►B DIRECTIVE 2001/18/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

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

of 12 March 2001

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

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

Whereas:

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

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

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

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

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

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

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

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

(9) Respect for ethical principles recognised in a Member State is particularly important. Member States may take into considera-

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

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tion ethical aspects when GMOs are deliberately released or placed on the market as or in products.

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

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

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

(13) The content of this Directive duly takes into account international experience in this field and international trade commitments and should respect the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. As soon as possible, and in any case before July 2001, the Commission should, in the context of the ratification of the Protocol, submit the appropriate proposals for its implementation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(31) Part C of this Directive does not apply to products covered by Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal

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

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Products [1], provided that it includes an environmental risk assessment equivalent to that provided for by this Directive.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(61) In order to increase the effective implementation of the provisions adopted under this Directive it is appropriate to provide

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

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for penalties to be applied by Member States, including in the event of release or placing on the market contrary to the provisions of this Directive, particularly as a result of negligence.

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

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

HAVE ADOPTED THIS DIRECTIVE:

PART A

GENERAL PROVISIONS

Article 1

Objective

In accordance with the precautionary principle, 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 into the environment of genetically modified organisms for any other purposes than placing on the market within the Community,

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

Article 2

Definitions

For the purposes of this Directive:

(1) ‘organism’ means any biological entity capable of replication or of transferring genetic material;

(2) ‘genetically modified organism (GMO)’ means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;

Within the terms of this definition:

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

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

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

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

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

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

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

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

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

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

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

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

Article 3

Exemptions

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

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

Article 4

General obligations

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

2. Any person shall, before submitting a notification under part B or part C, carry out an environmental risk assessment. The information which may be necessary to carry out the environmental risk assessment is laid down in Annex III. Member States and the Commission shall ensure that GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment are taken into particular consideration when carrying out an environmental risk assessment, with a view to identifying and phasing out antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment. This phasing out shall take place by the 31 December 2004 in the case of GMOs placed on the market according to part C and by 31 December 2008 in the case of GMOs authorised under part B.

3. Member States and where appropriate the Commission shall ensure that potential adverse effects on human health and the environment, which may occur directly or indirectly through gene transfer

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

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from GMOs to other organisms, are accurately assessed on a case-by-case basis. This assessment shall be conducted in accordance with Annex II taking into account the environmental impact according to the nature of the organism introduced and the receiving environment.

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

5. Member States shall ensure that the competent authority organises inspections and other control measures as appropriate, to ensure compliance with this Directive. In the event of a release of GMO(s) or placing on the market as or in products for which no authorisation was given, the Member State concerned shall ensure that necessary measures are taken to terminate the release or placing on the market, to initiate remedial action if necessary, and to inform its public, the Commission and other Member States.

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

PART B

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

Article 5

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

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

(b) for explicit consent prior to release;

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

(d) in an appropriate manner for requirements relating to treatment of new items of information, information to the public, information on the results of releases, and exchanges of information at least equivalent to those contained in this Directive and in the measures taken in accordance therewith.

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

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

Article 6

Standard authorisation procedure

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

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

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

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

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

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

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

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

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

(vii) a summary of the dossier;

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

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

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

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

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

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

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

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

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

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

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

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

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Article 7

Differentiated procedures

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

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

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

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

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

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

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

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

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

(d) the environmental risk assessment.

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

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

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

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

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

Article 8

Handling of modifications and new information

1. In the event of any modification of, or unintended change to, the deliberate release of a GMO or of a combination of GMOs which could have consequences with regard to risks for human health and the environment after the competent authority has given its written consent, or if

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

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

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

(c) revise the measures specified in the notification.

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

Article 9

Consultation of and information to the public

1. Member States shall, without prejudice to the provisions of Articles 7 and 25, consult the public and, where appropriate, groups on the proposed deliberate release. In doing so, Member States shall lay down arrangements for this consultation, including a reasonable time-period, in order to give the public or groups the opportunity to express an opinion.

2. Without prejudice to the provisions of Article 25:

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

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

Article 10

Reporting by notifiers on releases

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

Article 11

Exchange of information between competent authorities and the Commission

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

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

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3. The competent authorities shall inform the Commission of the final decisions taken in compliance with Article 6(5), including where relevant the reasons for rejecting a notification, and of the results of the releases received in accordance with Article 10.

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

PART C

PLACING ON THE MARKET OF GMOs AS OR IN PRODUCTS

Article 12

Sectoral legislation

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

2. As far as Council Regulation (EEC) No 2309/93 is concerned, Articles 13 to 24 of this Directive shall not apply to any GMO as or in products as far as they are authorised by that Regulation provided that a specific environmental risk assessment is carried out in accordance with the principles set out in Annex II to this Directive and on the basis of the type of information specified in Annex III to this Directive without prejudice to other relevant requirements as regards risk assessment, risk management, labelling, monitoring as appropriate, information to the public and safeguard clause provided by Community legislation concerning medicinal products for human and veterinary use.

3. Procedures ensuring that the risk assessment, requirements regarding risk management, labelling, monitoring as appropriate, information to the public and safeguard clause are equivalent to those laid down in this Directive shall be introduced, in a Regulation of the European Parliament and of the Council. Future sectoral legislation based on the provisions of that Regulation shall make a reference to this Directive. Until the Regulation enters into force, any GMO as or in products as far as they are authorised by other Community legislation shall only be placed on the market after having been accepted for placing on the market in accordance with this Directive.

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

Article 13

Notification procedure

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

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

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

2. The notification shall contain:

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

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

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

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

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

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

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

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

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

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

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

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

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

Article 14

Assessment report

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

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

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

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

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

3. The assessment report shall indicate whether:

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

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

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

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

Article 15

Standard procedure

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

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

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

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

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

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

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

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

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

Article 16

Criteria and information for specified GMOs

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

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

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

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

Article 17

Renewal of consent

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

(a) consents granted under part C; and

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

2. At the latest nine months before the expiry of the consent, for the consents referred to in paragraph 1(a), and before 17 October 2006, for the consents referred to in paragraph 1(b), the notifier under this

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

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

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

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Article shall submit a notification to the competent authority which received the original notification, which shall contain:

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

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

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

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

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

3. The assessment report shall indicate whether:

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

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

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

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

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

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

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

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

Article 18

Community procedure in case of objections

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

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

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

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

Article 19

Consent

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

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

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

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

(b) the period of validity of the consent;

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

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

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

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

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

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Article 20

Monitoring and handling of new information

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

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

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

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

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

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

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

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

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

Article 21

Labelling

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

2. For products where adventitious or technically unavoidable traces of authorised GMOs cannot be excluded, a minimum threshold may be

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established below which these products shall not have to be labelled according to the provision in paragraph 1. The threshold levels shall be established according to the product concerned, under the procedure laid down in Article 30(2).

Article 22

Free circulation

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

Article 23

Safeguard clause

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

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

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

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

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

Article 24

Information to the public

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

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

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PART D

FINAL PROVISIONS

Article 25

Confidentiality

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

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

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

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

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

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

— environmental risk assessment.

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

Article 26

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

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

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

Article 27

Adaptation of Annexes to technical progress

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

Article 28

Consultation of Scientific Committee(s)

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

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relevant Scientific Committee(s) shall be consulted by the Commission, on its own initiative or at the request of a Member State, on the objection.

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

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

Article 29

Consultation of Committee(s) on Ethics

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

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

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

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

Article 30

Committee procedure

1. The Commission shall be assisted by a committee.

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

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

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

Article 31

Exchange of information and reporting

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

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

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

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

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

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

— be notified to the competent authorities, and

— be made known to the public

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

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

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

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

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

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

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

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

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

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

Article 32

Implementation of the Cartagena Protocol on biosafety

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

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

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Article 33

Penalties

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

Article 34

Transposition

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

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

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

Article 35

Pending notifications

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

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

Article 36

Repeal

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

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

Article 37

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

Article 38

This Directive is addressed to the Member States.

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ANNEX I A

TECHNIQUES REFERRED TO IN ARTICLE 2(2)

PART 1

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

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

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

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

PART 2

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

(1) in vitro fertilisation,

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

(3) polyploidy induction.

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ANNEX I B

TECHNIQUES REFERRED TO IN ARTICLE 3

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

(1) mutagenesis,

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

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ANNEX II

PRINCIPLES FOR THE ENVIRONMENTAL RISK ASSESSMENT

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

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

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

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

  Observations of indirect effects are likely to be delayed;

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

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

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

A. Objective

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

B. General Principles

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

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

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

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

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

  — determine whether the risk has changed;

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

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C. **Methodology**

C.1. Characteristics of GMOs and releases

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

— the recipient or parental organism(s);

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

— the GMO;

— the intended release or use including its scale;

— the potential receiving environment; and

— the interaction between these.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

— phenotypic and genetic instability,

— interactions with other organisms,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Likelihood of the GMO to become persistent and invasive in natural habitats under the conditions of the proposed release(s).
2. Any selective advantage or disadvantage conferred to the GMO and the likelihood of this becoming realised under the conditions of the proposed release(s).
3. Potential for gene transfer to other species under conditions of the proposed release of the GMO and any selective advantage or disadvantage conferred to those species.
4. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO and target organisms (if applicable).
5. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO with non-target organisms, including impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.
6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMO and persons working with, coming into contact with or in the vicinity of the GMO release(s).
7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any product derived from it, if it is intended to be used as animal feed.
8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).
9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific techniques used for the management of the GMO where these are different from those used for non-GMOs.

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

1. Likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.
2. Any selective advantage or disadvantage conferred to the GMHP.

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3. Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species.
4. Potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable).
5. Possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens.
6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with or in the vicinity of the GMHP release(s).
7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed.
8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).
9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.

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GUIDANCE NOTES ON THE OBJECTIVE, ELEMENTS, GENERAL PRINCIPLES AND METHODOLOGY OF THE ENVIRONMENTAL RISK ASSESSMENT REFERRED TO IN ANNEX II TO DIRECTIVE 2001/18/EC

1. INTRODUCTION

Environmental risk assessment (ERA) is defined in Article 2(8) of Directive 2001/18/EC as 'the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose'. As one of the general obligations under the Directive, Article 4(3) requires Member States and, where appropriate, the Commission to ensure that potential adverse effects on human health and the environment, which may occur in particular directly or indirectly, are accurately assessed on a case-by-case basis taking into account the environmental impact according to the nature of the organism introduced and the receiving environment. ERA is carried out in accordance with Annex II to the Directive, and is also referred to in Parts B and C thereof. Annex II describes in general terms the objective to be achieved, the elements to be considered and the general principles and methodology to be followed to perform the ERA, taking into account the impact on human health and the environment according to the nature of the organism introduced and the receiving environment.

Notifiers must submit a notification including an ERA for deliberate release under Article 6(2) or for placing on the market under Article 13(2).

This guidance note supplements Annex II to Directive 2001/18/EC and outlines the objectives and principles as well as the methodology for the ERA, in order to assist notifiers, to facilitate the performance by the competent authorities of a comprehensive and appropriate ERA under Directive 2001/18/EC and to make the process of ERA transparent to the general public.

The six steps in the ERA are set out in Chapter 4.2.

2. OBJECTIVE

In accordance with Annex II to Directive 2001/18/EC, *the objective of an ERA is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or placing on the market of GMOs may have. The ERA should be conducted with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used* [1].

The ERA therefore covers deliberate release (Part B) and placing on the market (Part C) as referred to in Directive 2001/18/EC. Placing on the market very often, but not necessarily, includes deliberate release into the environment, but is always an intentional introduction on the market (for example, agricultural products containing or consisting of GMOs, only for the use of food, feed and processing). In these cases too an ERA has to be included in the notification process. In general there may be a difference between the ERA for deliberate release and that for placing on the market, due, for example, to the differences in existing data, time-scale and area.

In addition, these guidance notes cover all GMOs, including microorganisms, plants and animals. Although so far most GMOs deliberately released or placed on the market are higher plants, this may change in future.

The ERA will serve as the basis for identifying the need for risk management and, if so, the most appropriate methods to be used, and for focused monitoring (see Chapter 3).

The overall case-by-case assessment covers the GMO(s) concerned (GMO-by-GMO assessment) and the environment(s) in which the GMO is to be released (for example, site-by-site assessment and region-by-region assessment, if applicable).

Future developments in genetic modification may make it necessary to adapt Annex II and these guidance notes to technical progress. Further differentiation of information requirements for different types of GMOs, like single cell organisms, fish or insects, or for particular uses of GMOs, like the development of vaccines, may be possible once there is sufficient experience with notifications for the release of particular GMOs in the Community (Annex III, fourth paragraph, and Chapter 6).

Risk assessment of the use of antibiotic resistance marker genes is a very specific issue and further guidance on this item may be recommended.

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[1] The text in italics is taken directly from Annex II to Directive 2001/18/EC.

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Different 'effect categories' of GMOs on human health or the environment are described in Annex II to Directive 2001/18/EC. In the interests of a common interpretation, the definitions given in the Directive of the following terms are illustrated as follows:

— *'direct effects' refers to primary effects on human health or the environment which are a result of the GMO itself and which do not occur through a causal chain of events* (for example, the direct effect of the Bt toxin on target organisms, or the pathogenic effect of a GM microorganism on human health),

— *'indirect effects' refers to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management; observations of indirect effects are likely to be delayed* (for example, where reducing the target population of insects affects the population of other insects, or where the development of multiple resistance or systemic effects will require assessment of long-term interaction; however, some indirect effects such as reductions in usage of pesticides could be immediate),

— *'immediate effects' refers to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect* (for example, death of insects foraging on transgenic plants that have pest-resistant traits, or the induction of allergies in susceptible humans due to exposure to a particular GMO),

— *'delayed effects' refers to effects on human health or the environment, which may not be observed during the period of the release of the GMO but become apparent as a direct or indirect effect either at a later stage or after termination of the release* (for example, establishment or invasive behaviour of a GMO after several generations following deliberate release, which is very important if the GMO lives for a long time, for example, genetically modified tree species; or hybrids of close relatives of a transgenic crop becoming invasive in natural ecosystems).

The delayed effects in particular may be difficult to determine, especially if they become apparent only in the long term. Appropriate measures such as monitoring (see below) can help in detecting these effects.

3. **GENERAL PRINCIPLES**

In accordance with the precautionary principle, the ERA should be based on the following general principles:

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

A baseline of the receiving environment, including its organisms and their interactions and their known variations, should be determined before any (harmful) characteristics of the GMO can be identified. The baseline serves as a point of reference against which future changes can be compared. For example, in the case of vegetatively propagated crops, comparative analysis should include the parental species used to generate the transgenic lines. In the case of crops that reproduce sexually, comparators would include appropriate isogenic lines. If crops are developed using back-crossing, it is important that in such cases substantial equivalence testing uses the most appropriate controls and does not simply rely on comparisons with original parental material.

If the existing data are not sufficient, a baseline has to be defined on other references to allow a comparison. The baseline will depend to a considerable extent on the receiving environment, including biotic and abiotic factors (for example, natural preserved habitats, agricultural farmland or contaminated land) or a combination of different environments.

— *The ERA should be carried out in a scientifically sound and transparent manner based on available scientific and technical data.*

Evaluation of potential adverse effects should be based on scientific and technical data and on common methodology for the identification, gathering and interpretation of the relevant data. Data, measurements and tests should be clearly described. In addition, the use of scientifically sound modelling procedures could provide missing data useful for ERA.

ERA has to take into account uncertainty at various levels. Scientific uncertainty results usually from five characteristics of the scientific method: the variable chosen, the measurements made, the samples taken, the models used and the causal relationships employed. Scientific uncertainty may also arise from a controversy on existing data or lack of some relevant data. Uncertainty may relate to qualitative or quantitative elements of the analysis. The level of knowledge or data for a baseline is reflected by the level of uncertainty, which has to be provided by the notifier (assessment of uncer-

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tainty, including lack of data, knowledge gaps, standard deviation, complexity, etc.) in comparison with the scientific uncertainties in current practice.

The ERA may not always result in definitive answers to all the questions considered because of lack of data. For potential long-term effects, in particular, the availability of data may be very low. In these cases in particular appropriate risk management (safeguards) has to be considered in accordance with the precautionary principle in order to prevent adverse effects on human health and the environment.

As a general principle, the ERA should include the results of adequate research into the potential risks involved in the deliberate release or placing on the market of GMOs, along with any clearly documented comparable experience.

Use of the step-by-step approach (i.e. all the steps beginning with experiments in the contained use system through deliberate release up to placing on the market) can be useful. Data from each step should be collected as early as possible during the procedure. Simulated environmental conditions in a contained system could give results of relevance to deliberate release (for example, the behaviour of microorganisms can be simulated in microcosms, or the behaviour of plants can be simulated in greenhouses to a certain extent).

For GMOs to be placed on the market, relevant and available data from deliberate releases should be provided from the types of environment where the GMO will be used.

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

The ERA should use the case-by-case principle because of the broad range of individual characteristics of different organisms (GMO by GMO) and different environments (site by site and region by region).

There may be a huge variety in the environmental effects of genetically modified microorganisms (because of their small size and their often unknown interactions), plants (for example, higher plants used for food and feed, or trees because of their potential longevity), and animals (for example, insects because of their small size and their high potential for overcoming barriers; or saltwater fish because of their high distribution potential).

Moreover, there may be a broad range of environmental characteristics (site-specific or regional-specific) to be taken into account. To support a case-by-case assessment, it may be useful to classify regional data by habitat area, reflecting aspects of the receiving environment relevant to GMOs (for example, botanical data on the occurrence of wild relatives of GMO plants in different agricultural or natural habitats of Europe).

The notifier must also take into account potentially harmful interactions of the GMO with any relevant GMOs that may have been deliberately released or placed on the market in the past, including repeated releases of the same GMO, such as the use of plant protection products. Repeated releases, as compared to occasional releases, might in time cause a high background level of the GMO to become permanent in the environment.

If new information on the GMO and its effects on human health or the environment becomes available, the ERA may need to be re-addressed in order to:

— determine whether the risk has changed,

— determine whether there it is necessary to amend the risk management accordingly.

In the case of new information, irrespective of whether immediate measures need to be taken, there may have to be a new ERA to assess the need to change the terms of authorisation for the GMO's release or placing on the market, or to adjust risk management measures (see also Chapter 6). New information can arise from research or from monitoring plans, or from relevant experience elsewhere.

ERA and monitoring are closely linked. The ERA provides the basis for the monitoring plans, which focus on adverse effects on human health and the environment. The requirements for the monitoring plans for the deliberate release of GMOs (Part B in accordance with the relevant parts of Annex III) and the placing on the market of GMOs (Part C in accordance with Annex VII) are different. The Part C monitoring, including general surveillance, may also play an important role in providing data for long-term, potentially adverse effects of GMOs. Monitoring results may confirm the ERA or may lead to re-evaluation of the ERA.

— *A general principle for ERA is also that an analysis of the 'cumulative long-term effects' relevant to the release and the placing on the market is to be carried out. 'Cumulative long-term effects' refers to the accumulated effects of consents on human health and the environment, including flora and*

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fauna, soil fertility, soil degradation of organic material, the feed/food chain, biological diversity, animal health and resistance problems in relation to antibiotics.

In considering the potential cumulative long-term effects, the ERA should take into account issues such as:

— the long-term interactions of the GMO and the receiving environment,

— the characteristics of a GMO which become important on a long-term basis,

— repeated deliberate releases or placings on the market over a long period,

— the GMOs deliberately released or placed on the market in the past.

Further information may be required on long-term effects in particular (for instance, multiple herbicide resistances) and there must be adequate research, partly within the framework of the monitoring plans, which can provide important data for assessing cumulative long-term effects. Further guidance on this item may be recommended.

4. **METHODOLOGY**

4.1. **Characteristics of GMOs and releases**

The ERA has to take into account the relevant technical and scientific details regarding characteristics of:

— the recipient or parental organism(s),

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

— the GMO,

— the intended release or use including its scale,

— the potential receiving environment, and

— the interaction between these.

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

Prior to deliberate release of a GMO or a combination of GMOs under Part B or to the placing on the market under Part C of the Directive, a notification including the information set out in Annexes IIIA and IIIB to the Directive (information on the GMO, the donor, the recipient, the vector, the conditions of the release and the environment, the interactions between the GMOs and the environment and of monitoring GMOs) should be submitted to the competent authority of the Member State where the release or the placing on the market is to take place for the first time.

Those notifications should contain a technical dossier of information including a full ERA in accordance with Article 6(2) and Article 13(2) of the Directive, the amount of detail needed to substantiate any point depending on its importance in the ERA. Notifiers shall provide bibliographic references and indicate the methods used.

The information on recipient, donor, vector, genetic modification and the GMO, on the basis of information requested in Annexes IIIA and IIIB to the Directive, is independent of the environment in which the GMO is to be experimentally released or placed on the market, and the conditions under which it will be experimentally released or marketed. This information is the basis for identifying any potential harmful characteristics (potential hazards) of the GMO. Knowledge and experience gained in releases of the same or similar GMOs may provide important information on the potential hazards of the release in question.

Information on intended release, receiving environment and interaction between these, as requested in Annexes IIIA and IIIB to the Directive relates to the particular environment into which the GMO will be released, and the conditions, including the scale of the release. This information will determine the extent of any potentially harmful characteristics of the GMO.

4.2. **Steps in the analysis of ERA**

In drawing conclusions for the ERA referred to in Articles 4, 6, 7 and 13 of Directive 2001/18/EC, the following points should be addressed as main steps in the ERA.

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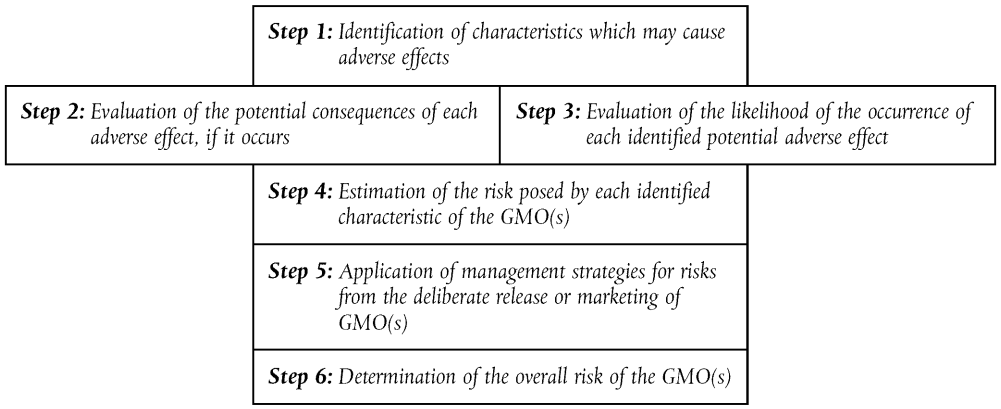
Diagram 1: The six steps in the analysis of ERA



A 'hazard' (harmful characteristics) is defined as the potential of an organism to cause harm to or adverse effects on human health and/or the environment.

A 'risk' is the combination of the magnitude of the consequences of a hazard, if it occurs, and the likelihood that the consequences occur.

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

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

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

— disease to humans including allergenic or toxic effects,

— disease to animals and plants including toxic, and where appropriate, allergenic effects,

— effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations,

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

— compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine,

— effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material.

Examples of the above potential adverse effects are given in Annexes IIIA and IIIB to Directive 2001/18/EC.

Most of the identifiable hazards (harmful characteristics) which may cause adverse effects will be related to the gene or genes of interest, deliberately introduced into the GMO and the corresponding protein(s) being expressed from these genes. Additional adverse effects, for example, pleiotropic effects, might have been generated as a result of the method used to create the transgenes, and of the location of the construction in the genome of the GMO where the transgenes were inserted. Where more than one transgene is transferred into a recipient or where a transgene is transferred into a GMO, the potential interaction of the different transgenes has to be taken into account considering potentially epigenetic or regulatory effects.

While it is important to define the hazard as accurately as possible, it will, in many cases, be useful to consider hazards under the headings set out below, and then to specify the particular hazard identified for the purposes of ERA (for example, if in a specific case a potential for adverse effects on human health — allergenicity and toxigenicity — were identified, these should be considered separately in the ERA).

If a hazard is present in the GMO, it is always present and it can be regarded as an inherent property. Hazards can give rise — with a given likelihood (step 3) — to negative consequences and these consequences in turn can have different

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orders of magnitude (step 2). Finally, the individual hazards have to be summarised for the GMO.

At this stage of the ERA, however, it is only necessary to consider the hazards introduced as a result of genetic modification that could cause adverse effects. Step 1 provides the scientific basis for the following steps in the ERA. Even at this stage, it is critical to identify, for each potential hazard, the specific level of scientific uncertainty so that it can be taken into account at a later stage.

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

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

Distribution pathways show the potential pathways of distribution of the GMO or of the potential hazard into and within the environment (for example, human toxicity: inhalation of toxic microorganisms or toxic proteins).

The potential of a GMO to spread into the environment will depend, for example, on:

— its biological fitness (GMOs designed for better performance in the environment of interest by the expression of traits leading to increased competitiveness in natural environments, or qualitative and quantitative change in composition of ingredients, or GMOs with resistance to natural selection pressure like disease, or abiotic stress like heat, cold, salt, or production of anti-microbial substances in microorganisms),

— the conditions of the deliberate release or placing on the market (particularly the area of release and the scale, that is to say, the number of GMOs released),

— the likelihood of a deliberate release or placing on the market, or unintentional releases into the environment (for example, GMOs for processing),

— pathways of dispersal of viable material (for example, seeds, spores and so on) by wind, water, animals, etc.,

— particular environmental considerations (site-specific or regional-specific): to allow a site-by-site or a region-by-region assessment it may be useful to classify data by habitat area, reflecting aspects of the receiving environment relevant to the GMO (for example, botanical data on the occurrence of crossable wild relatives of GMO plants in different agricultural or natural habitats of Europe).

It is also important to assess the length of time an individual GMO or a specific number of GMOs of a certain species is generally likely to survive, and the readiness with which it can be disseminated and become established in a variety of habitats. Consideration will need to be given to reproductive, survival and dormant forms, including, for example:

— for plants: the viability of pollen, seeds and vegetative structures,

— for microorganisms: the viability of spores as survival forms, or the potential of the microorganisms to enter the viable but not cultivable state.

The overall spread potential may vary considerably, depending on the species, the genetic modification and the receiving environment, for example plant cultivation in the desert or fish cultivation in the sea.

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

A hazard could result in adverse effects through gene transfer within the same species or to other species (vertical and horizontal gene transfer). The speed and extent of gene transfer to other species (usually sexually compatible in the case of higher organisms) will depend, for example, on:

— the reproductive properties of the GMO itself, including the modified sequences,

— the conditions of release, and particular environmental considerations such as climate (for example, wind),

— differences in reproduction biology,

— agricultural practices,

— the availability of potential crossing partners,

— transport and pollinating vectors (for example, insects or birds, animals in general),

— the availability of hosts for parasites.

The occurrence of specific adverse effects through gene transfer may be linked to the number of GMOs released. Large fields of transgenic plants may have a completely different potential for gene transfer from small fields, even on a proportional basis. Moreover, qualitative and quantitative

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information about the existence of potential crossing partners or recipients (for plants within relevant distances) is very important.

For higher plants and animals, further distinctions should be made regarding possible gene transfer to the same, closely related, distantly related and unrelated species.

In the case of microorganisms, horizontal gene transfer plays a more important role. Certain genetic material can be easy transferred between more closely related organisms, for example, via plasmids or phages. The potential rapid growth rate of microorganisms can enable gene transfer at relatively high levels compared to higher organisms.

Transfer of transgenes may lead to a mixed population of GMOs or to different gene-plant combinations after a time, which can then give rise to complex patterns of especially long-term adverse effects. These will become more complex as more transgenic material is transferred into a population (for example, gene stacking).

In some cases, the method of genetic modification may change the potential for gene transfer, such as in the case of non-integrating plasmids or viral vectors. The method of genetic modification may also decrease the potential for gene transfer, for example, chloroplast transformation.

Gene transfer may result in persistence of the introduced genetic material in natural populations. If a GMO has the potential for gene transfer, this does not necessarily mean intrinsic risk, or a change in the capacity to survive, to become established or cause adverse effects. This will depend on the genetic material inserted, the species and the receiving environment, including the potential recipients.

— Phenotypic and genetic instability

The extent to which genetic (in)stability might lead to phenotypic (in)stability and result in a hazard should be considered. Instability of the genetic modification may in certain cases result in reversion into the wild type phenotype. Other cases should be considered, for example:

- — if in a transgenic plant line that contains more than one transgene, the subsequent segregation process results in these transgenes being divided up in the progeny, there could be plants with less transgenes but new phenotypes,
- — if attenuated mutants may, due to instability (because of the construction of the particular mutation) revert to virulence,
- — if duplication of transgenes leads to gene silencing,
- — if copy numbers are very high,
- — if re-insertion of transposable elements results in new phenotypes, due to inactivation of the transgene by the insertion of mobile genetic elements,
- — if the level of transgene expression is important (for example, a very low expression of a toxic substance), the genetic instability of the regulatory element(s) may result in a higher transgene expression.

Phenotypic instability could result from interaction with the environment during cultivation, so the effects of environmental and agronomic factors on expression of transgenes should be considered in the ERA.

If transgene expression is limited to a certain compartment in the GMO (such as a certain plant tissue), instability of regulation could result in expression of the transgene in the entire organism. In this context regulatory signals (such as promoters) play an important role and should be considered.

Also the expression of the transgene at a certain time in the life cycle of the organism or under specific environmental conditions should be considered.

Specific infertility transgenes may have been introduced into the GMO to make it infertile (for example, to prevent transfer and spread of certain transgenes). Instability of the infertility transgenes could result in reactivation of the fertility of the plant allowing the spread of the transgenes, which could have adverse affects.

The stability of the different transgene(s) not only in the primary GMO but also in its progeny is of importance for long-term effects in particular.

— Interactions with other organisms (other than exchange of genetic material/pollen)

Possible interactions with other organisms, including other GMOs, have to be carefully assessed, taking into account the complexity of multitrophic interactions. Directly hazardous interactions which could cause adverse effects might include:

- — exposure to humans (such as farmers, consumers),
- — exposure to animals,

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— competition for natural resources like soil, area, water, light,

— displacement of natural populations of other organisms,

— delivery of toxic substances,

— different growth patterns.

In general, if biological fitness is enhanced by the genetic modification, the GMO may invade new environments and replace existing species. Often the occurrence of specific adverse effects is proportionally linked to scale of release.

— Changes in management, including, where applicable, in agricultural practices

The relevance of changes in management procedures as an unavoidable consequence of the deliberate release of the GMO has to be assessed on the basis of existing procedures. Changes in farm management could, for example, relate to:

— sowing, planting, growing, harvesting or transporting crops (for example, planting in small or large fields), timing,

— crop rotation (for example, cultivating the same plant species every year or every fourth year),

— disease and pest control (for example, type and dose of insecticide for plants, or antibiotics for animals, or alternative measures),

— resistance management (for example, type and dose of herbicide for herbicide-tolerant plants, or change in use of biological control via Bt proteins, or impact of viruses),

— isolation in land agricultural and aquatic agricultural systems (for example, isolation distances in plant cultivation or quality of isolation in fish farms),

— agricultural practices (farming GMOs and non transgenic farming, including organic farming),

— management in non-agricultural systems (for example, isolation distances of natural habitats from GMO planting areas).

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

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

Apart from the likelihood that the potential harmful characteristics will occur (see Chapter 4.2.3, step 3), evaluating the magnitude of the consequences is an important part of risk assessment. The magnitude is the extent to which the consequences of any potential hazards of the GMOs to be deliberately released or placed on the market will be realised.

The magnitude is to be seen in relation to the baseline and likely to be influenced by:

— genetic construction,

— each adverse effect identified,

— the number of GMOs released (scale),

— the environment into which the GMO(s) is (are) to be released,

— the conditions of the release, including control measures,

— combinations of the above.

For each adverse effect identified, the consequences for other organisms, populations, species or ecosystems exposed to the GMO have to be evaluated. This requires detailed knowledge of the environment into which the GMO is to be released (site, region) and the method of release. Consequences will range from ‘negligible’ or insignificant and self-limiting to ‘high’ or significant, either having an immediate and serious adverse effect or possibly leading to long-term, permanent adverse effects.

In quantitative terms the magnitude should, if possible, be expressed as ‘high’, ‘moderate’, ‘low’ or ‘negligible’. In some cases, it is not possible to identify an adverse effect in a particular environment. In such cases, the risk associated with that particular adverse effect could be assessed as ‘negligible’ or insignificant.

The following are suggested as illustrative and qualitative examples in a very broad sense. They are not intended to be definitive or exclusive, but to give an indication of the considerations that might be taken into account when weighing up the consequences:

— ‘high level consequences’ might be significant changes in the numbers of one or more species of other organisms, including endangered and beneficial species in the short or long term. Such changes might include a reduction in or complete eradication of a species leading to a negative effect on the func-

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tioning of the ecosystem and/or other connected ecosystems. Such changes would probably not be readily reversible and any recovery of the ecosystem that did take place would probably be slow,

— 'moderate consequences' might be significant changes in population densities of other organisms, but not a change which could result in the total eradication of a species or any significant effect on endangered or beneficial species. Transient and substantial changes in populations might be included if likely to be reversible. There could be long-term effects, provided there are no serious negative effects on the functioning of the ecosystem,

— 'low level consequences' might be non-significant changes in population densities of other organisms, which do not result in the total eradication of any population or species of other organisms and have no negative effects on functioning of the ecosystem. The only organisms that might be affected would be non-endangered, non-beneficial species in the short or long term,

— 'negligible consequences' would mean that no significant changes had been caused in any of the populations in the environment or in any ecosystems.

The above examples reflect the potential adverse effects of GMOs on populations, although in some cases, it may be more appropriate to consider the likely effects on individual organisms. One single hazard could have more than one adverse effect, and in fact the magnitudes of the individual adverse effects could be different. The adverse effects of one single hazard on human health, and agricultural and natural habitats could vary.

The potential consequences could be summarised in such a way as to cover all the ecological entities which could be affected (such as species, populations, trophic levels, ecosystems) including the potential effect and the level of uncertainty.

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

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

Besides the magnitude of the consequences of the hazards (see Chapter 4.2.2, step 2) evaluating the likelihood of adverse effects occurring is another important part in assessing risks. This step is to estimate how likely it is that adverse effects will actually occur. In some cases both the likelihood and the frequency should be addressed. As in step 2 (evaluate the potential consequences of each adverse effect if it occurs), besides the hazard itself, the number of GMOs, the receiving environment and the conditions of the release are important for defining the likelihood. Climatic, geographical, soil and demographic conditions, and the types of flora and fauna in the potential receiving environment are some of the important considerations.

For capability of survival, therefore, it is appropriate to assess the proportion of GMOs that are likely to survive, outside the intended risk management measures proposed for the deliberate release or placing on the market. Where gene transfer is likely, the probable number of such events or the extent to which transfer will occur should be considered. If the GMO has pathogenic or toxic characteristics, the proportion of target organisms in the environment likely to be affected should be assessed.

Moreover, the likelihood of the occurrence of an effect will depend on the specific risk management measures that may prevent that risk from occurring (for example, if pollen dispersal is impossible due to the destruction of the inflorescences).

For each adverse effect identified, the relative likelihood of the consequence can probably not be assessed quantitatively, but it can be expressed in terms of 'high', 'moderate', 'low' or 'negligible'.

The above examples reflect the potential adverse effect of the GMO on populations, although in some cases, it may be more appropriate to consider the likely effects on individual organisms. One single hazard could have more than one adverse effect, so the likelihood of individual adverse effects could also be different. The adverse effects of one single hazard on human health, agricultural and natural habitats could vary.

Likelihood could be summarised in a way which covers all the ecological entities which could be affected (such as species, populations, trophic levels, ecosystems) including measures about the potential effect as well as the level of uncertainty.

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

An estimation of the risk to human health or the environment posed by each identified characteristic of the GMO which has the potential to cause adverse

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effects should be made as far as possible, given the state of the art, by combining the likelihood of the adverse effect occurring and the magnitude of the consequences, if it occurs.

On the basis of the conclusions reached in steps 2 and 3, an estimate of the risk of adverse effects should be made for each hazard identified in step 1. Again quantitative evaluation is unlikely to be possible. The evaluation for each hazard should consider:

— the magnitude of the consequences ('high', 'moderate', 'low' or 'negligible'),

— the likelihood of the adverse effect ('high', 'moderate', 'low' or 'negligible'),

— if a hazard has more than one adverse effect, the magnitude and likelihood of each individual adverse effect.

Each GMO has to be considered on a case-by-case basis. Any general attempt to quantify what has been described before has to be made very carefully. For example, in one case the high magnitude of the consequences of an adverse effect may be combined with a negligible likelihood of it occurring, resulting in the whole range from high risk down to negligible risk. The result will depend on the circumstances of the case and the weighting of certain factors by the notifier, all of which should be set out clearly and justified in the recorded ERA.

The overall uncertainty for each identified risk has to be described, possibly including documentation relating to:

— assumptions and extrapolations made at various levels in the ERA,

— different scientific assessments and viewpoints,

— uncertainties,

— the known limits of mitigation measures,

— conclusions that can be derived from the data.

Although the ERA should be based on quantifiable outcomes, it is likely that many of the results of the ERA will have to be qualitative. But it is necessary, wherever possible, to have ERA results which are relative (compared with a non-GM reference, for instance), even if they are qualitative.

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

The ERA may identify risks that require measures to manage them, and a risk management strategy should be defined.

Before applying risk management, consideration should be given, with a view to prevention, to modifying the release, preferably until the risk is negligible. For example, genetic elements, which may cause adverse effects or are undefined, should be avoided in the gene construction process. If this is not possible, these genetic elements should preferably be removed from the GMO at a later stage, prior to its deliberate release or placing on the market.

This should be taken into account in steps 1 to 4. Risk management should control an identified risk and cover the uncertainties. Safeguard measures should be proportionate to the level of risk and to the level of uncertainty. When relevant data becomes available at a later stage, risk management should be adapted in line with that new data.

To reduce the risk by management, the measures should clearly achieve that end. For example, if there is a risk of a gene toxic to insects inserted into a crop plant being transferred to related plant species, suitable control measures might include spatial or temporal isolation from those related species or perhaps changing the release site to an area where there is no exposure to a specific risk (such as plant species).

Management strategies can include isolation measures at every relevant stage of the handling and use of GMOs. They can also include a wide range of measures, including various means to isolate reproduction, physical or biological barriers, and cleaning machines or containers in contact with GMOs, and so on.

Detailed risk management procedures will depend on:

— the use of the GMO (type and scale of deliberate release or placing on the market),

— the type of GMO (for example, genetically modified microorganisms, higher annual plant, higher long-life plant or animal, GMO with single or multiple modification, one or different kinds of GMOs),

— the general type of habitat (for example, biogeochemical status, climate, availability of inter- and interspecific crossing partners, centres of origin, connection of different habitats),

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— the type of agricultural habitat (for example, agriculture, forestry, aquatic culture, rural areas, size of sites, number of different GMOs),

— the type of natural habitat (for example, status of preserved areas).

There should be a clear statement of the implications of risk management in terms of the necessary adjustments to experiments, conditions for placing on the market, and so on, and the consequent reduction in risk likely to be achieved.

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

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

On the basis of step 4 and, if appropriate, step 5, a final evaluation should be made of the overall risk, including the magnitude and likelihood of the adverse effects of the GMO, based on the combination of the risks from each individual adverse effect, including cumulative effects from other GMOs. This final evaluation should be expressed in the form of a summary of the overall risks from deliberate release or placing on the market, including the overall uncertainties.

5. CONCLUSIONS ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OR THE PLACING ON THE MARKET OF GMOs

On the basis of an ERA, carried out in accordance with the general principles and methodology outlined in sections 3 and 4, information on the points listed in sections D1 or D2 of Annex II to Directive 2001/18/EC should be included, as appropriate, in notifications with a view to assisting in drawing conclusions on the potential environmental impact from the release or the placing on the market of GMOs.

Future developments, especially in the non-plant area, may give further guidance on the information to be included in the notifications.

6. REVIEW AND ADAPTATION

6.1. Review and adaptation of an ERA

An ERA should not be viewed as static. It should be regularly reviewed and updated or perhaps changed to take account of relevant new data (in accordance with Articles 8 or 20 of Directive 2001/18/EC). Any reviews should consider the effectiveness, efficiency and accuracy of the ERA and risk management, taking account of data from research, other deliberate releases and monitoring data. This will also depend on the level of uncertainty determined by the ERA.

Following any such reviews, the ERA and risk management should be adapted or upgraded as appropriate.

6.2. Review and adaptation of the ERA guidance

Future developments in genetic modification may make it necessary to adapt to technical progress Annex II and these guidance notes. Further differentiation of information requirements for different types of GMOs, like single cell organisms, fish or insects, or for particular use of GMOs, like the development of vaccines, may be possible once there is sufficient experience with notifications for the release of particular GMOs in the Community (Annex III, fourth paragraph).

The review and adaptation of the ERA guidance should also take into account, where appropriate, the need to adapt to technical progress and the need to develop further guidance based on experience — where sufficient — with releases of certain GMOs into certain ecosystems, in accordance with the criteria set out in Annex V (Article 7(1)) of the Directive, as well as experience and scientific evidence relating to the safety of human health and the environment in connection with the placing on the market of certain GMOs (Article 16(2)).

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ANNEX III

INFORMATION REQUIRED IN THE NOTIFICATION

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

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

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

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

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

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

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

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ANNEX III A

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

I. GENERAL INFORMATION

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

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

C. Title of the project

II. INFORMATION RELATING TO THE GMO

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

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

B. **Characteristics of the vector**

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

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3. frequency of mobilisation of inserted vector and/or genetic transfer capabilities and methods of determination,
4. information on the degree to which the vector is limited to the DNA required to perform the intended function.

C. **Characteristics of the modified organism**

1. Information relating to the genetic modification:
   (a) methods used for the modification;
   (b) methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;
   (c) description of the insert and/or vector construction;
   (d) purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;
   (e) methods and criteria used for selection;
   (f) sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.
2. Information on the final GMO:
   (a) description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;
   (b) structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;
   (c) stability of the organism in terms of genetic traits;
   (d) rate and level of expression of the new genetic material. Method and sensitivity of measurement;
   (e) activity of the expressed protein(s);
   (f) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;
   (g) sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
   (h) history of previous releases or uses of the GMO;
   (i) considerations for human health and animal health, as well as plant health:
      (i) toxic or allergenic effects of the GMOs and/or their metabolic products;
      (ii) comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
      (iii) capacity for colonisation;
      (iv) if the organism is pathogenic to humans who are immunocompetent:
         — diseases caused and mechanism of pathogenicity including invasiveness and virulence,
         — communicability,
         — infective dose,
         — host range, possibility of alteration,
         — possibility of survival outside of human host,
         — presence of vectors or means of dissemination,
         — biological stability,
         — antibiotic resistance patterns,
         — allergenicity,
         — availability of appropriate therapies.
      (v) other product hazards.

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

A. **Information on the release**

1. description of the proposed deliberate release, including the purpose(s) and foreseen products,

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

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

1. geographical location and grid reference of the site(s) (in case of notifications under part C the site(s) of release will be the foreseen areas of use of the product),
2. physical or biological proximity to humans and other significant biota,
3. proximity to significant biotopes, protected areas, or drinking water supplies,
4. climatic characteristics of the region(s) likely to be affected,
5. geographical, geological and pedological characteristics,
6. flora and fauna, including crops, livestock and migratory species,
7. description of target and non-target ecosystems likely to be affected,
8. a comparison of the natural habitat of the recipient organism with the proposed site(s) of release,
9. any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

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

A. **Characteristics affecting survival, multiplication and dissemination**

1. biological features which affect survival, multiplication and dispersal,
2. known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.),
3. sensitivity to specific agents.

B. **Interactions with the environment**

1. predicted habitat of the GMOs,
2. studies of the behaviour and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses,
3. genetic transfer capability
   (a) postrelease transfer of genetic material from GMOs into organisms in affected ecosystems;
   (b) postrelease transfer of genetic material from indigenous organisms to the GMOs;
4. likelihood of postrelease selection leading to the expression of unexpected and/or undesirable traits in the modified organism,
5. measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimise dispersal of genetic material. Methods to verify genetic stability,
6. routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.,

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7. description of ecosystems to which the GMOs could be disseminated,
8. potential for excessive population increase in the environment,
9. competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s),
10. identification and description of the target organisms if applicable,
11. anticipated mechanism and result of interaction between the released GMOs and the target organism(s) if applicable,
12. identification and description of non-target organisms which may be adversely affected by the release of the GMO, and the anticipated mechanisms of any identified adverse interaction,
13. likelihood of postrelease shifts in biological interactions or in host range,
14. known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens,
15. known or predicted involvement in biogeochemical processes,
16. other potential interactions with the environment.

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

A. **Monitoring techniques**

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

B. **Control of the release**

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

C. **Waste treatment**

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

D. **Emergency response plans**

1. methods and procedures for controlling the GMOs in case of unexpected spread,
2. methods for decontamination of the areas affected, for example eradication of the GMOs,
3. methods for disposal or sanitation of plants, animals, soils, etc., that were exposed during or after the spread,
4. methods for the isolation of the area affected by the spread,

5 plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

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ANNEX III B

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

A. GENERAL INFORMATION

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

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

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

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

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

D. INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

1. Description of the trait(s) and characteristics which have been introduced or modified.
2. Information on the sequences actually inserted/deleted:
   (a) size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP;
   (b) in case of deletion, size and function of the deleted region(s);
   (c) copy number of the insert;

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

3. Information on the expression of the insert:

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

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

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

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

(b) dissemination;

(c) survivability.

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

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

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

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

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

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

11. Potential interactions with the abiotic environment.

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

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

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

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

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

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

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

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

1. Purpose of the release.

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

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

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

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

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

1. Any precautions taken:

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

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

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

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

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4. Description of monitoring plans and techniques.
5. Description of any emergency plans.
6. Methods and procedures to protect the site.

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ANNEX IV

ADDITIONAL INFORMATION

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

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

1. proposed commercial names of the products and names of GMOs contained therein, and any specific identification, name or code used by the notifier to identify the GMO. After the consent any new commercial names should be provided to the competent authority,
2. name and full address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor,
3. name and full address of the supplier(s) of control samples,
4. description of how the product and the GMO as or in product are intended to be used. Differences in use or management of the GMO compared to similar non-genetically modified products should be highlighted,
5. description of the geographical area(s) and types of environment where the product is intended to be used within the Community, including, where possible, estimated scale of use in each area,
6. intended categories of users of the product e.g. industry, agriculture and skilled trades, consumer use by public at large,
7. information on the genetic modification for the purposes of placing on one or several registers modifications in organisms, which can be used for the detection and identification of particular GMO products to facilitate post-marketing control and inspection. This information should include where appropriate the lodging of samples of the GMO or its genetic material, with the competent authority and details of nucleotide sequences or other type of information which is necessary to identify the GMO product and its progeny, for example the methodology for detecting and identifying the GMO product, including experimental data demonstrating the specificity of the methodology. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register should be identified,
8. proposed labelling on a label or in an accompanying document. This must include, at least in summarised form, a commercial name of the product, a statement that 'This product contains genetically modified organisms', the name of the GMO and the information referred to in point 2, the labelling should indicate how to access the information in the publicly accessible part of the register.

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

1. measures to take in case of unintended release or misuse,
2. specific instructions or recommendations for storage and handling,
3. specific instructions for carrying out monitoring and reporting to the notifier and, if required, the competent authority, so that the competent authorities can be effectively informed of any adverse effect. These instructions should be consistent with Annex VII part C,
4. proposed restrictions in the approved use of the GMO, for example where the product may be used and for what purposes,
5. proposed packaging,
6. estimated production in and/or imports to the Community,
7. proposed additional labelling. This may include, at least in summarised form, the information referred to in points A 4, A 5, B 1, B 2, B 3 and B 4.

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ANNEX V

CRITERIA FOR THE APPLICATION OF DIFFERENTIATED PROCEDURES (ARTICLE 7)

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

1. The taxonomic status and the biology (for example mode of reproduction and pollination, ability to cross with related species, pathogenecity) of the non-modified (recipient) organism shall be well-known.
2. There shall be sufficient knowledge about the safety for human health and the environment of the parental, where appropriate, and recipient organisms in the environment of the release.
3. Information shall be available on any interaction of particular relevance for the risk assessment, involving the parental, where appropriate, and recipient organism and other organisms in the experimental release ecosystem.
4. Information shall be available to demonstrate that any inserted genetic material is well characterised. Information on the construction of any vector systems or sequences of genetic material used with the carrier DNA shall be available. Where a genetic modification involves the deletion of genetic material, the extent of the deletion shall be known. Sufficient information on the genetic modification shall also be available to enable identification of the GMO and its progeny during a release.
5. The GMO shall not present additional or increased risks to human health or the environment under the conditions of the experimental release that are not presented by releases of the corresponding parental, where appropriate, and recipient organisms. Any capacity to spread in the environment and invade other unrelated ecosystems and capacity to transfer genetic material to other organisms in the environment shall not result in adverse effects.

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ANNEX VI

GUIDELINES FOR THE ASSESSMENT REPORTS

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

1. Identification of the characteristics of the recipient organism which are relevant to the assessment of the GMO(s) in question. Identification of any known risks to human health and the environment resulting from the release into the environment of the recipient non-modified organism.
2. Description of the result of the genetic modification in the modified organism.
3. Assessment of whether the genetic modification has been characterised sufficiently for the purpose of evaluating any risks to human health and the environment.
4. Identification of any new risks to human health and the environment that may arise from the release of the GMO(s) in question as compared to the release of the corresponding non-modified organism(s), based on the environmental risk assessment carried out in accordance with Annex II.
5. A conclusion on whether the GMO(s) in question should be placed on the market or as (a) product(s) and under which conditions, whether the GMOs in question shall not be placed on the market or whether the views of other competent authorities and the Commission are sought for on specific issues of the e.r.a.. These aspects should be specified. The conclusion should clearly address the use proposed, risk management and the monitoring plan proposed. In the case that it has been concluded that the GMOs should not be placed on the market, the competent authority shall give reasons for its conclusion.

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ANNEX VII

MONITORING PLAN

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

These guidance notes shall be completed by 17 October 2002.

A. **Objective**

The objective of a monitoring plan is to:

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

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

B. **General principles**

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

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

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

C. **Design of the monitoring plan**

The design of the monitoring plan should:

1. be detailed on a case by case basis taking into account the e.r.a.,
2. take into account the characteristics of the GMO, the characteristics and scale of its intended use and the range of relevant environmental conditions where the GMO is expected to be released,
3. incorporate general surveillance for unanticipated adverse effects and, if necessary, (case-) specific monitoring focusing on adverse effects identified in the e.r.a.:
   - 3.1. whereas case-specific monitoring should be carried out for a sufficient time period to detect immediate and direct as well as, where appropriate, delayed or indirect effects which have been identified in the e.r.a.,
   - 3.2. whereas surveillance could, if appropriate, make use of already established routine surveillance practices such as the monitoring of agricultural cultivars, plant protection, or veterinary and medical products. An explanation as to how relevant information collected through established routine surveillance practices will be made available to the consent-holder should be provided.
4. facilitate the observation, in a systematic manner, of the release of a GMO in the receiving environment and the interpretation of these observations with respect to safety to human health or the environment.
5. identify who (notifier, users) will carry out the various tasks the monitoring plan requires and who is responsible for ensuring that the monitoring plan is set into place and carried out appropriately, and ensure that there is a route by which the consent holder and the competent authority will be informed on any observed adverse effects on human health and the environment. (Time points and intervals for reports on the results of the monitoring shall be indicated).
6. give consideration to the mechanisms for identifying and confirming any observed adverse effects on human health and environment and enable the consent holder or the competent authority, where appropriate, to take the measures necessary to protect human health and the environment.

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ANNEX VIII

CORRELATION TABLE

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