A consultation paper on the implementation of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms / Department for Environment, Food and Rural Affairs.

DEFRA

Department for
Environment,
Food & Rural Affairs

A consultation paper on the implementation of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms

July 2001
Department for Environment, Food and Rural Affairs

Department for Environment, Food and Rural Affairs
Nobel House
17 Smith Square
London SW1P 3JR
Telephone 020 7238 6000
Internet service www.defra.gov.uk

Further copies of this report are available from:

Directive 2001/18/EC Consultation
Biotechnology Safety Unit
Department for Environment, Food and Rural Affairs
3/E8 Ashdown House
123 Victoria Street
London SW1E 6DE

This document is also available on the DEFRA website: www.defra.gov.uk/environment/index.htm

Published by the Department for Environment, Food and Rural Affairs. Printed in the UK, July 2001 on material containing 100% post-consumer waste.

TABLE OF CONTENTS

CHAPTER 1

Genetically modified organisms (GMOs): new EU rules on deliberate release

- **Directive 2001/18/EC improves the framework for controlling the deliberate release into the environment of GMOs in the European Union (EU).**

- **Member States have until 17 October 2002 to bring into force national measures to comply with the new Directive's provisions.**

- **The Department for Environment, Food and Rural Affairs (DEFRA) and the devolved administrations are jointly responsible for UK implementation.**

- **This paper is to explain the background and context of the new EU rules and to stimulate debate and invite comments on key implementation issues.**

An improved EU framework for GMO deliberate release: Directive 2001/18/EC

1.1 GMOs are living organisms that have been artificially modified using modern biotechnology to give them an advantage over their conventional counterparts. For instance, GM crop plants can be modified to make them grow easier or faster, or to be more nutritious. To date, most GM crops have been modified to be tolerant to certain herbicides or resistant to certain insect pests. Whether released into the environment in small amounts for experimental purposes or in large amounts as commercial products, GMOs may reproduce and cause unintended or irreversible effects. Since problems arising from the deliberate release of GMOs may cross national boundaries, particularly when products are traded widely, it is important to have common EU rules ensuring that all risks are properly assessed and controlled.

1.2 Since 1990, the UK and other EU Member States have had a harmonised framework (under Directive 90/220/EEC[1]) for protecting human health and the environment when GMOs are released to the environment. This Directive applies to the release and marketing of all GMOs except to the marketing of products (eg novel foods, or human and veterinary medicines) covered by separate EU legislation which provides for an environmental risk assessment similar to that laid down in Directive 90/220.

1.3 In December 1996, the European Commission completed a review of the operation of Directive 90/220 and subsequently made proposals for improvements. There followed four years of intensive and wide-ranging negotiations on these proposals between the Commission, the European Council and the European Parliament, resulting in substantial amendments. Negotiations concluded on 15 February 2001 with the adoption by Member States of Directive 2001/18/EC[2]. The new Directive contains extensive improvements to the regime established by Directive 90/220, and these are summarised in Chapter 3 of this paper.

[1] Directive 90/220/EEC, OJ L117/15 of 8 May 1990
[2] Directive 2001/18/EC, OJ L106/1 of 17 April 2001

Putting the new Directive into practice: the timetable for transposition

1.4 Directive 2001/18 entered into force on 17 April 2001. Member States (including the UK) are now required to reflect the new Directive in their national regulations. We have until 17 October 2002 to bring implementing measures into force. Until then, the relevant provisions of Directive 90/220 will remain in force, although we intend as far as possible to apply the principles of the new Directive ahead of formal implementation.

1.5 The planned timetable for achieving implementation of the Directive in England is:

1st Consultation exercise starts	July 2001
1st Consultation exercise ends	October 2001
Drafting of legislation	October 2001 to February 2002
2nd Consultation on draft legislation	March 2002 to May 2002
Lay Regulations before Parliament	June 2002
Regulations come into force	July 2002

1.6 Adjustments to this timetable may be needed to take account of issues raised in consultations. Since the Devolved Administrations will each be drawing up separate implementing legislation, transposition of the Directive into UK law will only be complete when all the relevant legislation has entered into force. However, we envisage that all the UK administrations will have brought implementing legislation into force by the October 2002 deadline.

Fitting together the pieces of UK implementation

1.7 The Scottish Parliament, the National Assembly for Wales, and the Department of the Environment in Northern Ireland will be conducting separate consultations for their areas on the implementation issues for which they have devolved powers.

1.8 The Department for Environment, Food and Rural Affairs (DEFRA) is responsible both for implementing relevant aspects of the Directive in England and for co-ordinating any necessary action on aspects of the Directive dealing with matters reserved to the UK Government under the devolution arrangements. For example, DEFRA will be responsible for co-ordinating and securing agreement on a single UK position when matters are referred for decision to the Regulatory Committee set up under Article 30 of the Directive.

This paper

1.9 This paper sets out the background to and context of the new Directive, examines the main changes, and asks for your comments on key implementation issues. It also contains at **Annex I** a summary of the partial regulatory impact assessment of the effects of implementation on business. A copy of the text of the Directive itself is at **Annex II**.

1.10 The Government wants implementation of the Directive to be transparent and accessible. This consultation is the first step in seeking views to ensure that the UK's implementing measures deliver the improvements to the regulation and control of GMO deliberate releases that the new Directive promises. There will be further consultations at a later date on the specific implementing measures proposed, including draft legislation. **Comments are invited by mail or by e-mail and should be sent to arrive no later than October 26th 2001 to:**

Directive 2001/18/EC Consultation
Biotechnology Safety Unit
Zone 3/E8
DEFRA
Ashdown House
123 Victoria Street
London
SW1E 6DE

E-mail: gmo.consultation@defra.gsi.gov.uk
Telephone: 020 7944 5257
Fax: 020 7944 5229

1.11 DEFRA may wish to make the responses to this consultation paper available to the public and to Parliament. Please indicate whether your response is confidential by clearly marking this at the top of the page (we will assume unmarked responses are suitable for public inspection). DEFRA will acknowledge all responses and will provide a full analysis of the responses to accompany the draft Regulations.

1.12 If you wish to make a complaint, or query the consultation process, please address your responses to "Head of Biotechnology Safety Unit" at the address above.

CHAPTER 2

The existing EU rules on GMO deliberate release and the need for change

- **Controls over the deliberate release of GMOs are necessary to ensure that any risks to human health or the environment are prevented or minimised.**

- **The EU regulatory framework sets out common procedures for decision-making on R&D releases and on the marketing of GMO products.**

- **The existing framework is over 10 years old and needs updating to reflect advances in scientific thinking and risk analysis techniques, public concerns, and to provide greater predictability, openness and clarity.**

The need for controls over deliberate releases of GMOs

2.1 A GMO is defined in Directive 2001/18 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"*[3]. So, for example, a plant produced from traditional breeding methods to be tolerant to herbicide (weed killer) would not be a GMO. On the other hand, a herbicide-tolerant plant produced by artificially inserting specific genes into the plant's DNA that cause the plant to become tolerant to a herbicide would be a GMO.

2.2 The production and use of GMOs with potentially useful agricultural, nutritional, health or other characteristics requires thorough assessment and management of any risks involved. Most types of activities for producing and using GMOs are carried out under containment in, for example, laboratories, industrial production plants, or greenhouses. The main control over the risks of such activities is the containment measures used to limit the contact of the GMOs concerned with people and the environment and to provide for a high level of safety proportionate to the identified risks. There are specific and separate controls over contained-use activities, with which this consultation is not concerned[4].

2.3 The subject of the consultation is the "deliberate release" into the environment of GMOs, either for research purposes or for marketing. Deliberate release happens when GMOs are intentionally introduced into the environment without specific containment measures. It would include, for example, the planting of GMO seeds for crop or seed production. It would also include the import from other countries of agricultural commodities, such as soya or maize, for direct use as food or animal feed, or for processing into food products such as refined oils.

[3] The only difference between this definition and that in Directive 90/220 is that the new Directive clarifies that human beings cannot be regarded as GMOs.
[4] Directive 90/219/EEC, OJ L117/1 of 8 May 1990, as amended by Directive 98/81/EC, and implemented in the UK by the Genetically Modified Organisms (Contained Use) Regulations 2000.

2.4 The risks involved in the deliberate release of GMOs into the environment vary according to many factors. Like conventional species, each type of GMO has different characteristics and their impacts may vary according to local environmental conditions: so each case should be assessed on its own merits. Depending on the case, impacts might include, for example, harm to human health if the GMO is toxic or allergenic, or to the environment if the presence of the GMO in the environment affects population dynamics of particular species of animals or plants, resulting in reductions of native species. Regulatory controls over deliberate releases of GMOs, whether for research and development purposes or for marketing, are necessary to ensure that any risks to human health or the environment are prevented or minimised through appropriate risk assessment and risk management measures.

The EU regulatory framework for deliberate releases of GMOs

2.5 In the EU, the regulatory framework for ensuring appropriate risk assessment and management of research and development (R&D) releases and the placing on the market of GMOs has been harmonised for about 10 years. The main features of the EU-wide framework set out in Directive 90/220/EEC are:

- Common principles for decisions by individual Member States on proposed R&D releases of GMOs in their own territories (Part B releases).

- 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 (Part C releases).

- 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 assessment, and other, information between Member States, particularly as regards proposed Part C releases.

- A centralised procedure for resolving differences between Member States on Part C notifications and for reaching collective decisions on matters such as guidance.

2.6 In Great Britain, Directive 90/220 has been implemented by Part VI of the Environmental Protection Act 1990 and the Genetically Modified Organisms (Deliberate Release) Regulations 1992, as amended in 1995 and 1997. In Northern Ireland there is separate but equivalent legislation. Under the UK implementing legislation, a statutory expert advisory body, the Advisory Committee on Releases to the Environment (ACRE), advises the responsible Ministers on the scientific and risk assessment issues surrounding proposed releases. The legislation also covers the provision of information to the public about GMO releases, including the establishment and maintenance of a public register of information on www.defra.gov.uk/environment/index.htm.

2.7 In 1994, Member States and the Commission reached agreement on a "simplified procedure" for Part B releases meeting certain criteria, which was implemented in the UK in 1995. Under this procedure, GMOs whose characteristics are well understood and which are intended for use in a defined programme of work, for instance for plant breeding, may be included in a single application for a Part B

consent. The programme of work may spread over a defined period of time and involve the planting of the same GMO at several locations within that period. The original application must include all the information relating to risk assessment and other matters required for any Part B release. This information must be made publicly available in the normal way. However, the original application need only contain information about the location of the first site to be planted. Subsequent plantings on other sites in the programme need only be notified 15 days before they are to take place. The regulatory authorities may, however, stop the planting if the risk assessment is not applicable to the particular site.

Why the EU framework needed updating

2.8 Since 1993, there have been about 190 consents for experimental purposes in the UK under Part B of Directive 90/220. 18 products have been approved for commercial release on the EU market under Part C - including soya beans, oilseed rape, chicory, carnations and four types of GM maize. The maize, soya and oilseed rape are already imported into Europe for processing and use in animal feed.

2.9 The underlying principles and basic procedures for the approval of GMO releases in Directive 90/220 are still valid. For instance the Directive is still firmly based on the scientific assessment of environmental risk, and the generally precautionary approach still follows the "step by step" principle. This involves evaluating each release on its own merits in terms of risks to human health and the environment and only increasing the scale of the release when those risks have been further evaluated and found to justify taking the next step. The differentiation between Part B and Part C procedures provides a practicable means of balancing considerations that are properly a matter for individual Member States and those requiring collective EU agreement.

2.10 Despite the continuing validity of much of this regime, experience over the last 10 years has pointed to the need for significant clarification, improvement and strengthening of several aspects. The following broad areas are the most important:

- Harmonising the principles of environmental risk assessment to ensure Member States take decisions about GMO releases on a consistent basis.

- Managing the possible longer term, indirect, delayed and cumulative effects on the environment and wildlife of releasing and using GMOs such as crop plants.

- The post-market monitoring of GMO products, including how long each consent is valid for, what should be included in monitoring plans, and measures to aid traceability and identification.

- Consultation with the public on experimental releases of GMOs and information to the public on the release and marketing of all GMOs.[5]

[5] UK experience is reflected in DETR/ACRE Guidance Note 12: "Guidance on the Principles of Risk Assessment and Monitoring for the Release of Genetically Modified Organisms".

- The predictability and transparency of the procedures for reaching decisions on GMO releases, including the resolution of differences between Member States.

2.11 Recent experience has emphasised the need to make improvements in these areas and to make the regime established by Directive 90/220 more effective and workable. Since 1998, Member States have been unable to reach agreement on the approval of any new products under Part C of the Directive (that is, commercial releases). Part of the reason for this impasse is concern about the longer-term environmental effects of the management of commercial cultivation of certain GM crops, particularly those expressing herbicide tolerance. This concern is focussed not on the GM crop itself but on the possibility that GM herbicide tolerant crops could exacerbate wildlife declines if they encouraged higher levels of weed control than necessary, which in turn could reduce invertebrate and bird numbers.

2.12 In response to this concern, which is widely shared by the public, the UK Government decided in 1999 to initiate a programme of farm-scale evaluations of the wider biodiversity effects of managing the three GM herbicide tolerant crops closest to achieving clearance for commercial cultivation in the UK. The GM crops concerned are herbicide tolerant maize, oilseed rape, and fodder beet. The evaluations are looking at the effects on biodiversity of managing these crops in farm sized fields (up to 10 hectares) compared with managing their non-GM counterparts on the same scale. Further details can be found on www.defra.gov.uk/environment/index.htm.

2.13 The evaluations are underpinned by a voluntary agreement between government and industry. The agreement includes an undertaking that there will be no commercial cultivation of GM crops in the UK until the farm-scale evaluations are complete in 2003. The evaluations are a one-off exercise, and the UK Government takes the view that it would not be right to hold up the consideration of new consent applications for GMO products under the Directive until they are complete. However, such consideration should include looking at each application as if it were being made under the revised Directive. This applies particularly to measures proposed to assess and monitor the kind of longer-term effects the farm-scale evaluations are addressing.

CHAPTER 3

The new EU rules on GMO deliberate release and the main implementation issues

- **Directive 2001/18 introduces changes that meet concerns about the existing EU regulatory framework, but raises some key implementation issues.**

- **This chapter summarises the main areas of change and outlines the key issues surrounding implementation.**

The main changes introduced by Directive 2001/18

3.1 Directive 2001/18 strengthens the regime established by Directive 90/220 by addressing the concerns and areas for improvement identified in Chapter 2. Given the relatively large number of changes made, the new Directive will replace the old on 17 October 2002 to make the revised rules clearer and easier to understand. The main changes and key implementation issues are summarised below.

Principles for environmental risk assessment

3.2 Article 2.8 and Annex II set out a harmonised approach to risk assessment based on best practice in Member States.[6] In particular, 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". This provides the basis for requiring consideration of the wider biodiversity effects that are a concern of larger scale releases of GMOs. In December 1998, EU Environment Ministers decided that the principles underlying the Annex should apply to all releases pending formal implementation of the Directive.

Post-market monitoring

3.3 EU Ministers' 1998 decision also covered early application of principles for monitoring that had been agreed up to that date, and which are now reflected in the revised Directive. The new provisions provide the basis for the kind of precautionary approach to the collection of relevant data about the management and performance of GM crops and other products in the environment with which the farm-scale evaluations are concerned. The key feature is that each application for a Part C consent must include a proposed monitoring plan to be carried out after the marketing consent has been granted (Article 13.2 and Annex VII). The main purpose of the plan will be to confirm that the assumptions made in the original risk assessment are valid, or any unanticipated adverse effects are identified and acted on. The specific requirements of the plan as regards, for example, the responsibilities of users of the product or where the crops are grown, will be an enforceable condition of the Part C consent (Article 19.3).

[6] UK experience is reflected in DETR/ACRE Guidance Note 12: "Guidance on the Principles of Risk Assessment and Monitoring for the Release of Genetically Modified Organisms".

3.4 Should post market monitoring results, or any other new information, show that the GMO constitutes a risk to human health or the environment, any Member State may provisionally restrict or prohibit the use of that GMO as or in a product on its territory (Article 23). Following such action, Member States and the Commission are required to take a decision on whether the conditions of the consent should be amended or the consent should be terminated.

Antibiotic resistance markers

3.5 In addition to their primary modifications (e.g. herbicide tolerance) many GMOs have been modified to be resistant to certain antibiotics to make them easier to identify at the laboratory stage of their development. There is no scientific evidence that demonstrates transfer of functional genes from plant material to bacteria in the environment. However, there could be serious consequences for the therapeutic use of antibiotics in humans and animals should such transfer occur. In the case of some antibiotics (e.g. kanamycin) no risks arise because they are not used for medical or veterinary treatment, but in other cases the risk cannot be ignored. The UK has, on precautionary grounds, voted against commercial release of GMOs containing antibiotic resistance genes that may have adverse effects on human health and the environment.

3.6 The new Directive sets target dates of 31 December 2004 and 31 December 2008, respectively for Part C and Part B, for the phasing out of antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment (Article 4.2).

Traceability and labelling

3.7 One of the main concerns about GMO products is the ability of the authorities to identify what and where they are in order to be able to control any possible risks to human health or the environment. The new Directive seeks to meet this concern by requiring Member States to take measures to ensure "traceability" at all stages of the placing on the market of GMOs authorised under Part C (Article 4.6 and Annex IV). The Directive also requires that the words "This product contains genetically modified organisms" must be on a label or in a document accompanying any GMO product (Article 19.2 and Annex 4)[7].

3.8 "Traceability" can be defined as being able to ensure "the retrieval of the history and use or location of an article or an activity through a registered identification"[8]. The new Directive seeks to establish the data and documentation required for such identification by requiring written consents under Part C to specify the identity of the GMOs to be placed on the market as or in products, and their "unique identifier" (Article 19).

3.9 Each GMO that receives a consent for commercial release will be assigned a unique identifier code. This code will contain information about the GMO (e.g. the

[7] Specific rules, laid down in EC Regulations 1139/98, 49/2000 and 50/2000, apply to the labelling of food containing GM ingredients.
[8] ISO Standard 8402

nature of its modification) and all the codes will be recorded on a central register maintained by the European Commission (Article 31.2). The aim is that this identifier will aid detection and identification of particular GMO products to make post-market control and inspection easier. A decision on the exact form of the identifier will be taken by the Regulatory Committee under Article 30 of the Directive, taking account of developments on this issue in international fora such as the OECD.

3.10 When the revised Directive was adopted in February 2001, six Member States reaffirmed their intention not to approve new authorisations for cultivating and marketing GMOs pending the adoption of a more comprehensive traceability and labelling regime than that set out in Directive 2001/18. As well as "live GMOs" covered by the Directive, they argue that such a regime should cover products derived from GMOs but containing no viable genetically modified protein or DNA (such as refined oils). On adoption, the Commission reaffirmed its intention to produce new proposals for such a regime during 2001 that would harmonise the approach of Member States to this issue.

3.11 This consultation does not cover the new Commission proposals, nor is it concerned with products derived from GMOs, which are beyond the scope of the new Directive. However, it is possible to envisage achieving a harmonised approach between Member States in terms of GMOs covered by the Directive by setting traceability requirements on a case by case basis as part of the authorisation process. The lead competent authority would assess the type of traceability requirements necessary in each case when drawing up the written consent for placing on the market. As part of the standard authorisation procedure, Member States would then have an opportunity to comment on the lead competent authority's assessment, and any disagreements would be resolved through the Regulatory Committee under Article 30 as necessary.

Consultation with the public

3.12 Directive 90/220 contains optional provisions for consultation with members of the public on R&D releases of GMOs under Part B of the Directive. In the UK, we have had since 1993 a statutory system for informing certain interested groups (such as English Nature) about proposed releases, of advertising proposed releases in local newspapers, and of public registers containing specified detailed information, including risk assessment information, proposed locations, and advice given by ACRE. A policy of openness has also been adopted in relation to the programme of farm scale evaluations.

3.13 This policy of openness has, in practice, given members of the public and those with a special interest, such as organic farmers and beekeepers, an opportunity to express an opinion on proposed releases, and for their views to be taken into account. However, many people feel strongly that the current procedures do not add up to a system of active consultation that takes adequate account of views. The new Directive provides a basis for improvement by introducing a mandatory requirement for Member States to consult the public or groups on proposed releases under Part B of the Directive (Article 9.1). The precise form of consultation is a matter for individual Member States to decide, but the Directive requires that consultations should include "a reasonable time period". However, these procedures are without

prejudice to differentiated or simplified procedures (Article 7) discussed in paragraph 2.7.

3.14 Several issues arise as regards the implementation of these requirements in the UK. There is the question of what is a "reasonable time period" for any consultation given that no public inquiry or consultation should extend by more than 30 days the 90 day period within which competent authorities are required to reach a decision on Part B releases (Article 6.5). Another major issue is the form the consultation will take. Questions here include whether the range of specified groups who should be notified of releases in advance should be widened, whether notification could be speeded up by the use of electronic methods, and whether there is scope for some form of direct public participation to inform decision-making. Linked to these issues is that of how comments made should be disseminated and taken into account by advisors and decision-makers given that the scope of the Directive is focussed on human health and environmental factors rather than ethical or socio-economic factors.

3.15 The new Directive also contains other specific requirements for seeking views from the public. These include the opportunity to make comments to the Commission on: proposals for differentiated procedures for categories of Part B releases (Article 7.2); summaries of applications for Part C marketing consents that a Member State proposes should be approved (Article 24.1); and proposals to vary the criteria and information requirements for Part C applications (Article16.3).

Information to the public

3.16 One of the main concerns of the public is to have readily accessible information connected with GMO releases and products. We need to balance this against the need for companies to protect commercially confidential information, for example in respect of intellectual property rights. This latter need is covered in Article 25 of the new Directive, which is similar to requirements in Directive 90/220.

3.17 The UK has a good record of openness on matters to do with GMO deliberate release, including a well-established system of public registers of information and electronically accessible data. The format and maintenance of such information is largely a matter for individual Member States. However, the new Directive considerably enhances the public information principles and procedures that all Member States must respect. It also requires the Commission to develop and implement certain centralised information requirements. The split of main responsibilities is as follows:

The Commission is required to:

- establish a register or registers on genetic modifications (Article 31.2 and Annex IV);

- make available to the public information exchanged between Member States and the Commission (Article 11) on: (a) summaries of Part B applications (b) decisions taken on a Part B applications; (c) the reported results of authorised Part B releases; and (d) annual lists of GMOs released on Member States' territories under Part B (Article 9.2);

- make available to the public a summary of a Part C applications and assessment reports on such applications (Article 24.1)

Member States are required to:

- make available to the public information on all Part B releases of GMOs in their territory (Article 9.2)

- establish public registers of information recording the location of Part B GMOs (Article 31.3a).

- establish public registers recording the locations of Part C GMOs grown in accordance with the monitoring requirements for the product (Article 31.3b)

There is also an unspecified responsibility for the results of the post market monitoring of Part C GMOs to be made publicly available.

3.18 In the UK, we already comply with most of these new requirements, so it should be relatively easy to ensure our existing system of statutory public registers and electronic data complies with the new Directive. However, certain aspects of the Directive raise issues on which further work will need to be done. These include the relationship between our national register and that maintained by the Commission, as well as establishing clarity and proportionality on the level of detail required in giving the location of GMOs grown under Part C of the Directive. The latter includes questions on whether new obligations should be placed on the "users" of GMOs, such as farmers planting crops that have been cleared for general cultivation within the EU single market area.

Predictability and transparency of decision-making

3.19 One of the difficulties of the current regime under Directive 90/220 is the potential for delay and lack of transparency in decision-making caused by not having clear deadlines within which decisions must be reached and communicated. Directive 2001/18 provides a more predictable and transparent regime by setting deadlines for each stage of the regulatory process. These deadlines will need to be reflected in implementing legislation.

3.20 The Directive also sets a maximum term for Part C marketing consents of ten years (Article 15.4). Consent holders will need to re-apply for consent when the limit is reached, which can be modified or withdrawn as appropriate. All existing consent holders will need to re-apply for a further Part C consent by October 2006 (Article 17). Renewed consents will also be limited to a ten year maximum, although there is a degree of flexibility for renewed consents if there are particular reasons a consent should be granted for a longer period. Although the information and other requirements for renewed consents are the same as for first-time consents, the amount of information required will be proportionate to the risks to human health and the environment gained from experience of use of the product on the market.

Differentiated and "simplified" procedures

3.21 The public has expressed concern that the "simplified procedure" for defined programmes of development work, such as plant breeding, under Part B of the Directive is not adequate in terms of information to the public. In particular, many people feel that the 15 days period of notice that they have of an intention to plant a GMO in their locality is not sufficient. On the other hand, because they relate to GMOs which assessors are content pose a low risk (often because they are familiar with them from previous applications), reduced notification times have been considered valid in terms of safety. Most Part B releases in the UK take place under simplified procedures, including some crops included in the farm scale evaluations.

3.22 Directive 2001/18 retains the simplified procedure agreed in 1994. However, use of the procedure by Member States is optional. Although it would be possible to withdraw from the procedure or to seek amendment of the procedure, particularly as regards the period of notice for planting, a more open and transparent option might be to seek to use one of the new features in the revised Directive. This allows Member States or the Commission to propose "differentiated procedures" (Article 7) for certain categories of GMOs under Part B. Decisions on agreeing such procedures are taken by the Regulatory Committee under Article 30, but only after consulting the public, among others. This would provide 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.

Ethical and socio-economic issues

3.23 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 (Article 31.7). The issue therefore arises as to how UK views in these areas can be best assessed and communicated.

Guidance

3.24 Detailed implementation of many of the provisions in the Directive will be informed by the drawing up of guidance that will need to be agreed on an EU-wide basis by the Regulatory Committee under Article 30. Not all such guidance has to be in place by the implementation date of October 2002. However, guidance on, and elaboration of, the risk assessment and monitoring principles respectively in Annexes II and III will need to be agreed by that date. UK input into this work will largely be channelled through ACRE.

CHAPTER 4

Putting the new rules into practice: having your say

- **We want implementation of Directive 2001/18 in the UK to be as open and transparent as possible.**
- **We are particularly interested to have your views on the issues identified in paragraphs 3.2 to 3.24 of Chapter 3.**
- **We also want to hear your views on any other issues that you think are raised by UK implementation of the Directive.**
- **It would be helpful if you structured your response as below.**

1. Principles for environmental risk assessment (paragraph 3.2)

What are your views on the application of the principles for environmental risk assessment set out in Annex II to the Directive and their relationship with the monitoring plan?

2. Monitoring (paragraphs 3.3 to 3.4)

What are your views on the specific issues to be addressed in designing and carrying out a monitoring plan in line with the objectives and principles set out in Annex VII to the Directive?

3. Phasing out of antibiotic resistance markers (paragraphs 3.5 to 3.6)

How should the phasing out of potentially harmful antibiotic resistance markers be approached in practical terms?

4. Traceability and labelling (paragraphs 3.7 to 3.11)

What are your views on the practical issues surrounding implementation of the new Directive's requirements on traceability and labelling?

5. Consultation with the public (paragraphs 3.12 to 3.15)

How should the public be consulted on proposals for GMO releases and how should their views be taken into account?

6. Information to the public (paragraphs 3.16 to 3.18)

What should be done to improve the information made available to the public on the deliberate release and marketing of GMOs?

7. Predictability and transparency of decision-making (paragraphs 3.19 to 3.20)

What should be done to improve the predictability and transparency of decision-making within the deadlines set by the Directive?

8. Differentiated procedures (paragraphs 3.21 to 3.22)

Should the UK make a proposal under the new Directive's provisions on differentiated procedures to replace the existing simplified procedure applicable to certain categories of GMO?

9. Ethical and socio-economic issues (paragraph 3.23)

How should consideration of general ethical and socio-economic issues in terms of the Directive be addressed?

10. Guidance (paragraph 3.24)

Do you have views on the priorities for guidance on issues that would help understanding and effective implementation of the Directive?

11. Other issues

Do you have views on any other issues arising from implementation of the Directive that you would like to raise?

SUMMARY OF PARTIAL REGULATORY IMPACT ASSESSMENT

Implementation of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms

1. Before new regulations can be introduced a Regulatory Impact Assessment (RIA) must be carried out. This summary illustrates where the main impacts of Directive 2001/18/EC are likely to be. A full RIA will be issued when we consult on draft new regulations in early 2002.

Issue

2. Directive 2001/18/EC updates EU law on the deliberate release into the environment of GMOs. It replaces former Directive 90/220/EC, which underpins the current UK regulations on the release of GMOs. Member States, including the UK, are required to transpose it into national legislation by 17 October 2002.

Purpose of new legislation

3. To update EU and Member State legislation to take account of advances in genetic modification technology and scientific knowledge, and to introduce a more straightforward and transparent regime to control the release of GMOs.

Risks

4. The new Directive introduces a more robust regime to limit possible risks posed to human health or the environment by the release of GMOs.

Benefits of the new legislation

5. The new Directive promises a number of benefits to human health, the environment, the public and GMO producers. For instance
   - human health and the environment benefit from more robust provisions e.g. setting common principles for environmental risk assessment, the post market monitoring of GMOs, and monitoring of longer term and delayed effects
   - the public benefits from greater provision of information on certain aspects of releases (the UK has always provided information over and above the requirements of the previous Directive) and a requirement for the public to be consulted on proposed releases before they can be authorised
   - industry benefits from a more predictable regulatory system, which helps their forward planning

Business sectors effected

6. The new Directive will have most impact on the agri-food sector. This includes about 15% of an estimated 281 small and medium sized enterprises in the UK dedicated to biotechnology. Many other enterprises will be affected, including most major companies involved in agricultural and food biotechnology. The biopharmaceutical sector will also be affected.

Compliance costs

7. Industry is familiar with the costs of compliance under existing regulations and they have been kept informed of developments throughout the negotiation of the new Directive. Detailed costing of compliance will be included in the full RIA in early 2002. Additional costs may come from:

- the new requirement for mandatory monitoring of GMOs following approval of a marketing consent
- the new limit on the duration of commercial consent to a maximum of ten years, after which the consent will have to be reapplied for
- the new requirement to notify, to an appropriate level of detail, the location of the sites where GMOs approved for commercial release are being grown
- the new requirement to phase out by 2008 antibiotic resistance markers which could have an adverse effect on human health and the environment.

Impact on small businesses

8. The new aspects of the regulatory framework introduced by the new Directive mainly effect commercial releases of GMOs rather than experimental releases. Generally, larger businesses are involved in commercial releases whilst smaller enterprises tend to focus on experimental releases. So the additional direct compliance costs caused by the new Directive are likely to be proportionately less for smaller businesses than for larger businesses.

Other costs

9. There are resource implications for DEFRA and other Government Departments which operate the legislation, although running costs may be recouped from application fees. There may also be costs involved in operating public consultations on proposed releases, and in making information available to the public.

Securing compliance

10. The UK is required to introduce penalties for breaches of the implementing regulations introduced under the Directive. However a system of penalties is already established under the existing regime.

Consultation

11. Most of the changes we must make to the regulatory regime are mandatory – i.e. they are prescribed in the Directive and we must implement them. However, there are some areas, such as the provision of information to the public, where Member States have individual discretion.

12. During the negotiation of the new Directive the Government was informed by regular meetings with interested stakeholders. As part of the process of implementing the new Directive we are conducting a 1st public consultation on broad issues of policy and principle raised by the new Directive. In early 2002 we will conduct a 2nd public consultation on draft new regulations for England under the new Directive. We will meet with stakeholders during both consultation periods.

Monitoring and evaluation

13. The European Commission will issue regular reports, based on information supplied by Member States, on the operation of the Directive.

Recommendation

14. The Government is legally required to implement the new Directive by October 2002. The new Directive is a considerable improvement on its predecessor in a wide range of areas. We feel that the benefits it offers, in particular to reducing potential risks to human health and the environment, significantly outweigh any related compliance costs.

17.4.2001 EN Official Journal of the European Communities L 106/1

I

(Acts whose publication is obligatory)

DIRECTIVE 2001/18/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 March 2001

on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social Committee (2),

Acting in accordance with the procedure laid down in Article 251 of the Treaty, in the light of the joint text approved by the Conciliation Committee on 20 December 2000 (3),

Whereas:

(1) The Report of the Commission on the Review of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (4), adopted on 10 December 1996, identified a number of areas where improvement is needed.

(2) There is a need for clarification of the scope of Directive 90/220/EEC and of the definitions therein.

(3) Directive 90/220/EEC has been amended. Now that new amendments are being made to the Directive, it is desirable, for reasons of clarity and rationalisation, that the provisions in question should be recast.

(4) Living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting other Member States. The effects of such releases on the environment may be irreversible.

(5) The protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release into the environment of genetically modified organisms (GMOs).

(6) Under the Treaty, action by the Community relating to the environment should be based on the principle that preventive action should be taken.

(7) It is necessary to approximate the laws of the Member States concerning the deliberate release into the environment of GMOs and to ensure the safe development of industrial products utilising GMOs.

(8) The precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it.

(9) Respect for ethical principles recognised in a Member State is particularly important. Member States may take into consideration ethical aspects when GMOs are deliberately released or placed on the market as or in products.

(10) For a comprehensive and transparent legislative framework, it is necessary to ensure that the public is consulted by either the Commission or the Member States during the preparation of measures and that they are informed of the measures taken during the implementation of this Directive.

(11) Placing on the market also covers import. Products containing and/or consisting of GMOs covered by this Directive cannot be imported into the Community if they do not comply with its provisions.

(12) Making GMOs available to be imported or handled in bulk quantities, such as agricultural commodities, should be regarded as placing on the market for the purpose of this Directive.

(13) The content of this Directive duly takes into account international experience in this field and international

(1) OJ C 139, 4.5.1998, p. 1.
(2) OJ C 407, 28.12.1998, p. 1.
(3) Opinion of the European Parliament of 11 February 1999 (OJ C 150, 28.5.1999, p. 363), Council Common Position of 9 December 1999 (OJ C 64, 6.3.2000, p. 1) and Decision of the European Parliament of 12 April 2000 (OJ C 40, 7.2.2001, p. 123). Decision of the European Parliament of 14 February 2001 and Decision of the Council of 15 February 2001.
(4) OJ L 117, 8.5.1990, p. 15. Directive as last amended by Commission Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72).

trade commitments and should respect the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. As soon as possible, and in any case before July 2001, the Commission should, in the context of the ratification of the Protocol, submit the appropriate proposals for its implementation.

(14) Guidance on the implementation of provisions related to the definition of the placing on the market in this Directive should be provided by the Regulatory Committee.

(15) When defining 'genetically modified organism' for the purpose of this Directive, human beings should not be considered as organisms.

(16) The provisions of this Directive should be without prejudice to national legislation in the field of environmental liability, while Community legislation in this field needs to be complemented by rules covering liability for different types of environmental damage in all areas of the European Union. To this end the Commission has undertaken to bring forward a legislative proposal on environmental liability before the end of 2001, which will also cover damage from GMOs.

(17) This Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record.

(18) It is necessary to establish harmonised procedures and criteria for the case-by-case evaluation of the potential risks arising from the deliberate release of GMOs into the environment.

(19) A case-by-case environmental risk assessment should always be carried out prior to a release. It should also take due account of potential cumulative long-term effects associated with the interaction with other GMOs and the environment.

(20) It is necessary to establish a common methodology to carry out the environmental risk assessment based on independent scientific advice. It is also necessary to establish common objectives for the monitoring of GMOs after their deliberate release or placing on the market as or in products. Monitoring of potential cumulative long-term effects should be considered as a compulsory part of the monitoring plan.

(21) Member States and the Commission should ensure that systematic and independent research on the potential risks involved in the deliberate release or the placing on the market of GMOs is conducted. The necessary resources should be secured for such research by Member States and the Community in accordance with their budgetary procedures and independent researchers should be given access to all relevant material, while respecting intellectual property rights.

(22) The issue of antibiotic-resistance genes should be ta into particular consideration when conducting the assessment of GMOs containing such genes.

(23) The deliberate release of GMOs at the research stag in most cases a necessary step in the developmen new products derived from, or containing GMOs.

(24) The introduction of GMOs into the environment sho be carried out according to the 'step by step' princi This means that the containment of GMOs is redu and the scale of release increased gradually, step by st but only if evaluation of the earlier steps in terms protection of human health and the environm indicates that the next step can be taken.

(25) No GMOs, as or in products, intended for deliber release are to be considered for placing on the mar without first having been subjected to satisfactory fi testing at the research and development stage ecosystems which could be affected by their use.

(26) The implementation of this Directive should be carr out in close liaison with the implementation of otl relevant instruments such as Council Direct 91/414/EEC of 15 July 1991 concerning the placing plant protection products on the market [1]. In t context the competent authorities concerned with t implementation of this Directive and of th instruments, within the Commission and at natio level, should coordinate their action as far as possible.

(27) Concerning the environmental risk assessment for p C, risk management, labelling, monitoring, informati to the public and safeguard clause, this Directive sho be a point of reference for GMOs as or in produ authorised by other Community legislation whi should therefore provide for a specific environmen risk assessment, to be carried out in accordance w the principles set out in Annex II and on the basis information specified in Annex III without prejudice additional requirements laid down by the Commun legislation mentioned above, and for requirements regards risk management, labelling, monitoring appropriate, information to the public and safegu clause at least equivalent to that laid down in t Directive. To this end it is necessary to provide cooperation with the Community and Member St bodies mentioned in this Directive for the purpose of implementation.

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended Commission Directive 1999/80/EC (OJ L 210, 10.8.1999, p. 13)

(28) It is necessary to establish a Community authorisation procedure for the placing on the market of GMOs, as or in products, where the intended use of the product involves the deliberate release of the organism(s) into the environment.

(29) The Commission is invited to conduct a study which should contain an assessment of various options to improve further the consistency and efficiency of this framework, particularly focusing on a centralised authorisation procedure for the placing on the market of GMOs within the Community.

(30) For sectoral legislation, monitoring requirements may have to be adapted to the product concerned.

(31) Part C of this Directive does not apply to products covered by Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [1], provided that it includes an environmental risk assessment equivalent to that provided for by this Directive.

(32) Any person, before undertaking a deliberate release into the environment of a GMO, or the placing on the market of GMOs, as or in products, where the intended use of the product involves its deliberate release into the environment, is to submit a notification to the national competent authority.

(33) That notification should contain a technical dossier of information including a full environmental risk assessment, appropriate safety and emergency response, and, in the case of products, precise instructions and conditions for use, and proposed labelling and packaging.

(34) After notification, no deliberate release of GMOs should be carried out unless the consent of the competent authority has been obtained.

(35) A notifier should be able to withdraw his dossier at any stage of the administrative procedures laid down in this Directive. The administrative procedure should come to an end when a dossier is withdrawn.

(36) Rejection of a notification for the placing on the market of a GMO as or in products by a competent authority should be without prejudice to the submission of a notification of the same GMO to another competent authority.

(37) An agreement should be reached at the end of the mediation period when no objections remain.

(38) Rejection of a notification following a confirmed negative assessment report should be without prejudice to future decisions based on the notification of the same GMO to another competent authority.

(39) In the interests of the smooth functioning of this Directive, Member States should be able to avail themselves of the various provisions for the exchange of information and experience before having recourse to the safeguard clause in this Directive.

(40) In order to ensure that the presence of GMOs in products containing, or consisting of, genetically modified organisms is appropriately identified, the words 'This product contains genetically modified organisms' should appear clearly either on a label or in an accompanying document.

(41) A system should be designed using the appropriate committee procedure, for the assignment of a unique identifier to GMOs, taking into account relevant developments in international fora.

(42) It is necessary to ensure traceability at all stages of the placing on the market of GMOs as or in products authorised under part C of this Directive.

(43) It is necessary to introduce into this Directive an obligation to implement a monitoring plan in order to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs as or in products after they have been placed on the market.

(44) Member States should be able, in accordance with the Treaty, to take further measures for monitoring and inspection, for example by official services, of the GMOs as or in products placed on the market.

(45) Means should be sought for providing possibilities for facilitating the control of GMOs or their retrieval in the event of severe risk.

(46) Comments by the public should be taken into consideration in the drafts of measures submitted to the Regulatory Committee.

(47) The competent authority should give its consent only after it has been satisfied that the release will be safe for human health and the environment.

(48) The administrative procedure for granting consents for the placing on the market of GMOs as or in products should be made more efficient and more transparent and first-time consent should be granted for a fixed period.

(49) For products for which consent has been granted for a fixed period a streamlined procedure should apply as regards the renewal of consent.

[1] OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).

(50) The existing consents granted under Directive 90/220/EEC have to be renewed in order to avoid disparities between consents granted under that Directive and those pursuant to this Directive and in order to take full account of the conditions of consent under this Directive.

(51) Such renewal requires a transitional period during which existing consents granted under Directive 90/220/EEC remain unaffected.

(52) When a consent is renewed, it should be possible to revise all the conditions of the original consent, including those related to monitoring and the time limitation of the consent.

(53) Provision should be made for consultation of the relevant Scientific Committee(s) established by Commission Decision 97/579/EC [1] on matters which are likely to have an impact on human health and/or the environment.

(54) The system of exchange of information contained in notifications, established under Directive 90/220/EEC, has been useful and should be continued.

(55) It is important to follow closely the development and use of GMOs.

(56) When a product containing a GMO, as or in products, is placed on the market, and where such a product has been properly authorised under this Directive, a Member State may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive. A safeguard procedure should be provided in case of risk to human health or the environment.

(57) The Commission's European Group on Ethics in Science and New Technologies should be consulted with a view to obtaining advice on ethical issues of a general nature regarding the deliberate release or placing on the market of GMOs. Such consultations should be without prejudice to the competence of Member States as regards ethical issues.

(58) Member States should be able to consult any committee they have established with a view to obtaining advice on the ethical implications of biotechnology.

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

(60) The information exchange set up under this Dir should also cover experience gained with consideration of ethical aspects.

(61) In order to increase the effective implementation provisions adopted under this Directive it is appro to provide for penalties to be applied by Member S including in the event of release or placing o market contrary to the provisions of this Dire particularly as a result of negligence.

(62) A report to be issued every three years by Commission, taking into account the inform provided by Member States, should contain a sep chapter regarding the socioeconomic advantages disadvantages of each category of GMOs authorise placing on the market, which will take due accou the interest of farmers and consumers.

(63) The regulatory framework for biotechnology shou reviewed so as to identify the feasibility of impr further the consistency and efficiency of that frame Procedures may need to be adapted so as to opt efficiency, and all options which might achieve should be considered,

HAVE ADOPTED THIS DIRECTIVE:

PART A

GENERAL PROVISIONS

Article 1

Objective

In accordance with the precautionary principle, the obje of this Directive is to approximate the laws, regulations administrative provisions of the Member States and to pr human health and the environment when:

— carrying out the deliberate release into the environme genetically modified organisms for any other pur than placing on the market within the Community,

— placing on the market genetically modified organisms in products within the Community.

Article 2

Definitions

For the purposes of this Directive:

(1) 'organism' means any biological entity capabl replication or of transferring genetic material;

(2) 'genetically modified organism (GMO)' means organism, with the exception of human beings, in v the genetic material has been altered in a way that not occur naturally by mating and/or n recombination;

[1] OJ L 237, 28.8.1997, p. 18.
[2] OJ L 184, 17.7.1999, p. 23.

Within the terms of this definition:

(a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;

(b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification;

(3) 'deliberate release' means any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment;

(4) 'placing on the market' means making available to third parties, whether in return for payment or free of charge;

The following operations shall not be regarded as placing on the market:

— making available genetically modified microorganisms for activities regulated under Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified microorganisms [1] including culture collections,

— making available GMOs other than microorganisms referred to in the first indent, to be used exclusively for activities where appropriate stringent containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment, the measures should be based on the same principles of containment as laid down in Directive 90/219/EEC,

— making available GMOs to be used exclusively for deliberate releases complying with the requirements laid down in part B of this Directive;

(5) 'notification' means the submission of the information required under this Directive to the competent authority of a Member State;

(6) 'notifier' means the person submitting the notification;

(7) 'product' means a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market;

(8) 'environmental risk assessment' means the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose and carried out in accordance with Annex II.

[1] OJ L 117, 8.5.1990, p. 1. Directive as amended by Directive 98/81/EC (OJ L 330 5.12.1998, p. 13).

Article 3

Exemptions

1. This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.

2. This Directive shall not apply to the carriage of genetically modified organisms by rail, road, inland waterway, sea or air.

Article 4

General obligations

1. Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs. GMOs may only be deliberately released or placed on the market in conformity with part B or part C respectively.

2. Any person shall, before submitting a notification under part B or part C, carry out an environmental risk assessment. The information which may be necessary to carry out the environmental risk assessment is laid down in Annex III. 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 the 31 December 2004 in the case of GMOs placed on the market according to part C and by 31 December 2008 in the case of GMOs authorised under part B.

3. Member States and where appropriate the Commission shall ensure that potential adverse effects on human health and the environment, which may occur directly or indirectly through gene transfer from GMOs to other organisms, are accurately assessed on a case-by-case basis. This assessment shall be conducted in accordance with Annex II taking into account the environmental impact according to the nature of the organism introduced and the receiving environment.

4. Member States shall designate the competent authority or authorities responsible for complying with the requirements of this Directive. The competent authority shall examine notifications under part B and part C for compliance with the requirements of this Directive and whether the assessment provided for in paragraph 2 is appropriate.

5. Member States shall ensure that the competent authority organises inspections and other control measures as appropriate, to ensure compliance with this Directive. In the event of a release of GMO(s) or placing on the market as or in products for which no authorisation was given, the Member

State concerned shall ensure that necessary measures are taken to terminate the release or placing on the market, to initiate remedial action if necessary, and to inform its public, the Commission and other Member States.

6. Member States shall take measures to ensure traceability, in line with the requirements laid down in Annex IV, at all stages of the placing on the market of GMOs authorised under part C.

PART B

DELIBERATE RELASE OF GMOs FOR ANY OTHER PURPOSE THAN FOR PLACING ON THE MARKET

Article 5

1. Articles 6 to 11 shall not apply to medicinal substances and compunds for human use consisting of, or containing, a GMO or combination of GMOs provided that their deliberate release for any purpose other than that of being placed on the market is authorised by Community legislation which provides:

(a) for a specific environmental risk assessment in accordance with Annex II and on the basis of the type of information specified in Annex III without prejudice to additional requirements provided for by the said legislation;

(b) for explicit consent prior to release;

(c) for a monitoring plan in accordance with the relevant parts of Annex III, with a view to detecting the effects of the GMO or GMOs on human health or the environment;

(d) in an appropriate manner for 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 this Directive and in the measures taken in accordance therewith.

2. Assessment of the risks to the environment presented by such substances and compounds shall be carried out in coordination with the national and Community authorities mentioned in this Directive.

3. Procedures ensuring conformity of the specific environmental risk assessment and equivalence with the provisions of this Directive must be provided for by the said legislation, which must refer to this Directive.

Article 6

Standard authorisation procedure

1. Without prejudice to Article 5, any person must, before undertaking a deliberate release of a GMO or of a combination of GMOs, submit a notification to the competent authority of the Member State within whose territory the release is to take place.

2. The notification referred to in paragraph 1 shall include:

(a) a technical dossier supplying the information specified in Annex III necessary for carrying out the environmental risk assessment of the deliberate release of a GMO or combination of GMOs, in particular:

(i) general information including information on personnel and training,

(ii) information relating to the GMO(s),

(iii) information relating to the conditions of release and the potential receiving environment,

(iv) information on the interactions between the GMO(s) and the environment,

(v) a plan for monitoring in accordance with the relevant parts of Annex III in order to identify effects of the GMO(s) on human health or the environment,

(vi) information on control, remediation methods, waste treatment and emergency response plans,

(vii) a summary of the dossier;

(b) the environmental risk assessment and the conclusions required in Annex II, section D, together with any bibliographic reference and indications of the methods used.

3. The notifier may refer to data or results from notifications previously submitted by other notifiers, provided that the information, data and results are non confidential or these notifiers have given their agreement in writing, or may submit additional information he considers relevant.

4. The competent authority may accept that releases of the same GMO or of a combination of GMOs on the same site or on different sites for the same purpose and within a defined period may be notified in a single notification.

5. The competent authority shall acknowledge the date of receipt of the notification and, having considered, where appropriate, any observations by other Member States made in accordance with Article 11, shall respond in writing to the notifier within 90 days of receipt of the notification by either:

(a) indicating that it is satisfied that the notification is in compliance with this Directive and that the release may proceed; or

(b) indicating that the release does not fulfil the conditions of this Directive and that notification is therefore rejected.

6. For the purpose of calculating the 90 day period referred to in paragraph 5, no account shall be taken of any periods of time during which the competent authority:

(a) is awaiting further information which it may have requested from the notifier, or

(b) is carrying out a public inquiry or consultation in accordance with Article 9; this public inquiry or consultation shall not prolong the 90 day period referred to in paragraph 5 by more than 30 days.

7. If the competent authority requests new information it must simultaneously give its reasons for so doing.

8. The notifier may proceed with the release only when he has received the written consent of the competent authority, and in conformity with any conditions required in this consent.

9. Member States shall ensure that no material derived from GMOs which are deliberately released in accordance with part B is placed on the market, unless in accordance with part C.

Article 7

Differentiated procedures

1. If sufficient experience has been obtained of releases of certain GMOs in certain ecosystems and the GMOs concerned meet the criteria set out in Annex V, a competent authority may submit to the Commission a reasoned proposal for the application of differentiated procedures to such types of GMOs.

2. Following its own initiative or at the latest 30 days following the receipt of a competent authority's proposal, the Commission shall,

(a) forward the proposal to the competent authorities, which may, within 60 days, present observations and at the same time;

(b) make available the proposal to the public which may, within 60 days, make comments; and

(c) consult the relevant Scientific Committee(s) which may, within 60 days give an opinion.

3. A decision shall be taken on each proposal in accordance with the procedure laid down in Article 30(2). This decision shall establish the minimum amount of technical information from Annex III necessary for evaluating any foreseeable risks from the release, in particular:

(a) information relating to the GMO(s);

(b) information relating to the conditions of release and the potential receiving environment;

(c) information on the interactions between the GMO(s) and the environment;

(d) the environmental risk assessment.

4. This decision shall be taken within 90 days of the date of the Commission's proposal or of receipt of the competent authority's proposal. This 90 day period shall not take into account the period of time during which the Commission is awaiting the observations of competent authorities, the comments of the public or the opinion of Scientific Committees, as provided for in paragraph 2.

5. The decision taken under paragraphs 3 and 4 shall provide that the notifier may proceed with the release only when he has received the written consent of the competent authority. The notifier shall proceed with the release in conformity with any conditions required in this consent.

The decision taken under paragraphs 3 and 4 may provide that releases of a GMO or of a combination of GMOs on the same site or on different sites for the same purpose and within a defined period may be notified in a single notification.

6. Without prejudice to paragraphs 1 to 5, Commission Decision 94/730/EC of 4 November 1994 establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6(5) of Council Directive 90/220/EEC [1] shall continue to apply.

7. Where a Member State decides to make use or not of a procedure established in a decision taken in accordance with paragraphs 3 and 4 for releases of GMOs within its territory, it shall inform the Commission thereof.

Article 8

Handling of modifications and new information

1. In the event of any modification of, or unintended change to, the deliberate release of a GMO or of a combination of GMOs which could have consequences with regard to risks for human health and the environment after the competent authority has given its written consent, or if new information has become available on such risks, either while the notification is being examined by the competent authority of a Member State or after that authority has given its written consent, the notifier shall immediately:

[1] OJ L 292, 12.11.1994, p. 31.

(a) take the measures necessary to protect human health and the environment;

(b) inform the competent authority in advance of any modification or as soon as the unintended change is known or the new information is available;

(c) revise the measures specified in the notification.

2. If information becomes available to the competent authority referred to in paragraph 1 which could have significant consequences with regard to risks for human health and the environment or under the circumstances described in paragraph 1, the competent authority shall evaluate such information and make it available to the public. It may require the notifier to modify the conditions of, suspend or terminate the deliberate release and shall inform the public thereof.

Article 9

Consultation of and information to the public

1. Member States shall, without prejudice to the provisions of Articles 7 and 25, consult the public and, where appropriate, groups on the proposed deliberate release. In doing so, 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.

2. Without prejudice to the provisions of Article 25:

— Member States shall make available to the public information on all part B releases of GMOs in their territory;

— the Commission shall make available to the public the information contained in the system of exchange of information pursuant to Article 11.

Article 10

Reporting by notifiers on releases

After completion of a release, and thereafter, at any intervals laid down in the consent on the basis of the results of the environmental risk assessment, the notifier shall send to the competent authority the result of the release in respect of any risk to human health or the environment, with, where appropriate, particular reference to any kind of product that the notifier intends to notify at a later stage. The format for the presentation of this result shall be established in accordance with the procedure laid down in Article 30(2).

Article 11

Exchange of information between competent authorities and the Commission

1. The Commission shall set up a system of exchange of the information contained in the notifications. The competent authorities shall send to the Commission, within 30 days of receipt, a summary of each notification received under Arti 6. The format of this summary shall be established a modified if appropriate in accordance with the procedure l down in Article 30(2).

2. The Commission shall, at the latest 30 days followi their receipt, forward these summaries to the other Mem States, which may, within 30 days, present observatio through the Commission or directly. At its request, a Mem State shall be permitted to receive a copy of the f notification from the competent authority of the releva Member State.

3. The competent authorities shall inform the Commissi of the final decisions taken in compliance with Article 6(including where relevant the reasons for rejecting notification, and of the results of the releases received accordance with Article 10.

4. For the releases of GMOs referred to in Article 7, once year Member States shall send a list of GMOs which have be released on their territory and a list of notifications that we rejected to the Commission, which shall forward them to t competent authorities of the other Member States.

PART C

PLACING ON THE MARKET OF GMOs AS OR IN PRODUCT

Article 12

Sectoral legislation

1. Articles 13 to 24 shall not apply to any GMO as or products as far as they are authorised by Communi legislation which provides for a specific environmental ri assessment carried out in accordance with the principles s out in Annex II and on the basis of information specified Annex III without prejudice to additional requiremer provided for by the Community legislation mentioned abo and for requirements as regards risk management, labellir monitoring as appropriate, information to the public a safeguard clause at least equivalent to that laid down in t Directive.

2. As far as Council Regulation (EEC) No 2309/93 concerned, Articles 13 to 24 of this Directive shall not ap to any GMO as or in products as far as they are authorised that Regulation provided that a specific environmental ri assessment is carried out in accordance with the principles s out in Annex II to this Directive and on the basis of the ty of information specified in Annex III to this Directive witho prejudice to other relevant requirements as regards ri assessment, risk management, labelling, monitoring appropriate, information to the public and safeguard cla provided by Community legislation concerning medici products for human and veterinary use.

3. Procedures ensuring that the risk assessme requirements regarding risk management, labelling, monitori as appropriate, information to the public and safeguard cla are equivalent to those laid down in this Directive shall

introduced, in a Regulation of the European Parliament and of the Council. Future sectoral legislation based on the provisions of that Regulation shall make a reference to this Directive. Until the Regulation enters into force, any GMO as or in products as far as they are authorised by other Community legislation shall only be placed on the market after having been accepted for placing on the market in accordance with this Directive.

4. During evaluation of the requests for the placing on the market of the GMOs referred to in paragraph 1, the bodies established by the Community under this Directive and by Member States for the purpose of implementing this Directive shall be consulted.

Article 13

Notification procedure

1. Before a GMO or a combination of GMOs as or in products is placed on the market, a notification shall be submitted to the competent authority of the Member State where such a GMO is to be placed on the market for the first time. The competent authority shall acknowledge the date of receipt of the notification and immediately forward the summary of the dossier referred to in paragraph 2(h) to the competent authorities of the other Member States and the Commission.

The competent authority shall without delay examine whether the notification is in accordance with paragraph 2 and shall, if necessary, ask the notifier for additional information.

When the notification is in accordance with paragraph 2, and at the latest when it sends its assessment report in accordance with Article 14(2), the competent authority shall forward a copy of the notification to the Commission which shall, within 30 days of its receipt, forward it to the competent authorities of the other Member States.

2. The notification shall contain:

(a) the information required in Annexes III and IV. This information shall take into account the diversity of sites of use of the GMO as or in a product and shall include information on data and results obtained from research and developmental releases concerning the impact of the release on human health and the environment;

(b) the environmental risk assessment and the conclusions required in Annex II, section D;

(c) the conditions for the placing on the market of the product, including specific conditions of use and handling;

(d) with reference to Article 15(4), a proposed period for the consent which should not exceed ten years;

(e) a plan for monitoring in accordance with Annex VII, including a proposal for the time-period of the monitoring plan; this time-period may be different from the proposed period for the consent;

(f) a proposal for labelling which shall comply with the requirements laid down in Annex IV. The labelling shall clearly state that a GMO is present. The words 'this product contains genetically modified organisms' shall appear either on a label or in an accompanying document;

(g) a proposal for packaging which shall comprise the requirements laid down in Annex IV;

(h) a summary of the dossier. The format of the summary shall be established in accordance with the procedure laid down in Article 30(2).

If on the basis of the results of any release notified under part B, or on other substantive, reasoned scientific grounds, a notifier considers that the placing on the market and use of a GMO as or in a product do not pose a risk to human health and the environment, he may propose to the competent authority not to provide part or all of the information required in Annex IV, section B.

3. The notifier shall include in this notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by the notifier either inside or outside the Community.

4. The notifier may also refer to data or results from notifications previously submitted by other notifiers or submit additional information he considers relevant, provided that the information, data and results are non-confidential or these notifiers have given their agreement in writing.

5. In order for a GMO or combination of GMOs to be used for a purpose different from that already specified in a notification, a separate notification shall be submitted.

6. If new information has become available with regard to the risks of the GMO to human health or the environment, before the written consent is granted, the notifier shall immediately take the measures necessary to protect human health and the environment, and inform the competent authority thereof. In addition, the notifier shall revise the information and conditions specified in the notification.

Article 14

Assessment report

1. On receipt and after acknowledgement of the notification in accordance with Article 13(2), the competent authority shall examine it for compliance with this Directive.

2. Within 90 days after receipt of the notification the competent authority shall:

— prepare an assessment report and send it to the notifier. A subsequent withdrawal by the notifier shall be without prejudice to any further submission of the notification to another competent authority;

— in the case referred to in paragraph 3(a), send its report, together with the information referred to in paragraph 4 and any other information on which it has based its report, to the Commission which shall, within 30 days of its receipt, forward it to the competent authorities of the other Member States.

In the case referred to paragraph 3(b), the competent authority shall send its report, together with the information referred to in paragraph 4 and any other information on which it has based its report, to the Commission no earlier than 15 days after sending the assessment report to the notifier and no later than 105 days after receipt of the notification. The Commission shall, within 30 days of its receipt, forward the report to the competent authorities of the other Member States.

3. The assessment report shall indicate whether:

(a) the GMO(s) in question should be placed on the market and under which conditions; or

(b) the GMO(s) in question should not be placed on the market.

The assessment reports shall be established in accordance with the guidelines laid down in Annex VI.

4. For the purpose of calculating the 90 day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier shall not be taken into account. The competent authority shall state the reasons in any request for further information.

Article 15

Standard procedure

1. In the cases referred to in Article 14(3), a competent authority or the Commission may ask for further information, make comments or present reasoned objections to the placing on the market of the GMO(s) in question within a period of 60 days from the date of circulation of the assessment report.

Comments or reasoned objections and replies shall be forwarded to the Commission which shall immediately circulate them to all competent authorities.

The competent authorities and the Commission may discuss any outstanding issues with the aim of arriving at an agreement within 105 days from the date of circulation of the assessment report.

Any periods of time during which further information from the notifier is awaited shall not be taken into account for the purpose of calculating the final 45 day period for arriving at an agreement. Reasons shall be stated in any request for further information.

2. In the case referred to in Article 14(3)(b), if the competent authority which prepared the report decides that the GMO(s) should not be placed on the market, the notification shall be rejected. This decision shall state the reasons.

3. If the competent authority which prepared the report decides that the product may be placed on the market, in the absence of any reasoned objection from a Member State or the Commission within 60 days following the date of circulation of the assessment report referred to in Article 14(3)(a) or if outstanding issues are resolved within the 105 day period referred to in paragraph 1, the competent authority which prepared the report shall give consent in writing for placing on the market, shall transmit it to the notifier and shall inform the other Member States and the Commission thereof within 30 days.

4. The consent shall be given for a maximum period of ten years starting from the date on which the consent is issued.

For the purpose of approval of a GMO or a progeny of that GMO intended only for the marketing of their seeds under the relevant Community provisions, the period of the first consent shall end at the latest ten years after the date of the first inclusion of the first plant variety containing the GMO on an official national catalogue of plant varieties in accordance with Council Directives 70/457/EEC [1] and 70/458/EEC [2].

In the case of forest reproductive material, the period of the first consent shall end at the latest ten years after the date of the first inclusion of basic material containing the GMO on an official national register of basic material in accordance with Council Directive 1999/105/EC [3].

Article 16

Criteria and information for specified GMOs

1. A competent authority, or the Commission on its own initiative, may make a proposal on criteria and information requirements to be met for the notification, by way of derogation from Article 13, for the placing on the market of certain types of GMOs as or in products.

---

(1) Council Directive 70/457/EEC of 29 September 1970 on the common catalogue of varieties of agricultural plant species (OJ L 225, 12.10.1970, p. 1). Directive as last amended by Directive 98/96/EC (OJ L 25, 1.2.1999, p. 27).

(2) Council Directive 70/458/EEC of 29 September 1970 on the marketing of vegetable seed (OJ L 225, 12.10.1970, p. 7). Directive as last amended by Directive 98/96/EC.

(3) Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material (OJ L 11, 15.1.2000, p. 17).

2. These criteria and information requirements as well as any appropriate requirements for a summary shall be adopted, after consultation of the relevant Scientific Committee(s), in accordance with the procedure laid down in Article 30(2). The criteria and the information requirements shall be such as to ensure a high level of safety to human health and the environment and be based on the scientific evidence available on such safety and on the experience gained from the release of comparable GMOs.

The requirements set out in Article 13(2) shall be replaced by those adopted above, and the procedure set out in Article 13(3), (4), (5) and (6) and Articles 14 and 15 shall apply.

3. Before the procedure laid down in Article 30(2) for a decision on criteria and information requirements referred to in paragraph 1 is initiated, the Commission shall make the proposal available to the public. The public may make comments to the Commission within 60 days. The Commission shall forward any such comments, together with an analysis, to the Committee set up pursuant to Article 30.

Article 17

Renewal of consent

1. By way of derogation from Articles 13, 14 and 15, the procedure set out in paragraphs 2 to 9 shall be applied to the renewal of:

(a) consents granted under part C; and

(b) before 17 October 2006 of consents granted under Directive 90/220/EEC for placing on the market of GMOs as or in products before 17 October 2002,

2. At the latest nine months before the expiry of the consent, for the consents referred to in paragraph 1(a), and before 17 October 2006, for the consents referred to in paragraph 1(b), the notifier under this Article shall submit a notification to the competent authority which received the original notification, which shall contain:

(a) a copy of the consent to the placing on the market of the GMOs;

(b) a report on the results of the monitoring which was carried out according to Article 20. In the case of consents referred to in paragraph 1(b), this report shall be submitted when the monitoring was carried out;

(c) any other new information which has become available with regard to the risks of the product to human health and/or the environment; and

(d) as appropriate, a proposal for amending or complementing the conditions of the original consent, *inter alia* the conditions concerning future monitoring and the time limitation of the consent.

The competent authority shall acknowledge the date of receipt of the notification and when the notification is in accordance with this paragraph it shall without delay forward a copy of the notification and its assessment report to the Commission, which shall, within 30 days of their receipt, forward them to the competent authorities of the other Member States. It shall also send its assessment report to the notifier.

3. The assessment report shall indicate whether:

(a) the GMO(s) should remain on the market and under which conditions; or

(b) the GMO(s) should not remain on the market.

4. The other competent authorities or the Commission may ask for further information, make comments, or present reasoned objections within a period of 60 days from the date of circulation of the assessment report.

5. All comments, reasoned objections and replies shall be forwarded to the Commission which shall immediately circulate them to all competent authorities.

6. In the case of paragraph 3(a) and in the absence of any reasoned objection from a Member State or the Commission within 60 days from the date of circulation of the assessment report, the competent authority which prepared the report shall transmit to the notifier the final decision in writing and shall inform the other Member States and the Commission thereof within 30 days. The validity of the consent should not, as a general rule, exceed ten years and may be limited or extended as appropriate for specific reasons.

7. The competent authorities and the Commission may discuss any outstanding issues with the aim of arriving at an agreement within 75 days from the date of circulation of the assessment report.

8. If outstanding issues are resolved within the 75 day period referred to in paragraph 7, the competent authority which prepared the report shall transmit to the notifier its final decision in writing and shall inform the other Member States and the Commission thereof within 30 days. The validity of the consent may be limited as appropriate.

9. Following a notification for the renewal of a consent in accordance with paragraph 2, the notifier may continue to place the GMOs on the market under the conditions specified in that consent until a final decision has been taken on the notification.

Article 18

Community procedure in case of objections

1. In cases where an objection is raised and maintained by a competent authority or the Commission in accordance with Articles 15, 17 and 20, a decision shall be adopted and published within 120 days in accordance with the procedure laid down in Article 30(2). This decision shall contain the same information as in Article 19(3).

For the purpose of calculating the 120 day period, any period of time during which the Commission is awaiting further information which it may have requested from the notifier or is seeking the opinion of the Scientific Committee which has been consulted in accordance with Article 28 shall not be taken into account. The Commission shall state reasons in any request for further information and inform the competent authorities of its requests to the notifier. The period of time during which the Commission is awaiting the opinion of the Scientific Committee shall not exceed 90 days.

The period of time that the Council takes to act in accordance with the procedure laid down in Article 30(2) shall not be taken into account.

2. Where a favourable decision has been taken, the competent authority which prepared the report shall give consent in writing to the placing on the market or to the renewal of the consent, shall transmit it to the notifier and shall inform the other Member States and the Commission thereof within 30 days following the publication or notification of the decision.

Article 19

Consent

1. Without prejudice to requirements under other Community legislation, only if a written consent has been given for the placing on the market of a GMO as or in a product may that product be used without further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to.

2. The notifier may proceed with the placing on the market only when he has received the written consent of the competent authority in accordance with Articles 15, 17 and 18, and in conformity with any conditions required in that consent.

3. The written consent referred to in Articles 15, 17 and 18 shall, in all cases, explicitly specify:

(a) the scope of the consent, including the identity of the GMO(s) to be placed on the market as or in products, and their unique identifier;

(b) the period of validity of the consent;

(c) the conditions for the placing on the market of the product, including any specific condition of use, handling and packaging of the GMO(s) as or in products, and conditions for the protection of particular ecosystems/environments and/or geographical areas;

(d) that, without prejudice to Article 25, the notifier shall make control samples available to the competent authority on request;

(e) the labelling requirements, in compliance with the requirements laid down in Annex IV. The labelling shall clearly state that a GMO is present. The words 'This product contains genetically modified organisms' shall appear either on a label or in a document accompanying the product or other products containing the GMO(s);

(f) monitoring requirements in accordance with Annex VII, including obligations to report to the Commission and competent authorities, the time period of the monitoring plan and, where appropriate, any obligations on any person selling the product or any user of it, *inter alia*, in the case of GMOs grown, concerning a level of information deemed appropriate on their location.

4. Member States shall take all necessary measures to ensure that the written consent and the decision referred to in Article 18, where applicable, are made accessible to the public and that the conditions specified in the written consent and the decision, where applicable, are complied with.

Article 20

Monitoring and handling of new information

1. Following the placing on the market of a GMO as or in a product, the notifier shall ensure that monitoring and reporting on it are carried out according to the conditions specified in the consent. The reports of this monitoring shall be submitted to the Commission and the competent authorities of the Member States. On the basis of these reports, in accordance with the consent and within the framework for the monitoring plan specified in the consent, the competent authority which received the original notification may adapt the monitoring plan after the first monitoring period.

2. If new information has become available, from the users or other sources, with regard to the risks of the GMO(s) to human health or the environment after the written consent has been given, the notifier shall immediately take the measures necessary to protect human health and the environment, and inform the competent authority thereof.

In addition, the notifier shall revise the information and conditions specified in the notification.

3. If information becomes available to the competent authority which could have consequences for the risks of the GMO(s) to human health or the environment, or under the circumstances described in paragraph 2, it shall immediately forward the information to the Commission and the competent authorities of the other Member States and may avail itself of the provisions in Articles 15(1) and 17(7) where appropriate, when the information has become available before the written consent.

When the information has become available after the consent has been given, the competent authority shall within 60 days after receipt of the new information, forward its assessment report indicating whether and how the conditions of the consent should be amended or the consent should be terminated to the Commission which shall, within 30 days of its receipt, forward it to the competent authorities of the other Member States.

Comments or reasoned objections to further placing on the market of the GMO or on the proposal for amending the conditions of the consent shall, within 60 days following the circulation of the assessment report, be forwarded to the Commission which shall immediately forward them to all competent authorities.

The competent authorities and the Commission may discuss any outstanding issues with the aim of arriving at an agreement within 75 days from the date of circulation of the assessment report.

In the absence of any reasoned objection from a Member State or the Commission within 60 days following the date of circulation of the new information or if outstanding issues are resolved within 75 days, the competent authority which prepared the report shall amend the consent as proposed, shall transmit the amended consent to the notifier and shall inform the other Member States and the Commission thereof within 30 days.

4. So as to ensure its transparency, the results of the monitoring carried out under part C of the Directive shall be made publicly available.

Article 21

Labelling

1. Member States shall take all necessary measures to ensure that at all stages of the placing on the market, the labelling and packaging of GMOs placed on the market as or in products comply with the relevant requirements specified in the written consent referred to in Articles 15(3), 17(5) and (8), 18(2) and 19(3).

2. For products where adventitious or technically unavoidable traces of authorised GMOs cannot be excluded, a minimum threshold may be established below which these products shall not have to be labelled according to the provision in paragraph 1. The threshold levels shall be established according to the product concerned, under the procedure laid down in Article 30(2).

Article 22

Free circulation

Without prejudice to Article 23, Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive.

Article 23

Safeguard clause

1. Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory.

The Member State shall ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including information to the public.

The Member State shall immediately inform the Commission and the other Member States of actions taken under this Article and give reasons for its decision, supplying its review of the environmental risk assessment, indicating whether and how the conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based.

2. A decision shall be taken on the matter within 60 days in accordance with the procedure laid down in Article 30(2). For the purpose of calculating the 60 day period, any period of time during which the Commission is awaiting further information which it may have requested from the notifier or is seeking the opinion of the Scientific Committee(s) which has/have been consulted shall not be taken into account. The period of time during which the Commission is awaiting the opinion of the Scientific Committee(s) consulted shall not exceed 60 days.

Likewise, the period of time the Council takes to act in accordance with the procedure laid down in Article 30(2) shall not be taken into account.

Article 24

Information to the public

1. Without prejudice to Article 25, upon receipt of a notification in accordance with Article 13(1), the Commission shall immediately make available to the public the summary referred to in Article 13(2)(h). The Commission shall also make available to the public assessment reports in the case referred to in Article 14(3)(a). The public may make comments to the Commission within 30 days. The Commission shall immediately forward the comments to the competent authorities.

2. Without prejudice to Article 25, for all GMOs which have received written consent for placing on the market or whose placing on the market was rejected as or in products under this Directive, the assessment reports carried out for these GMOs and the opinion(s) of the Scientific Committees consulted shall be made available to the public. For each product, the GMO or GMOs contained therein and the use or uses shall be clearly specified.

PART D

FINAL PROVISIONS

Article 25

Confidentiality

1. The Commission and the competent authorities shall not divulge to third parties any confidential information notified or exchanged under this Directive and shall protect intellectual property rights relating to the data received.

2. The notifier may indicate the information in the notification submitted under this Directive, the disclosure of which might harm his competitive positionand which should therefore be treated as confidential. Verifiable justification must be given in such cases.

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

4. In no case may the following information when submitted according to Articles 6, 7, 8, 13, 17, 20 or 23 be kept confidential:

— general description of the GMO or GMOs, name and address of the notifier, purpose of the release, location of release and intended uses;

— methods and plans for monitoring of the GMO or GMOs and for emergency response;

— environmental risk assessment.

5. If, for whatever reasons, the notifier withdraws th notification, the competent authorities and the Commissio must respect the confidentiality of the information supplied.

Article 26

Labelling of GMOs referred to in Article 2(4), second subparagraph

1. The GMOs to be made available for operations referred to under Article 2(4), second subparagraph, shall be subject to adequate labelling requirements in accordance with the relevant sections of Annex IV in order to provide for clear information, on a label or in an accompanying document, on the presence of GMOs. To that effect the words 'This product contains genetically modified organisms' shall appear either on a label or in an accompanying document.

2. The conditions for the implementation of paragraph 1 shall, without duplicating or creating inconsistencies with existing labelling provisions laid down in existing Community legislation, be determined in accordance with the procedure laid down in Article 30(2). In doing so, account should be taken, as appropriate, of labelling provisions established by Member States in accordance with Community legislation.

Article 27

Adaptation of Annexes to technical progress

Sections C and D of Annex II, Annexes III to VI, and section C of Annex VII shall be adapted to technical progress in accordance with the procedure laid down in Article 30(2).

Article 28

Consultation of Scientific Committee(s)

1. In cases where an objection as regards the risks of GMOs to human health or to the environment is raised by a competent authority or the Commission and maintained in accordance with Article 15(1), 17(4), 20(3) or 23, or where the assessment report referred to in Article 14 indicates that the GMO should not be placed on the market, the relevant Scientific Committee(s) shall be consulted by the Commission, on its own initiative or at the request of a Member State, on the objection.

2. The relevant Scientific Committee(s) may also be consulted by the Commission, on its own initiative or at the request of a Member State, on any matter under this Directive that may have an adverse effect on human health and the environment.

3. The administrative procedures laid down in this Directive shall not be affected by paragraph 2.

Article 29

Consultation of Committee(s) on Ethics

1. Without prejudice to the competence of Member States as regards ethical issues, the Commission shall, on its own initiative or at the request of the European Parliament or the Council, consult any committee it has created with a view to obtaining its advice on the ethical implications of biotechnology, such as the European Group on Ethics in Science and New Technologies, on ethical issues of a general nature.

This consultation may also take place at the request of a Member State.

2. This consultation is conducted under clear rules of openness, transparency and public accessibility. Its outcome shall be accessible to the public.

3. The administrative procedures provided for in this Directive shall not be affected by paragraph 1.

Article 30

Committee procedure

1. The Commission shall be assisted by a committee.

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

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

3. The committee shall adopt its own rules of procedure.

Article 31

Exchange of information and reporting

1. Member States and the Commission shall meet regularly and exchange information on the experience acquired with regard to the prevention of risks related to the release and the placing on the market of GMOs. This information exchange shall also cover experience gained from the implementation of Article 2(4), second subparagraph, environmental risk assessment, monitoring and the issue of consultation and information of the public.

Where necessary, guidance on the implementation of Article 2(4), second subparagraph, may be provided by the committee established under Article 30(1).

2. The Commission shall establish one or several register(s) for the purpose of recording the information on genetic modifications in GMOs mentioned in point A No 7 of Annex IV. Without prejudice to Article 25, the register(s) shall include a part which is accessible to the public. The detailed arrangements for the operation of the register(s) shall be decided in accordance with the procedure laid down in Article 30(2).

3. Without prejudice to paragraph 2 and point A No 7 of Annex IV,

(a) Member States shall establish public registers in which the location of the release of the GMOs under part B is recorded.

(b) Member States shall also establish registers for recording the location of GMOs grown under part C, *inter alia* so that the possible effects of such GMOs on the environment may be monitored in accordance with the provisions of Articles 19(3)(f) and 20(1). Without prejudice to such provisions in Articles 19 and 20, the said locations shall:

— be notified to the competent authorities, and

— be made known to the public

in the manner deemed appropriate by the competent authorities and in accordance with national provisions.

4. Every three years, Member States shall send the Commission a report on the measures taken to implement the provisions of this Directive. This report shall include a brief factual report on their experience with GMOs placed on the market in or as products under this Directive.

5. Every three years, the Commission shall publish a summary based on the reports referred to in paragraph 4.

6. The Commission shall send to the European Parliament and the Council, in 2003 and thereafter every three years, a report on the experience of Member States with GMOs placed on the market under this Directive.

7. When submitting this report in 2003, the Commission shall at the same time submit a specific report on the operation of part B and part C including an assessment of:

(a) all its implications, particularly to take account of the diversity of European ecosystems and the need to complement the regulatory framework in this field;

(b) the feasibility of various options to improve further the consistency and efficiency of this framework, including a centralised Community authorisation procedure and the arrangements for the final decision making by the Commission;

(c) whether sufficient experience has accumulated on the implementation of part B differentiated procedures to justify a provision on implicit consent in these procedures

and on part C to justify the application of differentiated procedures; and

(d) the socioeconomic implications of deliberate releases and placing on the market of GMOs.

8. The Commission shall send to the European Parliament and the Council every year, a report on the ethical issues referred to in Article 29(1); this report may be accompanied, if appropriate, by a proposal with a view to amending this Directive.

Article 32

Implementation of the Cartagena Protocol on biosafety

1. The Commission is invited to bring forward as soon as possible and in any case before July 2001 a legislative proposal for implementing in detail the Cartagena Protocol on biosafety. The proposal shall complement and, if necessary, amend the provisions of this Directive.

2. This proposal shall, in particular, include appropriate measures to implement the procedures laid down in the Cartagena Protocol and, in accordance with the Protocol, require Community exporters to ensure that all requirements of the Advance Informed Agreement Procedure, as set out in Articles 7 to 10, 12 and 14 of the Cartagena Protocol, are fulfilled.

Article 33

Penalties

Member States shall determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive. Those penalties shall be effective, proportionate and dissuasive.

Article 34

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 17 October 2002. They shall forthwith inform the Commission thereof.

When Member States adopt these measures they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

2. Member States shall communicate to the Commission the texts of the main provisions of domestic law which they adopt in the field covered by this Directive.

Article 35

Pending notifications

1. Notifications concerning placing on the market of GMOs as or in products received pursuant to Directive 90/220/EEC, and in respect of which the procedures of that Directive have not been completed by 17 October 2002 shall be subject to the provisions of this Directive.

2. By 17 January 2003 notifiers shall have complemented their notification in accordance with this Directive.

Article 36

Repeal

1. Directive 90/220/EEC shall be repealed on 17 October 2002.

2. References made to the repealed Directive shall be construed as being made to this Directive and should be read in accordance with the correlation table in Annex VIII.

Article 37

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 38

This Directive is addressed to the Member States.

Done at Brussels, 12 March 2001.

For the European Parliament	*For the Council*
N. FONTAINE	L. PAGROTSKY
The President	*The President*

ANNEX I A

TECHNIQUES REFERRED TO IN ARTICLE 2(2)

PART 1

Techniques of genetic modification referred to in Article 2(2)(a) are *inter alia*:

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

(2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

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

PART 2

Techniques referred to in Article 2(2)(b) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Annex I B:

(1) in vitro fertilisation,

(2) natural processes such as: conjugation, transduction, transformation,

(3) polyploidy induction.

ANNEX I B

TECHNIQUES REFERRED TO IN ARTICLE 3

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

(1) mutagenesis,

(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

ANNEX II

PRINCIPLES FOR THE ENVIRONMENTAL RISK ASSESSMENT

This Annex describes in general terms the objective to be achieved, the elements to be considered and the general principles and methodology to be followed to perform the environmental risk assessment (e.r.a.) referred to in Articles 4 and 13. It will be supplemented by guidance notes to be developed in accordance with the procedure laid down in Article 30(2). These guidance notes shall be completed by 17 October 2002.

With a view to contributing to a common understanding of the terms 'direct, indirect, immediate and delayed' when implementing this Annex, without prejudice to further guidance in this respect and in particular as regards the extent to which indirect effects can and should be taken into account, these terms are described as follows:

— 'direct effects' refers to primary effects on human health or the environment which are a result of the GMO itself and which do not occur through a causal chain of events;

— 'indirect effects' refers to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management.

Observations of indirect effects are likely to be delayed;

— 'immediate effects' refers to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect;

— 'delayed effects' refers to effects on human health or the environment which may not be observed during the period of the release of the GMO, but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

A general principle for environmental risk assessment is also that an analysis of the 'cumulative long-term effects' relevant to the release and the placing on the market is to be carried out. 'Cumulative long-term effects' refers to the accumulated effects of consents on human health and the environment, including *inter alia* flora and fauna, soil fertility, soil degradation of organic material, the feed/ food chain, biological diversity, animal health and resistance problems in relation to antibiotics.

A. Objective

The objective of an e.r.a. is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of GMOs may have. The e.r.a. should be conducted with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used.

B. General Principles

In accordance with the precautionary principle, the following general principles should be followed when performing the e.r.a.:

— identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations;

— the e.r.a. should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;

— the e.r.a. should be carried out on a case by case basis, meaning that the required information may vary depending on the type of the GMOs concerned, their intended use and the potential receiving environment, taking into account, i.a., GMOs already in the environment;

— if new information on the GMO and its effects on human health or the environment becomes available, the e.r.a. may need to be readdressed in order to:

— determine whether the risk has changed;

— determine whether there is a need for amending the risk management accordingly.

C. Methodology

C.1. Characteristics of GMOs and releases

Depending on the case the e.r.a. has to take into account the relevant technical and scientific details regarding characteristics of:

— the recipient or parental organism(s);

— the genetic modification(s), be it inclusion or deletion of genetic material, and relevant information on the vector and the donor;

— the GMO;

— the intended release or use including its scale;

— the potential receiving environment; and

— the interaction between these.

Information from releases of similar organisms and organisms with similar traits and their interaction with similar environments can assist the e.r.a.

C.2. Steps in the e.r.a.

In drawing conclusions for the e.r.a. referred to in Articles 4, 6, 7 and 13 the following points should be addressed:

1. *Identification of characteristics which may cause adverse effects:*

Any characteristics of the GMOs linked to the genetic modification that may result in adverse effects on human health or the environment shall be identified. A comparison of the characteristics of the GMO(s) with those of the non-modified organism under corresponding conditions of the release or use, will assist in identifying the particular potential adverse effects arising from the genetic modification. It is important not to discount any potential adverse effect on the basis that it is unlikely to occur.

Potential adverse effects of GMOs will vary from case to case, and may include:

— disease to humans including allergenic or toxic effects (see for example items II.A.11. and II.C.2(i) in Annex III A, and B 7 in Annex III B);

— disease to animals and plants including toxic, and where appropriate, allergenic effects (see for example items II.A.11. and II.C.2(i) in Annex III A, and B 7 and D 8 in Annex III B);

— effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations (see for example items IV B 8, 9 and 12 in Annex III A);

— altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;

— compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine (see for example items II.A.11(e) and II.C.2(i)(iv) in Annex III A);

— effects on biogeochemistry(biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see for example items II.A.11(f) and IV.B.15 in Annex III A, and D 11 in Annex III B).

Adverse effects may occur directly or indirectly through mechanisms which may include:

— the spread of the GMO(s) in the environment,

— the transfer of the inserted genetic material to other organisms, or the same organism whether genetically modified or not,

— phenotypic and genetic instability,

— interactions with other organisms,

— changes in management, including, where applicable, in agricultural practices.

2. *Evaluation of the potential consequences of each adverse effect, if it occurs*

The magnitude of the consequences of each potential adverse effect should be evaluated.

This evaluation should assume that such an adverse effect will occur. The magnitude of the consequences is likely to be influenced by the environment into which the GMO(s) is (are) intended to be released and the manner of the release.

3. *Evaluation of the likelihood of the occurrence of each identified potential adverse effect*

A major factor in evaluating the likelihood or probability of adverse effects occurring is the characteristics of the environment into which the GMO(s) is intended to be released, and the manner of the release.

4. *Estimation of the risk posed by each identified characteristic of the GMO(s)*

An estimation of the risk to human health or the environment posed by each identified characteristic of the GMO which has the potential to cause adverse effects should be made as far as possible, given the state of the art, by combining the likelihood of the adverse effect occurring and the magnitude of the consequences, if it occurs.

5. *Application of management strategies for risks from the deliberate release or marketing of GMO(s)*

The risk assessment may identify risks that require management and how best to manage them, and a risk management strategy should be defined.

6. *Determination of the overall risk of the GMO(s)*

An evaluation of the overall risk of the GMO(s) should be made taking into account any risk management strategies which are proposed.

D. **Conclusions on the potential environmental impact from the release or the placing on the market of GMOs**

On the basis of an e.r.a. carried out in accordance with the principles and methodology outlined in sections B and C, information on the points listed in sections D1 or D2 should be included, as appropriate, in notifications with a view to assisting in drawing conclusions on the potential environmental impact from the release or the placing on the market of GMOs:

D.1. In the case of GMOs other than higher plants

1. Likelihood of the GMO to become persistent and invasive in natural habitats under the conditions of the proposed release(s).

2. Any selective advantage or disadvantage conferred to the GMO and the likelihood of this becoming realised under the conditions of the proposed release(s).

3. Potential for gene transfer to other species under conditions of the proposed release of the GMO and any selective advantage or disadvantage conferred to those species.

4. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO and target organisms (if applicable).

5. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO with non-target organisms, including impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMO and persons working with, coming into contact with or in the vicinity of the GMO release(s).

7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any product derived from it, if it is intended to be used as animal feed.

8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).

9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific techniques used for the management of the GMO where these are different from those used for non-GMOs.

D.2. In the case of genetically modified higher plants (GMHP)

1. Likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.

2. Any selective advantage or disadvantage conferred to the GMHP.

3. Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species.

4. Potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable).

5. Possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens.

6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with or in the vicinity of the GMHP release(s).

7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed.

8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).

9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.

ANNEX III

INFORMATION REQUIRED IN THE NOTIFICATION

A notification referred to in part B or part C of the Directive is to include, as appropriate, the information set out below in the sub-Annexes.

Not all the points included will apply to every case. It is to be expected that individual notifications will address only the particular subset of considerations which is appropriate to individual situations.

The level of detail required in response to each subset of considerations is also likely to vary according to the nature and the scale of the proposed release.

Future developments in genetic modification may necessitate adapting this Annex to technical progress or developing guidance notes on this Annex. Further differentiation of information requirements for different types of GMOs, for example single celled organisms, fish or insects, or for particular use of GMOs like the development of vaccines, may be possible once sufficient experience with notifications for the release of particular GMOs has been gained in the Community.

The description of the methods used or the reference to standardised or internationally recognised methods shall also be mentioned in the dossier, together with the name of the body or bodies responsible for carrying out the studies.

Annex III A applies to releases of all types of genetically modified organisms other than higher plants. Annex III B applies to release of genetically modified higher plants.

The term 'higher plants' means plants which belong to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae).

ANNEX III A

INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS

I. GENERAL INFORMATION

A. Name and address of the notifier (company or institute)

B. Name, qualifications and experience of the responsible scientist(s)

C. Title of the project

II. INFORMATION RELATING TO THE GMO

A. **Characteristics of (a) the donor, (b) the recipient or (c) (where appropriate) parental organism(s):**

1. scientific name,
2. taxonomy,
3. other names (usual name, strain name, etc.),
4. phenotypic and genetic markers,
5. degree of relatedness between donor and recipient or between parental organisms,
6. description of identification and detection techniques,
7. sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques,
8. description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors, symbionts and hosts,
9. organisms with which transfer of genetic material is known to occur under natural conditions,
10. verification of the genetic stability of the organisms and factors affecting it,
11. pathological, ecological and physiological traits:
    (a) classification of hazard according to existing Community rules concerning the protection of human health and/or the environment;
    (b) generation time in natural ecosystems, sexual and asexual reproductive cycle;
    (c) information on survival, including seasonability and the ability to form survival structures;
    (d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). Ability to colonise other organisms;
    (e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;
    (f) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.
12. Nature of indigenous vectors:
    (a) sequence;
    (b) frequency of mobilisation;
    (c) specificity;
    (d) presence of genes which confer resistance.
13. History of previous genetic modifications.

B. **Characteristics of the vector**

1. nature and source of the vector,

2. sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO,

3. frequency of mobilisation of inserted vector and/or genetic transfer capabilities and methods of determination,

4. information on the degree to which the vector is limited to the DNA required to perform the intended function.

C. **Characteristics of the modified organism**

1. Information relating to the genetic modification:

   (a) methods used for the modification;

   (b) methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;

   (c) description of the insert and/or vector construction;

   (d) purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;

   (e) methods and criteria used for selection;

   (f) sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.

2. Information on the final GMO:

   (a) description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;

   (b) structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;

   (c) stability of the organism in terms of genetic traits;

   (d) rate and level of expression of the new genetic material. Method and sensitivity of measurement;

   (e) activity of the expressed protein(s);

   (f) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;

   (g) sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;

   (h) history of previous releases or uses of the GMO;

   (i) considerations for human health and animal health, as well as plant health:

      (i) toxic or allergenic effects of the GMOs and/or their metabolic products;

      (ii) comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

      (iii) capacity for colonisation;

(iv) if the organism is pathogenic to humans who are immunocompetent:

— diseases caused and mechanism of pathogenicity including invasiveness and virulence,

— communicability,

— infective dose,

— host range, possibility of alteration,

— possibility of survival outside of human host,

— presence of vectors or means of dissemination,

— biological stability,

— antibiotic resistance patterns,

— allergenicity,

— availability of appropriate therapies.

(v) other product hazards.

III. INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT

A. Information on the release

1. description of the proposed deliberate release, including the purpose(s) and foreseen products,
2. foreseen dates of the release and time planning of the experiment including frequency and duration of releases,
3. preparation of the site previous to the release,
4. size of the site,
5. method(s) to be used for the release,
6. quantities of GMOs to be released,
7. disturbance on the site (type and method of cultivation, mining, irrigation, or other activities),
8. worker protection measures taken during the release,
9. post-release treatment of the site,
10. techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment,
11. information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

B. Information on the environment (both on the site and in the wider environment):

1. geographical location and grid reference of the site(s) (in case of notifications under part C the site(s) of release will be the foreseen areas of use of the product),
2. physical or biological proximity to humans and other significant biota,
3. proximity to significant biotopes, protected areas, or drinking water supplies,
4. climatic characteristics of the region(s) likely to be affected,
5. geographical, geological and pedological characteristics,
6. flora and fauna, including crops, livestock and migratory species,
7. description of target and non-target ecosystems likely to be affected,

8. a comparison of the natural habitat of the recipient organism with the proposed site(s) of release,

9. any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOs AND THE ENVIRONMENT

A. Characteristics affecting survival, multiplication and dissemination

1. biological features which affect survival, multiplication and dispersal,

2. known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.),

3. sensitivity to specific agents.

B. Interactions with the environment

1. predicted habitat of the GMOs,

2. studies of the behaviour and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses,

3. genetic transfer capability

   (a) postrelease transfer of genetic material from GMOs into organisms in affected ecosystems;

   (b) postrelease transfer of genetic material from indigenous organisms to the GMOs;

4. likelihood of postrelease selection leading to the expression of unexpected and/or undesirable traits in the modified organism,

5. measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimise dispersal of genetic material. Methods to verify genetic stability,

6. routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.,

7. description of ecosystems to which the GMOs could be disseminated,

8. potential for excessive population increase in the environment,

9. competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s),

10. identification and description of the target organisms if applicable,

11. anticipated mechanism and result of interaction between the released GMOs and the target organism(s) if applicable,

12. identification and description of non-target organisms which may be adversely affected by the release of the GMO, and the anticipated mechanisms of any identified adverse interaction,

13. likelihood of postrelease shifts in biological interactions or in host range,

14. known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens,

15. known or predicted involvement in biogeochemical processes,

16. other potential interactions with the environment.

V. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

A. **Monitoring techniques**

1. methods for tracing the GMOs, and for monitoring their effects,
2. specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques,
3. techniques for detecting transfer of the donated genetic material to other organisms,
4. duration and frequency of the monitoring.

B. **Control of the release**

1. methods and procedures to avoid and/or minimise the spread of the GMOs beyond the site of release or the designated area for use,
2. methods and procedures to protect the site from intrusion by unauthorised individuals,
3. methods and procedures to prevent other organisms from entering the site.

C. **Waste treatment**

1. type of waste generated,
2. expected amount of waste,
3. description of treatment envisaged.

D. **Emergency response plans**

1. methods and procedures for controlling the GMOs in case of unexpected spread,
2. methods for decontamination of the areas affected, for example eradication of the GMOs,
3. methods for disposal or sanitation of plants, animals, soils, etc., that were exposed during or after the spread,
4. methods for the isolation of the area affected by the spread,
5 plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

ANNEX III B

INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED HIGHER PLANTS (GMHPs) (GYMNOSPERMAE AND ANGIOSPERMAE)

A. GENERAL INFORMATION

1. Name and address of the notifier (company or institute),
2. Name, qualifications and experience of the responsible scientist(s),
3. Title of the project,

B. INFORMATION RELATING TO (A) THE RECIPIENT OR (B) (WHERE APPROPRIATE) PARENTAL PLANTS

1. Complete name:
   (a) family name
   (b) genus
   (c) species
   (d) subspecies
   (e) cultivar/breeding line
   (f) common name.
2. (a) Information concerning reproduction:
      (i) mode(s) of reproduction
      (ii) specific factors affecting reproduction, if any
      (iii) generation time.
   (b) Sexual compatibility with other cultivated or wild plant species, including the distribution in Europe of the compatible species.
3. Survivability:
   (a) ability to form structures for survival or dormancy
   (b) specific factors affecting survivability, if any.
4. Dissemination:
   (a) ways and extent (for example an estimation of how viable pollen and/or seeds declines with distance) of dissemination
   (b) specific factors affecting dissemination, if any.
5. Geographical distribution of the plant.
6. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.
7. Other potential interactions, relevant to the GMO, of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification.
2. Nature and source of the vector used.
3. Size, source (name) of donor organism(s) and intended function of each constituent fragment of the region intended for insertion.

D. INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

1. Description of the trait(s) and characteristics which have been introduced or modified.

2. Information on the sequences actually inserted/deleted:

   (a) size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP;

   (b) in case of deletion, size and function of the deleted region(s);

   (c) copy number of the insert;

   (d) location(s) of the insert(s) in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination.

3. Information on the expression of the insert:

   (a) information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterisation;

   (b) parts of the plant where the insert is expressed (for example roots, stem, pollen, etc.).

4. Information on how the genetically modified plant differs from the recipient plant in:

   (a) mode(s) and/or rate of reproduction;

   (b) dissemination;

   (c) survivability.

5. Genetic stability of the insert and phenotypic stability of the GMHP.

6. Any change to the ability of the GMHP to transfer genetic material to other organisms.

7. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.

8. Information on the safety of the GMHP to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the GMHP is intended to be used in animal feedstuffs.

9. Mechanism of interaction between the genetically modified plant and target organisms (if applicable).

10. Potential changes in the interactions of the GMHP with non-target organisms resulting from the genetic modification.

11. Potential interactions with the abiotic environment.

12. Description of detection and identification techniques for the genetically modified plant.

13. Information about previous releases of the genetically modified plant, if applicable.

E. INFORMATION RELATING TO THE SITE OF RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6 AND 7)

1. Location and size of the release site(s).

2. Description of the release site ecosystem, including climate, flora and fauna.

3. Presence of sexually compatible wild relatives or cultivated plant species.

4. Proximity to officially recognised biotopes or protected areas which may be affected.

F. INFORMATION RELATING TO THE RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6 AND 7)

1. Purpose of the release.

2. Foreseen date(s) and duration of the release.

3. Method by which the genetically modified plants will be released.

4. Method for preparing and managing the release site, prior to, during and postrelease, including cultivation practices and harvesting methods.

5. Approximate number of plants (or plants per m^2).

G. INFORMATION ON CONTROL, MONITORING, POSTRELEASE AND WASTE TREATMENT PLANS (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6 AND 7)

1. Any precautions taken:

   (a) distance(s) from sexually compatible plant species, both wild relatives and crops

   (b) any measures to minimise/prevent dispersal of any reproductive organ of the GMHP (for example pollen, seeds, tuber).

2. Description of methods for postrelease treatment of the site.

3. Description of postrelease treatment methods for the genetically modified plant material including wastes.

4. Description of monitoring plans and techniques.

5. Description of any emergency plans.

6. Methods and procedures to protect the site.

ANNEX IV

ADDITIONAL INFORMATION

This Annex describes in general terms the additional information to be provided in the case of notification for placing on the market and information for labelling requirements regarding GMOs as or in product to be placed on the market, and GMO exempted under Article 2(4), second subparagraph. It will be supplemented by guidance notes, as regards i.a. the description of how the product is intended to be used, to be developed in accordance with the procedure laid down in Article 30(2). The labelling of exempted organisms as required by Article 26 shall be met by providing appropriate recommendations for, and restrictions on, use:

A. The following information shall be provided in the notification for placing on the market of GMOs as or in product in addition to that of Annex III:

1. proposed commercial names of the products and names of GMOs contained therein, and any specific identification, name or code used by the notifier to identify the GMO. After the consent any new commercial names should be provided to the competent authority,

2. name and full address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor,

3. name and full address of the supplier(s) of control samples,

4. description of how the product and the GMO as or in product are intended to be used. Differences in use or management of the GMO compared to similar non-genetically modified products should be highlighted,

5. description of the geographical area(s) and types of environment where the product is intended to be used within the Community, including, where possible, estimated scale of use in each area,

6. intended categories of users of the product e.g. industry, agriculture and skilled trades, consumer use by public at large,

7. information on the genetic modification for the purposes of placing on one or several registers modifications in organisms, which can be used for the detection and identification of particular GMO products to facilitate post-marketing control and inspection. This information should include where appropriate the lodging of samples of the GMO or its genetic material, with the competent authority and details of nucleotide sequences or other type of information which is necessary to identify the GMO product and its progeny, for example the methodology for detecting and identifying the GMO product, including experimental data demonstrating the specificity of the methodology. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register should be identified,

8. proposed labelling on a label or in an accompanying document. This must include, at least in summarised form, a commercial name of the product, a statement that 'This product contains genetically modified organisms', the name of the GMO and the information referred to in point 2, the labelling should indicate how to access the information in the publicly accessible part of the register.

B. The following information shall be provided in the notification, when relevant, in addition to that of point A, in accordance with Article 13 of this Directive:

1. measures to take in case of unintended release or misuse,

2. specific instructions or recommendations for storage and handling,

3. specific instructions for carrying out monitoring and reporting to the notifier and, if required, the competent authority, so that the competent authorities can be effectively informed of any adverse effect. These instructions should be consistent with Annex VII part C,

4. proposed restrictions in the approved use of the GMO, for example where the product may be used and for what purposes,

5. proposed packaging,

6. estimated production in and/or imports to the Community,

7. proposed additional labelling. This may include, at least in summarised form, the information referred to in points A 4, A 5, B 1, B 2, B 3 and B 4.

ANNEX V

CRITERIA FOR THE APPLICATION OF DIFFERENTIATED PROCEDURES (ARTICLE 7)

The criteria referred to in Article 7(1) are set out below.

1. The taxonomic status and the biology (for example mode of reproduction and pollination, ability to cross with related species, pathogenecity) of the non-modified (recipient) organism shall be well-known.

2. There shall be sufficient knowledge about the safety for human health and the environment of the parental, where appropriate, and recipient organisms in the environment of the release.

3. Information shall be available on any interaction of particular relevance for the risk assessment, involving the parental, where appropriate, and recipient organism and other organisms in the experimental release ecosystem.

4. Information shall be available to demonstrate that any inserted genetic material is well characterised. Information on the construction of any vector systems or sequences of genetic material used with the carrier DNA shall be available. Where a genetic modification involves the deletion of genetic material, the extent of the deletion shall be known. Sufficient information on the genetic modification shall also be available to enable identification of the GMO and its progeny during a release.

5. The GMO shall not present additional or increased risks to human health or the environment under the conditions of the experimental release that are not presented by releases of the corresponding parental, where appropriate, and recipient organisms. Any capacity to spread in the environment and invade other unrelated ecosystems and capacity to transfer genetic material to other organisms in the environment shall not result in adverse effects.

ANNEX VI

GUIDELINES FOR THE ASSESSMENT REPORTS

The assessment report provided for by Articles 13, 17, 19 and 20 should include in particular the following:

1. Identification of the characteristics of the recipient organism which are relevant to the assessment of the GMO(s) in question. Identification of any known risks to human health and the environment resulting from the release into the environment of the recipient non-modified organism.

2. Description of the result of the genetic modification in the modified organism.

3. Assessment of whether the genetic modification has been characterised sufficiently for the purpose of evaluating any risks to human health and the environment.

4. Identification of any new risks to human health and the environment that may arise from the release of the GMO(s) in question as compared to the release of the corresponding non-modified organism(s), based on the environmental risk assessment carried out in accordance with Annex II.

5. A conclusion on whether the GMO(s) in question should be placed on the market or as (a) product(s) and under which conditions, whether the GMOs in question shall not be placed on the market or whether the views of other competent authorities and the Commission are sought for on specific issues of the e.r.a.. These aspects should be specified. The conclusion should clearly address the use proposed, risk management and the monitoring plan proposed. In the case that it has been concluded that the GMOs should not be placed on the market, the competent authority shall give reasons for its conclusion.

ANNEX VII

MONITORING PLAN

This Annex describes in general terms the objective to be achieved and the general principles to be followed to design the monitoring plan referred to in Articles 13(2), 19(3) and 20. It will be supplemented by guidance notes to be developed in accordance with the procedure laid down in Article 30(2).

These guidance notes shall be completed by 17 October 2002.

A. Objective

The objective of a monitoring plan is to:

— confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the e.r.a. are correct, and

— identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the e.r.a.

B. General principles

Monitoring, as referred to in Articles 13, 19 and 20, takes place after the consent to the placing of a GMO on the market.

The interpretation of the data collected by monitoring should be considered in the light of other existing environmental conditions and activities. Where changes in the environment are observed, further assessment should be considered to establish whether they are a consequence of the GMO or its use, as such changes may be the result of environmental factors other than the placing of the GMO on the market.

Experience and data gained through the monitoring of experimental releases of GMOs may assist in designing the post marketing monitoring regime required for the placing on the market of GMOs as or in products.

C. Design of the monitoring plan

The design of the monitoring plan should:

1. be detailed on a case by case basis taking into account the e.r.a.,

2. take into account the characteristics of the GMO, the characteristics and scale of its intended use and the range of relevant environmental conditions where the GMO is expected to be released,

3. incorporate general surveillance for unanticipated adverse effects and, if necessary, (case-) specific monitoring focusing on adverse effects identified in the e.r.a.:

   3.1. whereas case-specific monitoring should be carried out for a sufficient time period to detect immediate and direct as well as, where appropriate, delayed or indirect effects which have been identified in the e.r.a.,

   3.2. whereas surveillance could, if appropriate, make use of already established routine surveillance practices such as the monitoring of agricultural cultivars, plant protection, or veterinary and medical products. An explanation as to how relevant information collected through established routine surveillance practices will be made available to the consent-holder should be provided.

4. facilitate the observation, in a systematic manner, of the release of a GMO in the receiving environment and the interpretation of these observations with respect to safety to human health or the environment.

5. identify who (notifier, users) will carry out the various tasks the monitoring plan requires and who is responsible for ensuring that the monitoring plan is set into place and carried out appropriately, and ensure that there is a route by which the consent holder and the competent authority will be informed on any observed adverse effects on human health and the environment. (Time points and intervals for reports on the results of the monitoring shall be indicated).

6. give consideration to the mechanisms for identifying and confirming any observed adverse effects on human health and environment and enable the consent holder or the competent authority, where appropriate, to take the measures necessary to protect human health and the environment.

ANNEX VIII

CORRELATION TABLE

Directive 90/220/EEC	This Directive
Article 1 (1)	Article 1
Article 1 (2)	Article 3 (2)
Article 2	Article 2
Article 3	Article 3 (1)
Article 4	Article 4
—	Article 5
Article 5	Article 6
Article 6 (1) to 4	
Article 6 (5)	Article 7
Article 6 (6)	Article 8
Article 7	Article 9
Article 8	Article 10
Article 9	Article 11
Article 10 (2)	Article 12
Article 11	Article 13
Article 12 (1) to (3) and (5)	Article 14
Article 13 (2)	Article 15 (3)
—	Article 15 (1), (2) and (4)
—	Article 16
—	Article 17
Article 13 (3) and (4)	Article 18
Article 13 (5) and (6)	Article 19 (1) and (4)
Article 12 (4)	Article 20 (3)
Article 14	Article 21
Article 15	Article 22
Article 16	Article 23
—	Article 24 (1)
Article 17	Article 24 (2)
Article 19	Article 25
—	Article 26
Article 20	Article 27
—	Article 28
—	Article 29
Article 21	Article 30
Article 22	Article 31 (1), (4) and (5)
Article 18 (2)	Article 31 (6)
Article 18 (3)	Article 31 (7)
—	Article 32
—	Article 33
Article 23	Article 34
—	Article 35
—	Article 36
—	Article 37
Article 24	Article 38
Annex I A	Annex I A
Annex I B	Annex I B
—	Annex II
Annex II	Annex III
Annex II A	Annex III A
Annex II B	Annex III B
Annex III	Annex IV
—	Annex V
—	Annex VI
—	Annex VII