, Regulation 1829/2003 on GM food and feed provides an alternative route for authorisation for placing GM crops on the market. Consultees from CAs and industry suggested that it is likely that that, from 2004, GM crops will be authorised under Regulation 1829/2003 and authorisation for placing on the market under Directive 2001/18/EC will probably only be sought for non-food GM crops and other organisms. Thus, in future, the number of applications under Part C of Directive 2001/18/EC may be reduced as a consequence of the evolving legislative framework in the field of biotechnology.

Table 4.1: Number of Part C Applications by Year

Year	Member State								
	BE	DE	DK	ES	FR	GB	NL	SE	EU
1996	1	1		1	1			1	5
1997			1	1					2
1998	1	1					1		3
1999	1			1		1			3
2000		1		1			1		3
2001				1					1
2002		1				1			2
2003				1		1			2
2004				1			1		2
Total	3	4	1	7	1	3	3	1	23

A number of the current applications were submitted under Directive 90/220/EEC (prior to 17 October 2002). Article 35 of Directive 2001/18/EC requires that notifications received under Directive 90/220/EEC, for which the procedures were not completed by 17 October 2002, shall be subject to the provisions of Directive 2001/18/EC. The majority of outstanding applications have now been resubmitted under Directive 2001/18/EC. However, it appears from the consultation that CAs and industry have different interpretations of this Article, which has led to some CAs requesting additional data that industry does not believe is necessary. Whilst industry respondents accept that Article 35 requires post-market monitoring plans to be submitted (which had not been required under Directive 90/220/EEC) industry does not believe that Article 35 should be interpreted as requiring the revision of risk assessments that had been agreed under Directive 90/220/EEC. Although it may be

questioned as to what is meant by 'agreed' (given that the whole application had not yet been approved), one industry respondent indicated that they had been required to revise what they believed was a previously agreed risk assessment, resulting in additional costs to the company. Other industry respondents were aware of such cases, although not directly affected themselves. It is likely that only a few companies would be affected by Article 35 and, although the number of consultation responses was small, given that this issue was only raised in more detailed telephone conversations (rather than the questionnaire responses) it is unlikely that it is a significant issue.

Industry respondents generally agree that the uncertainty in the approval process for commercial releases after 1998 caused a reduction in investment, with two companies indicating a 50% reduction. In addition, the uncertainty has led to increased costs throughout the research and development process; this is seen as a particular problem for small biotechnology companies and large non-biotechnology based companies which may consider Part C applications.

4.2.3 Restarting the Decision-making Process

All of the responding CAs believe that Directive 2001/18/EC has helped to restart the decision-making process. The introduction of the regulations on traceability and labelling, as well as GM food and feed, are expected to facilitate and support the decision-making process. In addition, the defined time limits will also benefit the process.

However, additional issues concerning liability and coexistence are causing concern in some Member States and, as these are to be addressed on the basis of subsidiarity, Member States may need to resolve them before the decision-making process can restart. These issues are discussed below.

4.2.4 Public Consultation

For Part C applications, Directive 2001/18/EC requires the Commission to make the SNIF (the summary of notification) and the assessment report publicly accessible and foresees a period of thirty days for public consultation on each. Although the Directive does not state explicitly how public comments are to be dealt with, the timing would normally allow CAs to take these comments into account:

- in the preparation of the assessment report by the lead Member State CA during the 90 days foreseen for this phase (Article 14); and
- in the comments/objections/requests for further information forwarded by all CAs during the 60 days foreseen for this phase (Article 15).

In addition, an individual Member State may take its own public's comments into account when defining its voting position, should a notification be required to follow the Community procedure in case of objections.

Public interest groups express dissatisfaction with the public consultation procedure for Part C applications as set out in Directive 2001/18/EC and believe that, in several cases, only the SNIF has been made available for public consultation. In addition, they also suggest that the period for public comment is too short.

As for the public consultation on Part B applications, this dissatisfaction may be caused by a misunderstanding of the requirements of the Directive and a lack of experience in the operation of public consultation for Part C applications. However, this is not helped by the information provided on the Joint Research Centre (JRC) website[4], which provides public access to the SNIFs and assessment reports, and which explains the process as follows:

"*the Commission shall immediately make available to the public a "summary notification information format" (SNIF). The Commission shall also make available to the public the so-called "assessment reports". The public may make comments on the Part C SNIFs and on the assessment reports to the Commission within 30 days and the Commission shall immediately forward the comments to the competent authorities."*

Although this statement is technically correct, and follows the provisions of the Directive, it does not make clear to the public that the SNIF and the assessment report for each application will be published separately and 30 days will be allowed for comment on each. Any misunderstanding may be exacerbated by the differences in the time taken to publish the assessment report, following publication of the SNIF. For example, based on the information from the JRC website, the following observations can be made:

- in two cases, the SNIF and assessment report were published at the same time;
- in four cases, the assessment report was published within six months of the SNIF being published; and
- nine notifications, for which the SNIF was published over a year ago in February or March 2003, are still awaiting publication of the assessment report.

Therefore, although the assessment reports will be made available for public consultation, as provided for by Directive 2001/18/EC, the time taken to produce the reports, together with a lack of clear explanation about the consultation process, leads the public interest groups to believe that the consultation process is not working correctly.

A few Member States have made the full application files publicly accessible at a government library; however this is not provided for in Directive 2001/18/EC and is the decision of individual Member States. Public interest groups suggest making the complete application file publicly accessible at the website of the JRC. They further suggest making the comments by other national CAs on the initial assessment report publicly accessible, as they

[4] http://gmoinfojrc.it/info.asp

believe this increases the transparency of regulatory decision-making on Part C applications. These suggestions are not provided for in Directive 2001/18/EC and there would be issues of confidentiality and legalities if CA opinions were made public.

For industry, the provision of information on locations of commercial releases is the key issue in relation to public information. If this information is too precise, it could lead to further damage of crops, unless there is legislation that would make this a criminal offence. Such damage could result in significant costs for users of GMOs and could thus affect the overall market. However, the provision in the regulations on notification of the location of releases has been left deliberately vague. It will be decided on a case-by-case basis and if locations are defined broadly rather than specifically, then such costs are unlikely to be incurred in practice.

Non-industry stakeholders have expressed concern over the transposition of certain matters. In particular there is concern over the workability of public registers. This is important because registers are one of the measures that will assist conventional and organic farmers to avoid contamination of their crops.

As for Part B, there a number of issues relating to the transparency of the overall process, in terms of information provision, comments made and how these are dealt with. Public interest groups suggest that a clear procedure is needed for how public comments should be taken into account, including those to do with ethical and socio-economic principles. In addition, based on the misunderstanding of the process that appears to exist, there is a need for clearer guidance on the timeframe for consultation.

4.2.5 Environmental Risk Assessment

The issues raised in relation to the Part B ERA and the definition of various terms also apply to Part C. In addition, Regulation 1829/2003 foresees that the ERA for food and feed GMO releases should be conducted by the European Food Safety Authority (EFSA) in conformity with Directive 2001/18/EC and the ERA guidance notes (COM Decision 2002/623/EC). Some CAs expressed concern that environmental risks might not receive an adequate level of attention. In relation to specific regional issues concerning the ERA, it was also suggested that national CAs for Directive 2001/18/EC and their scientific bodies should be very closely involved by the EFSA. A need for more homogenous assessments reports for Part C applications was also identified.

Furthermore, Directive 2001/18/EC foresees that for medicines consisting of or containing genetically modified organisms (GM medicines) for both human and veterinary use, the centralised authorisation procedure as defined in Regulation 2309/93 must be followed. COGEM[5] (2003) reports that both procedures include an extensive ERA in order to establish a high level of environmental protection. However, contrary to the procedure for other GM

[5] The Commission on Genetic Modification (COGEM) is the scientific biosafety advisory body to the Dutch Competent Authority.

products, COGEM (2003) believes that the centralised procedure for GM medicines, as co-ordinated by EMEA, does not appear to be in line with the precautionary and participation principles. For example, COGEM (2003) states that experts with knowledge and experience of environmental risk assessments appear to be absent from EMEA. It is suggested that it is therefore questionable whether EMEA is capable of making the right decisions one environmental risk assessments, and interpreting these according to national environments. Furthermore, COGEM (2003) highlights that the procedure has no public consultation process. The general public is only informed about the produce after the marketing procedure for a medicine has been finalised, via publication on the EMEA website. There is also no opportunity for the general public to verify the procedure.

4.2.6 Antibiotic Resistance Markers

The issue of ARMs has been considered in relation to Part B applications. However it is worth noting that the requirements for post-market monitoring of Part C authorisations for non-plant GMOs, like GM vaccines, and the availability of alternatives to ARMs, should be carefully considered when considering the issue of banning ARMs.

4.2.7 Ten-year Limit on Part C Authorisations

Directive 2001/18/EC sets a maximum time limit of 10 years on Part C consents, although these can be renewed. The majority of CAs do not expect this to have any effect on the number of future applications as they believe that ten years is already a substantial part of the life-time of a new variety and it is possible for the consent to be renewed. However, one CA believes that this restriction may be too short for the development of new varieties of certain plants and thus may reduce the number of future applications.

SBC (2003a) reports that developing an event into a GM variety through conventional plant breeding requires four to six years. The limited validity of authorisation of an event to a maximum of ten years and the uncertainty whether the consent will be renewed thereafter makes the time left for commercialisation unpredictable. In addition, because the period of approval under Directive 2001/18/EC starts at first market registration of the GM variety, which is "the vehicle for introducing the event", development of further GM varieties based upon that event is only allowed to begin at that time. These further GM varieties could only reach the market seven years later at best. If approval for the event has been granted for ten years and renewal of consent is uncertain, the commercial risks to develop further GM varieties based on that event would be too high. If 'GM variety-approval' trials would be allowed under Part B of Directive 2001/18/EC, this could increase the time left for commercialisation of an 'event'. Given that 'GM variety-approval' trials usually need to take place without confinement, the main condition for a Part B authorisation should therefore be that a preliminary safety assessment has established that the adventitious presence of experimental GMOs in neighbouring commercial production is not an

'unacceptable risk'. Other industry respondents are uncertain whether this ten-year restriction will have any impact.

Furthermore, SBC (2003a) reports that different views between Member States on whether GM variety-approval procedures may only start after an authorisation under Part C has been obtained, or may begin under Part B conditions, also impact the time left for commercialisation. In addition, containment and monitoring requirements imposed on event-approval trials by Part B are not always compatible with requirements for GM variety-approval trials. One CA noted that there might be a need for flexibility in the ten year limit to allow other authorisations to be obtained, for example, national list approval or pesticide use. Such flexibility would not be possible under Directive 2001/18/EC unless the Directive was amended.

4.2.8 Post-market Monitoring and Guidance

Four CAs had carried out or planned post-marketing for commercial releases under Directive 90/220/EEC. Two of these do not expect Directive 2001/18/EC to change the type of monitoring required. Industry believes there will be increased requirements although there is little experience at this stage and the specific additional requirements are not yet detailed.

Table 4.1: Requirements for Post-market Monitoring of Releases

Requirements	Member States answering question											
	AT	BE	DE	DK	ES	FR	GB	IE	IT	NL	PT	SE
Directive 90/220/EEC – monitoring planned or carried out?	N	Y	Y	N	Y	Y	N	N	N	N	?	N
Directive 2001/18/EC – modifications to monitoring?	Y	Y	Y	-	N	N	-	Y	-	Y	Y	-

Public interest groups believe that the requirements under Directive 2001/18/EC are an improvement to those under Directive 90/220/EEC but do not believe that they are adequate. Further suggestions for improvement include that monitoring is undertaken by independent scientists and the reports should be peer-reviewed before publication; monitoring should continue as long as adverse environmental effects can occur; and that the size of the area to be monitored should depend on the capacity of the GM crop in question to spread its pollen and seeds.

This view is supported by AEBC (2001), which suggests that post-market monitoring should be undertaken in a way that is independent of the plant breeding industry and of interest groups, and that it should be kept under periodic review. It noted that there should also be agreement on how the results of the monitoring would be used and, in particular, on how the powers for withdrawing approval if the monitoring revealed adverse effects would be used, and on issues relating to reversibility and product recall.

There is a general view among CAs that general surveillance monitoring may become more consistent across the EU under Directive 2001/18/EC in the long-term, assisted by the Guidance Document to Annex VII. One CA believes though that the general nature of the guidance may not be helpful in the short-term. A number of industry stakeholders and CAs report widely differing approaches between Member States, to the extent that it may affect where an application is submitted (although the approach to monitoring may be indicative of the general approach to regulating GMOs). It is noted that experience may lead to harmonisation, but this will take several years. Greater variation is expected to occur in case-specific monitoring and one CA suggests that the possibility of developing case-specific guidance should also be explored. Specific issues and guidance for non-plant GMOs should also be addressed.

One public interest stakeholder believes that, as the guidelines are not legally binding, the only way to ensure consistency is through detailed EU legislation. One industry respondent suggests that monitoring and surveillance may be affected by national approaches to coexistence and, more generally, industry respondents expect national guidelines to vary significantly. Several consultees questioned the appropriateness of insisting on the same post-market monitoring across the EU, given the differences in ecosystems and agricultural practices, but the standards for observations and reporting should be consistent across the EU.

Industry suggests that realistic, clear and practical guidelines are needed for both case-specific and general surveillance monitoring and CAs note that an EU working group will be set up to discuss this aspect. More specifically, industry respondents believe that general surveillance monitoring should not require risks that the risk assessment concluded to be negligible to be re-addressed, and that guidance is needed on statistical significance. Furthermore, one industry respondent notes that the boundary between general surveillance and case-specific monitoring is well defined in Directive 2001/18/EC but is not consistently applied in practice. Again, industry and CA respondents suggest that clearer guidance may improve this situation.

One CA suggests that further issues to be addressed include:

- how to develop post-market monitoring from a conceptual level to practical implementation;
- how to make use of existing long-term monitoring projects;
- how to gather and compile data in a practical way (an EU-wide database based on a harmonised approach for documentation and compilation of monitoring results is suggested); and
- a discussion of the baseline for general surveillance.

In addition, it is not yet clear what the responsibilities are for the farmers, who commercially grow the event as regards post-marketing monitoring and informing CAs about the locations where the events are grown.

4.3 Implications for the Diversity of European Ecosystems

There are a range of uncertainties associated with any Part C (or Part B) release. The risk assessment and authorisation process has been designed to reduce the potential for adverse consequences on the basis of scientific investigation. However, because genetic modification and the widespread use of GMOs is a relatively new issue, there is a lack of experience on which to base and calibrate ecological and agronomic models to establish the medium and longer-term risks with a degree of certainty. The requirement for post-market monitoring of effects is an important tool for identifying the occurrence of impacts.

However, there are issues associated with the irreversibility of these impacts given that genetic pollution is self replicating in nature. Uncertainties and implications cover not only the effects of the GMOs and associated transgenes themselves, but also the indirect effects from changes in agronomic practices. Implications and uncertainties include:

- the potential for more widely invasive or persistent species and the implications for agricultural and natural ecosystems;

- the potential for toxicity of GM crops to wildlife and associated impacts. The issue is perhaps more related to future pharmaceutical or other novel uses and pest resistance than those of herbicide tolerance;

- particularly in the case of pest resistant and herbicide-tolerant crops, the new pest control strategies may result in changes to agronomic practices. These might include changes in the quantity, type and timing of pesticide applications, cropping patterns, drilling and harvesting, soil management, etc. The positive and negative effects of these is unknown;

- the potential for stacking of transgenes in crop plants, wild relatives or other species. Predicting the ecological behaviour of such species and associated consequences is difficult;

- in the medium to longer term, there may be applications for GMOs for certain non-food purposes: pharmaceuticals, speciality and bulk chemicals and biomass for energy. In addition, there is a longer term possibility for the development of tolerance to marginal environments (e.g. tolerance of drought, heat or salt). The wider implications of such traits are likely to be considered on a case-by-case basis in future; and

- the potential for gene flow to bacteria and viruses and associated consequences.

Collectively, these uncertainties suggest that environmental damage from GM releases is at least feasible. In light of this potential, there has been concern over how such environmental damage should be addressed should it occur.

The need to establish a liability regime for environmental damage has been a long running and contentious issue for Member States and the international community more generally. In its first reading in the European Parliament, amendments to the revised Deliberate Release Directive (now Directive 2001/18) were proposed to provide for EU-wide environment liability rules "*to provide wide-ranging regulation of possible cases of damage"* and to make those legally responsible for deliberate releases of genetically modified organisms "*have full civil and criminal liability for any damage to human health and the environment caused by the releases in question*".

In the event, the Parliament dropped that amendment in the light of a Commission undertaking to bring forward proposals for a general environmental liability regime by 2001, which is now close to completion under the proposed Environmental Liability Directive (ELD). A Common Position on the ELD was adopted by the Council of Ministers on 18 September 2003 and a second reading Resolution was adopted by the European Parliament on 17 December. This Draft ELD is aimed at prevention and remediation of significant damage to water, land and protected species and habitats. It provides Member States with a duty to order responsible operators to undertake preventive or remedial action, and a discretionary power to carry out the work themselves and then recover the costs from the operator. A regime of strict liability is proposed for environmental damage from GMOs, i.e. there is no requirement to demonstrate negligence or criminal damage.

However, the regime imposes liability only for the following restricted aspects of environmental damage (AEBC, 2003):

- damage to species and natural habitats protected under the EC Habitats and Birds Directives, where this has significant adverse effects on reaching or maintaining the favourable conservation status of such species or habitats, with Member States given discretion on whether to extend these rules to additional species and/or habitats designated for equivalent protection under national legislation;

- water damage, defined as damage that significantly adversely affects the ecological, chemical and/or quantitative status and/or ecological potential of waters subject to the Water Framework Directive 2000/60/EC; and

- land damage, which is any land contamination that creates a significant risk of adverse effects on human health.

The draft ELD specifically excludes civil liability for property damage or economic loss from, for example, adventitious presence of unwanted GM material/traits/species from neighbouring properties in crops or wild relatives. Only harm which qualifies as environmental damage as defined above will be covered. Individuals whose interests have been harmed or rights have been infringed, together with recognised environmental organisations, will have a right to request enforcement action from CAs in cases where such action seems justified but has not been taken, with the authorities required to give a reasoned response. Beyond that, however, individuals will have no right of

direct legal action, other than that already available under national law. Damage to property and issues of pure economic loss are therefore left to Member State criminal and civil liability laws.

The Cartagena Protocol on Biosafety came into force on 11 September 2003 to control transboundary movements of GMOs. The issue of liability for environmental and health damage in the receiving state was eventually deferred for further consideration in future.

In light of these issues there is, at present, no consistent EU regime of liability for damage that may be caused by the release of GMOs under Parts C or B, or the import of these GMOs, beyond the existing liability laws of Member States. This has general implications for releases under Parts B and C and specific implications regarding effects on ecosystems and health. Similarly, the biotechnology industry and operators are unlikely to be able to account for their own future liability in relation to these issues. With respect to both issues, it is of note that the draft ELD will not have retrospective effect. This means that strict liability under the ELD will not apply to environmental damage caused by existing releases under Directive2001/18/EC (and 90/220/EEC) which occur before the deadline for Member States to bring the ELD into effect (currently expected to be around mid-2007).

Several Member States and devolved institutions have been considering liability rules of their own to address GMO issues, but most have preferred to wait for common EC legislation. Insofar as rules are adopted at national and sub-national level, these may not be consistent across the EU, which, in turn, has implications for the smooth functioning of the regulations and the market.

4.4 Socio-economic Implications

4.4.1 Biotechnology Industry Stakeholders

Most industry respondents agree that the uncertainty in the approval process for Part C releases of GM crops after 1998 has caused a significant reduction in investment in GM plant breeding (R&D) in Europe. Several industry respondents suggest that the regulatory burden under Directive 2001/18/EC substantially increases research and development costs, which makes it unlikely for small companies and public research institutes to bring products to the market. In their view, the regulatory burden strongly discourages EU investment. In addition, some industry respondents express concern that this has already led to a brain-drain in some European countries, while at the same time students might not feel attracted to be trained in this publicly controversial research field. Only a few industry respondents believe Directive 2001/18/EC will have a positive impact on innovation, because there is at least an agreed set of regulations and guidance.

Depending on the nature of the crop/release, there are a number of claimed agronomic and/or environmental benefits from the introduction of GM crops. As such, delays in the regulatory process may represent an opportunity cost for

farmers who want to grow GM crops, or for the wider environment, but are prevented from doing so because the crops are unavailable.

The biotechnology industry sponsored National Centre for Food and Agriculture Policy (NCFAP) study estimated the potential impact for improving pest management in European agriculture on the basis of the effects of adoption of a series of GM crops in Europe. In June 2003 the first three case studies were published, covering Bt maize, herbicide-tolerant (HR) sugar beet and potato with fungal resistance. Case studies were based on the assumption that the Part C applications of the crops would have been approved. According to the industry sponsored study the situation could have been as follows:

- 40 % adoption of Bt maize on Europe's total maize crop would result in a production increase of 1.9 million tonnes (Mt), a decrease of insecticide use of 52.6 tonnes and a net value increase of €250 million per year;
- 100 % adoption of HR sugar beet on Europe's total sugar crop would annually result in a production increase of 5Mt, a decrease of herbicide use of 2,200 tonnes and a net value increase of €390 million per year;
- 40 % adoption of HR maize would decrease herbicide use by 1,700t and a net value increase of €24 million per year; and
- 25 % adoption of HR oilseed rape would lead to a production increase of 124,000t, a decrease of herbicide use of 117t and a net value increase of €28 million.

Arundel (2002) estimates that the greatest economic and employment impact of biotechnology would occur not in the pharmaceutical sector but in the agro-food production chain. Arundel estimated that there were 50,000 direct biotechnology jobs in the agro-food chain in the late 1990s. However, as a process technology, it is anticipated that agro-biotechnology will increase productivity by reducing inputs, which in turn will reduce employment. Arundel quotes a German biotechnology industry study expecting that most agro-biotechnology innovation will reduce employment though it could provide a small increase the number of higher-skilled jobs.

Implications, uncertainties and cost components including the following should be considered alongside the estimates of opportunity costs of delays in the regulation:

- consumer demand will dictate the market value of GM crops. This may be low at present;

- a market for GM crops may inflate the prices for conventional or organic crops, depending on consumer demand. This may make conventional or organic crops more financially attractive to the farmer despite the claimed savings of GM crops in agronomic costs of production;

- coexistence issues are to be addressed on the basis of subsidiarity. Depending on the measures for coexistence implemented at Member State

level (and the AP threshold issues outlined below), there will be costs to GM and non-GM farmers associated with complying with these;

- there may be additional costs to GM and non-GM farmers associated with infringements of AP thresholds and the need to secure insurance against loss or liability; and

- there may be problems with the use of farmer-saved seed concerning both the build up of AP levels in a non-GM crop and accidental infringement of patent.

These implications will not be predictable until coexistence measures have been established by the individual Member States and there have been a more significant number of Part C authorisations.

In addition to the agro-economic issues highlighted above, there are a number of agronomic considerations and potential implications. These include:

- GM crop volunteers may be persistent. There are agronomic costs associated with the existence of these volunteers in following crops, and need to identify and eliminate them from conventional and organic crops for reasons of AP thresholds (among others);

- there may be implications from the development of resistant insects, weeds and diseases, particularly to the chemicals used on crops more generally. Additional measures may be necessary to control these in GM and conventional crop situations, with associated costs;

- stacking of transgenes in crop plants or wild relatives is a possibility in the future (as it has with herbicide-tolerance genes in oil seed rape in Canada). This may cause agronomic problems in the form of superweeds or other problem species; and

- there is uncertainty over the agronomic consequences of transfer of genetic material soil microbes and viruses.

To the extent possible, these issues are covered under the risk assessment procedures to reduce the potential for adverse consequences of Part C (and Part B) releases. At the same time, owing to uncertainties, the potential for adverse consequences may still exist, albeit at a much reduced probability.

4.4.2 Implications for the Marketing of Agricultural Products

One of the main reasons for certain Member States joining the blocking majority, which led to the effective suspension of decision-making on pending Part C applications in 1999, was the absence of rules for the traceability and labelling of GM products from farm to fork. Two new EU regulations (1829/2003 and 1830/2003) entered into force in November 2003 which, together with Directive 2001/18/EC, ensure the traceability and labelling of the use of GMOs from farm to fork. Another consequence of the Regulations

is an amendment to Directive 2001/18/EC, which allows Member States to take measures for coexistence of GM, conventional and organic crops on the basis of subsidiarity.

Biotechnology and seed companies generally do not view the requirements for traceability and labelling of GMOs up to the stage of farming as problematic, but from that stage on the complexity of traceability and labelling of GMOs significantly increases. Farmers would be responsible for providing operators in the next stage with information about the GM events in their harvest and for segregation of GM crops and non-GM crops.

Whilst downstream operators in the agro-food chain feel confronted with a regulatory framework which is perceived as technically difficult and costly to implement, retailers and consumer and environmental organisations appreciate the switch from 'detectability-based' labelling to labelling based on whether food and feed is produced from GMOs, regardless of detectability. But many of the consumer and environmental organisations view the labelling-threshold of 0.9 % for the adventitious presence of GM material in non-GM food and feed as too high.

Adventitious Presence (AP)

Under the new EU legislation[6] food will have to be labelled as containing GM material if it has a content of GM elements of 0.9% or more. Below this level, it does not have to be labelled, provided that the GM content is of constructs that have been authorised for use in the EU and can be shown to be adventitious and technically unavoidable.

In order to maintain the 0.9% standard and associated consumer choice, it is necessary to establish protocols for the coexistence of GM cropping with non-GM crops. To achieve this, a legal basis for Member States to take national measures to promote coexistence of organic and conventional crops with GM crops was introduced during the second reading in the European Parliament of the food and feed and traceability and labelling regulations[7]. Accordingly, the Commission published a Recommendation for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming[8] (i.e. making the issue one of subsidiarity).

Of particular note is that the Recommendation declares that these measures should be efficient, cost-effective, and proportionate and should not go "*beyond what is necessary in order to ensure that adventitious traces of*

6 Regulation (EC) No 1829/2003 on genetically modified food and feed; and Regulation (EC) No 1830/2003 concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

7 Article 44(2) of Regulation (EC) No 1829/2003 (Food and Feed Regulation).

8 Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming

GMOs stay below the tolerance thresholds set out in Community legislation. They should avoid any unnecessary burden for farmers, seed producers, cooperatives and other actors associated with any production type".

However, with regard to 'any production type', a number of actors in the food chain (and particularly the organic sector) wish to work to standards below the 0.9% threshold set out in the Community legislation. This has a number of implications for choice, equity and competition, liability and the smooth functioning of regulations on GMOs.

As noted in the Commission Recommendation on coexistence, the organic farming Regulation[9] establishes that no GMOs shall be used in production. It also notes that the organic farming Regulation does allow for the setting of a specific threshold for the unavoidable presence of GMOs, but no threshold has been set. In the absence of such a specific threshold, the general thresholds apply.

In at least some countries, including the UK, Italy, Denmark and Austria, the organic certifying bodies are operating a policy of working to a lower threshold than 0.9%, in fact as low as 0.1%. Others appear not to have taken a formal position on a threshold as yet, although it is likely that all organic producers would wish to work to levels below the 0.9% threshold (AEBC, 2003).

Whilst the 1999 EU Regulation on Organic Production bans the use of GMOs in organic production, it does not appear at present to directly prohibit the marketing of organic produce containing GM material at any level (AEBC, 2003). However, organic production methods are primarily defined and managed by the certification bodies. As such, it is not entirely clear whether the *de facto* limits set by the certification bodies for the production of organic crops represent the general thresholds referred to in the Recommendations, or whether these general thresholds are the statutory 0.9% levels in Regulation 1830/2003.

In considering this issue it must be noted that, until certification bodies are given statutory authority by legislation, they are voluntary bodies whose definitions probably carry little or no official weight. Accordingly, despite growing government support and sympathy for organic methods, the limits set by self-regulating industry bodies are highly contentious in this context and do not seem to have been granted official recognition. There appears, therefore, to be no legal imperative to work to lower levels. What is unclear is whether Member States will make use of their rights to enforce more stringent controls in this respect.

In general terms, the motive for working to a lower threshold is ultimately driven by consumer choice. At present, many organic certifying bodies and multiple retailers operate a GM-free policy for consumers and wish to

[9] Council Regulation (EC) No 1804/1999 supplementing Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs to include Livestock production.

continue operating in the market with such policies. This inevitably means that a number of actors in the food chain, both organic and conventional, wish to work to levels below the 0.9% threshold.

In considering the coexistence of GM and non-GM crops in Europe, JRC (2003) concludes that "a 0.1% limit will be extremely difficult to meet for any farm-crop combination in the scenarios considered (10% and 50% GMOs in the region), even with significant changes in farming practices. Perhaps some farm types producing seed of oilseed rape could approach such thresholds, but only with significant changes of farming practices". A recent Danish study (Tolsrup *et al*, 2003) draws similar conclusions concerning the difficulties of working to lower thresholds for some crops.

The interaction of issues concerning the measures required to ensure coexistence to the 0.9% and lower (0.1%) thresholds raises a number of implications.

Consumer and Farmer Choice

As there is no legal imperative to work to a lower threshold (such as 0.1%) there is debate within some Member States concerning whether GM farmers should work to the lower threshold so as not to interfere with the existing markets or whether they should work to the statutory (0.9%) threshold. However, it is not known whether it will be practically possible to continue to provide consumers with a choice of below 0.9% AP for a number of existing crops (and probably a range of future crops).

Under the scenario where GM farmers work to the statutory (0.9%) threshold, this will necessarily impinge on neighbouring farms working to a lower threshold for reasons of organic certification or to fulfil contractual requirements for a crop. This will influence the decision of neighbouring farmers concerning which crops to grow, where and using what controls to avoid AP levels over their contractual or certification limits. This may raise issues concerning whether the new technology unfairly impedes the carrying out of existing economic activities. The question of whether any rights are actually infringed is unresolved, as organic farmers do not have the right to insist that others recognise their purity limits. Increasing support for organic farming from governments and pressure from retailers both seem to strengthen the organic farmers' position, but whether that is enough for AP levels above 0.1% to be deemed a nuisance actionable in law is very hard to say and would pose several difficult problems for any court hearing such an action.

These issues raise complications when trying to satisfy the Commission's Recommendation concerning coexistence that "*farmers should be able to choose the production type they prefer, without imposing the necessity to change already established production patterns in the neighbourhood*".

Burden and Allocation of Costs

The Commission's recommendations for coexistence note that "*as a general principle, during the phase of introduction of a new production type in a region, operators (farmers) who introduce the new production type should bear the responsibility of implementing the farm management measures necessary to limit gene flow*". There is, however, debate within some Member States concerning whether GM farmers should bear the cost burden of measures to achieve lower thresholds in situations where neighbouring farmers are working to these, or whether these costs should be borne by the farmers operating to the lower levels.

In addition to social and economic rights issues and mutual infringement, there are issues for the smooth operation of the European market (particularly for organic foods), as the costs of meeting lower thresholds are very significant. The implementation of different levels of AP in food and differences between Member States concerning which sector these costs are allocated has implications for both trade and competition in the established markets.

Thus, while the Recommendation notes that "*National strategies for coexistence should ensure an equitable balance between the interests of farmers of all production types*", it is possible that a lack of consistency between the measures and allocation of costs to different production types between Member States may mean that there is an inconsistency between the interests of farmers of all production types across the EU.

Liability for Infringement of AP Levels

At present, it is not clear whether conventional or organic farmers working to the 0.9% (or lower) thresholds will be able to seek remedy for economic loss should AP levels in their crops become elevated despite measures taken by GM farmers or the organic farmers themselves. The Commission's Recommendation on coexistence advises Member States "*to examine their civil liability laws to find out whether the existing national laws offer sufficient and equal possibilities in this regard*" (the issue is, thus, one of subsidiarity and beyond the scope of Directive 2001/18/EC).

In terms of economic loss there are two separate questions here: firstly, whether pure economic loss (without direct physical damage) is recoverable under any circumstances in each jurisdiction. Here there are long-standing differences between the Member States. Pure economic loss cannot be recovered in at least several of them. Secondly, even where pure economic loss is recoverable in principle, such a claim is unlikely to succeed where no statutory threshold has been breached, unless under civil law a court can be persuaded that organic farming practices are normal and that a below 0.9% threshold is reasonable. In this case, third party intrusion causing a breach of such standards might constitute a nuisance. However, Courts are generally reluctant to make public policy in such fields without some clear indication that they are in line with the will of public policymakers.

There is a lack of clarity concerning future national arrangements. However, unless a strict liability regime is in place, the burden of proof will be on a claimant to demonstrate that a given farmer owed a duty of care or other grounds for action under civil law. The rules for such actions vary from country to country, including the relative burden of proof placed on the claimant, the defences to liability, the test of causation, the severity of any duty of care, etc.

There will be a number of different legal avenues to seek redress within each Member State, however, most of these avenues do not include pure economic loss in the award of damages, being limited to direct physical harm to person or property and any associated financial losses. In the case where a farmer is unable to sell a crop owing to levels of AP above the statutory 0.9%, at present he/she will not be able to seek remedy for pure economic loss in most Member States. However, the Commission has advised Member States to examine their civil liability laws in this regard. Whether Member States are willing or able to make changes to regimes which have excluded pure economic loss from civil claims for decades is unclear at present.

In the event that the conventional or organic farmer had implemented measures on his/her own farm to ensure a lower AP level but the AP level was still exceeded, it would become difficult to prove whose measures had failed and, thus, to construct a case against a GM farmer for economic loss. In any case, the scale of legal costs in some jurisdictions might be disproportionately expensive relative to the victim's losses, making legal action unwise. There is also the issue of awarding legal costs against the losing litigant; although this allows a successful claimant to have his/her costs paid by the defendant, it also exposes him/her to the risk of having to pay the, often much larger, defendant's legal bill.

Member States may well vary in their rules for the claimant's responsibility to mitigate their losses, for example, by selling the contaminated crop for the highest available price on the non-organic market or by monitoring coexistence, detecting contamination early and responding efficiently upon detection (where possible).

There could also be differences between Member States on defendants' rights to claim a contribution from other potentially responsible parties, such as other causers of the contamination in a multiple party case or GMO producers and suppliers, perhaps involving a product liability action where the specific GMO or GMO contract is seen as defective[10].

Considered together, then, there may be implications for the marketplace and the phased introduction of the technology because of possible variations between Member States concerning coexistence measures, thresholds, cost allocation and liability. It is important to note that, as issues of subsidiarity,

[10] A Liability for Release of Genetically Modified Organisms (Scotland) Bill, has recently been proposed for introduction to the Scottish Parliament. The proposed legislation would make agricultural biotechnology companies liable for any economic loss arising from adventitious presence (AEBC, 2003).

these are implications for the introduction of the technology rather than the smooth functioning of Directive 2001/18/EEC (even though, until the issues are addressed at Member State level, they may interfere with the decision making process). The Commission Recommendation of 23 July 2003 concerning guidelines on coexistence in Member States may act to minimise the variations amongst Member States.

4.4.3 Non-Industry Stakeholders

Whilst Directive 90/220/EEC had no provisions for public consultation in case of Part C releases, Directive 2001/18/EEC foresees that the Commission should provide the public the opportunity to comment during a period of 30 days after publication of the notification. Non-industry stakeholders have so far gained little experience with the public consultation procedure, as in none of the cases has decision-making on pending Part C applications been completed yet.

Environmental organisations have also highlighted the lack of clear and transparent criteria as regards the ARMs to be phased out in Part C releases, as well as the lack of a procedure through which public interest groups could comment on this matter.

Whilst considered as part of the risk assessment procedures for all releases there is the possibility, however remote, of damage to human health. Such damage may arise as a result of the realisation of risks considered slight under the Part C approval process or from unforeseen risks. These include:

- possible nutritional and toxicological effects (including allergy) of GM food or adventitious presence of non-food crop genetic material; and
- adverse effects of GM derived feed on livestock animal and human food chain.

4.5 Conclusions on the Operation of Part C

Practical experience with the operation of Part C has been limited as Directive 2001/18/EC only came into force on 17 October 2002 and, as would be expected, the number of Part C applications is generally less than Part B applications. Although the absence of regulations on traceability and labelling were cited as the main problem under Directive 90/220/EEC, the recent adoption of Regulation 1830/2003 may not be enough to ease the situation. Further issues related to coexistence and liability, may need to be resolved to increase the acceptability of commercial releases of GMOs for certain stakeholders, however these are issues of subsidiarity and, thus, to be dealt with by individual Member States. As they are to be largely addressed on the basis of subsidiarity, such issues perhaps relate more to the uptake of the technology than the smooth functioning of the Directive. As such, while coexistence and liability issues may present obstacles to the process, this is a matter for arrangements at Member State level rather than Commission level.

However, the overall number of applications for Part C authorisations under Directive 2001/18/EC is likely to be reduced in the near future as GM crops can be authorised under Regulation 1829/2003 and GMO medicines under Regulation 2309/93. These applications form the majority of GMO developments at present, but non-food GM crops and GM animals, which may be developed for commercialisation in the future, could be regulated by Directive 2001/18/EC. Thus the authorisation of GMOs under alternative regulations raises questions about the effectiveness of central authorization bodies to effectively assess the environmental impacts of the GMOs, particularly at a regional level.

Furthermore, significant difference in Member States' current approaches to post-market monitoring and liability issues may result in uncertainty for industry, who may favour certain countries. Further clarification is required to ensure a more harmonised approach to monitoring across the EU, but the need for flexibility to consider different ecosystems and regional situations is likely to limit the degree to which this can be achieved.

5. IMPROVING THE CONSISTENCY AND EFFICIENCY OF DIRECTIVE 2001/18/EC

5.1 Overview

The previous sections highlight a number of areas where information is lacking, where further guidance is needed, and/or where there is uncertainty as to how the Directive should be implemented in practice. These issues, and potential solutions, are summarised below.

5.2 Restarting the Decision-making Process

Although many stakeholders believe that Directive 2001/18/EC, and the associated framework, will assist with restarting the decision-making process, a number of outstanding issues will need to be resolved before this can happen.

National implementation of Directive 2001/18/EC needs to be addressed. At present, seven Member States have implemented the legislation. The remaining Member States have been taken to Court by the Commission for non-transposition. Where Member States have regulations in place which transpose the old Directive 90/220/EEC but may not have transposed the new Directive 2001/18/EC into their national legislation, they still have to apply its provisions irrespective of national transposition. Nonetheless, the differences amongst Member States regarding the state of implementation of the new Directive 2001/18/EC causes uncertainty for industry and other stakeholders who wish to participate in the new authorisation procedures. Member States should be encouraged to implement the Directive as soon as possible.

The **processing of Part C applications submitted under Directive 90/220/EEC** may also cause delays in a small number of cases. Industry stakeholders have different interpretations of Article 35 compared to the CAs, and this has lead to at least one situation where industry has been asked to review what they believed to be an agreed ERA under Directive 90/220/EEC. As it is difficult to determine what constitutes an 'agreed' ERA, or a 'reasonable' request for additional information, on a case-by-case basis within the scope of this study, it is not possible to establish whether such claims by industry are valid. Although it is unlikely that this is a significant problem, the Commission should be aware that it has been raised as an issue which may result in additional delays and costs for industry.

Finally, **coexistence measures and liability issues** may need to be addressed by Member States before Part C applications are authorised for commercial release. The Commission Recommendation of 23 July 2003 concerning guidelines for the development of national strategies and best practices to ensure the coexistence of GM crops with conventional and organic farming provides assistance for Competent Authorities. At present, a number of

Member States are considering coexistence and liability measures and determining whether they are best achieved through voluntary or statutory instruments. At the same time, the farming and biotechnology industries more generally will need time to assess insurance and arrangements for accounting for any liability regime.

One solution to such issues is to legislate at EU level for a consistent and equitable civil liability regime including pure economic loss. Clearly, this would mean that it was no longer based on subsidiarity. In practice this would be extremely difficult to achieve because of significant differences in liability regimes between (and even within) Member States. In addition, there is likely to be considerable resistance among Member States because the issues that may need to be addressed would also have ramifications for other aspects of liability law, particularly in respect of pure economic loss.

A further option regarding the issue of AP thresholds in organic crops is to clarify the issue by setting an AP threshold under the existing provisions of Council Regulation (EC) No 1804/1999 on Organic Production.

5.3 Removing Uncertainty from the Authorisation Procedures

The need for **clearer guidance, both for Competent Authorities and for industry and research organisations** was identified in relation to the environmental risk assessment and post-market monitoring was identified, specifically in relation to:

- what are considered to be acceptable and unacceptable risks;
- the baseline for evaluating the potential effects of GMOs;
- application of the precautionary principle;
- how to make use of existing long-term monitoring projects;
- how to gather data and compile data in a practical way (an EU-wide database based on a harmonised approach for documentation and compilation of monitoring results is suggested);
- a discussion of the baseline for general surveillance; and
- specific guidance for non-plant GMOs.

It is noted that an EU working group has been set up to discuss the issue of post-market monitoring. Also, further guidance on the presentation of results from Part B GM higher plant releases has now been issued[11].

Informal discussions between the notifier and the CA before submission of an application may reduce the need to request further information from the notifier and thus reduce the time and resources required to process the application. However, different Member States have different approaches to

[11] Commission Decision of 29 September 2003 of the European Parliament and the of the Council establishing a format for presenting the results of the deliberate release into the environment of GM higher plants for purposes other than placing on the market.

these discussions, which are not provided for, nor prohibited by, Directive 2001/18/EC.

There is a consensus among all stakeholders that there is a lack of guidance on which **antibiotic resistance markers** (ARMs) are to be phased out and on the criteria to be used to assess whether ARMs are harmful or not. There is a suggestion that uncertainty over ARMs is currently hindering industry's research and development activities and, potentially, Competent Authorities' approval process. It is noted that the Commission has established a Working Group on this issue and that, regardless of the development of an 'approved' or 'prohibited' list, case-specific risk assessment would still be undertaken.

Finally, the current authorisation process (in terms of forms and guidance) is focused on GM plants. GM medicines and GM animals are also under development and their authorisation will require consideration of different issues. A lack of familiarity of these issues is likely to delay the authorisation process; it is therefore suggested that **specific guidance is developed on the authorisation of non-plant GMOs**, both for Competent Authorities and for industry and research organisations.

5.4 Assisting Innovation

Part C authorisations are granted with a **ten-year limit**; this may have implications for the development of new varieties of certain plants and may reduce the number of future applications. The limited validity of authorisation of an event to a maximum of ten years, and uncertainty over whether the consent will be renewed thereafter, makes the time left for commercialisation unpredictable. In order to facilitate innovation it may be necessary to have a flexible approach towards the ten-year limit, with respect to other authorisations which also have to be obtained at the same time, such as national variety registration or pesticide use. Member States could for example consider allowing 'GM variety-approval' trials under Part B of Directive 2001/18/EC, so as to increase the time left for commercialisation of an 'event'. In this way, unnecessary delays that reduce the period over which a GM plant (event) can be commercialised are avoided. However, such flexibility would not be possible under Directive 2001/18/EC unless the Directive was amended.

GM plant material which is developed under contained use conditions and which is exported for contained use may not require a full risk assessment to be conducted before export, depending on the specific use. However, GM plant research material which is developed under contained use conditions but which is exported for experimental release may require a full risk assessment (according to the Regulation on transboundary movements of GMOs). Industry therefore argues that export of GM plant research material developed under contained use conditions and intended for experimental release should be exempted from the Advance Informed Agreement (AIA) procedure, in other not to block exchange of research material with non-EU countries.

5.5 Enabling Effective Public Consultation

Directive 2001/18/EC provides for public information and national procedures for consultation. As more experience is gained, improvement of the Directive may need to be considered. A clear procedure is needed on how public comments should be taken into account, including those concerning ethical and socio-economic principles. In addition, clearer guidance is needed on the timeframe for consultation. A detailed description of the decision-making process under Directive 2001/18/EC and Regulation (EC) No 1829/2003 could be made available on the websites of the JRC and EFSA. These descriptions should include a clear statement of the authorities involved and their powers, including a detailed explanation of the provisions for public information and public consultation. In addition, non-industry stakeholders have requested that the applicant's technical dossier, except confidential business information, the (initial) assessment report and the comments and objections from (other) national Competent Authorities should be made available for the public to comment, in order to increase their involvement in the consultation process. It should however be noted that there are issues of confidentiality and legalities to be considered if Member States comments were to be made public.

The centralised authorisation procedure for medicines consisting of, or containing GMOs as defined by Regulation (EEC) 2309/93 and co-ordinated by EMEA does not foresee public consultation. Only at the final stage of authorisation is the public informed via publication on the EMEA website (COGEM, 2003). Provisions for public information and public consultation within the centralised authorisation procedure of Regulation (EEC) 2309/93 similar to those of Directive 2001/18/EC and Regulation (EC) No 18929/2003 would result in equivalent socially responsible procedures for market authorisation of GMOs.

5.6 Increasing Independent Research and Transparency

Public interest groups suggest that independent scientists should be involved in providing data for the environmental risk assessment and the post-market monitoring, so that this important information is not provided solely by the consent holders. However, it is likely that that the majority of scientists with the relevant experience to conduct such research either work for biotechnology companies or have some links with them. Thus it may be difficult to meet this demand for independent research.

Furthermore, the final decision-making by the Commission on applications under Directive 2001/18/EC, Regulation (EC) 1829/2003 and Regulation (EEC) 2309/93 should explain in a transparent way how comments and objections received from CAs and other parties have been considered.

5.7 Facilitating Consumer Choice

Competent Authorities have requested further guidance on the development of homogenous traceability systems and sampling methods. It should be noted that the Commission is developing guidance on sampling and testing in the context of Regulation 1830/2003. Furthermore, public interest groups are concerned that industry may interpret the threshold as being for any presence of GMOs in conventional products, whereas the threshold is meant for adventitious presence, and care should be taken that this interpretation does not occur.

There is some concern that **GM labelling based on origin instead of detectability of GM material**, in particular for imports of food and feed with 'non-detectable' ingredients from non-EU countries, will not be workable nor enforceable. Stakeholders operating in the agro-food chain suggest that it will be necessary to establish an international accreditation body in order to audit and verify labelling claims in relation to GM and non-GM supply chains worldwide (SBC, 2003a). Whilst this would ensure confidence in what is perceived by consumers and retailers as an important part of the legislative framework, this approach would require significant resources.

Issues relating to the **traceability requirements for farm saved seed** and **thresholds for the adventitious presence of GMOs not authorised in the EU and not having benefited from a favourable risk evaluation by the Community Scientific Committees or EFSA before the date of application of the Regulation (EC) No 1829/2003** have not yet been addressed and should be resolved as soon as possible.

The publication of information on (Part B) releases has facilitated activists in some countries to locate and destroy GM crops. Several industry responses further suggest that public consultation activities significantly increase the costs of field trials for GM crops compared to conventional crop trials. The approach of Competent Authorities to this issue may cause industry to submit applications in certain Member States and not in others. However there is concern that, in some cases, the transposition of the requirement for a public register is not complete and it may not enable conventional and organic farmers to identify areas of GM crops. It is understood that the Commission and the Competent Authorities are working towards an agreement of the provision of location details.

5.8 Increasing Knowledge

Areas which were identified as lacking data and information were:

- rates of gene flow and introgression in relation to the adventitious presence of GMOs in (non-GM) seeds, food and feed;
- the efficacy of measures to limit pollen flow has not been systematically evaluated; and

- AEBC (2001) notes that there have been few detailed studies to provide information on the environmental impact of different methods of conventional farming against which to compare the findings from GM crop monitoring.

Research should be encouraged to address these data gaps. The efficacy of measures to limit pollen flow can be assessed during Part B trials, at present Competent Authorities only verify that the measures are undertaken. The more general environmental impact of conventional farming would need to be researched at a regional level to allow for variations in ecosystems and farming methods.

5.9 Continuity of Authorisation Procedures and Decision-making within the Legislative Framework

There is a need to clarify EFSA's obligation to consult national CAs and advisory bodies under Regulation (EC) No 1829/2003, particularly with regard to the ERA. In addition, there is some concern that the ERA will not receive due attention, as EFSA is primarily set up as a body for food safety assessment.

Industry stakeholders generally advocated the establishment of a centralised EU approvals procedure. It was also suggested by one CA that GMO authorisation procedures should be modelled on the authorisation procedure followed by the European Agency for the evaluation of Medicinal Products (EMEA). Although CAs of Member States are involved, the EMEA decides on the scientific advice which forms the basis for decision-making by the Commission. Yet this centralised procedure, in relation to GMO medicines, was criticised by COGEM (2003) for the following reasons:

- there is limited access to the technical dossier and the risk assessment report written by EMEA. This means that the Competent Authorities are not able to verify EMEA's decision concerning the environmental risks;

- although the Competent Authorities are consulted, EMEA is not obliged to take their comments into account;

- experts with knowledge and experience of environmental risk assessments appear to be absent from EMEA. This raises the question as to whether EMEA is capable of making the right decisions on environmental risk assessment, and interpreting these according to national environments;

- the procedure has no public consultation process. Only after the marketing procedure for a medicine has been finalised is the general public informed about the product via publication on the EMEA website. Furthermore, there is no opportunity for the general public to verify the procedure; and

- it is not clear whether the licences granted by EMEA also include the production process.

It is noted that EMEA is responding to parts of this criticism, e.g. by developing guidance for the ERA of GMO medicines.

A comparison of four authorisation procedures is presented in Table 5.1, overleaf.

Some stakeholders have requested further guidance on the interaction between different pieces of legislation and how these will work in practice. For example, although Article 12.2 of Directive 2001/18/EC clearly states that GMOs for medical use are excluded from Part C of Directive 2001/18/EC, industry stakeholders believe that it may be necessary to submit applications under both the Deliberate Release Directive and the medical authorisation procedures, based on their experience for Part B applications. In addition, the verification of traceability and labelling of GM food and feed may not fall under the same CA as for Directive 2001/18/EC. Thus, requirements are rather fragmented by various pieces of legislation and national administrations.

It is therefore necessary to provide a detailed description of the decision-making process under Directive 2001/18/EC, Regulation (EC) No 1829/2003 and Regulation (EEC) 2309/93 on the websites of the JRC, EFSA and EMEA. These descriptions should include a clear statement of the scientific advisory bodies and authorities involved and their powers, and the role that the general public plays.

There should be full access for national CAs specialised in environmental risk assessment to the technical dossier submitted by the applicant, as well as the scientific assessment report by EFSA or EMEA. This access will give national CAs the opportunity to evaluate the considerations of these agencies and to make their own judgement on the risks for their particular national environments.

All remarks and objections by the national CAs regarding the applicant's technical dossier and the assessment report should be presented to all members of the agency's scientific committee. Where enduring differences of opinion exist between EFSA or EMEA and the national CAs, there should be the opportunity to submit this disagreement to a second independent advisory committee, i.e. an arbitrator.

If objections are raised against an (initial) assessment report on an application under Directive 2001/18/EC, EFSA may be asked for an opinion (depending on the GMO). However, it is possible that individuals may be a member of EFSA's Scientific Panel on GMOs and represent a national CA at the Regulatory Committee under Directive 2001/18/EC which may be regarded as a conflict of interest.

Table 5.1: A Comparison of Authorisation Procedures				
Regulation	**Directive 2001/18/EC – Part C**	**Regulation 1829/2003 on GM food and feed**	**Directive 91/414/EEC concerning the placing of plant protection products on the market**	**Regulation (EEC) 2309/93 on medicinal products**
Who is the application submitted to?	National CA	National CA	National CA for each MS where it is to be marketed	EMEA
Who is it circulated to?	CAs of other MS and Commission	EFSA, then other Member States and the Commission	A file on each application must be available on request to other CAs and the Commission	It is not circulated
Who assesses the application?	The first CA prepares an assessment report which is circulated to other CAs and the Commission	EFSA In case of GM seeds or plant propagating the national CA must be consulted	Each CA, but where a product is already approved in another MS, the CA is bound to use existing test data, to the extent that the relevant conditions in the regions are comparable.	EMEA
What is the role of other CAs and/or the Commission?	They may ask for further information, make comments or present reasoned objections after the assessment report is circulated.	CAs may request additional information. CAs under Dir. 2001/18/EC are consulted by the EFSA. The EFSA submits its decision to the Commission.	Each CA acts independently. The Commission only intervenes when a CA refuses to authorise a product.	CAs may request additional information. EMEA submits its decision to the Commission.
Is the public consulted?	Yes, the public has 30 days to comment on the notification	Yes, a summary of the dossier is made available to the public. When the EFSA publishes its opinion, the public has 30 days to make comments to the Commission.	No	No
What happens if an objection is raised?	The issue has to be referred to the EFSA for its opinion.	It is not clear from the Regulation what will happen if an objection is raised.	If a CA refuses to authorise the product it must inform the Commission. The Commission will decide whether the CA has valid reasons to refuse the product.	It is considered by EMEA but does not have to be taken into account.
What is the maximum time frame for a decision?	120 days, not counting time when further information is requested from the notifier	Approx. 180 days (6 months)	A reasonable period	210 days
Is there a time limit on the consent?	Yes, 10 years	Yes, 10 years	Yes, 10 years	Yes, 5 years

Similar to the authorisation procedures under Directive 2001/18/EC and Regulation (EC) No 1829/2003, which provide the public a period of 30 days to comment on an application, the authorisation procedure for GMO medicines

should also provide the public the opportunity to submit comments. The technical dossier for a GM food and feed or a GMO medicine submitted by the applicant, except confidential business information, the scientific assessment report by EFSA or EMEA and all remarks and objections by national CAs should be made publicly available. This would enable meaningful public consultation and increase the transparency of the Community scientific review and the Commission decision-making.

ANNEX I

TECHNICAL SPECIFICATIONS

Study Contract - Means to improve the consistency and efficiency of the legislative framework in the field of biotechnology Article 31 (7a, 7b and 7d) of Directive 2001/18/EC

1. BACKGROUND

On 17 April 2001 Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms (GMOs) entered into force. This Directive became applicable as of 17 October 2002.

According to Article 31(7) of this Directive the Commission has to submit a specific report to the European Parliament and the Council on the operation of the deliberate release (part B) and placing on the market (part C) of genetically modified organisms (GMOs) by the year 2003.

In this report, the feasibility of various options to further improve the consistency and efficiency of this framework has to be assessed. In addition, different sorts of implications and consequences of the deliberate releases and placing on the market of GMOs have to be evaluated.

2. OBJECTIVES

The objective of this project is to collect and prepare background information and data as a basis for the report referred to in Directive 2001/18/EC Art. 31(7).

The specific objectives are:

- to prepare an overview and an analysis of available data gathered during the enforcement of existing and previous Community legislation in the field of Biotechnology;
- to describe experiences made with the implementation of part B and part C since 17 October 2002. The different implications of the operation of part B and part C shall be included;
- to analyse and evaluate the environmental and socioeconomic implications of deliberate releases and placing on the market of GMOs;
- to present the identification of data and knowledge gaps as well as bottlenecks and how to overcome these gaps and bottlenecks; and
- to recommend - if necessary - how to strengthen the consistency and efficiency of this legislative framework.

A secondary objective of the project is to contribute also to the present status and the experiences in the Member States, which will be achieved by working closely with the officials and experts from Member States.

3. TASKS

Directive 2001/18/EC on the deliberate release of GMOs is applicable as of 17 October 2002. The experience of the enforcement measures of this Directive by the Member States and the Commission has to be evaluated in its first year. This study shall include an assessment of part B and part C operations since 17 October 2002 and an analysis of options on how to improve the Directive in its consistency and efficiency, if necessary.

3.1 Legislation

A critical overview will be presented of existing and previous European legislation in the field of Biotechnology, particularly on GMOs This overview will take into account the framework on the EU level and the implemented legislation in the Member States. It should include a careful analysis and overview of procedures, available data and experience gathered under the existing and previous biotechnology regulatory framework (including Proposals from the Commission).

3.2 Operation of part B

An analysis and evaluation of the operation of the deliberate release of GMOs (part B under Directive 2001/18/EC) since 17 October 2002 in comparison with, or taking into account, the operation under Directive 90/220/EEC including

(a) its **implications in general;**

(b) its implications on the **diversity of European ecosystems** (including agricultural and natural ecosystems) and the need to **complement the regulatory framework** in this field;

(c) its **socio-economic implications.**

(d) In addition it should be assessed whether experience with differentiated procedures under Part B of the Directive is available to justify a provision on implicit consent in these procedures.

3.3 Operation of part C

An analysis and evaluation of the operation of the placing on the market of GMOs (part C under Directive 2001/18/EC) since 17 October 2002 in comparison with, or taking into account, the operation under Directive 90/220/EEC including:

(a) its **implications in general;**

(b) its implications on the **diversity of European ecosystems** (including agricultural and natural ecosystems) and the need to **complement the regulatory framework** in this field;

(c) its **socio-economic implications.**

3.4 Improve the consistency and efficiency of Directive 2001/18/EC

Different procedures for the placing on the market of more conventional products (e.g. medicinal, food and seed products) covered by other Community rules shall be compared with the procedures under part C of Directive 2001/18/EC.

The feasibility of various options to further improve the consistency and efficiency of this regulatory framework has to be assessed. This assessment shall particularly include the option of.

- a centralised Community authorisation procedure and
- the arrangements for the final decision making by the Commission.

3.5 General considerations

For all parts of this project:

- existing knowledge and experience in this field should be taken into consideration;

- existing data gaps and bottlenecks, and actions, required to fill them, shall be identified; and

- advantages and disadvantages of every option shall be presented considering the particularities of Directive 2001/18/EC and the particular political climate.

It is intended to perform, particularly for parts 3.2 and 3.3, the study in close cooperation with the relevant authorities and experts from the Member States. This is essential in order to assure availability and reliability of the data. Achieving appropriate co-operation with relevant authorities and experts from Member States will be the responsibility of the contractor. The tenderers should outline in their offer how they plan to achieve such a co-operation. Thus there will be a need to establish close contacts with these activities in the countries interested in.

Stakeholders, in particular notifiers, should be consulted for parts 3.2 and 3.3.

It is foreseen that a maximum of five visits to relevant Member States (such as UK, F, D, ES, NL) will form part of the budget for this contract.

In addition the contractor shall report to the Commission on a regular basis in the course of the enforcement of this project in particular, where decisions have to be made which may influence the outcome of the project.

MEANS TO IMPROVE THE CONSISTENCY AND EFFICIENCY OF THE LEGISLATIVE FRAMEWORK IN THE FIELD OF BIOTECHNOLOGY

Schenkelaars Biotechnology Consultancy (SBC) in association with Risk & Policy Analysts (RPA) have been commissioned by DG Environment of the European Commission to assist in the preparation of a report on the operation of Part C (placing on the market of GMOs as or in products) and Part B (deliberate release of GMOs for any other purposes than for placing on the market) of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (GMOs).

The objectives of this study are:

- *to describe the experience of Member States in implementing the new Directive;*
- *to identify any difficulties that have arisen particularly in relation to any differences between Part B and Part C;*
- *to analyze and evaluate the environmental and socio-economic implications of deliberate releases and placing on the market of GMOs;*
- *to identify data gaps and knowledge gaps and ways of overcoming these; and*
- *to recommend means of strengthening the consistency and efficiency of the legislative framework.*

The work being undertaken in meeting the above objectives requires close cooperation with Competent Authorities, the biotechnology industry, seed companies, farming organisations, and environmental and consumer groups. We will also be reviewing national and Community legislation, and literature covering policy, scientific and socio-economic issues. The questions set out below are aimed at gathering your views on how well the Parts B and C of Directive 2001/18/EC are operating. Please note that your answers will be treated in the strictest confidence and will not be linked to your organisation at any stage in our reporting to the Commission without your express permission.

Thank you very much for your assistance. Our time frame for this study is relatively short. In order for us to take account of your views and to contact you if there are any follow-up questions, we would appreciate your completed questionnaire to be **returned by 24 October 2003** to the address below:

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Contact Details

Competent Authority _____

Contact Person _____

Contact Address _____

Telephone _____ **Fax** _____

E-mail Address _____

PART B: Deliberate Release of GMOs for Any Other Purpose than Placing on the Market

Directive 2001/18/EC on the deliberate release into the environment of GMOs introduced a number of key changes in relation to Part B applications. Decision making on Part B releases remains at the Member State level, however, and is implemented through national legislation. Key changes include:

- clarifying and extending the scope of risk assessment requirements;
- mandatory public consultation on Part B applications;
- the introduction of differentiated procedures; and
- the phase-out of antibiotic resistance markers.

The questions set out below are aimed at gathering information on how these changes have affected Competent Authorities.

Changes in the Applications Process

1. Can you please outline the process that an applicant goes through when submitting an application for a Part B consent under your national legislation? Do you have a flow-chart available for this process?

   _____
   _____
   _____

2. What are the key changes in this process compared to the process under Directive 90/220/EEC?

   _____
   _____
   _____

3. Is there the potential for applicants to discuss their application prior to official submission? Please tick the relevant response.
   Yes ____ No ____

Please explain your answer. _____

_____

4. How often do you need to seek additional information from applicants compared with the system under Directive 90/220/EEC? Please tick the relevant response and add any comments you wish to make.

More often ——— Less often ——— As often ———

_____

_____

5. Have any applications been refused under the new system? Do you expect fewer or more to be refused than under the system which operated under Directive 90/220/EEC?

_____

_____

6. What is the biggest cause of delays in the process?

_____

_____

7. Are there ways in which the delays could be shortened or prevented?

_____

_____

8. Have the changes introduced by Directive 2001/18/EC provided for a more transparent and predictable regime within the EU?

Yes ____ No ____ Don't know ____

Please explain your answer. _____

_____

9. Has it provided industry with increased regulatory certainty?

Yes ____ No ____ Don't know ____

Please explain your answer. _____

_____

10. Is the time frame for decision making predictable?

Yes _____ No _____ Don't know _____

Please explain your answer. _____

_____

11. What aspects of implementation of the Part B process places the greatest burden on you as a Competent Authority? What could be done to improve the process?

_____

_____

_____

_____

Clarification of Environmental Risk Assessment Requirements

12. Has Directive 2001/18/EC led to any significant changes in what you actually required in the risk assessments under Directive 90/220/EEC? Please tick the relevant response.

Significantly increased the requirements in relation to direct effects _____
Significantly increased the requirements in relation to indirect effects _____
Significantly increased the requirements in relation to immediate effects _____
Significantly increased the requirements in relation to delayed effects _____
Has had no significant impact on risk assessment requirements _____

13. Is clear guidance provided by the Commission on what is required in the environmental risk assessment?

Yes _____ No _____ Don't know _____

14. Is clear guidance available from the Commission on what are considered acceptable risks and what are considered unacceptable risks? In other words, have clear evaluation criteria been set for use in decision making?

Yes _____ No _____ Don't know _____

Please add any comments.

_____

_____

_____

15. How has clarification and strengthening of the environmental risk assessment requirements affected the length of time required to gain approval?

Speeded up the process _____
Slowed down the process _____
Had no impact on the time required _____

Please add any comments. _____

_____

16. How are changes in requirements communicated to potential applicants and other stakeholders?

_____
_____
_____

Public Consultation

For each Part B application, there is a mandatory requirement for public consultation to be held by the Competent Authority. There is also a requirement on Part B applicants to publicise the consultation in a national newspaper.

17. Under Directive 90/220/EEC, it was not mandatory for the Competent Authority to consult the public. Did you as a Competent Authority nonetheless consult the public or public interest groups on Part B applications? If so, how, and what have been the results?

_____
_____
_____

18. Can you please provide details on your Member State's requirements under Directive 2001/18/EC in relation to public consultation and its timing for Part B applications?

_____
_____
_____
_____

Simplified Procedures

Part B of 90/220/EEC allowed for a simplified procedure for notifying the intention of releasing a GMO as part of a programme of research and development work (such as plant

breeding). Under Directive 2001/18/EC this simplified procedure is optional. The Directive also introduces the use of 'differentiated procedures' for certain categories of Part B releases.

19. How often were the simplified procedures under Directive 90/220/EEC used within your Member State?

Never	____
Less than 5 times	____
Between 5 and 10 times	____
More than 10 times	____

20. Have you retained use of simplified procedures within national legislation or have you moved to use of 'differentiated procedures'?

Retained use of simplified procedures	____
Moved to use of differentiated procedures	____

Please comment on the reasons for this.

_____

_____

_____

Antibiotic Resistance Markers

Directive 2001/18/EC requires the phasing out of Antibiotic Resistance Markers (ARMs) in GMOs that may have adverse effects on human health and the environment by 2008 for Part B GMOs.

21. Do you have any comments regarding implementation of Directive 2001/18/EC in relation to the phasing of ARMs in the EU?

_____

_____

22. Do you have any comments on the continued development and use of ARMs in non-EU countries?

_____

_____

_____

PART C: Placing on the Market of GMOS as or in Products

Directive 2001/18/EC also introduced a number of key changes in relation to the Part C approvals process, with the aim of providing a more harmonised, robust and transparent framework for the approval of GM products for the EU market. Key changes from Directive 90/220/EEC include:

- a 10 year time limit on the duration of an approval;
- requirements for post-release monitoring;
- the phase-out of antibiotic resistance markers; and
- labelling and traceability requirements.

General Impact of 2001/18/EC on Part C Applications

23. No Part C consents were approved under Directive 90/220/EEC after 1998. How many applications are currently pending according to Article 35 of Directive 2001/18/EC and how many 'new' applications have been made?

    Number of applications that are currently pending: _____
    Number of 'new' applications: _____

24. More generally, do you believe that implementation of Directive 2001/18/EC has helped restart the EU decision making process for Part C applications?

    Yes _____ No _____ Don't know _____

    Please give reasons for your answer.

    _____
    _____
    _____

25. The new Directive sets a maximum time limit of 10 years on Part C consents, although these can be renewed. How do you believe these will affect the number of applications coming forward?

    No effect _____
    Reduce the number of future applications _____
    Increase the number of applications _____
    Don't know _____

    Please give reasons for your answer.

    _____
    _____

26. Does the time limit make approval of Part C consents more acceptable to non-industry stakeholders within your Member State?

Yes ____ No ____ Don't know ____

27. Directive 2001/18/EC requires the phasing out of Antibiotic Resistance Markers (ARMs) in GMOs that may have adverse effects on human health and the environment by 31 December 2003 for Part C GMOs.

Do you have any comments regarding the implementation of Directive 2001/18/EC in relation to the phasing out of ARMs for Part C GMOs in the EU?

_____

_____

_____

28. Do you have any comments on the continued development and use of ARMs in non-EU countries?

_____

_____

_____

29. The new Directive removes the Best Available Techniques Not Entailing Excessive Costs condition relating to clean-up of damage caused by GMOs. In theory, this could mean that clean-up of any problems could be required, regardless of the cost. Does this increase in liability make approval of Part C consents more acceptable to non-industry stakeholders in your Member State?

Yes ____ No ____ Don't know ____

Please give reasons for your answer.

_____

_____

Traceability and Labelling

Directive 2001/18/EC establishes requirements for the labelling and traceability of GMOs and these are strengthened by the proposed Regulation on genetically modified food and feed (COM(2001)425) and the proposed Regulation concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (COM(2001)182).

30. What are your views as a Competent Authority on the workability of the systems set out in Directive 2001/18/EC and in the proposed Regulation concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (COM(2001)182)?

_____

_____

_____

31. Have any specific issues arisen with regard to import or export of food and feed for you as a Competent Authority?

_____

_____

_____

32. Have you developed any measures within your Member State for the purposes of verification?

_____

_____

_____

33. Do you have any comments to make about the thresholds that have been suggested in the proposed Regulation on genetically modified food and feed (COM(2001)425) with regard to the adventitious presence of GMOs for EU authorised materials and in relation to non-EU authorised materials in food and feed?

_____

_____

_____

34. In your opinion, is any further action or further regulation needed in relation to the adventitious presence of GMOs in food and feed?

_____

_____

_____

35. Do you have any comments to make about the thresholds that have been proposed in the Draft Commission Directive concerning the adventitious presence of genetically modified seeds in seed lots of non-genetically modified varieties?

_____

_____

36. What additional measures do you believe should be put in place to support the Directive 2001/18/EC and the proposed Regulations on traceability and labelling (referred to above)?

_____

_____

_____

Post-Market Monitoring

Part C applicants are required to supply a post-market monitoring plan setting out how the proposed releases will be monitored for unanticipated effects on the environment. Such plans were not required under Directive 90/220/EEC but may have been required under national regulations.

37. Was any post-market monitoring carried out on or planned for commercial releases made under Directive 90/220/EEC?

Yes ____ No ____ Don't know ____

38. If so, will the provisions under Directive 2001/18/EC lead to modifications of the types of monitoring required or planned?

Yes ____ No ____ Don't know ____

39. Given the guidance developed by the Commission, do you believe that the types of post-market monitoring that will be required will be consistent across the EU? If no, what would be needed to make them consistent?

_____

_____

_____

_____

40. Are there any issues concerning the development and implementation of case-specific post-market monitoring that you would like to see addressed?

_____

_____

41. Are there any issues concerning the development and implementation of general surveillance monitoring that you would like to see addressed?

_____

_____

_____

42. Are there any issues concerning the boundary between case-specific monitoring and general surveillance monitoring which you would like to see addressed?

_____

_____

_____

Other Issues

44. Would you like to comment on any other aspects of the Directive or of other related legislation that would improve consistency and efficiency of the EU legislative framework for GMOs? If so, please add your comments below.

_____

_____

_____

_____

_____

Contact Details

Name of Organisation _____

Contact Person _____

Contact Address _____

Telephone _____ **Fax** _____

E-mail Address _____

Please indicate which sector your organisation represents:

Biotechnology ____ Agriculture ____ Food ____ Other (please specify) _____

PART B: Deliberate Release of GMOs for Any Other Purpose than Placing on the Market

Directive 2001/18/EC on the deliberate release into the environment of GMOs introduced a number of key changes in relation to Part B applications. Decision making on Part B releases remains at the Member State level, however, and is implemented through national legislation. Key changes include:

- clarifying and extending the scope of risk assessment requirements;
- mandatory public consultation on Part B applications;
- the introduction of differentiated procedures; and
- the phase-out of antibiotic resistance markers.

The questions set out below are aimed at gathering information on how these changes have affected the biotechnology industry and research organisations.

General Impact of Directive

Prior to the adoption of Directive 2001/18/EC, the biotechnology industry expressed concern over the delays and lack of transparency in decision making that were taking place under Directive 90/220/EEC, owing in part to the relative lack of clear deadlines within which decisions must be made and communicated.

1. Have the changes introduced by Directive 2001/18/EC provided for a more transparent and predictable regime within the EU? Please tick the relevant response.

   Yes ____ No ____

   Please explain _____

2. Has Directive 2001/18/EC provided industry with increased regulatory certainty? Please tick the relevant response.

Yes _____ No _____ Don't know _____

3. What impact will Directive 2001/18/EC have on the number of Part B consents applied for over the next three years? Please tick the relevant response.

Increase the number of Part B consent applications _____
(please specify estimated percentage increase) _____*%*
Decrease the number of Part B consent applications _____
(please specify estimated percentage decrease) _____*%*
Have no effect on the number of Part B consent applications _____
Don't know _____

Please give reasons for your answer. _____

_____

4. What is the biggest cause of delays in the Part B applications process? Please explain your answer.

_____

_____

5. Are the requirements of Competent Authorities clear at the start of the process? Please explain your answer.

_____

_____

6. Is the time frame for decision making predictable? Please explain your answer.

_____

_____

Clarification of Risk Assessment Requirements

Directive 2001/18/EC requires that direct, indirect, immediate and delayed risks should be taken into account in the environmental risk assessment (ERA).

7. Has the Directive led to any significant changes in what was actually being required by Member States in risk assessments under Directive 90/220/EEC?

Directive 2001/18/EC increases significantly the risk assessment requirements faced by your organisations/organisations seeking approvals. _____

Directive 2001/18 does not significantly increase the level of risk assessment undertaken by your organisation/most organisations. _____

8. Is clear guidance now provided by Competent Authorities on what is required in the ERA?

Yes _____ No _____ Don't know _____

Please explain your answer.

_____

_____

9. How have the new requirements affected the length of time required to gain approval?

Clarification of the new requirements of the ERA have reduced delays _____

Clarification and the new requirements of the ERA have resulted in a longer approval process. _____

Clarification and the new requirements of the ERA make no difference to the length of the approval process. _____

Please provide any details on your organisation's/organisations' experience.

_____

_____

10. Is there clear guidance available from your Member State Competent Authority on what are considered acceptable risks and what are considered unacceptable risks? In other words, are the evaluation criteria clear?

Yes _____ No _____ Don't know _____

Please explain your answer.

_____

_____

11. Are the requirements of the ERA under Directive 2001/18/EC more consistent across the Member States than they were under Directive 90/220/EEC? Or are there still significant differences in what Member States are requiring for the ERA? Please describe the main areas where the requirements are inconsistent and the relevant countries.

_____

_____

_____

12. How do such inconsistencies affect your organisation/your member organisations operations with the same GMO in different countries? Please describe.

_____

_____

_____

_____

13. Can you suggest any measures for improving consistency, while still retaining some flexibility for Member States?

_____

_____

_____

_____

Public Consultation Costs

For each Part B application, there is a mandatory requirement for public consultation to be held by the Competent Authority. The period for this consultation is set by Member States. There is also a requirement on Part B applicants to publicise the consultation in a national newspaper.

14. Under Directive 90/220/EEC, it was not mandatory for Competent Authorities to consult the public or public interest groups. Competent Authorities in some countries, however, implemented provisions for public information and/or public participation in decision-making on Part B applications under this Directive. What impact did these provisions have on your organisation's/sector's activity in these countries?

_____

_____

_____

_____

15. What impact do you expect the public consultation requirements set out under Directive 2001/18/EC to have on your organisation/member organisations? Will the changes in the public consultation regime have business benefits for your organisation and the industry more generally?

Yes _____ No _____ Don't know _____

Please give reasons for your answer.

_____

_____

_____

_____

Simplified Procedures

Part B of 90/220/EEC allowed for a simplified procedure for notifying the intention of releasing a GMO as part of a programme of research and development work (such as plant breeding). Under Directive 2001/18/EC this simplified procedure is optional. The Directive also introduces the use of 'differentiated procedures' for certain categories of Part B releases.

16. How important were the simplified procedures under Directive 90/220/EEC to your organisation/member organisations?

Very important ——
Important ——
Not important ——
Don't know ——

Please explain. _____

_____

_____

17. How has the shift by some Member States to 'differentiated procedures' affected your organisation/member organisations?

_____

_____

_____

Antibiotic Resistance Markers

Directive 2001/18/EC requires the phasing out of Antibiotic Resistance Markers (ARMs) in GMOs that may have adverse effects on human health and the environment by 2008 for Part B GMOs.

18. Are you aware of any varieties (which hold approved Part B consents), developed by your organisation/member organisations, which contain ARMs that may be covered by the phasing out?

Yes —— No —— Don't know ——

If yes, how has this affected your organisation/the organisations in question? Has it led to significant costs? Has it led to the loss of key areas of development? Or may it lead to such effects in the future?

_____

_____

19. Does the use of ARMs in non-EU countries raise any problems for your organisation /industry sector? Or may it raise any problems in the future? What measures do you believe should be adopted to address these problems?

_____
_____
_____
_____

Other Issues

20. Has your organisation/member organisations identified any other significant differences in approach between Member States in relation to the systems operating under Directive 2001/18/EC in relation to Part B consents that you believe should be addressed?

_____
_____
_____
_____

21. What are the key factors underlying these differences in approach? Are they process related (e.g. informal discussion prior to submission of a Part B application; differences in the consultation process)? Data related (one country requires significantly more data than others)? Timing (e.g. in relation to consultation periods) or politically/culturally based?

_____
_____
_____
_____

PART C: Placing on the Market of GMOS as or in Products

Directive 2001/18/EC also introduced a number of key changes in relation to the Part C approvals process, with the aim of providing a more harmonised, robust and transparent framework for the approval of GM products for the EU market. Key changes from Directive 90/220/EEC include:

- a 10 year time limit on the duration of an approval;
- requirements for post-release monitoring;
- the phase-out of antibiotic resistance markers; and
- labelling and traceability requirements.

General Impact of 2001/18/EC on Part C Applications

22. No Part C consents were approved under Directive 90/220/EEC after 1998. Did the uncertainty in the approval process for commercial releases have an impact on investment by your organisation, or in your sector?

Increase in investment: _____ % change _____
Reduction in investment: _____ % change _____
No change in investment: _____

23. How many applications are currently pending according to Article 35 of Directive 2001/18/EC and how many 'new' applications have been made?

Did implementation of Directive 2001/18 help restart the EU decision making process for Part C applications? Please indicate which the following statements you believe most applies to your organisation, or member organisations in general.

The number of Part C applications currently pending or that are new is increasing from pre-1998 levels (please specify estimated percentage increase) _____%

The number of Part C applications currently pending or that are new is decreasing from pre-1998 levels (please specify estimated percentage decrease) _____%

The number of Part C applications currently pending or that are new will be the same as pre-1998 levels _____

Don't know _____

Not Applicable _____

Please give reasons for your answer.

_____

_____

_____

24. Directive 2001/18/EC sets a maximum time limit of 10 years on Part C consents, although these can be renewed. How has this affected you/your member companies? Has it affected the ability to earn a return on an investment?

Yes _____%
Only for some GMOs _____%
No _____%
Don't know _____%
More than ten years _____%

Please give reasons for your answer.

_____

_____

_____

25. Directive 2001/18/EC removes the Best Available Techniques Not Entailing Excessive Costs condition relating to clean-up of damage caused by GMOs. In theory, this could mean that clean-up of any problems could be required, regardless of the cost.

Do you anticipate that this change could result in additional costs?

Yes ____ No ____ Don't know ____

If your answer is **yes**, please indicate the type and scale of additional costs that may be incurred.

_____

_____

Antibiotic Resistance Markers

Directive 2001/18/EC requires the phasing out of Antibiotic Resistance Markers (ARMs) that may have adverse effects on human health or the environment in GMOs by 31 December 2003 for Part C consents.

26. Are you aware of any varieties, for which your organisation/members hold approved Part C consents, containing ARMs that may be covered by the phasing out?

Yes ____ No ____ If yes, how many? _____

27. What will be the implications for your organisation/members of phasing out ARMs in Part C GMOs?

_____

_____

Traceability and Labelling

Directive 2001/18/EC requires that GMOs are labelled, or accompanied by a document, with the commercial name of the product, a statement that the product contains GMOs, the name of the GMO, a unique identifier, the consent holder details and details of how to publicly access information on the register. To strengthen these provisions along all stages of placing on the market, e.g. along the entire agro-food production and distribution chain, requirements are to be put in place through the proposed Regulations on genetically modified food and feed (Com(2001)425) and on traceability and labelling of genetically modified organisms and

traceability of food and feed products produced from genetically modified organisms (COM(2001)182).

28. What are your views on the system set out in the proposed Regulation on traceability and labelling (COM(2001)182) and its workability?

29. Have any specific issues arisen with regard to import or export of food and feed that you are aware of?

30. Do you have any comments to make about the thresholds that have been suggested in the proposed Regulation on genetically modified food and feed (COM(2001)425) with regard to the adventitious presence of GMOs for EU authorised materials and in relation to non-EU authorised materials in food and feed?

31. In your opinion, is any further action or further regulation needed in relation to the adventitious presence of GMOs in food and feed?

32. Do you have any comments to make about the thresholds that have been proposed in the Draft Commission Directive concerning the adventitious presence of genetically modified seeds in seed lots of non-genetically modified varieties?

33. What additional measures do you believe should be put in place to support the Directive 2001/18/EC and the proposed Regulations on traceability and labelling (referred to above)?

Post-Release Monitoring

Part C applicants are required to supply a post-release monitoring plan setting out how the proposed releases will be monitored for unanticipated effects on the environment. Regulators are to review the monitoring plans and revise as required. The revised plans are then attached as a condition to any Part C consent that is authorised. Such plans were not required under Directive 90/220/EEC but may have been required under national regulations.

34. How have the provisions under Directive 2001/18/EC affected the actual types of monitoring required or planned for commercial releases compared to what may have been required by national legislation under Directive 90/220/EEC?

_____

_____

_____

35. Given the guidance that has been developed by the Commission, do you believe that the types of post-market monitoring that will be required will be consistent across the EU?

_____

_____

36. What differences in requirements do you expect to occur?

_____

_____

_____

37. Are there any issues concerning the development and implementation of case-specific post-release monitoring that you would like to see addressed?

_____

_____

38. Are there any issues concerning the development and implementation of general surveillance monitoring that you would like to see addressed?

_____

_____

39. Are there any issues concerning the boundary between general surveillance and case-specific monitoring, which you would like to see addressed?

_____

_____

Competitiveness and Innovation

40. Are there any aspects of how Directive 2001/18/EC is being implemented by Member States that will lead you to seek approvals in one country as opposed to another?

_____

_____

_____

41. Are there any measures that could be adopted which would minimize the degree to which any such differences between countries could arise in the future?

_____

_____

42. Do you expect Directive 2001/18/EC to have a positive or negative impact on innovation in the GMO sector?

Positive ——— Negative ——— Don't know ———

Please give the reasons for your answer.

_____

_____

43. Would you like to comment on any other aspects of Directive 2001/18/EC or of other related or proposed legislation that would improve consistency and efficiency of the EU legislative framework for GMOs? If so, please add your comments below.

_____

_____

_____

_____

_____

_____

Contact Details

Organisation _____

Contact Person _____

Contact Address _____

Telephone _____ **Fax** _____

E-mail Address _____

PART B: Deliberate Release of GMOs for Any Other Purpose than Placing on the Market

Directive 2001/18/EC on the deliberate release into the environment of GMOs introduced a number of key changes in relation to Part B applications. Decision making on Part B releases remains at the Member State level, however, and is implemented through national legislation. Key changes include:

- mandatory public consultation on Part B applications; and
- public registers of the location of Part B releases.
- strict requirements for the Environmental Risk Assessment

The questions set out below are aimed at gathering information on how these changes might have affected farming stakeholders.

Changes in the Public Consultation Process

Under Directive 90/220/EEC, Competent Authorities could consult the public on applications for Part B releases of GMOs. This is strengthened under Directive 2001/18/EC, as it states that Competent Authorities should consult the public.

1. Can you please indicate whether, under Directive 90/220/EEC, the Competent Authority of your country operated any legal, non-legal, or other mechanisms for making information on applications for Part B releases public available or for allowing public participation in decision-making on such applications?

   _____

   _____

   _____

2. If legal or non-legal mechanisms for public information and public participation in decision making for Part B applications of GMOs did exist under Directive

90/220/EEC, did your organisation make use of these mechanisms? If so, what were your experiences?

_____

_____

3. Under Directive 2001/18/EC, does the Competent Authority in your country foresee specific (legal) mechanisms for public information provision or for public participation in decision-making on applications for Part B releases of GMOs? If so what are the key changes compared to the situation under Directive 90/220/EEC?

_____

_____

_____

4. Has your organisation (already) made use of any new (legal) mechanisms for public information provision and/or public participation? If so, have your experiences been satisfactory, or do you have suggestions for improvement?

_____

_____

_____

5. What are your views on the provision of Directive 2001/18/EC that require Competent Authorities to make information on the location(s) of field trial site(s) publicly accessible through public registers?

_____

_____

_____

Other Issues

6. Do you consider the requirements for the Environmental Risk Assessment under Directive 2001/18/EC to be satisfactory? If not, why not?

_____

_____

7. Directive 2001/18/EC requires the phasing out of Antibiotic Resistance Markers (ARMs) in GMOs that may have adverse effects on human health and the environment by 2008 for Part B GMOs. What issues do you expect to arise in the future in relation to these provisions concerning Part B applications containing ARMs?

_____

_____

_____

8. Do you have any comments that you would like to make on the continued development and use of ARMs in non-EU countries? Do you believe that this may raise problems in the future for the EU? What measures do you believe should be adopted to address these problems?

_____

_____

_____

_____

9. Which other issues concerning the application procedures for Part B releases of GMOs in your country would you like to see addressed?

_____

_____

_____

PART C: Placing on the Market of GMOs as or in Products

Directive 2001/18/EC also introduced a number of key changes in relation to the Part C approvals process, with the aim of providing a more harmonised, robust and transparent framework for the approval of GM products for the EU market. Key changes from Directive 90/220/EEC include:

- limited validaty of consent;
- requirements for post-marketing monitoring;
- public consultation requirements, and;
- the provision of information on the location of commercial releases.

Public Consultation on Part C Applications under Directive 2001/18/EC

In contrast to Directive 90/220/EEC, the new Directive 2001/18/EC foresees that the European Commission should consult the public on applications for Part C releases of GMOs. So far, the European Commission has provided the public with the opportunity to comment on 23 applications for Part C releases of GMOs, which are currently pending.

10. Has your organisation submitted comments on one or more of these pending applications for Part C releases? And if so, what was the nature of your comments?

_____

_____

11. Do you view the mechanism which the European Commission has implemented for public consultation on Part C for releases of GMOs as being satisfactory? If not, why not? Do you have suggestions for improving the public consultation process?

_____

_____

12. What are your views on the provision of the new Directive 2001/18/EC that Competent Authorities should make information on the location(s) of commercial cultivation publicly accessible through public registers?

_____

_____

Antibiotic Resistance Markers

Directive 2001/18/EC requires the phasing out of Antibiotic Resistance Markers (ARMs) that may have adverse effects on human health or the environment in GMOs by 31 December 2003 for Part C consents.

13. Do you have any comments to make on these provisions and the impact that they may have on the EU industry?

_____

_____

Traceability, Labelling Thresholds and Co-existence

Directive 2001/18/EC requires that GMOs are labelled, or accompanied by a document, with the commercial name of the product, a statement that the product contains GMOs, the name of the GMO, a unique identifier, the consent holder details and details of how to publicly access information on the register. To strengthen these provisions along all stages of placing on the market, e.g. along the entire agro-food production and distribution chain, requirements are to be put in place through the proposed Regulations on genetically modified food and feed (COM(2001)425) and on traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms (COM(2001)182).

14. What are your views on the system set out in the proposed Regulation on traceability and labelling (COM(2001)182) and its workability?

_____

_____

_____

15. Have any specific issues arisen with regard to import or export of food and feed that you are aware of?

_____

_____

_____

16. Do you have any comments to make about the thresholds that have been suggested in the proposed Regulation on genetically modified food and feed (COM(2001)425) with regard to the adventitious presence of GMOs for EU authorised materials and in relation to non-EU authorised materials in food and feed? The proposed labelling thresholds are (0.3 % - 0.7 %) for the adventitious presence of GM seeds in non-GM seed lots, and 0.9 % for the adventitious presence of GMOs in GM food and GM feed.

_____

_____

_____

17. In your opinion, is any further action or further regulation needed in relation to the adventitious presence of GMOs in food and feed?

_____

_____

18. Do you have any comments to make about the thresholds that have been proposed in the Draft Commission Directive concerning the adventitious presence of genetically modified seeds in seed lots of non-genetically modified varieties?

_____

_____

_____

19. What additional measures do you believe should be put in place to support the Directive 2001/18/EC and the proposed Regulations on traceability and labelling (referred to above)?

_____

20. What are the views of your organisation on the European Commission's proposal for legally non-binding guidelines for co-existence, which essentially leaves it to the Member States to decide whether specific measures should be implemented?

21. What are the views of your organisation on specific measures for co-existence? And has the Competent Authority in your country consulted your organisation on the development of specific measures for co-existence?

Post-Release Monitoring

Part C applicants are required to supply a post-release monitoring plan setting out how the proposed releases will be monitored for unanticipated effects on the environment. Regulators are to review the monitoring plans and revise as required. The revised plans are then attached as a condition to any Part C consent that is authorised. Such plans were not required under Directive 90/220/EEC but may have been required under national regulations.

22. Do you believe the provisions laid out under Directive 2001/18/EC are adequate?

23. Given the guidance that has been developed by the Commission, do you believe that the types of post-release monitoring that will be required will be consistent across the EU?

24. Are there any issues concerning the development and implementation of case-specific post-release monitoring that you would like to see addressed?

_____

_____

25. Are there any issues concerning the development and implementation of general surveillance monitoring that you would like to see addressed?

_____

_____

Other Issues

26. Would you like to comment on any other aspects of Directive 2001/18/EC in relation to Part C releases or on the other related legislation that would improve consistency and efficiency of the EU legislative framework for GMOs? If so, please add your comments below.

_____

_____

Contact Details

Organisation _____

Contact Person _____

Contact Address _____

Telephone _____ **Fax** _____

E-mail Address _____

PART B: Deliberate Release of GMOs for Any Other Purpose than Placing on the Market

Directive 2001/18/EC on the deliberate release into the environment of GMOs introduced a number of key changes in relation to Part B applications. Decision making on Part B releases remains at the Member State level, however, and is implemented through national legislation. Key changes include:

- mandatory public consultation on Part B applications;
- public registers of the location of Part B releases, and;
- strict requirements for the Environmental Risk Assessment.

The questions set out below are aimed at gathering information on how these changes have affected public interest groups like environmental and consumers organisations.

Changes in the Public Consultation Process

Under Directive 90/220/EEC, Competent Authorities could consult the public on applications for Part B releases of GMOs. This is strengthened under Directive 2001/18/EC, as it states that Competent Authorities should consult the public.

1. Can you please indicate whether any legal, non-legal, or other mechanisms for making information on applications for Part B releases public or for allowing public participation in decision-making on such applications were operated by the Competent Authority of your country under Directive 90/220/EEC?

   _____

   _____

   _____

2. If legal or non-legal mechanisms for public information and public participation in decision making for Part B applications of GMOs did exist under Directive

90/220/EEC, did your organisation make use of these mechanisms? If so, what were your experiences?

_____

_____

3. Under Directive 2001/18/EC, does the Competent Authority in your country foresee specific (legal) mechanisms for public information provision or for public participation in decision-making on applications for Part B releases of GMOs? If so what are the key changes compared to the situation under Directive 90/220/EEC?

_____

_____

_____

4. Has your organisation (already) made use of any new (legal) mechanisms for public information provision and/or public participation? If so, have your experiences been satisfactory, or do you have suggestions for improvement?

_____

_____

_____

5. What other issues concerning public consultation during the application procedures for Part B releases of GMOs would you like to see addressed within your country?

_____

_____

Other Issues

6. Do you consider the requirements for the Environmental Risk Assessment under Directive 2001/18/EC to be satisfactory? If not, why not?

_____

_____

7. Directive 2001/18/EC requires the phasing out of Antibiotic Resistance Markers (ARMs) in GMOs that may have adverse effects on human health and the environment by 2008 for Part B GMOs. What issues do you expect to arise in the

future in relation to these provisions concerning Part B applications containing ARMs?

_____

_____

_____

8. Do you have any comments that you would like to make on the continued development and use of ARMs in non-EU countries? Do you believe that this may raise problems in the future for the EU? What measures do you believe should be adopted to address these problems?

_____

_____

_____

_____

9. Have you identified any significant differences in approach between Member States in relation to the systems proposed to date for Part B consents under Directive 2001/18/EC that you believe should be addressed?

_____

_____

_____

_____

PART C: Placing on the Market of GMOs as or in Products

Directive 2001/18/EC also introduced a number of key changes in relation to the Part C approvals process, with the aim of providing a more harmonised, robust and transparent framework for the approval of GM products for the EU market. Key changes from Directive 90/220/EEC include:

- public consultation requirements and the provision of information on the location of commercial releases;
- the phase-out of antibiotic resistance markers;
- requirements for traceability and labelling, and;
- post-marketing monitoring requirements.

Public Consultation on Part C Applications under Directive 2001/18/EC

In contrast to Directive 90/220/EEC, the new Directive 2001/18/EC foresees that the European Commission should consult the public on applications for Part C releases of

GMOs. So far, the European Commission has provided the public with the opportunity to comment on 23 applications for Part C releases of GMOs, which are currently pending.

10. Has your organisation submitted comments on one or more of these pending applications for Part C releases? And if so, what was the nature of your comments?

_____

_____

11. Do you view the mechanism which the European Commission has implemented for public consultation on Part C for releases of GMOs as being satisfactory? If not, why not? Do you have suggestions for improving the public consultation process?

_____

_____

Antibiotic Resistance Markers

Directive 2001/18/EC requires the phasing out of Antibiotic Resistance Markers (ARMs) that may have adverse effects on human health or the environment in GMOs by 31 December 2003 for Part C consents.

12. Do you have any comments to make on these provisions and the impact that they may have?

_____

_____

Traceability and Labelling

Directive 2001/18/EC requires that GMOs are labelled, or accompanied by a document, with the commercial name of the product, a statement that the product contains GMOs, the name of the GMO, a unique identifier, the consent holder details and details of how to publicly access information on the register. To strengthen these provisions along all stages of placing on the market, e.g. along the entire agro-food production and distribution chain, requirements are to be put in place through the proposed Regulations on genetically modified food and feed (COM(2001)425) and on traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms (COM(2001)182).

13. What are your views on the system set out in the Directive and the proposed Regulation on traceability and labelling (COM(2001)182) and its workability?

_____

_____

14. Have any specific issues arisen with regard to import or export of food and feed that you are aware of?

_____

_____

_____

15. Do you have any comments to make about the thresholds that have been suggested in the proposed Regulation on genetically modified food and feed (COM(2001)425) with regard to the adventitious presence of GMOs for EU authorised materials and in relation to non-EU authorised materials in food and feed? The proposed labelling thresholds are (0.3 % - 0.7 %) for the adventitious presence of GM seeds in non-GM seed lots, and 0.9 % for the adventitious presence of GMOs in GM food and GM feed.

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_____

16. In your opinion, is any further action or further regulation needed in relation to the adventitious presence of GMOs in food and feed?

_____

_____

17. Do you have any comments to make about the thresholds that have been proposed in the Draft Commission Directive concerning the adventitious presence of genetically modified seeds in seed lots of non-genetically modified varieties?

_____

_____

_____

18. What additional measures do you believe should be put in place to support the Directive 2001/18/EC and the proposed Regulations on traceability and labelling (referred to above)?

_____

_____

_____

Post-Release Monitoring

Part C applicants are required to supply a post-release monitoring plan setting out how the proposed releases will be monitored for unanticipated effects on the environment. Regulators are to review the monitoring plans and revise as required. The revised plans are then attached as a condition to any Part C consent that is authorised. Such plans were not required under Directive 90/220/EEC but may have been required under national regulations.

19. Do you believe the provisions laid out under Directive 2001/18/EC are adequate?

_____

_____

_____

20. Given the guidance that has been developed by the Commission, do you believe that the types of post-release monitoring that will be required will be consistent across the EU?

_____

_____

_____

_____

21. Are there any issues concerning the development and implementation of case-specific post-release monitoring that you would like to see addressed?

_____

_____

22. Are there any issues concerning the development and implementation of general surveillance monitoring that you would like to see addressed?

_____

_____

Other Issues

23. Would you like to comment on any other aspects of Directive 2001/18/EC or of other related legislation that would improve consistency and efficiency of the EU legislative framework for GMOs? If so, please add your comments below.

_____

_____

ANNEX III: LIST OF CONSULTEES

Competent Authorities

Austria
Ministry of Health and Women
Ministry of Social Security and Generations
Federal Ministry of Education, Science and Culture

Belgium
FPS Health, Food Chain Safety and Environment

Germany
Robert Koch-Institut
Bundesministerium fur Verbraucherschutz

Denmark
Ministry of the Environment
Danish Forest and Nature Agency

Spain
Ministerio de Medio Ambiente

Finland
Ministry of Social Affairs and Health – Board for Gene Technology

France
Ministere de l'Agriculture
Ministerede l'Agriculture de l'Alimentation, de la Peche et des Affaires Rurales
Ministere de l'Ecologie et du Developpement

Greece
Ministere de l'Environnement, Amenagement de Territoire et Travaux Publics

Ireland
EPA

Italy
Ministry of Health – Prevention Dpt

Luxembourg
Ministry of Health

The Netherlands
Directorate-General for Environmental protection

Portugal
Instituto do Ambiente

Sweden
Board of Agriculture

UK
DEFRA

Iceland
Environmental and Food Agency of Iceland

Liechtenstein

Norway
Directorate for Nature Management

Industry and Research

Acambis Research Ltd
UK

ADAS Nutritional Sciences
UK

Advanced Technologies (Cambridge) Ltd
UK

Advanta Ltd
The Netherlands
UK

ASDA Stores Ltd
UK

Avebe
The Netherlands

Bayer CropScience
France
Germany
The Netherlands
UK

Biogemma Ltd
France
UK

BioIndustry Association
UK

Biologische Bundesanstalt fur lund und Forstwirtschaft, Kleinmachnow
Germany

Biostrategy Associates Ltd
UK

British Society of Plant Breeders
UK

Bundesverband deutschere Planzenzuechter
Germany

CPB Twyford Ltd
UK

Crop Performance and Improvement
UK

Crop Protection Association
UK

Dept of Bioscience & Biotechnology
University of Strathclyde
UK

EURALIS
France

EuropaBio
Belgium

Europarc du Chene
France

Genzyme Diagnostics
UK

Glaxo Smithkline Research & Development
UK

Groupe Limagrain
France

Horticulture Research International
UK

IACR
UK

Iceland Group Plc
UK

INRA Dijon
INRA Versailles Grigon
France

Institute for Agrofoods Research and Technology
Spain
IVEM/NERC
UK

J Sainsbury Plc
UK

John Innes Centre
UK

KWS SAAT AG
Germany

Leeds Institute for Plant Biotechnology & Agriculture
UK

Monsanto
Belgium
France
Germany
Spain
UK

Microscience Ltd
UK

National Institute for Agricultural Botany
UK

National Institute for Biological Standards and Control (NBSC)
UK

Pioneer (DuPont)
Belgium
Germany

Plant Research International
The Netherlands

Plant Science for Industry
Lancaster University
UK

Safeway Stores Plc.
UK

Scottish Crop Research Institute
UK

Somerfield Stores
UK

Syngenta International AG
Belgium
Germany
Spain
UK

Tesco Plc
UK

The Scottish Agricultural College
UK

UK Agricultural Suppliers Trade Association UK

Unilever
UK

University of Balearic Islands
Spain

WM Morrisons Supermarkets Plc
UK

Farmers Organisations

ASAJA-Aragon
Spain

Confederation Paysanne
France

COPA-COGECA
Belgium

Deutscher Bauernverband (DBV)
Germany

Farm and Food Society
UK

Federation of Agriculture Co-Operatives
UK

FNSEA
Bureau de l'Agriculture
Belgium

Foundation of Future Farming
Germany
LTO
The Netherlands

National Farmers Union
UK
Spanish Farmers Organisation

Public Interest Groups

BEUC
Belgium

BUND
Germany

Central Bureau Levensmiddelenhandel
The Netherlands

CIAA
Belgium

Compassion in World Farming
UK

Confederation de la consummation du logement et du cadre de vie
France

Consumers' Association
UK

Consumers Association of Catalonia
Spain

Consumer & Biotechnologie
Netherlands

Council for Protection of Rural England
UK

EuroCommerce
Belgium

Euro Coop
Belgium

Food Watch
Germany

Friends of the Earth
Europe
Belgium
Spain
UK

Greenpeace
European Unit
Germany
The Netherlands
UK

Genetic Engineering Alliance
London

Genewatch
UK

IFOAM Head Office
Germany

Leo Lagrange
Consumer NGO
France

National Consumer Council
UK

National Federation of Consumer Groups
UK

Oeko-Institut
Germany

Organic Farmers
Germany

Platform Biologica
Netherlands

Soil Association
UK

Union Feminine
Civique et sociale
France

University of Barcelona
Spain

VAI
The Netherlands

Verbraucherzentrale Bundesberband e.V.
Germany

WWF-Worldwide Fund for Nature
UK

ANNEX IV THE WIDER FRAMEWORK

A4.1 The EU Regulatory Framework for GMOs from Farm to Fork

As a result of the uncertainty in the approvals process for Part C applications under Directive 90/220/EEC the European Commission, the Parliament and the Council of Ministers have sought to improve the EU's regulatory framework for the use of GMOs from farm to fork. As a first result, Directive 2001/18/EC, which repeals Directive 90/220/EEC, was adopted and entered into force of 17 October 2002.

Besides Directive 2001/18/EC, the EU regulatory framework from farm to fork now further consists of Regulation (EC) 1829/2003 on GM food and feed and Regulation (EC) 1830/2003 on traceability and labelling of GMOs and traceability of food and feed derived from GMOs. Both Regulations entered into force on 7 November 2003 and will have to be applied after a transitional period as of April 2004.

Furthermore, the Regulation (EC) 1946/2003 on the transboundary movement of GMOs was adopted on 15 July 2003. This regulation will soon be published in the Official Journal. In essence, this Regulation is linked to the ratification by the European Community of the Cartagena Protocol on Biosafety and governs the exports of GMOs intended for deliberate release into the environment to non-EU countries. The Regulation also sets rules for the exports of GMOs intended to be used as food, feed or for processing.

Moreover, Directive 2002/53/EC requires the Commission to inscribe in the Common Catalogue of agricultural plant species any plant varieties, which have been added to national catalogues. In case of a GM plant variety the GMO ('event'), on which the GM plant variety is based, must be authorised under Directive 2001/18/EC for its use in cultivation and the GM material must be authorised for food and feed use under the Regulation GM food and feed.

In January 2002 the Commission made its first proposal for a Directive to amend the existing seed Directives. The proposal seeks to regulate the marketing and labelling of plant seeds derived from GMOs and to establish conditions and requirements for thresholds for the adventitious or technically unavoidable presence of GM seeds in seed lots of conventional, non-genetically modified plant varieties, below which no labelling would be required.

On 23 July 2003 the Commission issued a Recommendation on guidelines for the development of national strategies and best practices for the coexistence of genetically modified crops with conventional and organic farming. Whilst the Commission did thus not propose legally binding rules for coexistence, Article 26a of Regulation (EC) 1829/2203 amends Directive 2001/18/EC with a view to coexistence. Member states may now take measures to avoid the unintended presence of GMOs in other products. Previously under Directive

2001/18/EC (containment) measures were only allowed in the interest of the protection of human health and the environment.

Furthermore, in January 2002 the European Commission made its first proposal for a Directive on environmental liability. Annex 1 of the proposed Directive lists the risky and potentially risky activities, which would fall within the scope of this directive. The proposal regarded deliberate release of GMOs into the environment as defined and within the scope of Directive 2001/18/EC as an Annex 1 activity.

In essence, this EU regulatory framework for the use of GMOs from farm to fork has a twofold aim:

- harmonisation of environmental, food and feed risk/safety assessments procedures for GMOs, GM seeds and GM food and feed within centralised authorisation procedures; and
- consumer choice through mandatory traceability and labelling of GMOs, GM seeds and GM food and feed through establishment of thresholds for the presence of EU-authorised and non-EU-authorised GM material in non-GM seeds and non-GM food and feed.

Finally, prior to adoption the EU regulatory framework on the use of GMOs from farm to fork has been notified to the Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements of the World Trade Organisation (WTO), so as to ensure conformity with these agreements.

A4.2 Regulation (EC) 1829/2003 on GM Food and Feed

The Regulation (EC) 1829/2003 on GM food and feed entered into force on 7 November 2003 and replaces the GM part of Regulation (EC) 258/97 of 27 January 1997 on novel foods and novel food ingredients.

Until 7 November 2003 the Novel Foods Regulation set out rules for authorisation and labelling of novel foods, including food products containing, consisting or produced from GMOs. The first step of the authorisation procedure was an assessment of an application to market a GM food product by the Member State where the food was to be first placed on the market. In case of a favourable opinion, this Member State informed the other Member states via the Commission. If there were no objections against the application, this Member State could authorise the product for marketing in the entire EU. If there were objections by other Member States, a decision at the Community level was required. The Commission consulted the Scientific Committees on matters relating to public health and adopted a decision after receiving a favourable opinion from the Regulatory Committee composed of Member States representatives. As a derogation from the full authorisation procedure, the Novel Food Regulation provided for a simplified procedure for foods derived from GMOs but no longer containing GMOs, which are 'substantially equivalent' to existing foods with respect to composition, nutritional value, metabolism, intended use and the level of undesirable substances. In such

cases, the companies only had to notify the Commission when placing a product on the market together with either scientific justification that the product is substantially equivalent or an opinion to the same effect, delivered by the Competent Authorities of a Member State.

So far, products from 16 GMOs have been approved for food use in the EU. One GM soy and one GM maize were approved under Directive 90/220/EEC prior to the entering into force of the Novel Foods Regulation. Processed foods derived from seven GM oilseed rape, four GM maize and oil from two GM cottonseeds have been notified as substantially equivalent in accordance with the Novel Foods Regulation. Eight applications are currently pending at different stages in the authorisation procedure under the Novel Foods Regulation.

Moreover, until 7 November 2003 there was no Community legislation governing the use of material derived from GMOs in feed. However, four GM maize, three GM rape and one GM soy were authorised in accordance with Directive 90/220/EEC for the purpose of use in feed.

By contrast to (the GM part of) the Novel Foods Regulation, the new Regulation on GM food and feed governs both the use of GMOs for food as well as feed. Key elements of the new regulation include:

- a harmonised and centralised 'one door – one key' Community procedure for the scientific safety risk assessment to be carried out by the European Food Safety Authority (EFSA), covering both the environmental and human and animal health safety assessment;
- a single risk management process, involving the Commission and the Member States through a regulatory committee procedure;
- a summary of the application and the opinion of the EFSA shall be made available to the public, which may make comments to the Commission within thirty days;
- authorisation will be granted for a period of ten years, and if appropriate, subject to a post-market monitoring plan. After ten years the applicant may apply for renewal of the authorisation; and
- products authorised shall be entered into a register, including product specific information, studies on the safety of the product and the sampling, identification and detection methods as well as samples of the GM food and feed (reference materials), which have to be provided by the applicants.

In addition, the new Regulation on GM food and feed does not include the 'simplified' notification procedure of the Novel Foods Regulation for GM food (ingredients), which are 'substantially equivalent' to existing foods.

Authorisation of food additives, flavourings and feed additives, which contain, consist or produced from GM (micro-)organisms (GMMs) falls under the scope of several specific Directives for these substances, while this Regulation covers the safety assessment of the genetic modification. In other words, this Regulation only covers food and feed produced 'from' a GMO but not food

and feed produced 'with' a GMO. The determining criterion is whether or not material derived from the GM starting material is present in the food and feed. Processing aids, such as enzymes that are only used during the food and feed production process, are not covered by the definition of food and feed. Processing aids manufactured with the help of GMMs do therefore not fall under this Regulation and its labelling requirements. Also products obtained from animal fed with GM feed or treated with GM medicinal products are not subject to the authorisation and labelling requirements of this Regulation.

Moreover, the Regulation on GM food and feed leaves the applicant the choice either applying for an authorisation under Part C of Directive 2001/18/EC, or requesting the environmental risk assessment to be carried out at the same time as the food and feed safety assessment under this Regulation. In case the GMOs are seeds or other plant propagating material, however, the environmental risk assessment must delegated to a national Competent Authority for Directive 2001/18/EC.

Authorisation procedure under Regulation (EC) 1829/2003

1. Application sent to CA of a member state.

2. CA sends application to EFSA.
- Within 14 days CA acknowledges receipt to applicant.
- EFSA *may* ask food/feed safety assessment by national body: opinion to be delivered within 3 months.
- EFSA *may* ask environmental risk assessment by national CA for Directive 2001/18/EC: opinion to be delivered within 3 months. If GMOs are seeds or plant propagating material, national CA *must* be consulted.
- Community reference laboratory tests and validates methods of detection and identification.
- EFSA examines data and information. If EFSA seeks supplementary information from the application, a time limit may be imposed on applicant for supplying that information.

3. Within 6 months EFSA publishes opinion and sends it to Commission, member states and applicant. If EFSA has sought supplementary information, this time limit shall be extended. Within 30 days the public may comment.

4. Within 3 months Commission sends draft decision to Standing Committee.

5. Within 3 months Commission informs applicant and publishes decision in the official journal.
- In case of positive decision, authorisation is valid for ten years, which may be renewed
- Within 2 months a decision or failure to act by EFSA can be reviewed by the Commission or further to a request by a member state or any person directly and individually concerned.
- Within 2 months the Commission shall take a decision requiring, if appropriate, EFSA to withdraw its decision or remedy to its failure to act.

Furthermore, Article 46(1) of the new Regulation provides that applications for the authorisation of a GM food made under the Novel Foods Regulation, which have received a final scientific assessment before the coming into application of the new Regulation, are still processed under the Novel Foods

Regulation. Authorisation for a GM food will include labelling and traceability provisions as required by the new Regulation (EC) 1830/2003 on traceability and labelling of GMOs and GM food and feed. As mentioned, eight applications are currently pending under the Novel Foods Regulation.

A4.3 Regulation (EC) 1830/2003 on Traceability and Labelling

The Regulation (EC) 1830/2003 on the traceability and labelling of GMOs and the traceability and labelling of GM food and feed also entered into force on 7 November 2003. Together with Directive 2001/18/EEC and Regulation (EC) 1829/2003, this Regulation aims at a harmonised framework to ensure traceability and labelling of the use of GMOs from farm to fork. The Regulation views traceability as a tool for facilitating:

- post-market monitoring of GMOs and GM food and feed and targeted withdrawal, if unforeseen adverse effects on human health or the environment occur; and
- control and verification of labelling claims.

For that purpose all operators in the food and feed production chain shall transmit and retain specified information on the GMOs. As a means to specify the identity of GMOs, a system of 'unique identifiers' will be developed.

Traceability is viewed of importance, because in conjunction with the Regulation on GM food and feed, the Regulation introduces labelling of GM food and feed, irrespective of the detectability in the final product of DNA or protein resulting from the genetic modification. Under the former EU legislation labelling of a GM food or GM food ingredient (Regulation (EC) 1139/98, Regulation (EC) 49/2000 and Regulation (EC) 50/2000) was essentially triggered by the presence of DNA or protein resulting from the genetic modification. The new Regulations therefore impose labelling requirements for two categories of GM products that until 7 November 2003 did not need to be labelled: 1) GM feed produced from GMOs, and; 2) GM food produced from GMOs but not containing GM material. Products obtained from animals fed with GM feed or treated with GM medicinal products are not subject to mandatory labelling.

Whilst under former EU legislation the labelling-threshold was set at 1 % for the presence of 'modified' DNA or protein in conventional foods, the new Regulations introduce a threshold of 0.9 % for the 'adventitious' or 'technically unavoidable' presence of authorised GM material in non-GM food and feed. For the 'adventitious' or 'technically unavoidable' presence of GM material, which has not been authorised but has received a favourable EU scientific risk assessment, the threshold is set at 0.5 %. The period for this transitional measure is three years. Moreover, appropriate lower thresholds may be established, in particular in respect of food and feed containing or consisting of GMOs, or in order to take into account advances in science and technology.

The Regulation further provides an amendment of Directive 2001/18/EC, which in essence allows Member States to take appropriate measures for coexistence.

Finally, in October 2003 the Commission[12] reported that it is currently preparing the following implementing measures and guidance for Regulations (EC) 1829/2003 and 1830/2003 in order to ensure full applicability by April 2004:

- on 16 January 2004 Commission Regulation (EC) No 65/2004 was published in the Official Journal, which establishes a system for the development of unique identifiers for GMOs; and
- a draft document with guidance for sampling and detection of GMOs and GM food and feed will be presented to Member States and stakeholders for comments before the ends of 2003. A formal Commission Decision will (likely) be adopted in early 2004.

In terms of the Regulation on GM food and feed, the Commission is also planning to present proposals to the Standing Committee on the Food Chain and Animal Health in December 2003, concerning the implementation of the following articles and issues:

- implementing rules for Article 5 and 17 concerning the preparation and presentation of the application for authorisation;
- implementing rules for Article 8 and 20 concerning existing products; and
- implementing rules for Article 47 concerning transitional measures for adventitious presence of unauthorised GM materials.

A4.4 Community Legislation on Seeds

So far, 23 GM maize varieties are inscribed in national catalogues of France, the Netherlands and Spain and are awaiting inscription into the Common Catalogue of agricultural plant species in accordance with Directive 2002/53/EC.

According to that directive, the Commission is required to inscribe in the Common Catalogue any varieties, which have been added to national catalogues. The GMO ('event'), on which the variety is based, must be authorised under Directive 2001/18/EC for its use in cultivation and the GM material must be authorised under the Novel Foods Regulation, respectively under the Regulation on GM food and feed.

If a monitoring plan has to be submitted by the applicant to the Commission in accordance with Directive 2001/18/EC, it will be sent for opinion to EFSA, which will need a few months to deliver an opinion. In the case of a

[12] Commission of the European Communities, Commission Staff Working Document: Information note concerning forthcoming decisions on GMOs and GM food, feed and seed, SEC(2003) 1131, Brussel, 13.10.2003.

favourable opinion, the Commission should proceed with the inscription into the Common Catalogue. When all elements for an inscription are fulfilled, the next step is to publish the complement to the Common Catalogue in the Official Journal about two months later. Member States will be informed by the Commission of the inscription of the variety before this publication.

In October 2003 the Commission reported that it was examining the issue of post-marketing monitoring plans for twenty-three GM plant varieties and was discussing this aspect with the companies in question, in order to have comprehensive monitoring plans[13]. The Commission indicated that twelve GM Bt maize varieties of Syngenta, one GM herbicide-tolerant maize variety of Bayer Crop Science and ten GM Bt maize varieties of Monsanto were currently subject to discussion.

A4.5 Adventitious presence of GM seeds in non-GM seeds

In January 2002 the Commission made its first proposal for a Directive to amend the existing seed Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC and 70/548/EEC. The proposal sought:

- to regulate the marketing and labelling of plant seeds derived from GMOs by requiring precise information on the official label with the wording "genetically modified variety" (together with the name of the GMO); and
- to establish conditions and requirements for thresholds for the 'adventitious' or 'technically unavoidable' presence of GM materials (authorised by the EU) in seed lots of conventional non-GM plant varieties, below which no labelling would be required.

In October 2003 the Commission reported that a text for a Commission Directive (doc SANCO/1542/03) establishing labelling-thresholds for the adventitious or technically unavoidable presence of authorised GM seeds in seeds of non-GM varieties had been finalised by the Commission Services. The following labelling-thresholds in seeds being proposed by the Commission take into account the labelling-threshold of 0.9 % for GM material in non-GM food and feed:

- 0.3 % for swede rape and cotton (cross-pollinated);
- 0.5 % for tomato (self-pollinated), beet and chicory (cross-pollinated, cultivated vegetatively), maize (cross-pollinated for which the probability of volunteers is very low) and potato (propagated and cultivated vegetatively); and
- 0.7% for soya bean (self-pollinated for which the probability of volunteers is very low).

According to the Commission, the opinion of the Scientific Committee on Plants of January 2003 clearly confirms that starting with seeds at the limit of

[13] See previous footnote.

such thresholds will result in a product with a GM presence of around 0.8 %. This still leaves a margin *vis à vis* the 0.9 % threshold for the final product.

This draft Directive was discussed at the Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry on 22 September 2003[14]. Some delegations indicated to support the draft measure, while some other delegations indicated that the threshold levels should be set at the detection limit, or at 0.1 %, or a lower level than the ones proposed and that they should be set in the light of coexistence, order to allow organic farming. The Commission indicated that specific thresholds would be examined and discussed in the framework of the Regulation on organic farming. Some delegations expressed the view that seed lots exceeding the threshold should not be certified and marketed, even with special labelling. Some others expressed the view that according to the experience and controls in their country, a threshold of 0.1 % was feasible and higher levels would not be technically unavoidable. Moreover, a delegation raised the point whether the thresholds established in the Commission directive on seeds could be adopted under the management Committee procedure foreseen by the seed legislation or whether they shall be adopted in accordance with the provision of Article 21 (2) of Directive 2001/18/EC under a Regulatory Committee procedure.

The discussions on the levels of the seed thresholds in this Standing Committee were raised in the Agriculture Council on 29 September 2003 during a debate on coexistence. Whilst the Commission subsequently submitted the text to an indicative vote at the meeting of the Standing Committee on 27 – 28 October 2003, the result of the meeting was that the Commission decided to seek legal advice on the relation between this draft Directive and Directive 2001/18/EC. This, said a Commission official, will give an extra environmental check and avoid legal inconsistencies between both laws[15]. Recently, it has been decided that a Commission proposal for the thresholds of GM seeds in lots of non-GM seeds will be finalised under Directive 2001/18/EC. Identical thresholds will then be adopted under the seed Directives.

Moreover, sampling and testing conditions of seed placed on the market, in particular as regards GM presence, will be specified in a Commission Regulation on a protocol for sampling and testing of seed lots of non-GM varieties for the presence of GM seeds. This protocol has been prepared with experts of the Member States. A draft Regulation will be discussed in the Standing Committee on Seeds and voted on in January 2004, with a view of having the Regulation in application at the same time as the text on thresholds (April 2004).

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14 Short report of the meeting of the Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry held on 22 September 2003.

15 EU rethinks strategy of agreeing gene seed rules, by Jeremy Smith, Reuters, 27 October 2003.

A4.6 Recommendation of 23 July 2003 on Guidelines for Coexistence

On 23 July 2003 the Commission adopted the Recommendation on guidelines for the development of national strategies and best practices to ensure the coexistence of GM crops with conventional and organic farming.

This Recommendation emphasises that coexistence refers to the ability of farmers to make a practical choice between the different types of agriculture, in compliance with the legal obligations for labelling and/or purity. The adventitious presence of GMOs above the threshold set out in Community legislation triggers the need for a crop, which was intended to be a non-GM crop, to be labelled as containing GMOs. This could cause a loss of income, due to lower market price of the crop or difficulties in selling it. Moreover, additional costs might incur to farmers if they have to adopt monitoring systems and measures to minimise the admixture of GM and non-GM crops. Coexistence is therefore concerned with the potential *economic impact* of the admixture of GM and non-GM crops, the identification of workable management measures to minimise admixture, and the costs of these measures.

According to the Commission Recommendation, it is important to make a clear distinction between the economic aspects of coexistence and the environmental and health aspects dealt with under Directive 2001/18/EC.

Further, the Commission, at its meeting of 5 March 2003, expressed itself in favour of an approach that would leave it up to Member States to develop and implement management measures for coexistence. The role of the Commission would include gathering and co-ordinating relevant information based on on-going studies at Community and national level, offering advice and issuing guidelines, which should assist Member States in establishing best practices for coexistence. Strategies and best practices for coexistence need to be developed and implemented at national or regional level, with the participation of farmers and other stakeholders and taking into account national and regional factors. The present guidelines, which take the form of non-binding recommendations to the Member States, should be seen in this context, while their scope extends from agricultural crop production to the first point of sale, i.e. 'from the seed to the silo'.

The Recommendation contains an indicative and open-ended catalogue of measures for coexistence that may, to varying degrees and in various combinations, become part of national coexistence strategies and best practices. One of the measures of this catalogue suggests that the register established in accordance with Article 31.3 (b) of Directive 2001/18/EC can be a useful instrument to monitor developments of GM crops and to help farmers co-ordinate local production patterns and monitor developments concerning the different types of crops. It could be accompanied by a global positioning system-based map of GM, non-GM and organic fields. The information could be made publicly available at the Internet or other communication supports. Another measure is creating an identification system for field where GM crops are grown. The Recommendation further

pointed out that there is a legal requirement for farmers, who cultivate GM crops, to have systems for traceability and labelling in place to identify from whom they have received GMOs and to whom they have supplied GMOs, including GM crops and seeds.

The Recommendation also notes that the type of national instruments adopted may have an impact on the application of national liability rules in the event of economic damage resulting from admixture. Member States are therefore advised to examine their civil liability laws to find out whether the existing national laws offer sufficient and equal possibilities in this regard. Farmers, seed suppliers and other operators should be fully informed about the liability criteria that apply in their country in the case of damage caused by admixture. In this context, Member States may want to explore the feasibility and usefulness of adapting existing insurance schemes or setting up new schemes.

A4.7 The Regulation on Transboundary Movement of GMOs

The Regulation (EC) of the European Parliament and of the Council 1946/2003 on transboundary movement of GMOs was adopted on 15 July 2003. This Regulation will soon be published in the Official Journal.

In essence, the Regulation is linked to the ratification by the European Community of the Cartagena Protocol on Biosafety and further complements the Community regulatory framework. While other parts of the regulatory framework cover imports and trade in GMOs, the Regulation seeks to fulfil the requirements under the Protocol on exports by establishing a common system of notification and information. The main elements of the Regulation are:

- the obligation to notify exports of GMOs intended for deliberate release into the environment and secure express consent prior to a first transboundary movement;
- provisions for identifying GMOs for export;
- a set of rules for the exports of GMOs intended to be used as food, feed or for processing; and
- the obligation to provide information to the public and international partners on EU practices, legislation and decisions on GMOs, as well as on unintentional or illegal transboundary movements of GMOs.

Exports of GMOs intended for deliberate release into the environment should be notified by the exporter to the Party or non-Party of import and they should await the prior written consent before proceeding with the first transboundary movement of these GMOs. In cases where the importing Party or non-Party does not communicate its decision within 270 days from the receipt of the notification, the exporter shall send a written reminder with a deadline for response of days from the receipt of the reminders, to Competent Authority of that importing Party, with a copy to the secretariat of the Protocol Biosafety Clearing House (BCH) of the Protocol, to the Member State of export, and to the Commission.

Products consisting of or containing mixtures of GMOs for direct use as food, feed and processing are subject to the traceability requirements of Directive 2001/18/EC and, when applicable, of the Regulations (EC) 1829/2003 and 1830/2003. Any final decision regarding the use, including placing on the market, within the Community or Member State of a GMO for direct use as food, feed and processing, that may be subject to transboundary movement, shall be sent by the Commission or the Member State to the BCH within fifteen days of the adoption of that decision. This does not apply to decisions regarding the deliberate release in accordance with Part B of Directive 2001/18/EC of a GMO not intended for direct use as food, feed or processing in a third country without a subsequent decision.

GMOs intended for contained use are excluded from the Regulation, whereas transhipments of GMOs shall be notified by the exporter to Parties that have taken the decision to regulate transit of GMOs through their territory and have informed the BCH of this decision.

A4.8 Proposal for a Directive on Environmental Liability

On 23 January 2002 the Commission made its first proposal for a Directive on environmental liability with regard to the prevention and remedying of environmental damage[16]. According to the Commission, this proposal reflected its commitment to fight current unsustainable trends; ongoing loss of biodiversity throughout Europe and continuing pollution of water and soil. In line with the 'polluter pays' principle the proposal aimed at making operators financially responsible for the necessary preventive and remedial measures.

The proposal covered the risky and potentially risky activities listed in its Annex 1. Contained use of genetically modified micro-organisms as defined and within the scope of Directive 90/219/EEC as well as deliberate release of GMOs as defined and within the scope of Directive 2001/18/EC (repealing Directive 90/220/EEC) are listed in Annex 1. The proposal further covered biodiversity damage in all areas protected under EU and national legislation. EU protected species are also covered irrespective of location considerations. The reason for focusing the scope in this way was that these protected areas contain biodiversity, which has been found to be particularly rich and socially valuable in the EU. Therefore, and to ensure a system of liability to biodiversity, which is effective and manageable, priority has been given to cover the biodiversity in the protected areas. According to the Commission, the definition of 'biological diversity' in Article 2 of the Convention on Biological Diversity could not be considered at this stage as providing a suitable basis for the proposed regime. This included the liability to be attached to GMOs. The Convention's definition goes beyond habitats and species and subsumes the idea of 'variability'. Using this definition, it could be argued that damage to biological diversity would encompass injury to

[16] Proposal for a Directive of the European Parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage, COM(2002) 17 final, Brussels, 23.1.2002.

''variability among living organisms'. Such an approach raised the delicate question of how such a damage would be quantified, and what would be the threshold of damage entailing liability. In the case of an organic farmer, whose crop cannot be sold as 'biologically produced' or 'organic' due to contamination by GMOs, the Commission argued that damage caused is a purely economic one (the crop cannot be sold) not an environmental one. This is therefore a traditional damage, which is to be dealt with in accordance with national law.

On 18 September 2003 the Environment Council formally adopted its Common Position on the draft Directive and amendments introduced by the European Parliament in its first reading, on which the Environment Council had reached a political agreement at its meeting of 13 June 2003. The Common Position has been sent to the European Parliament for a second reading in accordance with the co-decision procedure.

A4.9 The Wider EU Framework and World Trade Organisation Agreements

A4.9.1 Introduction to WTO SPS and TBT Agreements

Because they were negotiated prior to the commercialization of any GM plants or GM food and GM feed commodities, neither the Sanitary and Phytosanitary (SPS) nor the Technical Barriers to Trade (TBT) agreements within the framework of the World Trade Organisation (WTO) contain provisions that are specific to these GM products. The SPS agreement sets out the basic rules for food safety and animal and plant health standards.

Under the SPS Agreement, nations are encouraged to adopt international standards, where they exist, but may define even higher standards provided they are based on a sound scientific risk assessment, and do not discriminate against imports. Recognising that a complete risk assessment may not be possible in the short term because of scientific uncertainty or the lack of sufficient evidence, Article 5.7 of the SPS Agreement allows countries to temporarily adopt restrictive measures. In such cases, countries are expected to seek the additional information required to complete a full risk assessment within a reasonable period. Maintaining restrictive measures indeterminately in the absence of scientific evidence of risk solely for "precautionary" reasons are not allowed. The SPS Agreement would apply to regulations to protect the environment and biodiversity against introductions of alien species and living modified organisms (LMOs) via trade pursuant to Articles 8(g) and 8 (h) of the Convention on Biological Diversity (CBD) and the Cartagena Biosafety Protocol.

The TBT Agreement is intended to ensure that WTO members do not use technical regulations and standards as disguised measures to protect domestic industries from foreign competition. In international trade law, health and environmental standards and regulations, labelling, symbols, and packaging marking can be considered as technical barriers to trade. In the agri-food

sector, the TBT agreement applies to all rules other than those specifically covered by the SPS agreement. The TBT agreement does not permit requirements for labelling of some products where "like products" remain unlabelled (Article 2.1).

For example, GM crop commodities that have been assessed and found to be "substantially equivalent" to their conventional counterparts would be considered "like products" and thus would not require specific labelling. Critics of the WTO stance are now disputing that "substantially equivalent" is an acceptable outcome of the risk assessment of GM products, and in so doing are asserting that these products are not "like products" for the purposes of labelling. Traditionally within the WTO, a consumer desire for a measure such as mandatory labelling would not be viewed as a legitimate objective within the context of Article 2.2 of the TBT agreement. This article states that regulatory measures that have the effect of disrupting trade must be designed to achieve a legitimate objective and must not be any more trade restrictive than necessary[17].

A4.9.2 The World Trade Organisation and the Cartagena Biosafety Protocol

The assessment of the rules for the regulation of GMOs falls within the remit of the WTO Committee on Trade and Environment (CTE), which also aims at clarifying the relationship between WTO rules and specific trade obligations of certain multilateral agreements (MEAs). Examples of such MEAs are the Convention on Biological Diversity (CBD) and the Cartagena Biosafety Protocol. The relationship between WTO rules and these MEAs was a major source of disagreement at the negotiations in Cartagena in 1999 and an essential core issue to be resolved in Montreal 2000. The negotiations led to a 'compromise' preamble to the protocol.

Whether the 'compromise' preamble has adequately clarified the relationship between the Cartagena Biosafety Protocol and WTO rules remains to be seen[18].

A4.9.3 The World Trade Organisation and the (draft) Regulations

In 2002 the European Commission notified the draft Regulations for GM food and feed and for their traceability and labelling to the WTO Committees on SPS and TBT. At meetings of the WTO Committees on SPS and TBT on 26 July 2002, the European Commission provided response to comments submitted by other WTO members on these draft Regulations[19, 20]. Most

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17 WTO (1994). The WTO Agreement on Technical Barriers to Trade (TBT Agreement). (http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm)

18 The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment & Development?, Christoph Bail, Robert Falkner & Helen Marquard (eds.), The Royal Institute of International Affairs, London (2002) ISBN 1 85383 840 3.

19 Response from the European Commission to comments submitted by WTO members under either or both G/TBT/N/EEC/6 and G/SPS/N/EEC/149, WTO Committee on Sanitary and Phytosanitary Measures and Committee on Technical Barriers to Trade, G/SPS/GEN/337 & G/TBT/W179, 26 July 2002.

comments were submitted by the delegations from the US, Canada, Argentina, Australia, Switzerland and South Africa. On each draft EU Regulation, a wide range of comments were made on a series of issues, among which:

- The scope and objectives of the draft Regulations and differences with the Novel Food Regulation.
- The authorisation procedure, including (environmental) risk assessment and management, the concept of substantial equivalence, post-marketing monitoring, detection methods, the role of the Community Reference Laboratory, time frame for decision-making and possibilities to appeal, consumer requirements, the role of EFSA and the criteria for emergency measures.
- The risk basis for labelling, labelling of method of production and "like products", the labelling term (genetically modified or bio-engineered), labelling when produced from a GMO but not containing a GMO, labelling for processing aids (enzymes), risk of fraud, threshold for authorised and unauthorised GM material, ethical or religious concerns and unique codes.
- The scientific basis for traceability, traceability for environmental monitoring and guaranteeing food safety, the difficulties to implement traceability with a view to workability, enforceability and additional costs involved, fraudulent claims in documentation, legal uncertainty and non-compliance costs, and alternative measures.
- The linkage between the two draft Regulations and their link to the Cartagena Biosafety Protocol.

On 13 May 2003 Canada and the US and Argentina on 14 May 2003 requested WTO consultations on the EU's authorisation system for GMOs and GM foods. They were alleging that the EU had suspended the consideration of the applications and approval and was maintaining a *de facto* 'moratorium' on new GM varieties. On 18 August 2003 the Commission indicated to regret this request to the Dispute Settlement Body to establish a Panel[21].

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[20] Response from the European Commission to comments submitted by WTO members under either or both G/TBT/N/EEC/6 and G/SPS/N/EEC/150, WTO Committee on Sanitary and Phytosanitary Measures and Committee on Technical Barriers to Trade, G/SPS/GEN/338 & G/TBT/W180, 26 July 2002.

[21] European Commission regrets the request for a WTO Panel on GMOs, IP/03/1165, Brussels, 18 August 2003.

ANNEX V: BIBLIOGRAPHY

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