COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 23.02.1998
COM(1998) 85 final

98/0072 (COD)

Proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

amending

DIRECTIVE 90/220/EEC

on the deliberate release into the environment of genetically modified organisms

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. INTRODUCTION

Biotechnology is a highly technical and fast-growing field which is currently governed according to the precautionary principle in the Community. Although safety represents a key element in existing Community legislation, it is at the same time essential to ensure that regulation does not unnecessarily hinder the potential for technological innovation. This growth sector has not yet reached its full potential and its cruising speed. In addition, this new technology will maintain the competitiveness of Europe on the world market and will make a major contribution to economy growth by enhancing the competitive position of industry and agriculture.

The safety of activities involving modern biotechnology is currently ensured in the European Union through four horizontal Directives (Directive 90/219/EEC, 90/220/EEC, 90/679/EEC and 94/55/EC) and sectoral measures. These include the Novel Food Regulation, which entered into force in May 1997 and provides specific authorisation and notification procedures as well as labelling provisions for novel foods and food ingredients. Other measures are under preparation, such as the Draft Novel Feed Regulation, or in discussion in the Council and the European Parliament, such as the proposed "seeds" Directive.

While Directive 90/219/EEC covers the contained use - the use in research and industrial facilities - of genetically modified micro-organisms (GMMs), Directive 90/220/EEC covers the deliberate release into the environment of genetically modified organisms (GMOs). The latter covers both deliberate releases for experimental purposes, and deliberate releases for placing on the market of products.

Directive 90/220/EEC came into force on 23 October 1991. Since then more than 1,000 experimental releases (Part B) have been notified to Member State Authorities and more than 20 product notifications have been submitted. International experience elsewhere has shown that these figures will increase rapidly in the next few years.

Since 1996, the summary notification information formats for Part B releases have been circulated between Member States and the Commission under the responsibility of the JRC (ISIS). At this stage all experimental releases have been collected in a database available in Ispra which can be consulted by request of the Competent Authorities of Member States.

In its Communication on Biotechnology and the White Paper on Growth, Competitiveness and Employment (June 1994), the Commission recognises the importance of modern biotechnology, and confirms that "in the future the whole network of interrelated biotechnological regulations needs to ensure that oversight is always appropriate to the risks involved, the building of public confidence and to the competitive development of the industries involved while guaranteeing the protection of human health and the environment.[1]"

As far as Directive 90/220/EEC was concerned, the Communication concluded that this "Directive was flexible enough to satisfy the needs of the time for adaptation to technical

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[1] Biotechnology and the White Paper on Growth, Competitiveness and Employment, preparing the next stage. Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee, p.3

progress and simplification of the procedures," but it concluded that "there were aspects of this Directive that might be improved in the future"[2].

It is in this context that the Commission adopted on 10 December 1996[3] a Report on the review of Directive 90/220/EEC with the aim of assessing the need for changes with regard to the objectives outlined in the Communication.

The Report, in which the different parts of Directive 90/220/EEC are carefully analysed, concludes that the Directive has helped Member States to introduce the appropriate and necessary infrastructure for assessing potential human health and environmental effects from the deliberate release of GMOs. Its implementation, however, has revealed a number of problem areas. Recognising the need for a horizontal regulatory framework to ensure high levels of safety for the environment and human health and of transparency, the Commission indicated in the conclusions of the Report its intention to adopt a Proposal for an amendment of Directive 90/220/EEC in the course of 1997.

Directive 90/220/EEC foresees the introduction of product based Community legislation which provides for a specific environmental risk assessment similar to that in the Directive. The Report considers the possibility of including in product legislation such a risk assessment which would allow the relevant Part B releases to be covered by that legislation. The Commission considers that this possibility should be included in the Proposal since it will promote the link between releases for purposes of research and development and product releases.

The current system for risk assessment which forms part of the notification for placing on the market under Part C of Directive 90/220/EEC, is decentralised and falls under the responsibility of the Competent Authorities of the Member States. The implementation of such a system has led to conflict, since the assessment of the notification by the forwarding Member State Competent Authority is usually not accepted by the other Member States.

Based on the discussions of the Risk Assessment Group established in the framework of the Committee of Competent Authorities for Directive 90/220/EEC, a common approach to risk assessment objectives and methodology has been further developed by the Commission.

Moreover, the case of Bt-maize (Novartis) underlined the necessity of an independent system for conflict resolution which would allow problems to be discussed and resolved on a scientific basis as in the case of Community legislation dealing with marketing authorisation for foods, pharmaceuticals and feed. The Proposal, therefore, includes an obligation for the Commission to consult a Scientific Committee on any matter in the clearance of applications for placing on the market which is likely to have an effect on human health and the environment.

In proposing this modification of Directive 90/220/EEC, the Commission has reviewed the existing provisions in the light of the experience of USA, Canada and Japan in their assessment and decision-making process for the release of GMOs as well as the international trade commitments linked to the placing on the market of genetically modified products. The

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2 Biotechnology and the White Paper on Growth, Competitiveness and Employment, preparing the next stage. Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee, p.5

3 COM (96) 630 Final

provisions in this Proposal also take into account the specific sensitivity and awareness of the public in Europe concerning genetically modified organisms.

In the last 12 months, the placing on the market of genetically modified organisms has led to growing concern on the part of the general public regarding the limited experience with certain uses of this new technology and criticisms have arisen regarding the lack of transparency in the decision-making process, including the difficulty of access to the notification dossiers. The public has expressed the need for users of genetically modified products to be fully aware of the method by which these products have been produced so that they can make an informed choice. In order to meet these concerns, the Commission adopted on 18 June 1997 a technical adaptation of Annex III of Directive 90/220/EEC to allow mandatory labelling of all GMOs approved for placing on the market under the Directive. The proposed amendments will maintain obligatory labelling for all GMOs approved for placing on the market under the Directive.

The current Directive 90/220/EEC does not provide for the possibility of a single procedure for multi-state experimental releases. As the field develops it will increasingly become necessary to test GMOs in more than one Member State. The introduction of provisions for multi-state experimental releases will benefit notifiers and should promote mutual recognition of the risk assessment between Member States. The provisions establishing simplified procedures under the current Directive are not repeated in the present Proposal but the provisions adopted pursuant to Article 6 (5) of the current Directive ie Commission Decision 94/730/EC establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants will remain applicable under the present Proposal when adopted.

As the field of Biotechnology develops, it may be possible to establish clearly defined criteria and information requirements which will allow to apply for a simplified administrative procedure for the placing on the market of products containing or consisting of GMOs. However, the experience gained in the release of products is at present not sufficient to fix these criteria. The Commission will prepare a proposal for criteria and information requirements for the simplified procedure as soon as possible and when sufficient scientific knowledge and experience is available. These criteria and information requirements will be based on scientific evidence available and generally recognised and on the experience gained with comparable releases. The Proposal introduces a simplified procedure for cases where such criteria and information requirements have been established according to the Article 21 procedure. The safety aspects will be ensured by the involvement of the relevant Scientific Committees in that procedure. The simplified procedure introduced into the Proposal does not remove the right of Member States to raise objections and the obligation for the Commission to consult a Scientific Committee on any matter in the clearance of applications for placing on the market which is likely to have an effect on human health and the environment.

When adopting its Resolution on 16 July 1997 on the Report on the Review of Directive 90/220/EEC submitted by the Commission, the European Parliament emphasised the need to include the possibility to deal with ethical concerns in the framework of the revision of the Directive. The Proposal confirms the possibility of the Commission to consult any committee it has created with a view to advising it on the ethical implications of biotechnology on any general matters which may raise ethical concerns.

A number of developments have taken place in the Community since the adoption of this Report by the Commission. These developments have a direct impact on the contents of this Proposal.

Thus,

- In its Communication on Consumer Health and Food Safety, adopted on 30 April 1997, the Commission outlined its new approach to consumer health and food safety, in particular with respect to scientific advice as well as to control and inspection. In the Communication the Commission indicated that "in order to implement Commission policy concerning scientific advice on matters relating to consumer health, it will propose or adopt the necessary acts to introduce, where necessary, compulsory consultation of a Scientific Committee".[4] In this context, for example, Scientific Committees can be consulted to determine if the presence of specific antibiotic resistance genes in a product could pose a risk to human health and the environment. The recently-adopted Commission Decisions creating the Scientific Committees enable, in certain cases, the Scientific Committees to be requested to deliver their opinion within a limited time period.

- On 23 July 1997 the Commission adopted a broad orientation for an extended Community labelling system for GMO products in which it states that such a system should be broad, transparent, and scientifically-based in order to help in the tracing of these products along the food chain. This system results in 3 categories[5]:

  - voluntary labelling ("this does not contain ...") for certified non-GMO products,
  - mandatory labelling ("this contains ....") for products known to be of GMO origin,
  - and mandatory labelling ("this may contain ...") in cases where material of GMO origin cannot be excluded but where no evidence of such material is available.

- Finally, on 10 September 1997, when deciding to adopt draft measures aimed at requesting the Member States which invoked Article 16 of Directive 90/220/EEC to ban or/and to restrict the use and/or the placing on the market of Bt maize, for which consent had been given on 5 February 1997 by the French authorities to repeal their bans, the Commission concluded that any weaknesses in the legislation on products should be addressed in the framework of the revision of Directive 90/220/EEC. In this context, monitoring and time limits were discussed.

In a IIIa Committee procedure it is possible that there is no qualified majority in the Council in favour of a Commission Proposal nor unanimity against it. In default of a decision on the part of Council the final responsibility lies with the Commission. This was the case of the Bt maize in the summer of 1996. By opting for a IIIb procedure, the Council may reject the Commission proposal by simple majority. This increases the role of the Member States in the decision-making process.

The legal text will provide for products already granted consents for placing on the market to be reassessed within 7 years of the date of entry into force of the amended Directive.

The Commission has thus taken into consideration

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[4] Communication from the Commission on Consumer Health and Food Safety (COM(97)183 final), p. 14

- the experience gained in the implementation of Directive 90/220/EEC;
- the latest scientific data on the assessment of deliberate releases;
- the exchange of views which has taken place in the Council on the possible amendment of Directive 90/220/EEC;
- the outcome of the discussions in the European Parliament and the Economic and Social Committee on the Report on the Review of Directive 90/220/EEC, and
- the developments which have taken place in the field of biotechnology since the adoption of the Report on the Review of Directive 90/220/EEC.

The review process of Directive 90/220/EEC has involved extensive consultation with the stakeholders, the Competent Authorities of Member States, Industrial and Research Associations, Environmental, Consumer and Trade Union Organisations.

2. OBJECTIVES

Directive 90/220/EEC regulates a high-technology field, which is developing rapidly. The Directive covers both the stages of development and the placing on the market of products containing or consisting of GMOs. The objectives of the present Proposal are to

- extend and clarify the scope of Directive 90/220/EEC so that the procedures to be followed are commensurate with the risks;
- speed up the administrative procedures by early transmission of information and the introduction of a mediation period;
- strengthen more uniform decision-taking between Member States, based on common principles for risk assessment;
- extend the flexibility of Directive 90/220/EEC while maintaining a high level of protection for health and the environment and in addition increase transparency, and
- facilitate the link between the Directive and product legislation.

3. MAIN ELEMENTS OF THE PROPOSAL

In essence the Commission proposes to:

- clarify further the scope and the definitions within Directive 90/220/EEC;
- introduce a mandatory monitoring after the placing on the market of products linked to a consent granted for a fixed time period. Since it is very difficult to draw up, in advance, the content of monitoring plans which cover different types of GMO (plants, animals, micro-organisms), only the objectives of the monitoring are defined in this Proposal. The specific post-marketing monitoring plans will be drawn up on a case by case basis and carried out under the control of the relevant Member State Competent Authority. The objectives of the monitoring are listed in Annex VII and the monitoring plan will become

part of the consent when the relevant Member State Competent Authority has checked that the monitoring proposed complies with the provisions of this Annex. For the renewal of the consent, the results of the monitoring will be reviewed by the Competent Authorities of Member States to determine whether the existing conditions and/or monitoring regime require modification

- confirms the possibility of the Commission to consult any committee it has created with a view to advising it on the ethical implications of biotechnology on any general matter that may raise ethical concerns;

- set out principles for the risk assessment under the Directive;

- classify, on the basis of common criteria, experimental releases and to provide for a distinct administrative procedure for each category of release as well as for a multi-state procedure;

- improve the administrative procedures and approval system for placing on the market of products and introduce simplified procedures for the renewal of a consent and for cases where specific criteria and information requirements on the basis of safety and experience have been established;

- provide for the obligation of formally consulting a Scientific Committee in order to assist the Commission in any matter which is likely to have an effect on human health and/or the environment under the implementation of Part C of Directive 90/220/EEC, and

- increase the transparency of the decision-making process by making available to the public the content of the notification for the placing on the market of GMOs as/or in a product, the assessment reports carried out for products placed on the market, the opinion of the Scientific Committee(s), and the decisions taken under Part B of the Directive;

- apply a IIIb procedure for the regulatory committee to increase the role of the Member States in the decision-making process by giving the Council the possibility to reject the Commission decision by a simple majority;

- detail further and broaden labelling requirements on the basis of the broad orientation for an extended Community labelling system for GMO products.

In addition to the above-mentioned main modifications, the Proposal contains amendments which were considered necessary in order to ensure consistency and clarity. Furthermore, it was considered necessary to update certain technical parts of the Directive on the basis of experience and scientific progress.

The annexed table presents a comparison of the main elements of the administrative procedures in the current Directive 90/220/EEC and the proposed modifications.

4. CONCLUSIONS

This Proposal integrates the conclusions of the 1996 Report on the Review of Directive 90/220/EEC, takes account of the recent developments in the area of Biotechnology, the growing scientific knowledgeas well as the concern of the general public about the effects of genetically modified products and incorporates the Commission Policy on Consumer Health and Food Safety. It should therefore meet the needs and concerns with regard to safety aspects for human health and the environment. The establishment in this Proposal of a common methodology to carry out the risk assessment based on independent scientific advice and of common objectives for the monitoring of genetically modified organisms after they have been released constitutes a step forward to a more centralised Community system of authorisation. In the light of experience, the Commission notes that the existing IIIA Committee procedure is not suitable for the authorisations envisaged in the proposed Directive. In the absence of any other suitable procedure available within the framework of the decision of July 1987 on Comitology, it is therefore appropriate to propose replacing this procedure by that of the IIIB Committee. Nevertheless, following the mandate of the Amsterdam European Council, the Commission retains the option of amending this proposal in view of the revision of Comitology procedures which it is required to present before the end of the first semester 1998. In addition the Proposal should also provide for sufficient flexibility which will help to increase employment potential of this particular fast-growing sector at the beginning of the 21st century.

Comparison in a tabulated form of the administrative procedures with the main elements in current Directive 90/220/EEC and in the Proposal

A. Main elements of the Proposal

Directive 90/220/EEC	Proposal for a modification of Directive 90/220/EEC
• The scope of the environmental risk assessment is misunderstandable and could be considered not to include agricultural environment; • ethical issues are not specifically addressed	• The scope of the environmental risk assessment was clarified to include all direct and indirect environmental aspects; • confirmation of the possibility for the Commission to consider ethical issues
• Only one standard administrative procedure for Part B releases • The same administrative procedure applies to all experimental releases irrespective of experience. Simplification can only be introduced if simplified procedures are adopted by Comitology procedure	• 2 categories of releases are foreseen: 1. *Category I*: Releases for which there is knowledge and safety (according to the criteria set out in Annex V) 2. *Category II:* All other releases • Administrative procedures are linked to the category. • *Category I* releases are subject to a streamlined procedure while *Category II* releases are subject to a standard full procedure which is similar to the one currently in force. • Introduction of the possibility for multi-state releases, both categories. • Introduction of the possibility for experimental releases to be covered by specific Community product legislation
• No common principles for risk assessment	• Annex II introduces for the first time principles for risk assessment. These principles apply to all releases, both experimental and placing on the market.
• Adoption of simplified procedure proven cumbersome and does not ensure rapid adaptation to technical progress	• The new classification system for experimental releases as well as the possibility for multi-state releases will take into account the experience gained in the field and thus streamline the procedures.

A. **Main elements of the Proposal** (cont'd)

• Cumbersome administrative procedures for the placing on the market of products	• An improved administrative procedure for the placing on the market of products by immediate dissemination of product application dossiers to extend the time for Member States to consider the implications of the notification, and introduction of a mediation period. • Simplified procedures for the renewal of a consent and for cases where specifc criteria and information requirements on the basis of safety and experience have been established.
• No obligation to seek independent scientific advice on controversial issues	• Obligation to consult the relevant Scientific Committee(s) on any matter which is likely to have an effect on human health and/or the environment before the Commission initiates the Article 21 procedure as required by Art 20a
• Labelling requirements only on the basis of safety concerns	• Labelling provisions according to the Commission labelling policy are included
• Lack of transparency	• Adaptation to technical progress of Annexes II - VII and decisions on products by Comitology procedure IIIb instead of IIIa. ◦ Access of the public to the summary of the notification dossier with the right to send comments to the Commission • Improvement of the labelling requirements for products; ◦ Obligatory consultation of the relevant Scientific Committee(s) on issues likely to have an effect on human health and/or the environment before the Commission initiates an Article 21 procedure; ◦ Publication of the assessment report carried out for products placed on the market and of the Opinion(s) of the Scientific Committee(s) consulted and publication of the decisions taken under Part B of the Directive.

A. Main elements of the Proposal (cont'd)

• Restriction of the scope of the authorisation (time limitation) and imposing of monitoring only on the basis of safety concerns	• Fixed seven year consent linked to the establishment of mandatory monitoring

B. Administrative procedures for experimental releases

I. Standard procedure

Current Directive	Proposal for a modification of Directive 90/220/EEC
• submission of a technical dossier to a national competent authority (CA). The dossier must provide all the relevant information as specified in Annex II • the CA has to decide on the dossier within 90 days. No common principles for the risk assessment • a summary of the dossier is circulated (SNIF) to the Commission within 30 days. The Commission circulates the SNIF to the CAs of the other MS • comments by other MS within 30 days • the release can only take place if the CA gives its consent	• submission of a technical dossier to a national competent authority (CA). The dossier must provide all the relevant information as specified in Annex III (currently Annex II) • the CA has to decide on the dossier within 90 days. The CA has to carry out the risk assessment on the basis of the common principles outlined in Annex II • a summary of the dossier (SNIF) is circulated to the Commission within 30 days. The Commission circulates immediately the SNIF to the CAs of the other MS • comments by other MS within 30 days. All CAs are informed about the results of the release submitted to the original CA by the notifier. • the release can only take place if the CA gives its consent • the original CA circulates to the other CAs the results of the release.

II. Streamlined procedure(applies only to Category I releases)

Current Directive	Proposal for a modication of Directive 90/220/EEC
Does not foresee a streamlined procedure. The procedure outlined below is the standard one that is currently in force.	The streamlined procedure is applicable to Category I releases which comply with the criteria of Annex V.
• submission of a technical dossier to a national competent authority (CA). The dossier must provide all the relevant information, as specified in Annex II	• submission of a technical dossier to a national competent authority (CA). The dossier must provide at least the minimum amount of information from Annex III(currently AnnexII). The minimum amount of information is to be decided before the coming into force of the Directive.The dossier should also supply the information on the basis of which the classification into Category I was made
• the CA has to decide on the dossier within 90 days. No common principles for the risk assessment	• CA has to decide within 30 days. It verifies the classification in accordance with the criteria outlined in Annex V. The principles for the risk assessment are outlined in Annex II
• a summary of the dossier is circulated (SNIF) to the Commission within 30 days. The Commission circulates the SNIF to the CAs of the other MS which have 30 days to express comments	• the dossier is not circulated to other CAs or the Commission. Every year each Member State submits a list with the releases which took place under this procedure and a list of notifications that were rejected
• the release can only take place if the CA gives its consent	• the release can only take place if the CA gives its consent

III. Simplified procedures

Current Directive	Proposal for a modification of Directive 90/220/EEC
• The Commission establishes criteria for releases which can be carried out under simplified procedures (Comitology procedure IIIa) • If Member State Authorities consider that they have obtained sufficient experience with releases of certain GMOs, they may submit proposals for simplified procedures to be followed for part B releases of such GMOs • A Decision is taken in accordance with Comitology procedure IIIa	Simplified procedures are replaced by the streamlined administrative procedure for category I GMOs and a multi-state procedure.

IV. Multi-state procedure

Current Directive	Proposal for a modification of Directive 90/220/EEC
• Does not foresee a multi-state procedure.	• Notifier sends dossier to Commission and CAs of chosen Member States where release is requested. • Commission circulates summary of the dossier to other CAs. • 60 days for other CAs to comment. • Chosen CAs issue individual consents within 90 days of receipt of the notification.

C. Administrative procedures for the placing on the market of products

I. Main elements

Current Directive	Proposal for a modification to Directive 90/220/EEC
• One administrative procedure which does not involve all MS right from the beginning and which has proven to be cumbersome and not very transparent • Comitology procedure IIIa	• One administrative procedure which involves all MS right from the beginning and ensures greater transparency at all stages and simplified administrative procedures for the renewal of a consent and for cases where specifc criteria and information requirements on the basis of safety and experience have been established. • Comitology procedure IIIb
• No principles for risk assessment	• Common principles for risk assessment are outlined in Annex II
• No obligation to consult a Scientific Committee on matters likely to have an effect on human health and/or the environment	• the relevant Scientific Committee(s) shall be consulted on issues likely to have an effect on human health and/or the environment before the Commission initiates an Article 21 procedure
• Labelling requirements as provided in the Commission Directive 97/35/EC	• Labelling requirements in line with the Commission labelling policy are included
• No obligation to require a monitoring programme, unless for health and environmental safety.	• Introduction of a mandatory monitoring programme linked to a consent granted for a limited time period; the objectives of the monitoring plan are specified in Annex VII

II. Standard procedure

Current Directive	Proposal for a modification to Directive 90/220/EEC
• Submission of a technical dossier to a national CA	• Submission of a technical dossier to a national CA. Copy of the dossier to the Commission and to all other CAs.
• No common principles for risk assessment. Examination of the dossier within 90 days.	• Common principles for risk assessment outlined in Annex II. Examination of the dossier within 90 days and preparation of an assessment report
• In case of a favourable opinion, the dossier is circulated to the Commission and via the Commission to all other CAs which have 60 days to express comments or raise objections. The original CA has *no* obligation to submit a detailed assessment of the dossier. The Commission has no possibility for comments or objections	• Submission of the assessment report to the Commission which circulates it to the other CAs. Other CAs and the Commission have 30 days to submit comments or raise objections
• In case of objections,Comitology procedure IIIa has to be followed	• In case of objections, total of 60 days from submission date to resolve disagreements. If, at the end of this period, there is no agreement or if the assessment report states that there is additional assessment required, Comitology procedure IIIb has to be followed
• In the absence of objections, consent should be granted by the original CA and the product may circulate freely throughout the Community	• In the absence of objections, consent should be granted by the original CA and the product may circulate freely throughout the Community • In any case, the consent is granted for a time period of seven years and linked to a mandatory monitoring after the placing on the market;
• No obligation to formally consult (a) Scientific Committee(s)	• Obligation to consult the relevant Scientific Committee(s) on any aspects which is likely to have an effect on human health and/or the environment before the Commission initiates an Article 21 procedure

III. Simplified procedure for cases where specifc criteria and information requirements on the basis of safety and experience have been established

Current Directive	Proposal for a modification to Directive 90/220/EEC
• Does not foresee a simplified procedure.	• For Part C releases where specific criteria and information requirements on the basis of safety and experience have been established, submission of a technical dossier to the lead CA. CA considers within 15 days whether application meets the requirements for the simplified procedure. If no, application is rejected. • If yes, CA circulates it to the Commission and the CAs of the other MS. • Comments/objections within 30 days. • Total of 45 days from submission date to resolve disagreements. • If, at the end of this period, there is no agreement, Comitology procedure IIIb has to be followed • In the absence of objections, consent issued by the lead CA within 15 days.

IV. Simplified procedure for the renewal of a consent

Current Directive	Proposal for a modification to Directive 90/220/EEC
• Does not foresee a simplified procedure.	• In the case of the renewal of a consent, submission of a technical dossier to the Commission. Commission circulates it to the CAs of all MS. • Comments/objections within 30 days. • Total of 45 days from submission date to resolve disagreements. • If, at the end of this period, there is no agreement, Comitology procedure IIIb has to be followed • In the absence of objections, consent issued by the lead CA responsible for the previous consent.

Proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

amending

DIRECTIVE 90/220/EEC

on the deliberate release into the environment of genetically modified organisms

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof;

Having regard to the proposal from the Commission[5] ;

Having regard to the opinion of the Economic and Social Committee[6] ;

Acting in accordance with the procedure laid down in Article 189b of the Treaty[7] ;

Whereas, under the Treaty, action by the Community relating to the environment should be based on the principle that preventive action should be taken;

Whereas, the Report of the Commission on the Review[8] of Council Directive 90/220/EEC[9] , as last amended by Commission Directive 97/35/EC[10] , adopted on 10 December 1996, identified a number of areas where improvement is needed;

Whereas there is a need for clarification of the scope of the Directive and of the definitions thereof;

Whereas deliberate releases of GMOs into the environment carried out for experimental purposes or for any other purposes than placing on the market can now be classified in two categories on the basis of common criteria and whereas it is appropriate to foresee different procedures for each category;

Whereas the provisions of the Directive concerning Part B releases of products shall not apply to products under development covered by Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive;

Whereas it is necessary to introduce in this Directive the obligation to carry out a monitoring in order to trace any direct or indirect, immediate or delayed effects on human health and the environment of GMOs as or in products after they have been placed on the market;

Whereas it is appropriate that the administrative procedure for granting consents to the placing on the market of GMOs as or in products should become more efficient and more transparent and that consent should only be granted for a fixed period;

Whereas it is appropriate to introduce a simplified administrative procedure for granting consents to the placing on the market of products in cases where specific criteria and information requirements on the basis of safety and experience have been established;

Whereas for products for which consent has been granted for a fixed period a simplified procedure should be applicable for the renewal of the consent;

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8 COM(96)630

9 OJ N° L117,8.5.1990,p.15

10 OJ N° L169,27.6.1997,p.72

Whereas there is a need for consultation of the relevant Scientific Committee(s) established by the Commission Decision 97/579/EC[11] on matters which are likely to have an impact on human health and/or the environment;

Whereas the content of the present Directive has duly taken into account international experience and international trade commitments in this field;

Whereas the Commission may consult any committee it has created with a view to advising it on the ethical implications of biotechnology on general matters which in the view of the Commission may raise ethical concerns;

Whereas establishing a common methodology to carry out the risk assessment based on independent scientific advice and common objectives for the monitoring of genetically modified organisms after their release, constitutes a step forward to a more centralised Community system of authorisation;

Whereas pending the implementation of such a system, it is appropriate to give the Council the possibility to reject the Commission decision by simple majority;

Whereas the provisions of this Directive apply without prejudice to the provisions of Council Regulation (EEC) N° 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries[12] ;

Whereas products containing and/or consisting of genetically modified organisms covered by this Directive cannot be imported into the Community if they do not comply with the provisions of this Directive;

Whereas the monitoring foreseen under the provisions of this Directive is complementary to the monitoring foreseen under specific product legislation;

Whereas in order to increase the effective implementation of the provisions adopted under this Directive it is appropriate to provide for sanctions to be applied by Member States,

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11 OJ N° L237, 28.8.1997,p.18

12 OJ N° L40, 17.2.1993,p.1

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 90/220/EEC is amended as follows:

1. Articles 1 to 6 are replaced by the following:

"Article 1

1. The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when carrying out the deliberate release of genetically modified organisms into the environment

   a) for research and development purposes or for any other purposes other than placing on the market
   b) for placing on the market of genetically modified organisms as or in products.

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

Article 2

For the purposes of this Directive:

1. 'organism' is any biological entity capable of replication or of transferring genetic material;

2. 'genetically modified organism (GMO)' means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

   Within the terms of this definition:

   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 without provisions for containment such as physical barriers, or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment;

4. 'placing on the market' means supplying or making available to third parties.

5. 'notification' means the presentation of documents containing the requisite information to the competent authority of a Member State. The person making the presentation shall be referred to as 'the notifier';

6. 'environmental risk assessment' means the evaluation of the direct and indirect risks to human health and the environmentwhich the deliberate release of GMOs into the environment may pose.

Article 3

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

Article 4

1. Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release of GMOs. To this end GMOs may only be deliberately released into the environment following an assessment of any potential risks for human health and/or the environment in conformity with part B or part C of this Directive. The risk assessment shall take account of the principles laid down in Annex II.

2. Member States shall designate the competent authority or authorities responsible for carrying out the requirements of this Directive and its Annexes.

3. Member States shall ensure that the competent authority organizes inspections and other control measures as appropriate, to ensure compliance with this Directive.

PART B

Deliberate release of GMOs into the environment for research and development purposes or for any other purpose than for placing on the market

Article 5

Articles 6 to 9 shall not apply to any products under development covered by Community legislation which provides for a specific environmental risk assessment similar to that laid down in those articles.

Article 6

1. Any person, before submitting a notification under Articles 6a, 6b and 6c concerning the release of a GMO or of a combination of GMOs for the purpose of research and development, or for any other purpose than for placing on the market, shall carry out a risk assessment of the deliberate release of GMOs as regards the risks to human health and/or the environment that may occur,

taking due account of the information which may be necessary for evaluating any potential risks, whether immediate or delayed, which the release may present for human health and/or the environment. This information is laid down in Annex III.

2. Deliberate releases which fall under this part are classified in 2 categories:

Category I: Deliberate releases of GMOs which comply with the criteria set out in Annex V parts A or B
Category II: All other releases."

2. The following articles 6a to 6d are inserted:

"Article 6a

1. Any person before undertaking a Category I deliberate release of a GMO or of a combination of GMOs, shall submit a notification to the competent authority referred to in Article 4(2) of the Member State within whose territory the release is to take place.

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

a technical dossier supplying the information on the basis of which the classification of the deliberate release was made. The notification referred to in paragraph 1 shall include a technical dossier supplying the information specified in Annex III necessary for evaluating any foreseeable risks from the deliberate release of a GMO or combination of GMOs, in particular:

a) information relating to the GMO(s),
b) information relating to the conditions of release and the receiving environment,
c) information on the interactions between the GMO(s) and the environment,
d) a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged;

3. The competent authority shall verify the classification into Category I in accordance with the criteria referred to in Article 6(2) and shall examine the dossier for any potential risks to human health and/or the environment. The competent authority shall respond in writing to the notifier within 30 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 the notification is therefore rejected.

4. Before this Directive is implemented, the Commission shall establish in accordance with the procedure laid down in Article 21 the minimum amount of technical information from Annex III to be included in the dossier referred to in paragraph 2.

Article 6b

1. Any person before undertaking a Category II deliberate release of a GMO or of a combination of GMOs, must submit a notification to the competent authority referred to in Article 4(2) of the Member State within whose territory the release is to take place.

2. The notification referred to in paragraph 1 shall include a technical dossier supplying the information specified in Annex III necessary for evaluating any foreseeable risks from the deliberate release of a GMO or combination of GMOs, in particular:

   a) general information including information on personnel and training,
   b) information relating to the GMO(s),
   c) information relating to the conditions of release and the receiving environment,
   d) information on the interactions between the GMO(s) and the environment,
   e) information on monitoring, control, waste treatment and emergency response plans;
   f) a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged;

3. The competent authority, having considered, where appropriate, any observations by other Member States made in accordance with Article 9, 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 the notification is therefore rejected.

4. For the purpose of calculating the 90-day period referred to in paragraph 3, 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 7

   shall not be taken into account.

5. 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

Article 6c

1. In the case of part B releases planned to take place in more than one Member State, the applicant may choose to follow the procedure outlined in the following paragraphs.

2. A notification shall be submitted to the Commission and to the competent authorities of the Member States where the release is to be carried out. The notification shall include a technical dossier supplying the information outlined in Article 6a(2) for deliberate releases under category I or Article 6b(2) for all other releases together with a summary of the technical dossier.

3. Upon receipt of the notification the Commission shall forward the summary of the dossier to the competent authorities of those Member States which have not received the full dossier. The competent authorities may forward comments within 60 days of receipt of the notification to the Commission. The Commission may immediately forward these comments to the competent authorities referred to in paragraph 2.

4. The notifier shall submit any additional information which may have been requested by one of the competent authorities referred to in paragraph 2 to the Commission and all the other competent authorities referred to in paragraph 2.

5. The competent authorities referred to in paragraph 2, having considered any comments by other competent authorities, 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 on their territory or
   b) indicating that the release does not fulfil the conditions of this Directive and the release cannot take place on their territory.

6. For the purpose of calculating the 90-day period referred to in paragraph 5, any periods of time during which the competent authorities

   a) are awaiting further information which it may have requested from the notifier, or
   b) are carrying out a public inquiry or consultation in accordance with Article 7

   shall not be taken into account.

Article 6d

1. In the event of any modification of the deliberate release of GMOs or of a combination of GMOs which could have consequences with regard to potential risks for human health or the environment 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:

   a) revise the measures specified in the notification,
   b) revise the measures specified in the notification, inform the competent authority in advance of any modification or as soon as the new information is available,
   c) take the measures necessary to protect human health and the environment

2. If information becomes available subsequently to the competent authority which could have significant consequences for the risks posed by the release, the competent authority may require the notifier to modify the conditions of, suspend or terminate the deliberate release."

3. Articles 9 to 13 are replaced by the following:

"Article 9

1. The competent authorities shall send to the Commission, within 30 days of its receipt, a summary of each Category II notification received under Article 6b. The format of this summary will be established by the Commission in accordance with the procedure laid down in Article 21.

2. The Commission shall immediately forward these summaries to the other Member States, which may, within 30 days, present observations through the Commission or directly.

3. The competent authorities shall inform the other Member States and the Commission of the final decisions taken in compliance with Article 6b(3) and 6c(5) and of the results of the releases received in accordance with Article 8.

4. Once a year Member States shall send to the Commission and the competent authorities of the other Member States a list of GMOs which have been released on their territory in accordance with Article 6a(3)(a) and a list of notifications that were rejected in accordance with Article 6a(3)(b).

PART C

Placing on the market of products containing GMOs

Article 10

1. Articles 11 to 18 shall not apply to any products covered by Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive.

Article 11

1. Before a GMO or a combination of GMOs are placed on the market as or in a product, a notification shall be submitted to the competent authority of the Member State where such a product is to be placed on the market for the first time. Upon receipt of the notification the competent authority shall without delay forward a copy of the notification to the Commission and 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 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/or the environment;

b) an assessment of any risks for human health and/or the environment related to the GMOs or the combination of GMOs contained in the product, taking due account of the principles laid down in Annex II;

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

d) a detailed plan for monitoring in order to identify any relevant direct, indirect, immediate or delayed effects of the GMOs on human health and/or the environment in accordance with the requirements outlined in Annex VII;

e) a proposal for labelling which shall comply with the requirements laid down in Annex IV and which shall inform the consumer of the presence of GMOs in the product(s) whenever there is evidence that the product(s) contain(s) GMOs.

f) a proposal for packaging which shall comprise the requirements laid down in Annex IV.

If on the basis of the results of any release notified under Part B of this Directive, or on substantive, reasoned scientific grounds, a notifier considers that the placing on the market and use of a product do not pose a risk to human health and the environment, he may propose not to comply with one or more of the requirements of Annex IVB.

3. The notification shall also include a summary of the dossier. The format of the summary shall be established in accordance with the procedure laid down in Article 21.

4. 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.

5. The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing.

6. In order for a GMO or combination of GMOs to be used for a use different than that already specified in a notification, a separate notification shall be submitted.

Article 12

1. On receipt and after acknowledgement of the notification referred to in Article 11, the competent authority shall examine it for compliance with this Directive.

2. At the latest 90 days after receipt of the notification, the competent authority shall forward to the Commission its assessment report.

3. The assessment report shall indicate whether the GMO(s) in question should be placed on the market and under which conditions, if any, or whether additional assessment is required.

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 motivate any request for further information. It shall inform the Commission and the other competent authorities of any additional information submitted by the notifier.

Article 13

1. On receipt of the assessment report referred to in Article 12(2), the Commission shall immediately forward it to the competent authorities of all Member States.

2. In the case of a favourable assessment by the competent authority referred to in paragraph 1, a competent authority designated under Article 4(2) or the Commission may make comments or present reasoned objections to the placing on the market of the GMO(s) in question within a period of 30 days from the date of circulation of the assessment report by the Commission.

   Comments or objections of competent authorities and replies by the notifier 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 60 days from the date of circulation of the assessment report.

3. In the absence of any reasoned objection from another Member State or the Commission within 30 days following the date of distribution of the assessment report or if possible outstanding issues are resolved within the 60 day period referred to in paragraph 2, the competent authority that had originally received and assessed the dossier shall give its consent in writing within 30 days so that the product can be placed on the market and shall inform the other Member States and the Commission thereof."

4. The following Articles 13a to 13e are inserted:

"Article 13a

1. By way of derogation from the procedures outlined in Articles 11, 12, 13 and 13c, the procedure laid down in Article 13b shall apply to GMOs which meet the criteria and information requirements established according to the following procedure.

2. The Commission, on its own initiative or on the proposal of a competent authority, may adopt criteria and information requirements to be met for the notification of deliberate releases for placing on the market of certain types of GMOs as or in products under the simplified procedure laid down in Article 13b, after consultation of the relevant Scientific Committee(s), in accordance with the procedure laid down in Article 21. The criteria and the information requirements shall be based on safety to human health and/or the environment and on the scientific evidence available on such safety and on the experience gained with the release of comparable GMOs.

3. Before the decision procedure in accordance with Article 21 on a decision for criteria and information requirements referred to in paragraph 2 is initiated, the Commission shall make available to the public this proposal. The public may make comments within 60 days.

Article 13b

1. For GMOs for which the criteria and information requirements have been laid down according to Article 13a(2), the notifier shall submit a notification including a summary of the dossier to the competent authority of the Member States where the product is to be placed on the market for the first time.

2. The competent authority shall respond in writing to the notifier within 15 days of receipt of the notification by either:

   a) indicating that the notification is in compliance with the critieria and information requirements established according to Article 13a and that the notification is accepted to be dealt with under the simplified procedure or

   b) indicating that the notification does not fulfil the conditions for the application of the simplified procedure and that the notification is rejected.

3. In the case where the notification is rejected the competent authority shall inform the Commission and the competent authorities of the other Member States thereof.

4. In cases where the notification is accepted to be dealt with under the simplified procedure, the competent authority shall circulate the notification dossier to the Commission and the competent authorities of the other Member States without delay. Upon receipt the Commission shall make available to the public the summary of the notification dossier.

5. The competent authorities or the Commission may make comments or present reasoned objections to the placing on the market of the GMO(s) in question within a period of 30 days from the date of circulation of the notification dossier. The comments or objections and replies by the notifier 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 45 days from the date of circulation of the notification.

6. In the absence of any reasoned objection from a competent authority of a Member State or the Commission within 30 days following the date of circulation of the notification dossier or if possible outstanding issues are resolved within the 45 day period referred to in paragraph 5, the competent authority that received the original notification shall give its consent in writing within 15 days so that the product can be placed on the market and shall inform the Commission and the competent authorities of the other Member States thereof. The consent shall be granted for a fixed period of seven years.

Article 13c

1. By way of derogation from the procedure outlined in Article 11, 12, 13 and 13b the following procedure shall apply to the renewal of the consent.

2. The notifier shall submit at the latest 12 months before the end of the consent a notification to the Commission which shall contain in particular

   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 13e(2) and
   c) any other new information which has become available with regard to the risks of the product to human health and/or the environment.

3. On receipt of the notification referred to in paragraph 2, the Commission shall immediately forward it to the Competent Authorities of all Member States.

   Comments or reasoned objections to the renewal of the consent shall be forwarded to the Commission within 30 days from the date of submission of the notification. The Commission shall without delay circulate any comments or objections to all competent authorities.

   The competent authorities of the Member States and the Commission may discuss any outstanding issues with the aim of arriving at an agreement within 45 days following the circulation of the notification.

4. In the absence of any reasoned objection from a Member State or the Commission within 30 days following the date of submission referred to in paragraph 3, the competent authority that received the original notification shall give its consent in writing for the renewal of the original consent and shall inform the other Member States and the Commission thereof. The consent shall be granted for a fixed period of seven years.

5. 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 renewal of the consent.

Article 13d

1. In cases where an objection is raised and maintained in accordance with Article 13(2), 13b(5) or 13c(3), or an additional assessment is required in accordance with Article 12(3), the Commission shall take a decision within three months in accordance with the procedure laid down in Article 21.

   For the purpose of calculating the three month 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 a Scientific Committee which has been consulted shall not be taken into account.

2. Where the Commission has taken a favourable decision, the competent authority that received the original notification shall give, within 30 days following the publication of the Commission decision, consent in writing to the notification so that the product may be placed on the market for the period of seven years and shall inform the other Member States and the Commission thereof.

Article 13e

1. Once a product has received a written consent, it may 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. Following the placing on the market of (a) GMO(s) as or in a product, notifier(s) shall carry out monitoring according to the plan referred to in Article 11(2) and the conditions specified in the consent. Regular reports of this monitoring shall be submitted to the Commission and the competent authorities of Member States.

3. Consent to the placing on the market of GMOs in or as a product shall be granted for a fixed period of seven years. 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 13, 13b, 13c and 13d, and in conformity with any conditions, including reference to particular ecosystems/environments, required in that consent.

4. If new information has become available with regard to the risks of the product to human health or the environment, either before or after the written consent, the notifier shall immediately:

   a) revise the information and conditions specified in the notification dossier,
   b) inform the competent authority, and
   c) take the measures necessary to protect human health and the environment

5. If the competent authority receives additional information pursuant to paragraph 4, it shall immediately inform the Commission and the competent authorities of the other Member States.

6. Member States shall take all necessary measures to ensure that users comply with the conditions of use specified in the written consent."

5. Article 14 is replaced by the following:

"Article 14

Member States shall take all necessary measures to ensure that the labelling and packaging of products containing, or consisting of, GMOs comply with relevant proposal in the dossier and with the relevant requirements specified in the written consent referred to in Articles 13(3), 13b(6), 13c(4) or 13d(2)."

6. In Article 15 the words "a deliberate release" are replaced by "the placing on the market".

7. Articles 16, 17 and 18 are replaced by the following:

"Article 16

1. Where a Member State, as a result of new information or reassessment of existing information, has detailed grounds for considering that 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 product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

2. A decision shall be taken on the matter within three months in accordance with the procedure laid down in Article 21.

Article 17

1. Without prejudice to Article 19, upon receipt of a notification in accordance with Article 11(1) the Commission shall immediately make available to the public the summary referred to in Article 11(3). The public may make comments within 30 days. The Commission shall immediately forward the comments to all competent authorities of the Member States.

2. Without prejudice to Article 19, all GMOs which have received written consent for the 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.

3. Without prejudice to Article 19, upon receipt the Commission shall make available to the public the information referred to in Article 9(3) and (4).

Article 18

1. Member States shall send to the Commission, at the end of each year, a brief factual report on the their experience with the GMOs placed on the market in or as products under this Directive.

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

3. When submitting this report for the first time, the Commission shall at the same time submit a specific report on the operation of this Part of this Directive including an assessment of all its implications."

8. In Article 19 paragraph 4 the words "Articles 5 or 11" are replaced by "Articles 6a, 6b, 6c, 6d, 11, 13b or 13c".

9. Article 20 is replaced by the following:

"Article 20

According to the procedure laid down in Article 21, the Commission shall adapt Annexes II to VII to technical progress."

10. The following Article 20a is inserted.

"Article 20a

The relevant Scientific Committee(s) shall be consulted by the Commission on any matter which is likely to have an effect on human health and/or the environment before the decision procedure referred to in Articles 13d(1) or 16(2) is initiated."

11. Article 21 is replaced by the following:

"Article 21

Where the procedure defined in this Article is to be implemented, the Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission, hereinafter referred to as the 'Committee'.

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority."

12. The following articles 22a and 22b are inserted:

"Article 22a

Member States shall determine the sanction arrangements applicable to violations of the national provisions made pursuant to this Directive, and take any measure necessary to ensure their implementation. The sanctions thus envisaged must be effective, proportional and dissuasive. Member States must notify these provisions to the Commission at the latest by .....[the date mentioned in Article 2], and any later modification concerning them as soon as possible.

Article 22b

Before ..... [a date seven years after the date forseen for the transposition according to Article 2], the consents granted for placing on the market of products containing or consisting of GMOs before ..... [the date mentioned in Article 2] shall be renewed according to the procedure outlined in Article 13c."

13. The Annexes are replaced by the Annexes to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than ..... They shall forthwith inform the Commission thereof.

When these measures are adopted by Member States, 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.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at .....

For the European Parliament
The President

For the Council
The President

Annexes

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 IB:

(1) in vitro fertilization,
(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 where the resulting organisms can also be produced by traditional breeding methods.

ANNEX II

Principles for the environmental risk assessment

A. The environmental risk assessment referred to in Articles 6 and 11 shall take into account the following:

1. Elements which may be considered as potentially harmful effects

- pathogenicity to humans, animals or plants
- compromising of prophylactic or therapeutic treatments
- effects on population dynamics within the receiving environment
- effects on geochemistry
- the uncontrolled spread of the GMO(s) in the environment and invasion of unrelated ecosystems
- effects resulting from the transfer of the inserted genetic material to other organisms
- phenotypic and genetic instability

2. Elements which form the basis of the risk assessment:

- the characteristics of the non-modified organism(s) and of the
- introduced trait(s) which give rise to the GMO(s);
- the characteristics of the intended use;
- the receiving environment, and
- the interaction between these

Information from releases of similar organisms and similar traits and their interaction with similar environments can assist the risk assessment.

B. In drawing conclusions for the risk assessment referred to in Articles 6 and 11 the following points should be addressed.

1. Identification of any hazardous characteristics of the GMO(s)

Hazards are intrinsic characteristics of a GMO which have the potential to cause harm, either directly or indirectly. Comparison of the identified hazards of the GMO(s) with those presented by the non-modified organism from which it was derived, under corresponding conditions, will permit identification of those hazards arising from the genetic modification. It is important not to discount any hazard on the basis that it is unlikely to occur.

2. The extent of the consequences of the hazard being realised

For each hazard identified, the consequences of the hazard occurring should be considered. The evaluation of the extent of the consequences is affected by the environment into which the GMO(s) is intended to be released and the manner of the release.

3. The likelihood of the hazard being realised

A major factor in determining the likelihood of a hazard being realised is the characteristics of the environment into which the GMO(s) is intended to be released.

4. Estimation of the risk posed by each identified hazard

On the basis of the hazardous characteristics, the likelihood of them being realised and the magnitude of the consequences a determination of the risk of adverse effects should be made for each hazard identified.

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

If for any release the estimated risk for any identified hazard is not at an acceptable level, the GMO(s) or the conditions of the release should be modified to reduce the risk.

6. Determination of the overall risk of adverse effects

An evaluation of the overall risk of adverse effects, whether direct or indirect, is determined from the combined effects of the risk from each hazard taking into account any management strategies applied.

ANNEX III

INFORMATION REQUIRED IN THE NOTIFICATION

The notification for a deliberate release 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.

Annex III A applies to releases of all types of genetically 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 groups *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 dentification 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. potential for genetic transfer and exchange with other organisms;
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 e.g.: seeds, spores or sclerotia;
(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 colonize 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 mobilization;
(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 mobilization 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) 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) health considerations:
      (i) toxic or allergenic effects of the non-viable GMOs and/or their metabolic products;
      (ii) product hazards;
      (iii) comparison of the modified organism to the donor, recipient or (where

appropriate) parental organism regarding pathogenicity;

(iv) capacity for colonization;

(v) 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.

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 or protected areas;
4. size of local population;
5. economic activities of local populations which are based on the natural resources of the area;
6. distance to closest areas protected for drinking water and/or environmental purpose;
7. climatic characteristics of the region(s) likely to be affected;
8. geographical, geological and pedological characteristics;
9. flora and fauna, including crops, livestock and migratory species;

10. description of target and non-target ecosystems likely to be affected;
11. a comparison of the natural habitat of the recipient organism with the proposed site(s) of release;
12. 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) post-release transfer of genetic material from GMOs into organisms in affected ecosystems;
   (b) post-release transfer of genetic material from indigenous organisms to the GMOs;
4. likelihood of post-release 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 minimize 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.

C. Potential environmental impact:

1. potential for excessive population increase in the environment;
2. competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s);
3. identification and description of the target organisms;
4. anticipated mechanism and result of interaction between the released GMOs and the target organism;
5. identification and description of non-target organisms which may be affected unwittingly;
6. likelihood of post-release shifts in biological interactions or in host range;
7. known or predicted effects on non-target organisms in the environment, impact on population levels of competitors: preys, hosts, symbionts, predators, parasites and pathogens;
8. known or predicted involvement in biogeochemical processes;
9. other potentially significant 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 minimize 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 unauthorized 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. possible risks;
4. 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, e.g. 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 (GMPHS) (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.
3. Survivability:
   (a) ability to form structures for survival or dormancy;
   (b) specific factors affecting survivability, if any.
4. Dissemination:
   (a) ways and extent 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. Potentially significant interactions of the plant with organisms other than plants in the ecosystem where it is usually grown, 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 GMPH or any carrier or foreign DNA remaining in the GMPH;
   (b) in case of deletion, size and function of the deleted region(s);
   (c) location of the insert in the plant cells (integrated in the chromesome, chloroplasts, mitochondria, or maintained in a non-intregated form), and methods for its determination;
   (d) copy number of the insert.
3. Information on the expression of the insert:
   (a) information on the expression of the insert and methods used for its characterization;
   (b) parts of the plant where the insert is expressed (e.g. roots, stem, pollen, etc.).
4. Informationen on how the genetically modified plant differs from the recipient plant in:
   (a) mode(s) and/or rate of replication;
   (b) dissemination;
   (c) survivability.
5. Genetic stability of the insert.
6. Potential for transfer of genetic material from the genetically modified plants to other organisms.
7. Information on any toxic or harmful effects on human health and the environment, arising from the genetic modification.
8. Mechanism of interaction between the genetically modified plant and target organisms (if applicable).
9. Potentially significant interactions with non-target organisms.
10. Description of detection and identification techniques for the genetically modified plant.
11. 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, 6a, 6b and 6c)

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 culivated plant species.
4. Proximity to officially recognized biotopes or protected areas which may be affected.

F. INFORMATION RELATING TO THE RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6, 6a, 6b and 6c)

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 post-release, including cultivation practices and harvesting methods.
5. Approximate number of plants (or plants per m^2).

G. INFORMATION ON CONTROL, MONITORING, POST-RELEASE AND WASTE TREATMENT PLANS (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6, 6a, 6b and 6c)

1. Any precautions taken:
   (a) distance(s) from sexually compatible plant species;
   (b) any measures to minimize/prevent pollen or seed dispersal.
2. Description of methods for post-release treatment of the site.
3. Description of post-release treatment methods for the genetically modified plant material including wastes.
4. Description of monitoring plans and techniques.
5. Description of any emergency plans.

H. INFORMATION ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OF THE GENETICALLY MODIFIED PLANTS

1. Likelihood of the GMPH 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 other sexually compatible plants species,
   which may result from genetic transfer from the genetically modified plant.
3. Potential environmental impact of the interaction between the genetically modified plant and target organisms (if applicable).
4. Possible environmental impact resulting from potential interactions with non-target organisms.

ANNEX IV

ADDITIONAL INFORMATION REQUIRED IN THE CASE OF NOTIFICATION FOR PLACING ON THE MARKET

A. The following information shall be provided in the notification for placing on the market of products, in addition to that of Annex III:

1. name of the product and names of GMOs contained therein;
2. name of the manufacturer or distributor and his address in the Community;
3. specificity of the product, exact conditions of use including, when appropriate, the type of environment and/or the geographical area(s) of the Community for which the product is suited;
4. type of expected use: industry, agriculture and skilled trades, consumer use by public at large.
5. information relating to the introduced genetic modification which could be of relevance to the establishment of a possible register of modifications introduced in organisms (species). This may include nucleotide sequences or other type of information which is relevant to the inclusion in such a register.

B. The following information shall be provided, when relevant, in addition to that of point A, in accordance with Article 11 of this Directive:

1. measures to take in case of unintended release or misuse;
2. specific instructions or recommendations for storage and handling;
3. estimated production in and/or imports to the Community;
4. proposed packaging. This must be appropriate so as to avoid unintended release of the GMOs during storage, or at a later stage;
5. proposed labelling. This must include, at least in summarized form, the information referred to in points A. 1, A. 2, A.3, B. 1 and B. 2

C. The following information concerning labelling shall be provided in the notification, in accordance with Article 11 of this Directive:

1. A Proposal for a mandatory labelling "this product contains GMOs", either on a label or in accompanying document, whenever there is evidence of the presence of GMOs in the product.

2. A Proposal for a mandatory labelling "this product may contain GMOs" where the presence of GMOs in a product cannot be excluded but there is no evidence of any presence of GMOs.

ANNEX V

CRITERIA FOR CLASSIFICATION OF RELEASES PROVIDED FOR IN ARTICLE 6

A. Part B releases shall be classified into category I if they satisfy the criteria set out below

1. The taxonomic status and the biology (e.g. mode of reproduction and pollination, ability to cross with related species) of the non-modified (recipient) organism should be well-known;

2. There should be sufficient knowledge about the safety for human health and the environment of the non-modified (recipient) organism in the environment of the release;

3. The genetically modified organism should not present additional or increased risks to human health and/or the environment under the conditions of the experimental release that are not presented by releases of the corresponding non-modified organism in terms of pathogenicity, allergenicity, toxigenicity. The capacity to spread in the environment and invade other unrelated ecosystems and capacity to transfer genetic material to other organisms in the environment should not create any adverse effect.

B. Part B releases shall also be classified into Category I if the release is similar, in terms of the genetically modified organism(s) involved and the conditions applied, to other releases which have already been given consent to and where the results submitted in accordance with Article 8 have not shown risks to human health and/or the environment.

ANNEX VI

GUIDELINES FOR THE ASSESSMENT REPORTS FORESEEN BY ARTICLE 12

The assessment report foreseen by Article 12 should include in particular the following :

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

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

3. Detailed description of the result of the genetic modification in the modified organism;

4. Identification of any new risks to human health and/or 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 risk assessment as described in Annex II;

5. A conclusion on whether the GMO(s) in question should be placed on the market in or as (a) product(s) and under which conditions or whether an additional assessment is required on certain aspects. The aspects which require additional assessment should be specified.

ANNEX VII

The monitoring plan foreseen by Article 11(2) shall provide for the appropriate methods and measures to identify any relevant direct, indirect, immediate or delayed effects on human health and/or the environment taking into account in particular the following elements, if appropriate:

- human health considerations
  - potential of the GMOs for pathogenic, toxic or allergenic effects
  - capacity of the GMOs for colonization
  - potential of the GMOs to compromise the efficacy of therapeutic, prophylactic or diagnostic measures

- environmental considerations
  - potential of the GMOs to persist and spread in the environment
  - potential of the GMOs for interactions with target or non-target organisms
  - potential of the GMOs to affect population dynamics

- effects resulting from potential horizontal gene transfer
- phenotypic and genetic stability of the GMOs

CONSOLIDATED TEXT

PART A

General provisions

Article 1

1. The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when carrying out the deliberate release of genetically modified organisms into the environment

   a) for research and development purposes or for any other purposes other than placing on the market
   b) for placing on the market of genetically modified organisms as or in products.

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

Article 2

For the purposes of this Directive:

1. 'organism' is any biological entity capable of replication or of transferring genetic material;

2. 'genetically modified organism (GMO)' means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

   Within the terms of this definition:

   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 without provisions for containment such as physical barriers, or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment;

4. 'placing on the market' means supplying or making available to third parties.

5. 'notification' means the presentation of documents containing the requisite information to the competent authority of a Member State. The person making the presentation shall be referred to as 'the notifier';

6. 'environmental risk assessment' means the evaluation of the direct and indirect risks to human health and the environmentwhich the deliberate release of GMOs into the environment may pose.

Article 3

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

Article 4

1. Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release of GMOs. To this end GMOs may only be deliberately released into the environment following an assessment of any potential risks for human health and/or the environment in conformity with part B or part C of this Directive. The risk assessment shall take account of the principles laid down in Annex II.

2. Member States shall designate the competent authority or authorities responsible for carrying out the requirements of this Directive and its Annexes.

3. Member States shall ensure that the competent authority organizes inspections and other control measures as appropriate, to ensure compliance with this Directive.

PART B

Deliberate release of GMOs into the environment for research and development purposes or for any other purpose than for placing on the market

Article 5

Articles 6 to 9 shall not apply to any products under development covered by Community legislation which provides for a specific environmental risk assessment similar to that laid down in those articles.

Article 6

1. Any person, before submitting a notification under Articles 6a, 6b and 6c concerning the release of a GMO or of a combination of GMOs for the purpose of research and development, or for any other purpose than for placing on the market, shall carry out a risk assessment of the deliberate release of GMOs as regards the risks to human health and/or the environment that may occur, taking due account of the information which may be necessary for evaluating any potential risks, whether immediate or delayed, which the release may present for human health and/or the environment. This information is laid down in Annex III.

2. Deliberate releases which fall under this part are classified in 2 categories:

Category I: Deliberate releases of GMOs which comply with the criteria set out in Annex V parts A or B
Category II: All other releases.

Article 6a

1. Any person before undertaking a Category I deliberate release of a GMO or of a combination of GMOs, shall submit a notification to the competent authority referred to in Article 4(2) of the Member State within whose territory the release is to take place.

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

a technical dossier supplying the information on the basis of which the classification of the deliberate release was made. The notification referred to in paragraph 1 shall include a technical dossier supplying the information specified in Annex III necessary for evaluating any foreseeable risks from the deliberate release of a GMO or combination of GMOs, in particular:

a) information relating to the GMO(s),
b) information relating to the conditions of release and the receiving environment,
c) information on the interactions between the GMO(s) and the environment,
d) a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged;

3. The competent authority shall verify the classification into Category I in accordance with the criteria referred to in Article 6(2) and shall examine the dossier for any potential risks to human health and/or the environment. The competent authority shall respond in writing to the notifier within 30 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 the notification is therefore rejected.

4. Before this Directive is implemented, the Commission shall establish in accordance with the procedure laid down in Article 21 the minimum amount of technical information from Annex III to be included in the dossier referred to in paragraph 2.

Article 6b

1. Any person before undertaking a Category II deliberate release of a GMO or of a combination of GMOs, must submit a notification to the competent authority referred to in Article 4(2) of the Member State within whose territory the release is to take place.

2. The notification referred to in paragraph 1 shall include a technical dossier supplying the information specified in Annex III necessary for evaluating any foreseeable risks from the deliberate release of a GMO or combination of GMOs, in particular:

   a) general information including information on personnel and training,
   b) information relating to the GMO(s),
   c) information relating to the conditions of release and the receiving environment,
   d) information on the interactions between the GMO(s) and the environment,
   e) information on monitoring, control, waste treatment and emergency response plans;
   f) a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged;

3. The competent authority, having considered, where appropriate, any observations by other Member States made in accordance with Article 9, 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 the notification is therefore rejected.

4. For the purpose of calculating the 90-day period referred to in paragraph 3, 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 7

   shall not be taken into account.

5. 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

Article 6c

1. In the case of part B releases planned to take place in more than one Member State, the applicant may choose to follow the procedure outlined in the following paragraphs.

2. A notification shall be submitted to the Commission and to the competent authorities of the Member States where the release is to be carried out. The notification shall include a technical dossier supplying the information outlined in Article 6a(2) for deliberate releases under category I or Article 6b(2) for all other releases together with a summary of the technical dossier.

3. Upon receipt of the notification the Commission shall forward the summary of the dossier to the competent authorities of those Member States which have not received the full dossier. The competent authorities may forward comments within 60 days of receipt of the notification to the Commission. The Commission may immediately forward these comments to the competent authorities referred to in paragraph 2.

4. The notifier shall submit any additional information which may have been requested by one of the competent authorities referred to in paragraph 2 to the Commission and all the other competent authorities referred to in paragraph 2.

5. The competent authorities referred to in paragraph 2, having considered any comments by other competent authorities, 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 on their territory or
   b) indicating that the release does not fulfil the conditions of this Directive and the release cannot take place on their territory.

6. For the purpose of calculating the 90-day period referred to in paragraph 5, any periods of time during which the competent authorities

   a) are awaiting further information which it may have requested from the notifier, or
   b) are carrying out a public inquiry or consultation in accordance with Article 7

   shall not be taken into account.

Article 6d

1. In the event of any modification of the deliberate release of GMOs or of a combination of GMOs which could have consequences with regard to potential risks for human health or the environment 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:

   a) revise the measures specified in the notification,
   b) revise the measures specified in the notification, inform the competent authority in advance of any modification or as soon as the new information is available,
   c) take the measures necessary to protect human health and the environment

2. If information becomes available subsequently to the competent authority which could have significant consequences for the risks posed by the release, the competent authority may require the notifier to modify the conditions of, suspend or terminate the deliberate release.

Article 7

Where a Member State considers it appropriate, it may provide that groups or the public shall be consulted on any aspect of the proposed deliberate release.

Article 8

After completion of a release, 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 particular reference to any kind of product that the notifier intends to notify at a later stage.

Article 9

1. The competent authorities shall send to the Commission, within 30 days of its receipt, a summary of each Category II notification received under Article 6b. The format of this summary will be established by the Commission in accordance with the procedure laid down in Article 21.

2. The Commission shall immediately forward these summaries to the other Member States, which may, within 30 days, present observations through the Commission or directly.

3. The competent authorities shall inform the other Member States and the Commission of the final decisions taken in compliance with Article 6b(3) and 6c(5) and of the results of the releases received in accordance with Article 8.

4. Once a year Member States shall send to the Commission and the competent authorities of the other Member States a list of GMOs which have been released on their territory in accordance with Article 6a(3)(a) and a list of notifications that were rejected in accordance with Article 6a(3)(b).

PART C

Placing on the market of products containing GMOs

Article 10

1. Articles 11 to 18 shall not apply to any products covered by Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive.

Article 11

1. Before a GMO or a combination of GMOs are placed on the market as or in a product, a notification shall be submitted to the competent authority of the Member State where such a product is to be placed on the market for the first time. Upon receipt of the notification the competent authority shall without delay forward a copy of the notification to the Commission and 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 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/or the environment;

b) an assessment of any risks for human health and/or the environment related to the GMOs or the combination of GMOs contained in the product, taking due account of the principles laid down in Annex II;

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

d) a detailed plan for monitoring in order to identify any relevant direct, indirect, immediate or delayed effects of the GMOs on human health and/or the environment in accordance with the requirements outlined in Annex VII;

e) a proposal for labelling which shall comply with the requirements laid down in Annex IV and which shall inform the consumer of the presence of GMOs in the product(s) whenever there is evidence that the product(s) contain(s) GMOs.

f) a proposal for packaging which shall comprise the requirements laid down in Annex IV.

If on the basis of the results of any release notified under Part B of this Directive, or on substantive, reasoned scientific grounds, a notifier considers that the placing on the market and use of a product do not pose a risk to human health and the environment, he may propose not to comply with one or more of the requirements of Annex IVB.

3. The notification shall also include a summary of the dossier. The format of the summary shall be established in accordance with the procedure laid down in Article 21.

4. 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.

5. The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing.

6. In order for a GMO or combination of GMOs to be used for a use different than that already specified in a notification, a separate notification shall be submitted.

Article 12

1. On receipt and after acknowledgement of the notification referred to in Article 11, the competent authority shall examine it for compliance with this Directive.

2. At the latest 90 days after receipt of the notification, the competent authority shall forward to the Commission its assessment report.

3. The assessment report shall indicate whether the GMO(s) in question should be placed on the market and under which conditions, if any, or whether additional assessment is required.

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 motivate any request for further information. It shall inform the Commission and the other competent authorities of any additional information submitted by the notifier.

Article 13

1. On receipt of the assessment report referred to in Article 12(2), the Commission shall immediately forward it to the competent authorities of all Member States.

2. In the case of a favourable assessment by the competent authority referred to in paragraph 1, a competent authority designated under Article 4(2) or the Commission may make comments or present reasoned objections to the placing on the market of the GMO(s) in question within a period of 30 days from the date of circulation of the assessment report by the Commission.

   Comments or objections of competent authorities and replies by the notifier 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 60 days from the date of circulation of the assessment report.

3. In the absence of any reasoned objection from another Member State or the Commission within 30 days following the date of distribution of the assessment report or if possible outstanding issues are resolved within the 60 day period referred to in paragraph 2, the competent authority that had originally received and assessed the dossier shall give its consent in writing within 30 days so that the product can be placed on the market and shall inform the other Member States and the Commission thereof.

Article 13a

1. By way of derogation from the procedures outlined in Articles 11, 12, 13 and 13c, the procedure laid down in Article 13b shall apply to GMOs which meet the criteria and information requirements established according to the following procedure.

2. The Commission, on its own initiative or on the proposal of a competent authority, may adopt criteria and information requirements to be met for the notification of deliberate releases for placing on the market of certain types of GMOs as or in products under the simplified procedure laid down in Article 13b, after consultation of the relevant Scientific Committee(s), in accordance with the procedure laid down in Article 21. The criteria and the information requirements shall be based on safety to human health and/or the environment and on the scientific evidence available on such safety and on the experience gained with the release of comparable GMOs.

3. Before the decision procedure in accordance with Article 21 on a decision for criteria and information requirements referred to in paragraph 2 is initiated, the Commission shall make available to the public this proposal. The public may make comments within 60 days.

Article 13b

1. For GMOs for which the criteria and information requirements have been laid down according to Article 13a(2), the notifier shall submit a notification including a summary of the dossier to the competent authority of the Member States where the product is to be placed on the market for the first time.

2. The competent authority shall respond in writing to the notifier within 15 days of receipt of the notification by either:

   a) indicating that the notification is in compliance with the critieria and information requirements established according to Article 13a and that the notification is accepted to be dealt with under the simplified procedure or

   b) indicating that the notification does not fulfil the conditions for the application of the simplified procedure and that the notification is rejected.

3. In the case where the notification is rejected the competent authority shall inform the Commission and the competent authorities of the other Member States thereof.

4. In cases where the notification is accepted to be dealt with under the simplified procedure, the competent authority shall circulate the notification dossier to the Commission and the competent authorities of the other Member States without delay. Upon receipt the Commission shall make available to the public the summary of the notification dossier.

5. The competent authorities or the Commission may make comments or present reasoned objections to the placing on the market of the GMO(s) in question within a period of 30 days from the date of circulation of the notification dossier. The comments or objections and replies by the notifier 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 45 days from the date of circulation of the notification.

6. In the absence of any reasoned objection from a competent authority of a Member State or the Commission within 30 days following the date of circulation of the notification dossier or if possible outstanding issues are resolved within the 45 day period referred to in paragraph 5, the competent authority that received the original notification shall give its consent in writing within 15 days so that the product can be placed on the market and shall inform the Commission and the competent authorities of the other Member States thereof. The consent shall be granted for a fixed period of seven years.

Article 13c

1. By way of derogation from the procedure outlined in Article 11, 12, 13 and 13b the following procedure shall apply to the renewal of the consent.

2. The notifier shall submit at the latest 12 months before the end of the consent a notification to the Commission which shall contain in particular

   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 13e(2) and
   c) any other new information which has become available with regard to the risks of the product to human health and/or the environment.

3. On receipt of the notification referred to in paragraph 2, the Commission shall immediately forward it to the Competent Authorities of all Member States.

   Comments or reasoned objections to the renewal of the consent shall be forwarded to the Commission within 30 days from the date of submission of the notification. The Commission shall without delay circulate any comments or objections to all competent authorities.

   The competent authorities of the Member States and the Commission may discuss any outstanding issues with the aim of arriving at an agreement within 45 days following the circulation of the notification.

4. In the absence of any reasoned objection from a Member State or the Commission within 30 days following the date of submission referred to in paragraph 3, the competent authority that received the original notification shall give its consent in writing for the renewal of the original consent and shall inform the other Member States and the Commission thereof. The consent shall be granted for a fixed period of seven years.

5. 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 renewal of the consent.

Article 13d

1. In cases where an objection is raised and maintained in accordance with Article 13(2), 13b(5) or 13c(3), or an additional assessment is required in accordance with Article 12(3), the Commission shall take a decision within three months in accordance with the procedure laid down in Article 21.

   For the purpose of calculating the three month 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 a Scientific Committee which has been consulted shall not be taken into account.

2. Where the Commission has taken a favourable decision, the competent authority that received the original notification shall give, within 30 days following the publication of the Commission

decision, consent in writing to the notification so that the product may be placed on the market for the period of seven years and shall inform the other Member States and the Commission thereof.

Article 13e

1. Once a product has received a written consent, it may 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. Following the placing on the market of (a) GMO(s) as or in a product, notifier(s) shall carry out monitoring according to the plan referred to in Article 11(2) and the conditions specified in the consent. Regular reports of this monitoring shall be submitted to the Commission and the competent authorities of Member States.

3. Consent to the placing on the market of GMOs in or as a product shall be granted for a fixed period of seven years. 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 13, 13b, 13c and 13d, and in conformity with any conditions, including reference to particular ecosystems/environments, required in that consent.

4. If new information has become available with regard to the risks of the product to human health or the environment, either before or after the written consent, the notifier shall immediately:

   a) revise the information and conditions specified in the notification dossier,
   b) inform the competent authority, and
   c) take the measures necessary to protect human health and the environment

5. If the competent authority receives additional information pursuant to paragraph 4, it shall immediately inform the Commission and the competent authorities of the other Member States.

6. Member States shall take all necessary measures to ensure that users comply with the conditions of use specified in the written consent.

Article 14

Member States shall take all necessary measures to ensure that the labelling and packaging of products containing, or consisting of, GMOs comply with relevant proposal in the dossier and with the relevant requirements specified in the written consent referred to in Articles 13(3), 13b(6), 13c(4) or 13d(2).

Article 15

Member States may not, on grounds relating to the notification and written consent of the placing on the market under this Directive, prohibit, restrict or impede the placing on the market of products containing, or consisting of, GMOs which comply with the requirements of this Directive.

Article 16

1. Where a Member State, as a result of new information or reassessment of existing information, has detailed grounds for considering that 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 product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

2. A decision shall be taken on the matter within three months in accordance with the procedure laid down in Article 21.

Article 17

1. Without prejudice to Article 19, upon receipt of a notification in accordance with Article 11(1) the Commission shall immediately make available to the public the summary referred to in Article 11(3). The public may make comments within 30 days. The Commission shall immediately forward the comments to all competent authorities of the Member States.

2. Without prejudice to Article 19, all GMOs which have received written consent for the 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.

3. Without prejudice to Article 19, upon receipt the Commission shall make available to the public the information referred to in Article 9(3) and (4).

Article 18

1. Member States shall send to the Commission, at the end of each year, a brief factual report on the their experience with the GMOs placed on the market in or as products under this Directive.

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

3. When submitting this report for the first time, the Commission shall at the same time submit a specific report on the operation of this Part of this Directive including an assessment of all its implications.

PART D

Final provisions

Article 19

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 position, that should therefore be treated as confidential. Verifiable justification must be given in such cases.

3. The Competent Authority shall decide, after consultation with the notifier, 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 6a, 6b, 6c, 6d, 11, 13b or 13c be kept confidential:

   - description of the GMO or GMOs, name and address of the notifier, purpose of the release and location of release;

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

   - the evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.

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

Article 20

According to the procedure laid down in Article 21, the Commission shall adapt Annexes II to VII to technical progress.

Article 20a

The relevant Scientific Committee(s) shall be consulted by the Commission on any matter which is likely to have an effect on human health and/or the environment before the decision procedure referred to in Articles 13d(1) or 16(2) is initiated.

Article 21

Where the procedure defined in this Article is to be implemented, the Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission, hereinafter referred to as the 'Committee'.

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

Article 22

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 of GMOs into the environment.

2. Every three years, Member States shall send the Commission a report on the measures taken to implement the provisions of this Directive, the first time being on 1 September 1992.

3. Every three years, the Commission shall publish a summary based on the reports referred to in paragraph 2, the first time being in 1993.

Article 22a

Member States shall determine the sanction arrangements applicable to violations of the national provisions made pursuant to this Directive, and take any measure necessary to ensure their implementation. The sanctions thus envisaged must be effective, proportional and dissuasive. Member States must notify these provisions to the Commission at the latest by .....[the date mentioned in Article 2 of the amending Directive], and any later modification concerning them as soon as possible.

Article 22b

Before ..... [a date seven years after the date forseen for the transposition according to Article 2 of the amending Directive], the consents granted for placing on the market of products containing or consisting of GMOs before ..... [the date mentioned in Article 2 of the amending Directive] shall be renewed according to the procedure outlined in Article 13c.

Article 23

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 23 October 1991.

2. Member States shall immediately inform the Commission of all laws, regulations and administrative provisions adopted in implementation of this Directive.

Article 24

This Directive is addressed to the Member States.

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 IB:

(1) in vitro fertilization,
(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 where the resulting organisms can also be produced by traditional breeding methods.

ANNEX II

Principles for the environmental risk assessment

A. The environmental risk assessment referred to in Articles 6 and 11 shall take into account the following:

1. Elements which may be considered as potentially harmful effects

- pathogenicity to humans, animals or plants
- compromising of prophylactic or therapeutic treatments
- effects on population dynamics within the receiving environment
- effects on geochemistry
- the uncontrolled spread of the GMO(s) in the environment and invasion of unrelated ecosystems
- effects resulting from the transfer of the inserted genetic material to other organisms
- phenotypic and genetic instability

2. Elements which form the basis of the risk assessment:

- the characteristics of the non-modified organism(s) and of the
- introduced trait(s) which give rise to the GMO(s);
- the characteristics of the intended use;
- the receiving environment, and
- the interaction between these

Information from releases of similar organisms and similar traits and their interaction with similar environments can assist the risk assessment.

B. In drawing conclusions for the risk assessment referred to in Articles 6 and 11 the following points should be addressed.

1. Identification of any hazardous characteristics of the GMO(s)

Hazards are intrinsic characteristics of a GMO which have the potential to cause harm, either directly or indirectly. Comparison of the identified hazards of the GMO(s) with those presented by the non-modified organism from which it was derived, under corresponding conditions, will permit identification of those hazards arising from the genetic modification. It is important not to discount any hazard on the basis that it is unlikely to occur.

2. The extent of the consequences of the hazard being realised

For each hazard identified, the consequences of the hazard occurring should be considered. The evaluation of the extent of the consequences is affected by the environment into which the GMO(s) is intended to be released and the manner of the release.

3. The likelihood of the hazard being realised

A major factor in determining the likelihood of a hazard being realised is the characteristics of the environment into which the GMO(s) is intended to be released.

4. Estimation of the risk posed by each identified hazard

On the basis of the hazardous characteristics, the likelihood of them being realised and the magnitude of the consequences a determination of the risk of adverse effects should be made for each hazard identified.

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

If for any release the estimated risk for any identified hazard is not at an acceptable level, the GMO(s) or the conditions of the release should be modified to reduce the risk.

6. Determination of the overall risk of adverse effects

An evaluation of the overall risk of adverse effects, whether direct or indirect, is determined from the combined effects of the risk from each hazard taking into account any management strategies applied.

ANNEX III

INFORMATION REQUIRED IN THE NOTIFICATION

The notification for a deliberate release 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.

Annex III A applies to releases of all types of genetically 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 groups *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 dentification 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. potential for genetic transfer and exchange with other organisms;
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 e.g.: seeds, spores or sclerotia;
(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 colonize 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 mobilization;
(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 mobilization 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) 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) health considerations:
      (i) toxic or allergenic effects of the non-viable GMOs and/or their metabolic products;
      (ii) product hazards;
      (iii) comparison of the modified organism to the donor, recipient or (where

appropriate) parental organism regarding pathogenicity;

(iv) capacity for colonization;

(v) 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.

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 or protected areas;
4. size of local population;
5. economic activities of local populations which are based on the natural resources of the area;
6. distance to closest areas protected for drinking water and/or environmental purpose;
7. climatic characteristics of the region(s) likely to be affected;
8. geographical, geological and pedological characteristics;
9. flora and fauna, including crops, livestock and migratory species;

10. description of target and non-target ecosystems likely to be affected;
11. a comparison of the natural habitat of the recipient organism with the proposed site(s) of release;
12. 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) post-release transfer of genetic material from GMOs into organisms in affected ecosystems;
   (b) post-release transfer of genetic material from indigenous organisms to the GMOs;
4. likelihood of post-release 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 minimize 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.

C. Potential environmental impact:

1. potential for excessive population increase in the environment;
2. competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s);
3. identification and description of the target organisms;
4. anticipated mechanism and result of interaction between the released GMOs and the target organism;
5. identification and description of non-target organisms which may be affected unwittingly;
6. likelihood of post-release shifts in biological interactions or in host range;
7. known or predicted effects on non-target organisms in the environment, impact on population levels of competitors: preys, hosts, symbionts, predators, parasites and pathogens;
8. known or predicted involvement in biogeochemical processes;
9. other potentially significant 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 minimize 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 unauthorized 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. possible risks;
4. 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, e.g. 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 (GMPHS) (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.
3. Survivability:
   (a) ability to form structures for survival or dormancy;
   (b) specific factors affecting survivability, if any.
4. Dissemination:
   (a) ways and extent 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. Potentially significant interactions of the plant with organisms other than plants in the ecosystem where it is usually grown, 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 GMPH or any carrier or foreign DNA remaining in the GMPH;
   (b) in case of deletion, size and function of the deleted region(s);
   (c) location of the insert in the plant cells (integrated in the chromesome, chloroplasts, mitochondria, or maintained in a non-intregated form), and methods for its determination;
   (d) copy number of the insert.
3. Information on the expression of the insert:
   (a) information on the expression of the insert and methods used for its characterization;
   (b) parts of the plant where the insert is expressed (e.g. roots, stem, pollen, etc.).
4. Informationen on how the genetically modified plant differs from the recipient plant in:
   (a) mode(s) and/or rate of replication;
   (b) dissemination;
   (c) survivability.
5. Genetic stability of the insert.
6. Potential for transfer of genetic material from the genetically modified plants to other organisms.
7. Information on any toxic or harmful effects on human health and the environment, arising from the genetic modification.
8. Mechanism of interaction between the genetically modified plant and target organisms (if applicable).
9. Potentially significant interactions with non-target organisms.
10. Description of detection and identification techniques for the genetically modified plant.
11. 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, 6a, 6b and 6c)

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 culivated plant species.
4. Proximity to officially recognized biotopes or protected areas which may be affected.

F. INFORMATION RELATING TO THE RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6, 6a, 6b and 6c)

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 post-release, including cultivation practices and harvesting methods.
5. Approximate number of plants (or plants per m^2).

G. INFORMATION ON CONTROL, MONITORING, POST-RELEASE AND WASTE TREATMENT PLANS (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6, 6a, 6b and 6c)

1. Any precautions taken:
   (a) distance(s) from sexually compatible plant species;
   (b) any measures to minimize/prevent pollen or seed dispersal.
2. Description of methods for post-release treatment of the site.
3. Description of post-release treatment methods for the genetically modified plant material including wastes.
4. Description of monitoring plans and techniques.
5. Description of any emergency plans.

H. INFORMATION ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OF THE GENETICALLY MODIFIED PLANTS

1. Likelihood of the GMPH 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 other sexually compatible plants species,
   which may result from genetic transfer from the genetically modified plant.
3. Potential environmental impact of the interaction between the genetically modified plant and target organisms (if applicable).
4. Possible environmental impact resulting from potential interactions with non-target organisms.

ANNEX IV

ADDITIONAL INFORMATION REQUIRED IN THE CASE OF NOTIFICATION FOR PLACING ON THE MARKET

A. The following information shall be provided in the notification for placing on the market of products, in addition to that of Annex III:

1. name of the product and names of GMOs contained therein;
2. name of the manufacturer or distributor and his address in the Community;
3. specificity of the product, exact conditions of use including, when appropriate, the type of environment and/or the geographical area(s) of the Community for which the product is suited;
4. type of expected use: industry, agriculture and skilled trades, consumer use by public at large.
5. information relating to the introduced genetic modification which could be of relevance to the establishment of a possible register of modifications introduced in organisms (species). This may include nucleotide sequences or other type of information which is relevant to the inclusion in such a register.

B. The following information shall be provided, when relevant, in addition to that of point A, in accordance with Article 11 of this Directive:

1. measures to take in case of unintended release or misuse;
2. specific instructions or recommendations for storage and handling;
3. estimated production in and/or imports to the Community;
4. proposed packaging. This must be appropriate so as to avoid unintended release of the GMOs during storage, or at a later stage;
5. proposed labelling. This must include, at least in summarized form, the information referred to in points A. 1, A. 2, A.3, B. 1 and B. 2

C. The following information concerning labelling shall be provided in the notification, in accordance with Article 11 of this Directive:

1. A Proposal for a mandatory labelling "this product contains GMOs", either on a label or in accompanying document, whenever there is evidence of the presence of GMOs in the product.

2. A Proposal for a mandatory labelling "this product may contain GMOs" where the presence of GMOs in a product cannot be excluded but there is no evidence of any presence of GMOs.

ANNEX V

CRITERIA FOR CLASSIFICATION OF RELEASES PROVIDED FOR IN ARTICLE 6

A. Part B releases shall be classified into category I if they satisfy the criteria set out below

1. The taxonomic status and the biology (e.g. mode of reproduction and pollination, ability to cross with related species) of the non-modified (recipient) organism should be well-known;

2. There should be sufficient knowledge about the safety for human health and the environment of the non-modified (recipient) organism in the environment of the release;

3. The genetically modified organism should not present additional or increased risks to human health and/or the environment under the conditions of the experimental release that are not presented by releases of the corresponding non-modified organism in terms of pathogenicity, allergenicity, toxigenicity. The capacity to spread in the environment and invade other unrelated ecosystems and capacity to transfer genetic material to other organisms in the environment should not create any adverse effect.

B. Part B releases shall also be classified into Category I if the release is similar, in terms of the genetically modified organism(s) involved and the conditions applied, to other releases which have already been given consent to and where the results submitted in accordance with Article 8 have not shown risks to human health and/or the environment.

ANNEX VI

GUIDELINES FOR THE ASSESSMENT REPORTS FORESEEN BY ARTICLE 12

The assessment report foreseen by Article 12 should include in particular the following :

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

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

3. Detailed description of the result of the genetic modification in the modified organism;

4. Identification of any new risks to human health and/or 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 risk assessment as described in Annex II;

5. A conclusion on whether the GMO(s) in question should be placed on the market in or as (a) product(s) and under which conditions or whether an additional assessment is required on certain aspects. The aspects which require additional assessment should be specified.

ANNEX VII

The monitoring plan foreseen by Article 11(2) shall provide for the appropriate methods and measures to identify any relevant direct, indirect, immediate or delayed effects on human health and/or the environment taking into account in particular the following elements, if appropriate:

- human health considerations
  - potential of the GMOs for pathogenic, toxic or allergenic effects
  - capacity of the GMOs for colonization
  - potential of the GMOs to compromise the efficacy of therapeutic, prophylactic or diagnostic measures

- environmental considerations
  - potential of the GMOs to persist and spread in the environment
  - potential of the GMOs for interactions with target or non-target organisms
  - potential of the GMOs to affect population dynamics

- effects resulting from potential horizontal gene transfer
- phenotypic and genetic stability of the GMOs

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