Is áis doiciméadúcháin amháin an téacs seo agus níl aon éifeacht dhlíthiúil aige. Ní ghabhann institiúidí an Aontais aon dliteanas orthu féin i leith inneachar an téacs. Is iad na leaganacha de na gníomhartha a foilsíodh in Iris Oifigiúil an Aontais Eorpaigh agus atá ar fáil ar an suíomh gréasáin EUR-Lex na leaganacha barántúla de na gníomhartha ábhartha, brollach an téacs san áireamh. Is féidir teacht ar na téacsanna oifigiúla sin ach na naisc atá leabaithe sa doiciméad seo a bhrú

►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

(IO L 106, 17.4.2001, lch. 1)

Arna leasú le:

		Iris Oifigiúil		
		Uimh	Leathanach	Dáta
►M1	Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 (*)	L 268	1	18.10.2003
►M2	Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 (*)	L 268	24	18.10.2003
►M3	Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008 (*)	L 81	45	20.3.2008
►M4	Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 (*)	L 68	1	13.3.2015
►M5	Commission Directive (EU) 2018/350 of 8 March 2018 (*)	L 67	30	9.3.2018
►M6	Rialachán (AE) 2019/1243 ó Pharlaimint na hEorpa agus ón gComhairle an 20 Meitheamh 2019	L 198	241	25.7.2019

(*) Níor foilsíodh an gníomh seo i nGaeilge.

▼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

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;

▼B

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

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

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

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

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

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

(6) ‘notifier’ means the person submitting the notification;

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

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

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.

([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).

▼B

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

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

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

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

▼M2

_____

▼B

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

(b) for explicit consent prior to release;

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

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

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

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

Article 6

Standard authorisation procedure

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

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

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

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

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

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

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

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

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

(vii) a summary of the dossier;

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

▼B

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

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

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

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

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

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

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

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

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

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

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

Article 7

Differentiated procedures

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

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

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

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

▼B

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

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

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

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

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

(d) the environmental risk assessment.

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

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

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

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

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

Article 8

Handling of modifications and new information

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

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

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

▼B

(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).

▼B

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.

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.

▼B

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.

▼M1

Article 12a

Transitional measures for adventitious or technically unavoidable presence of genetically modified organisms having benefited from a favourable risk evaluation

1. Placing on the market of traces of a GMO or combination of GMOs in products intended for direct use as food or feed or for processing shall be exempted from Articles 13 to 21 provided that they meet the conditions referred to in Article 47 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [1].

2. This Article shall be applicable for a period of three years after the date of application of Regulation (EC) No 1829/2003.

▼B

Article 13

Notification procedure

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

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

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

2. The notification shall contain:

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

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

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

[1] OJ L 268, 18.10.2003, p. 1.

▼B

(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.

▼B

Article 14

Assessment report

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

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

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

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

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

3. The assessment report shall indicate whether:

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

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

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

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

Article 15

Standard procedure

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

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

▼B

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

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

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

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

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

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

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

Article 16

Criteria and information for specified GMOs

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

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

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

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

▼M3

2. ►M6 Tugtar de chumhacht don Choimisiún chun gníomhartha tarmligthe a ghlacadh i gcomhréir le hAirteagal 29a chun an Treoir seo a fhorlíonadh trí na critéir agus na ceanglais faisnéise dá dtagraítear i mír 1 a bhunú, agus aon cheanglais iomchuí maidir le hachoimre den sainchomhad, tar éis dó dul i gcomhairle leis an gCoiste Eolaíoch ábhartha. Beidh na critéir agus na ceanglais faisnéise leordhóthanach chun ardleibhéal sábháilteachta don tsláinte dhaonna agus don chomhshaol a áirithiú agus bunófar iad ar an bhfianaise eolaíoch maidir leis an gcineál sábháilteachta sin agus ar an taithí a fuarthas ó orgánaigh ghéinmhodhnaithe a scaoileadh. ◄

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

▼M6

3. Roimh dó gníomh tarmligthe a ghlacadh de bhun mhír 2, déanfaidh an Coimisiún an togra a chur ar fáil don phobal. Féadfaidh an pobal barúlacha a thabhairt don Choimisiún laistigh de 60 lá oibre. Cuirfidh an Coimisiún aon bharúlacha den chineál sin ar aghaidh, mar aon le hanailís, chuig na saineolaithe dá dtagraítear in Airteagal 29a(4).

▼B

Article 17

Renewal of consent

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

(a) consents granted under part C; and

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

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

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

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

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

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

▼B

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).

▼B

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);

▼B

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

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

Article 20

Monitoring and handling of new information

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

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

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

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

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

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

▼B

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).

▼M6

2. Maidir le táirgí ina bhfuil rianta taismeacha d'orgánaigh ghéinmhodhnaithe nó rianta nach féidir a sheachaint go teicniúil, tugtar de chumhacht don Choimisiún chun gníomhartha tarmligthe a ghlacadh, i gcomhréir le hAirteagal 29a chun an Treoir seo a fhorlíonadh trí thairseacha íosta a bhunú agus ní gá na táirgí atá faoi bhun na dtairseach sin a lipéadú i gcomhréir le mír 1 den Airteagal seo. Déanfar leibhéil tairsí a bhunú i gcomhréir leis an táirgeadh lena mbaineann.

▼M3

3. For products intended for direct processing, paragraph 1 shall not apply to traces of authorised GMOs in proportions no higher than 0,9 % or lower thresholds, provided that these traces are adventitious or technically unavoidable.

▼M6

Tugtar de chumhacht don Choimisiún chun gníomhartha tarmligthe a ghlacadh i gcomhréir le hAirteagal 29a, chun an Treoir seo a fhorlíonadh trí na tairsí dá dtagraítear sa chéad fhomhír den mhír seo a bhunú.

▼B

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.

▼B

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.

▼M3

2. Within 60 days of the date of receipt of the information transmitted by the Member State, a decision shall be taken on the measure taken by that Member State in accordance with the regulatory procedure referred to 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 or Committees which has or 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 or Committees consulted shall not exceed 60 days.

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

▼B

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.

▼B

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

PART D

FINAL PROVISIONS

Article 25

Confidentiality

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

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

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

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

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

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

— environmental risk assessment.

5. If, for whatever reasons, the notifier withdraws 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.

▼M6

2. Tugtar de chumhacht don Choimisiún chun gníomhartha tarmligthe a ghlacadh i gcomhréir le hAirteagal 29a lena leasaítear Iarscríbhinn IV, trí na ceanglais shonracha maidir le lipéadú dá dtagraítear i mír 1, gan na ceanglais maidir le lipéadú a leagtar síos i reachtaíocht an Aontais atá ann cheana a dhúbláil ná neamhréireachtaí a chruthú iontu. Agus an méid sin á dhéanamh, ba cheart, mar is iomchuí, na forálacha maidir le lipéadú arna mbunú ag na Ballstáit i gcomhréir le reachtaíocht an Aontais a chur san áireamh.

▼M1

Article 26a

Measures to avoid the unintended presence of GMOs

1. Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.

▼M4

1a. As from 3 April 2017 Member States in which GMOs are cultivated shall take appropriate measures in border areas of their territory with the aim of avoiding possible cross-border contamination into neighbouring Member States in which the cultivation of those GMOs is prohibited, unless such measures are unnecessary in the light of particular geographical conditions. Those measures shall be communicated to the Commission.

▼M1

2. The Commission shall gather and coordinate information based on studies at Community and national level, observe the developments regarding coexistence in the Member States and, on the basis of the information and observations, develop guidelines on the coexistence of genetically modified, conventional and organic crops.

▼M4

Article 26b

Cultivation

1. During the authorisation procedure of a given GMO or during the renewal of consent/authorisation, a Member State may demand that the geographical scope of the written consent or authorisation be adjusted to the effect that all or part of the territory of that Member State is to be excluded from cultivation. That demand shall be communicated to the Commission at the latest 45 days from the date of circulation of the assessment report under Article 14(2) of this Directive, or from receiving the opinion of the European Food Safety Authority under Article 6(6) and Article 18(6) of Regulation (EC) No 1829/2003. The Commission shall present the demand of the Member State to the notifier/applicant and to the other Member States without delay. The Commission shall make the demand publicly available by electronic means.

2. Within 30 days from the presentation by the Commission of that demand, the notifier/applicant may adjust or confirm the geographical scope of its initial notification/application.

▼M4

In the absence of confirmation, the adjustment of the geographical scope of the notification/application shall be implemented in the written consent issued under this Directive and, where applicable, the decision issued in accordance with Article 19 of this Directive as well as the decision of authorisation adopted under Articles 7 and 19 of Regulation (EC) No 1829/2003.

The written consent issued under this Directive and, where applicable, the decision issued in accordance with Article 19 of this Directive, as well as the decision of authorisation adopted under Articles 7 and 19 of Regulation (EC) No 1829/2003, shall then be issued on the basis of the adjusted geographical scope of the notification/application.

Where a demand in accordance with paragraph 1 of this Article is communicated to the Commission after the date of circulation of the assessment report under Article 14(2) of this Directive, or after receipt of the opinion of the European Food Safety Authority under Article 6(6) and Article 18(6) of Regulation (EC) No 1829/2003, the timelines set out in Article 15 of this Directive to issue the written consent or, as the case may be, in Articles 7 and 19 of Regulation (EC) No 1829/2003 to submit to the Committee a draft of the decision to be taken, shall be extended by a single period of 15 days regardless of the number of Member States presenting such demands.

3. Where no demand was made pursuant to paragraph 1 of this Article, or where the notifier/applicant has confirmed the geographical scope of its initial notification/application, a Member State may adopt measures restricting or prohibiting the cultivation in all or part of its territory of a GMO, or of a group of GMOs defined by crop or trait, once authorised in accordance with Part C of this Directive or with Regulation (EC) No 1829/2003, provided that such measures are in conformity with Union law, reasoned, proportional and non-discriminatory and, in addition, are based on compelling grounds such as those related to:

(a) environmental policy objectives;

(b) town and country planning;

(c) land use;

(d) socioeconomic impacts;

(e) avoidance of GMO presence in other products without prejudice to Article 26a;

(f) agricultural policy objectives;

(g) public policy.

Those grounds may be invoked individually or in combination, with the exception of the ground set out in point (g) which cannot be used individually, depending on the particular circumstances of the Member State, region or area in which those measures will apply, but shall, in no case, conflict with the environmental risk assessment carried out pursuant to this Directive or to Regulation (EC) No 1829/2003.

▼M4

4. A Member State which intends to adopt measures pursuant to paragraph 3 of this Article shall first communicate a draft of those measures and the corresponding grounds invoked to the Commission. This communication may take place before the GMO authorisation procedure under Part C of this Directive or under Regulation (EC) No 1829/2003 has been completed. During a period of 75 days starting from the date of such communication:

(a) the Member State concerned shall refrain from adopting and implementing those measures;

(b) the Member State concerned shall ensure that operators refrain from planting the GMO or GMOs concerned; and

(c) the Commission may make any comments it considers appropriate.

On expiry of the 75-day period referred to in the first subparagraph, the Member State concerned may, for the whole duration of the consent/authorisation and as from the date of entry into force of the Union authorisation, adopt the measures either in the form originally proposed, or as amended to take account of any non-binding comments received from the Commission. Those measures shall be communicated to the Commission, the other Member States and the authorisation holder without delay.

Member States shall make publicly available any such measure to all operators concerned, including growers.

5. Where a Member State wishes all or part of its territory to be reintegrated into the geographical scope of the consent/authorisation from which it was previously excluded pursuant to paragraph 2, it may make a request to that effect to the competent authority which issued the written consent under this Directive or to the Commission if the GMO has been authorised under Regulation (EC) No 1829/2003. The competent authority which has issued the written consent or the Commission, as the case may be, shall amend the geographical scope of the consent or of the decision of authorisation accordingly.

6. For the purposes of an adjustment of the geographical scope of the consent/authorisation of a GMO under paragraph 5:

(a) for a GMO which has been authorised under this Directive, the competent authority which has issued the written consent shall amend the geographical scope of the consent accordingly and inform the Commission, the Member States and the authorisation holder once this is complete;

(b) for a GMO which has been authorised under Regulation (EC) No 1829/2003, the Commission shall amend the decision of authorisation accordingly, without applying the procedure set out in Article 35(2) of that Regulation. The Commission shall inform the Member States and the authorisation holder accordingly.

▼M4

7. Where a Member State has revoked measures taken pursuant to paragraphs 3 and 4, it shall notify the Commission and the other Member States without delay.

8. Measures adopted under this Article shall not affect the free circulation of authorised GMOs as, or in, products.

Article 26c

Transitional measures

1. From 2 April 2015 until 3 October 2015, a Member State may demand that the geographical scope of a notification/application submitted, or of an authorisation granted, under this Directive or Regulation (EC) No 1829/2003 before 2 April 2015 be adjusted. The Commission shall present the demand of the Member State to the notifier/applicant and to the other Member States without delay.

2. Where the notification/application is pending and the notifier/applicant has not confirmed the geographical scope of its initial notification/application within 30 days from the communication of the demand referred to in paragraph 1 of this Article, the geographical scope of the notification/application shall be adjusted accordingly. The written consent issued under this Directive and, where applicable, the decision issued in accordance with Article 19 of this Directive as well as the decision of authorisation adopted under Articles 7 and 19 of Regulation (EC) No 1829/2003 shall then be issued on the basis of the adjusted geographical scope of the notification/application.

3. Where the authorisation has already been granted and the authorisation holder has not confirmed the geographical scope of the authorisation within 30 days from the communication of the demand referred to in paragraph 1 of this Article, the authorisation shall be modified accordingly. For a written consent under this Directive, the competent authority shall amend the geographical scope of the consent accordingly and shall inform the Commission, the Member States, and the authorisation holder once this is complete. For an authorisation under Regulation (EC) No 1829/2003, the Commission shall amend the decision of authorisation accordingly, without applying the procedure set out in Article 35(2) of that Regulation. The Commission shall inform the Member States and the authorisation holder accordingly.

4. Where no demand was made pursuant to paragraph 1 of this Article, or where a notifier/applicant or, as the case may be, an authorisation holder has confirmed the geographical scope of its initial application or, as the case may be, authorisation, paragraphs 3 to 8 of Article 26b shall apply mutatis mutandis.

5. This Article is without prejudice to the cultivation of any authorised GMO seeds and plant propagating materials which were planted lawfully before the cultivation of the GMO is restricted or prohibited in the Member State.

6. Measures adopted under this Article shall not affect the free circulation of authorised GMOs as, or in, products.

▼M6

Airteagal 27

Iarscríbhinní a chur in oiriúint don dul chun cinn teicniúil

Tugtar de chumhacht don Choimisiún chun gníomhartha tarmligthe a ghlacadh i gcomhréir le hAirteagal 29a, lena leasaítear Roinn C agus Roinn D d'Iarscríbhinn II, Iarscríbhinní III go IV, agus Roinn C d'Iarscríbhinn VII chun iad a oiriúnú don dul chun cinn teicniúil.

▼B

Article 28

Consultation of Scientific Committee(s)

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

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

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

Article 29

Consultation of Committee(s) on Ethics

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

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

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

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

▼M6

Airteagal 29a

An tarmligean a fheidhmiú

1. Is faoi réir na gcoinníollacha a leagtar síos san Airteagal seo a thugtar an chumhacht don Choimisiún chun gníomhartha tarmligthe a ghlacadh.

▼M6

2. Déanfar an chumhacht chun gníomhartha tarmligthe dá dtagraítear in Airteagal 16(2), in Airteagal 21(2) agus (3), Airteagal 26(2) agus Airteagal 27 a thabhairt don Choimisiún go ceann tréimhse 5 bliana ón 26 Iúil 2019. Déanfaidh an Coimisiún, tráth nach déanaí ná 9 mí roimh dheireadh na tréimhse 5 bliana, tuarascáil a tharraingt suas maidir le tarmligean na cumhachta. Déanfar tarmligean na cumhachta a fhadú go hintuigthe go ceann tréimhsí comhfhaid, mura rud é go gcuireann Parlaimint na hEorpa nó an Chomhairle in aghaidh an fhadaithe sin tráth nach déanaí ná 3 mhí roimh dheireadh gach tréimhse.

3. Féadfaidh Parlaimint na hEorpa nó an Chomhairle tarmligean na gcumhachtaí dá dtagraítear in Airteagal 16(2), Airteagal 21(2) agus (3), Airteagal 26(2) agus Airteagal 27 a chúlghairm aon tráth. Déanfaidh cinneadh chun cúlghairm a dhéanamh deireadh a chur le tarmligean na cumhachta atá sonraithe sa chinneadh sin. Gabhfaidh éifeacht leis an lá tar éis fhoilsiú an chinnidh in *Iris Oifigiúil an Aontais Eorpaigh* nó ar dháta níos déanaí a shonrófar sa chinneadh. Ní dhéanfaidh sé difear do bhailíocht aon ghníomhartha tarmligthe atá i bhfeidhm cheana.

4. Roimh dó gníomh tarmligthe a ghlacadh, rachaidh an Coimisiún i mbun comhairliúchán le saineolaithe arna n-ainmniú ag gach Ballstát i gcomhréir leis na prionsabail a leagtar síos i gComhaontú Idirinstitiúideach an 13 Aibreán 2016 maidir le Reachtóireacht Níos Fearr ([1]).

5. A luaithe a ghlacfaidh sé gníomh tarmligthe, tabharfaidh an Coimisiún fógra, an tráth céanna, do Pharlaimint na hEorpa agus don Chomhairle faoi.

6. Ní thiocfaidh gníomh tarmligthe a ghlactar de bhun Airteagal 16(2), Airteagal 21(2) agus (3), Airteagal 26(2) agus Airteagal 27 i bhfeidhm ach amháin mura mbeidh aon agóid curtha in iúl ag Parlaimint na hEorpa ná ag an gComhairle laistigh de thréimhse 2 mhí tar éis fógra faoin ngníomh sin a thabhairt do Pharlaimint na hEorpa agus don Chomhairle nó más rud é, roimh dhul in éag na tréimhse sin, go mbeidh Parlaimint na hEorpa agus an Chomhairle araon tar éis a chur in iúl don Choimisiún nach ndéanfaidh siad aon agóid. Déanfar an tréimhse sin a fhadú 2 mhí ar thionscnamh Pharlaimint na hEorpa nó na Comhairle.

▼B

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.

▼M6

_____

([1]) IO L 123, 12.5.2016, lch. 1.

▼B

Article 31

Exchange of information and reporting

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

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

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

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

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

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

— be notified to the competent authorities, and

— be made known to the public

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

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

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

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

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

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

▼B

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

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

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

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

Article 32

Implementation of the Cartagena Protocol on biosafety

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

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

Article 33

Penalties

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

Article 34

Transposition

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

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

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

▼B

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.

▼B

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.

▼B

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.

▼B

ANNEX II

PRINCIPLES FOR THE ENVIRONMENTAL RISK ASSESSMENT

▼M3

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. Technical guidance notes may be developed in accordance with the regulatory procedure referred to in Article 30(2) in order to facilitate the implementation and explanation of this Annex.

▼B

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;

▼B

— 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.

▼M5

C. **Methodology**

Guidance issued by the European Food Safety Authority is available for the implementation of this section for Part C notifications.

C.1. General and specific considerations for the e.r.a.

1. *Intended and unintended changes*

As part of the identification and evaluation of the potential adverse effects referred to in Section A, the e.r.a shall identify the intended and unintended changes resulting from the genetic modification and shall evaluate their potential to cause adverse effects on human health and on the environment.

Intended changes resulting from the genetic modification are changes that are designed to occur and which fulfil the original objectives of the genetic modification.

Unintended changes resulting from the genetic modification are consistent changes which go beyond the intended change(s) resulting from the genetic modification.

Intended and unintended changes can have either direct or indirect, and either immediate or delayed effects on human health and on the environment.

2. *Long-term adverse effects and cumulative long-term adverse effects in the e.r.a. of Part C notifications*

Long-term effects of a GMO are effects resulting either from a delayed response by organisms or their progeny to long-term or chronic exposure to a GMO or from an extensive use of a GMO in time and space.

The identification and evaluation of the potential long-term adverse effects of a GMO on human health and on the environment shall take into account the following:

(a) the long-term interactions of the GMO and the receiving environment;

(b) the characteristics of the GMO which become important on a long-term basis;

(c) data obtained from repeated deliberate releases or placings on the market of the GMO over a long period.

The identification and evaluation of the potential cumulative long-term adverse effects referred to in the introductory part of Annex II shall also take into account the GMOs deliberately released or placed on the market in the past.

▼M5

3. *Quality of the data*

In order to carry out an e.r.a. for a notification under Part C of this Directive, the notifier shall collate already available data from scientific literature or from other sources, including monitoring reports, and shall generate the necessary data by performing, where possible, appropriate studies. Where applicable, the notifier shall justify in the e.r.a. why generating data by studies is not possible.

The e.r.a. for notifications under Part B of the Directive shall be based at least on already available data from scientific literature or from other sources and may be supplemented by additional data generated by the notifier.

Where data generated outside Europe is provided in the e.r.a., its relevance to receiving environment(s) in the Union shall be justified.

Data provided in the e.r.a for notifications under part C of this Directive shall comply with the following requirements:

(a) where toxicological studies carried out to assess risk to human or animal health are provided in the e.ra., the notifier shall provide evidence to demonstrate that they were conducted in facilities which comply with:

(i) the requirements of Directive 2004/10/EC; or

(ii) the 'OECD Principles on Good Laboratory Practice' (GLP), if carried out outside the Union;

(b) where studies other than toxicological studies are provided in the e.r.a., they shall:

(i) comply with the principles of Good Laboratory Practice (GLP) laid down in Directive 2004/10/EC, where relevant; or

(ii) be conducted by organisations accredited under the relevant ISO standard; or

(iii) in the absence of a relevant ISO standard, be conducted in accordance with internationally recognised standards;

(c) information on the results obtained from the studies referred to in points (a) and (b) and on the study protocols used shall be reliable and comprehensive and shall include the raw data in an electronic format suitable for carrying out statistical or other analysis;

(d) the notifier shall specify, where possible, the size of effect that each study performed intends to detect and justify it;

(e) the selection of sites for field studies shall be based on relevant receiving environments in view of the potential exposure and impact that would be observed where the GMO may be released. The selection shall be justified in the e.r.a.;

(f) the non-genetically modified comparator shall be appropriate for the relevant receiving environment(s) and shall have a genetic background comparable to the GMO. The choice of the comparator shall be justified in the e.r.a.

▼M5

4. *Stacked transformation events in Part C notifications*

The following shall apply to the e.r.a. of a GMO containing stacked transformation events in Part C notifications:

(a) the notifier shall provide an e.r.a. for each single transformation event in the GMO or refer to already submitted notifications for those single transformation events;

(b) the notifier shall provide an assessment of the following aspects:

(i) the stability of the transformation events;

(ii) the expression of the transformation events;

(iii) the potential additive, synergistic or antagonistic effects resulting from the combination of the transformation events;

(c) where the progeny of the GMO can contain various subcombinations of the stacked transformation events, the notifier shall provide a scientific rationale justifying that there is no need to provide experimental data for the concerned subcombinations, independently of their origin, or, in the absence of such scientific rationale, shall provide the relevant experimental data.

C.2. Characteristics of the GMO and of the releases

The e.r.a. shall take into account the relevant technical and scientific details regarding characteristics of:

— the recipient or parental organism(s),

— the genetic modification(s), be it insertion 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(s) into which the GMO will be released and into which the transgene may spread, and

— the interaction(s) between these characteristics.

Relevant information from previous releases of the same or similar GMOs and organisms with similar traits and their biotic and abiotic interaction with similar receiving environments, including information resulting from the monitoring of such organisms, shall be considered in the e.r.a., subject to Article 6(3) or Article 13(4).

C.3. Steps in the e.r.a.

The e.r.a. referred to in Articles 4, 6, 7 and 13 shall be conducted for each relevant area of risk referred to in Section D1 or in Section D2 in accordance with the following six steps:

1. *Problem formulation including hazard identification*

The problem formulation shall:

(a) identify any changes in the characteristics of the organism, linked to the genetic modification, by comparing the characteristics of the GMO with those of the chosen non-genetically modified comparator under corresponding conditions of release or use;

▼M5

(b) identify potential adverse effects on human health or the environment which are linked to the changes that have been identified under point (a) above;

Potential adverse effects shall not be discounted on the basis that they are unlikely to occur.

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

— effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations leading to a potential decline in biodiversity,

— altered susceptibility to pathogens facilitating the dissemination of infectious diseases 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), including carbon and nitrogen recycling through changes in soil decomposition of organic material,

— disease affecting humans, including allergenic or toxic reactions,

— disease affecting animals and plants, including toxic, and, in the case of animals, allergenic reactions, where appropriate.

Where potential long-term adverse effects of a GMO are identified, they shall be assessed in the form of desk based studies using, where possible, one or more of the following:

(i) evidence from previous experiences;

(ii) available data sets or literature;

(iii) mathematical modelling;

(c) identify relevant assessment endpoints.

Those potential adverse effects that could impact the identified assessment endpoints shall be considered in the next steps of the risk assessment;

(d) identify and describe the exposure pathways or other mechanisms through which adverse effects may occur.

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

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

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

— phenotypic and genetic instability,

— interactions with other organisms,

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

▼M5

(e) formulate testable hypotheses, and define relevant measurement endpoints, to allow, where possible, a quantitative evaluation of the potential adverse effect(s);

(f) consider possible uncertainties, including knowledge gaps and methodological limitations.

2. *Hazard characterisation*

The magnitude of each potential adverse effect shall be evaluated. This evaluation shall assume that such an adverse effect will occur. The e.r.a shall consider that the magnitude is likely to be influenced by the receiving environment(s) into which the GMO is intended to be released and by the scale and conditions of the release.

Where possible, the evaluation shall be expressed in quantitative terms.

Where the evaluation is expressed in qualitative terms, a categorical description ('high', 'moderate', 'low' or 'negligible') shall be used and an explanation of the scale of effect represented by each category shall be provided.

3. *Exposure characterisation*

The likelihood or probability of each identified potential adverse effect occurring shall be evaluated to provide, where possible, a quantitative assessment of the exposure as a relative measure of probability, or otherwise a qualitative assessment of the exposure. The characteristics of the receiving environment(s) and the scope of the notification shall be taken into consideration.

Where the evaluation is expressed in qualitative terms, a categorical description ('high', 'moderate', 'low' or 'negligible') of the exposure shall be used and an explanation of the scale of effect represented by each category shall be provided.

4. *Risk characterisation*

The risk shall be characterised by combining, for each potential adverse effect, the magnitude with the likelihood of that adverse effect occurring to provide a quantitative or semi quantitative estimation of the risk.

Where a quantitative or semi quantitative estimation is not possible, a qualitative estimation of the risk shall be provided. In that case, a categorical description ('high', 'moderate', 'low' or 'negligible') of the risk shall be used and an explanation of the scale of effect represented by each category shall be provided.

Where relevant, the uncertainty for each identified risk shall be described and, where possible, expressed in quantitative terms.

5. *Risk management strategies*

Where risks are identified that require, on the basis of their characterisation, measures to manage them, a risk management strategy shall be proposed.

The risk management strategies shall be described in terms of reducing the hazard or the exposure, or both, and shall be proportionate to the intended reduction of the risk, the scale and conditions of the release and the levels of uncertainty identified in the e.r.a.

The consequent reduction in overall risk shall be quantified where possible.

▼M5

6. *Overall risk evaluation and conclusions*

A qualitative and, where possible, quantitative evaluation of the overall risk of the GMO shall be made taking into account the results of the risk characterisation, the proposed risk management strategies and the associated levels of uncertainty.

The overall risk evaluation shall include, where applicable, the risk management strategies proposed for each identified risk.

The overall risk evaluation and conclusions shall also propose specific requirements for the monitoring plan of the GMO and, where appropriate, the monitoring of the efficacy of the proposed risk management measures.

For notifications under Part C of the Directive, the overall risk evaluation shall also include an explanation of the assumptions made during the e.r.a. and of the nature and magnitude of uncertainties associated with the risks, and a justification of the risk management measures proposed.

D. **Conclusions on the specific areas of risk of the e.r.a.**

Conclusions on the potential environmental impact in relevant receiving environments from the release or the placing on the market of GMOs shall be drawn for each relevant area of risk listed in Section D1 for GMOs other than higher plants or Section D2 for genetically modified higher plants, on the basis of an e.r.a. carried out in accordance with the principles outlined in Section B and following the methodology described in Section C, and on the basis of the information required pursuant to Annex III.

▼B

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.

▼B

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.

▼M5

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

'Higher plants' shall mean plants which belong to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae).

1. Persistence and invasiveness of the GMHP, including plant to plant gene transfer

2. Plant to micro-organisms gene transfer

3. Interactions of the GMHP with target organisms

4. Interactions of the GMHP with non-target organisms

5. Impacts of the specific cultivation, management and harvesting techniques

6. Effects on biogeochemical processes

7. Effects on human and animal health.

▼M5

ANNEX III

INFORMATION REQUIRED IN THE NOTIFICATION

Notifications referred to in Parts B and C of this Directive shall, as a rule, include the information set out in Annex III A, for GMOs other than higher plants, or in Annex III B, for genetically modified higher plants.

The provision of a given subset of information listed in Annex III A or in Annex III B shall not be required where it is not relevant or necessary for the purposes of risk assessment in the context of a specific notification, in view especially of the characteristics of the GMO, of the scale and conditions of the release or of its intended conditions of use.

The appropriate level of detail for each subset of information may also vary according to the nature and the scale of the proposed release.

For each required subset of information, the following shall be provided:

(i) the summaries and results of the studies referred to in the notification, including an explanation about their relevance to e.r.a., where applicable;

(ii) for notifications referred to in Part C of this Directive, Annexes with detailed information on those studies, including a description of the methods and materials used or the reference to standardised or internationally recognised methods and the name of the body or bodies responsible for carrying out the studies.

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 perennial plants and trees, 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 Union.

▼B

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.

▼B

12. Nature of indigenous vectors:

    (a) sequence;

    (b) frequency of mobilisation;

    (c) specificity;

    (d) presence of genes which confer resistance.

13. History of previous genetic modifications.

B. **Characteristics of the vector**

1. nature and source of the vector,

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

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

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

C. **Characteristics of the modified organism**

1. Information relating to the genetic modification:

    (a) methods used for the modification;

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

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

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

    (e) methods and criteria used for selection;

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

2. Information on the final GMO:

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

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

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

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

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

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

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

▼B

(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 immuno-competent:

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

— communicability,

— infective dose,

— host range, possibility of alteration,

— possibility of survival outside of human host,

— presence of vectors or means of dissemination,

— biological stability,

— antibiotic resistance patterns,

— allergenicity,

— availability of appropriate therapies.

(v) other product hazards.

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

A. **Information on the release**

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

2. foreseen dates of the release and time planning of the experiment including frequency and duration of releases,

3. preparation of the site previous to the release,

4. size of the site,

5. method(s) to be used for the release,

6. quantities of GMOs to be released,

7. disturbance on the site (type and method of cultivation, mining, irrigation, or other activities),

8. worker protection measures taken during the release,

9. post-release treatment of the site,

10. techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment,

11. information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

▼B

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,

▼B

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

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

8. potential for excessive population increase in the environment,

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

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

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

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

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

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

15. known or predicted involvement in biogeochemical processes,

16. other potential interactions with the environment.

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

A. **Monitoring techniques**

1. methods for tracing the GMOs, and for monitoring their effects,

2. specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques,

3. techniques for detecting transfer of the donated genetic material to other organisms,

4. duration and frequency of the monitoring.

B. **Control of the release**

1. methods and procedures to avoid and/or minimise the spread of the GMOs beyond the site of release or the designated area for use,

2. methods and procedures to protect the site from intrusion by unauthorised individuals,

3. methods and procedures to prevent other organisms from entering the site.

C. **Waste treatment**

1. type of waste generated,

2. expected amount of waste,

3. description of treatment envisaged.

▼B

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.

▼M5

ANNEX III B

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

I. INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6 AND 7

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

4. Information relating to the release

(a) Purpose of the release

(b) Foreseen date(s) and duration of the release

(c) Method by which the GMHP will be released

(d) Method for preparing and managing the release site, prior to, during and post release, including cultivation practices and harvesting methods

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

5. Information relating to the site of release

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

(b) Description of the release site ecosystem, including climate, flora and fauna.

(c) Presence of sexually compatible wild relatives or cultivated plant species.

(d) Proximity to officially recognised biotopes or protected areas which may be affected.

B. **Scientific information**

1. Information relating to the recipient plant or, where appropriate, to the parental plants

(a) Complete name:

(i) family name

(ii) genus

(iii) species

(iv) subspecies

(v) cultivar or breeding line

(vi) common name.

(b) Geographical distribution and cultivation of the plant within the Union.

(c) Information concerning reproduction:

(i) mode(s) of reproduction

(ii) specific factors affecting reproduction, if any

(iii) generation time.

▼M5

(d) Sexual compatibility with other cultivated or wild plant species, including the distribution in Europe of the compatible species.

(e) Survivability:

(i) ability to form structures for survival or dormancy

(ii) specific factors affecting survivability, if any.

(f) Dissemination:

(i) ways and extent of dissemination

(ii) specific factors affecting dissemination, if any.

(g) Where a plant species is not normally grown in the Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

(h) Potential interactions of the plant, that are relevant to the GMHP, with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

2. Molecular characterisation

(a) Information relating to the genetic modification

(i) Description of the methods used for the genetic modification.

(ii) Nature and source of the vector used.

(iii) Source of the nucleic acid(s) used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.

(b) Information relating to the GMHP

(i) General description of the trait(s) and characteristics which have been introduced or modified.

(ii) Information on the sequences actually inserted/deleted:

— size and copy number of all insert(s) and methods used for its/their characterisation,

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

— subcellular location(s) of the insert(s) in the plant cells (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination.

(iii) Parts of the plant where the insert is expressed.

(iv) Genetic stability of the insert and phenotypic stability of the GMHP.

(c) Conclusions of the molecular characterisation

▼M5

3. Information on specific areas of risk

(a) Any change to the persistence or invasiveness of the GMHP, and its ability to transfer genetic material to sexually compatible relatives and the adverse environmental effects thereof.

(b) Any change to the ability of the GMHP to transfer genetic material to microorganisms and the adverse environmental effects thereof.

(c) Mechanism of interaction between the GMHP and target organisms (if applicable) and the adverse environmental effects thereof.

(d) Potential changes in the interactions of the GMHP with non-target organisms resulting from the genetic modification and the adverse environmental effects thereof.

(e) Potential changes in agricultural practices and management of the GMHP resulting from the genetic modification and the adverse environmental effects thereof.

(f) Potential interactions with the abiotic environment and the adverse environmental effects thereof.

(g) Information on any toxic, allergenic or other harmful effects on human and animal health arising from the genetic modification.

(h) Conclusions on the specific areas of risk.

4. Information on control, monitoring, post-release and waste treatment plans

(a) Any measures taken, including:

(i) spatial and temporal isolation from sexually compatible plant species, both wild and weedy relatives and crops;

(ii) any measures to minimise or prevent the dispersal of any reproductive part of the GMHP.

(b) Description of methods for post-release treatment of the site.

(c) Description of post-release treatment methods for the genetically modified plant material including wastes.

(d) Description of monitoring plans and techniques.

(e) Description of any emergency plans.

(f) Description of the methods and procedures to:

(i) avoid or minimise the spread of the GMHPs beyond the site of release;

(ii) protect the site from intrusion by unauthorised individuals;

(iii) prevent other organisms from entering the site or minimise such entries.

▼M5

5. Description of detection and identification techniques for the GMHP.

6. Information about previous releases of the GMHP, if applicable.

II. INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLE 13

A. **General information**

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

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

3. Designation and specification of the GMHP.

4. Scope of the notification.

(a) Cultivation

(b) Other uses (to be specified in the notification).

B. **Scientific information**

1. Information relating to the recipient plant or, where appropriate, to the parental plants

(a) Complete name:

(i) family name

(ii) genus

(iii) species

(iv) subspecies

(v) cultivar/breeding line

(vi) common name.

(b) Geographical distribution and cultivation of the plant within the Union.

(c) Information concerning reproduction:

(i) mode(s) of reproduction

(ii) specific factors affecting reproduction, if any

(iii) generation time.

(d) Sexual compatibility with other cultivated or wild plant species, including the distribution in the Union of the compatible species.

(e) Survivability:

(i) ability to form structures for survival or dormancy

(ii) specific factors affecting survivability, if any.

(f) Dissemination:

(i) ways and extent of dissemination;

(ii) specific factors affecting dissemination, if any.

(g) Where a plant species is not normally grown in the Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

▼M5

(h) Potential interactions of the plant, that are relevant to the GMHP, with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

2. Molecular characterisation

(a) Information relating to the genetic modification

(i) Description of the methods used for the genetic modification.

(ii) Nature and source of the vector used.

(iii) Source of the nucleic acid(s) used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.

(b) Information relating to the genetically modified plant

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

(ii) Information on the sequences actually inserted or deleted:

— size and copy number of all detectable inserts, both partial and complete, and methods used for its characterisation,

— the organisation and sequence of the inserted genetic material at each insertion site in a standardised electronic format,

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

— subcellular location(s) of the insert(s) (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination,

— in the case of modifications other than insertion or deletion, function of the modified genetic material before and after the modification, as well as direct changes in expression of genes as a result of the modification,

— sequence information in a standardised electronic format for both 5′ and 3′ flanking regions at each insertion site,

— bioinformatic analysis using up-to-date databases, to investigate possible interruptions of known genes,

— all Open Reading Frames, (hereafter referred to as ‘ORFs’) within the insert (either due to rearrangement or not) and those created as a result of the genetic modification at the junction sites with genomic DNA. ORF is defined as a nucleotide sequence that contains a string of codons that is uninterrupted by the presence of a stop codon in the same reading frame,

▼M5

— bioinformatic analysis using up-to-date databases, to investigate possible similarities between the ORFs and known genes which may have adverse effects,

— primary structure (amino acid sequence) and, if necessary, other structures, of the newly expressed protein,

— bioinformatic analysis using up-to-date databases, to investigate possible sequence homologies and, if necessary, structural similarities between the newly expressed protein and known proteins or peptides which may have adverse effects.

(iii) Information on the expression of the insert:

— method(s) used for expression analysis together with their performance characteristics,

— information on the developmental expression of the insert during the life cycle of the plant,

— parts of the plant where the insert/modified sequence is expressed,

— potential unintended expression of new ORFs identified under the seventh indent of point (ii), which raise a safety concern,

— protein expression data, including the raw data, obtained from field studies and related to the conditions in which the crop is grown.

(iv) Genetic stability of the insert and phenotypic stability of the GMHP.

(c) Conclusions of molecular characterisation

3. Comparative analysis of agronomic and phenotypic characteristics and of composition

(a) Choice of conventional counterpart and additional comparators.

(b) Choice of sites for field studies.

(c) Experimental design and statistical analysis of data from field trials for comparative analysis:

(i) Description of field studies design

(ii) Description of relevant aspect of the receiving environments

(iii) Statistical analysis.

(d) Selection of plant material for analysis, if relevant.

(e) Comparative analysis of agronomic and phenotypic characteristics.

(f) Comparative analysis of composition, if relevant.

(g) Conclusions of comparative analysis.

▼M5

4. Specific information for each area of risk

For each of the seven areas of risk referred to in Section D.2 of Annex II the notifier shall first describe the pathway to harm explaining in a chain of cause and effect how the release of the GMHP could lead to harm, taking into account both hazard and exposure.

The notifier shall submit the following information, except where it is not relevant in view of the intended uses of the GMO:

(a) Persistence and invasiveness including plant to plant gene transfer

(i) Assessment of the potential for the GMHP to become more persistent or invasive and the adverse environmental effects thereof;

(ii) Assessment of the potential for the GMHP to transmit transgene(s) to sexually compatible relatives and the adverse environmental effects thereof;

(iii) Conclusions on the adverse environmental effect(s) of persistence and invasiveness of the GMHP including the adverse environmental effect(s) of plant-to-plant gene transfer.

(b) Plant to micro-organism gene transfer

(i) Assessment of the potential for transfer of newly inserted DNA from the GMHP to microorganisms and the adverse effects thereof;

(ii) Conclusions on the adverse effect(s) of the transfer of newly inserted DNA from the GMHP to microorganisms for human and animal health and the environment;

(c) Interactions of the GMHP with target organisms, if relevant

(i) Assessment of the potential for changes in the direct and indirect interactions between the GMHP and target organisms and the adverse environmental effect(s);

(ii) Assessment of the potential for evolution of resistance of the target organism to the expressed protein (based on the history of evolution of resistance to conventional pesticides or transgenic plants expressing similar traits) and any adverse environmental effect(s) thereof;

(iii) Conclusions on adverse environmental effect(s) of interactions of the GMHP with target organisms.

(d) Interactions of the GMHP with non-target organisms.

(i) Assessment of the potential for direct and indirect interactions of the GMHP with non-target organisms, including protected species, and the adverse effect(s) thereof.

▼M5

The assessment shall also take into account the potential adverse effect(s) on relevant ecosystem services and on the species providing those services.

(ii) Conclusions on adverse environmental effect(s) of interactions of the GMHP with non-target organisms.

(e) Impacts of the specific cultivation, management and harvesting techniques

(i) For GMHPs for cultivation, assessment of the changes in the specific cultivation, management and harvesting techniques used for the GMHP and the adverse environmental effect(s) thereof;

(ii) Conclusions on adverse environmental effect(s) of the specific cultivation, management and harvesting techniques.

(f) Effects on biogeochemical processes

(i) Assessment of the changes in the biogeochemical processes within the area in which the GMHP is to be grown and in the wider environment, and the adverse effects thereof;

(ii) Conclusions on adverse effects on biogeochemical processes.

(g) Effects on human and animal health

(i) Assessment of potential direct and indirect interactions between the GMHP and persons working with or coming into contact with the GMHPs, including through pollen or dust from a processed GMHP, and assessment of the adverse effects of those interactions on human health;

(ii) For GMHPs not destined for human consumption, but where the recipient or parental organism(s) may be considered for human consumption, assessment of the likelihood of and possible adverse effects on human health due to accidental intake;

(iii) Assessment of the potential adverse effects on animal health due to accidental consumption of the GMHP or of material from that plant by animals;

(iv) Conclusions on the effects on human and animal health.

(h) Overall risk evaluation and conclusions.

A summary of all the conclusions under each area of risk shall be provided.

The summary shall take into account the risk characterisation in accordance with steps 1 to 4 of the methodology described in Section C.3 of Annex II and the risk management strategies proposed in accordance with point 5 of Section C.3 of Annex II.

5. Description of detection and identification techniques for the GMHP.

6. Information about previous releases of the GMHP, if applicable.

▼B

ANNEX IV

ADDITIONAL INFORMATION

▼M3

This Annex describes in general terms the additional information to be provided in the case of notification for placing on the market and the information for labelling requirements regarding GMOs as or in products to be placed on the market and GMOs exempted under the second subparagraph of Article 2(4). Technical guidance notes, as regards, *inter alia*, the description of how the product is intended to be used, may be developed in accordance with the regulatory procedure referred to in Article 30(2) in order to facilitate the implementation and explanation of this Annex. The labelling requirements for exempted organisms set out in Article 26 shall be met by providing appropriate recommendations for, and restrictions on, use.

▼B

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:

▼M5

1. proposed commercial names of the products and names of GMOs contained therein, and a proposal for a unique identifier for the GMO, developed in accordance with Commission Regulation (EC) No 65/2004 ([1]). After the consent any new commercial names should be provided to the competent authority,

▼B

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,

▼M5

7. methods for detection, identification and, where appropriate, quantification of the transformation event; samples of the GMO(s) and their control samples, and information as to the place where the reference material can be accessed. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register(s) referred to in Article 31(2) should be identified,

([1]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

▼B

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.

▼B

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.

▼B

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.

▼B

ANNEX VII

MONITORING PLAN

▼M3

This Annex describes in general terms the objective to be achieved and the general principles to be followed in the design of the monitoring plan referred to in Article 13(2), Article 19(3) and Article 20. Technical guidance notes may be developed in accordance with the regulatory procedure referred to in Article 30(2) in order to facilitate the implementation and explanation of this Annex.

▼B

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.

▼B

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.

▼B

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

▼B

Directive 90/220/EEC	This Directive
—	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