II

(Preparatory Acts)

COMMISSION

Proposal for a European Parliament and Council Directive amending Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms

(98/C 139/01)

(Text with EEA relevance)

COM(1998) 85 final — 98/0072 (COD)

(Submitted by the Commission on 23 February 1998)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Acting in accordance with the procedure laid down in Article 189b of the Treaty,

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

Whereas, the report of the Commission on the review [1] of Council Directive 90/220/EEC [2], as last amended by Commission Directive 97/35/EC [3], adopted on 10 December 1996, identified a number of areas where improvement is needed;

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

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

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

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

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

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

(1) COM(96) 630.
(2) OJ L 117, 8.5.1990, p. 15.
(3) OJ L 169, 27.6.1997, p. 72.

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

Whereas there is a need for consultation of the relevant Scientific Committee(s) established by the Commission Decision 97/579/EC [1] on matters which are likely to have an impact on human health and/or the environment;

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

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

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

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

Whereas the provisions of this Directive apply without prejudice to the provisions of Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries [2];

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

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

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 90/220/EEC is amended as follows:

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

'*Article 1*

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

(a) for research and development purposes or for any other purposes other than placing on the market,

(b) for placing on the market of genetically modified organisms as or in products.

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

Article 2

For the purposes of this Directive:

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

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

Within the terms of this definition:

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

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

3. "deliberate release" means any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment such as physical barriers, or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment;

[1] OJ L 237, 28.8.1997, p. 18.
[2] OJ L 40, 17.2.1993, p. 1.

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

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

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

Article 3

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

Article 4

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

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

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

PART B

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

Article 5

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

Article 6

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

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

Category I: Deliberate releases of GMOs which comply with the criteria set out in Annex V Parts A or B

Category II: All other releases.'

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

'Article 6a

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

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

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

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

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

(d) a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged.

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

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

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

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

Article 6b

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

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

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

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

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

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

(e) information on monitoring, control, waste treatment and emergency response plans,

(f) a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged.

3. The competent authority, having considered, where appropriate, any observations by other Member States made in accordance with Article 9, shall respond in writing to the notifier within 90 days of receipt of the notification by either:

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

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

4. For the purpose of calculating the 90-day period referred to in paragraph 3, any periods of time during which the competent authority:

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

or

(b) is carrying out a public inquiry or consultation in accordance with Article 7

shall not be taken into account.

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

Article 6c

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

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

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

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

5. The competent authorities referred to in paragraph 2, having considered any comments by other competent authorities, shall respond in writing to the notifier within 90 days of receipt of the notification by either:

(a) indicating that it is satisfied that the notification is in compliance with this Directive and that the release may proceed on their territory,

or

(b) indicating that the release does not fulfil the conditions of this Directive and the release cannot take place on their territory.

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

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

or

(b) are carrying out a public inquiry or consultation in accordance with Article 7

shall not be taken into account.

Article 6d

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

(a) revise the measures specified in the notification,

(b) revise the measures specified in the notification, inform the competent authority in advance of any modification or as soon as the new information is available,

(c) take the measures necessary to protect human health and the environment.

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

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

'Article 9

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

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

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

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

PART C

Placing on the market of products containing GMOs

Article 10

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

Article 11

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

2. The notification shall contain:

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

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

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

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

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

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

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

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

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

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

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

Article 12

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

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

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

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

4. For the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier shall not be taken into account. The competent authority shall motivate any request for further information. It shall inform the Commission and the other competent authorities of any additional information submitted by the notifier.

Article 13

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

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

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

The competent authorities and the Commission may discuss any outstanding issues with the aim of arriving at an agreement within 60 days from the date of circulation of the assessment report.

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

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

'Article 13a

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

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

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

Article 13b

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

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

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

or

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

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

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

5. The competent authorities or the Commission may make comments or present reasoned objections to the placing on the market of the GMO(s) in question within a period of 30 days from the date of circulation of the notification dossier. The comments or objections and replies by the notifier shall be forwarded to the Commission which shall immediately circulate them to all competent authorities. The competent authorities and the Commission may discuss any outstanding issues with the aim of arriving at an agreement within 45 days from the date of circulation of the notification.

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

Article 13c

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

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

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

(b) a report on the results of the monitoring which was carried out according to Article 13e(2),

and

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

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

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

The competent authorities of the Member States and the Commission may discuss any outstanding issues

with the aim of arriving at an agreement within 45 days following the circulation of the notification.

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

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

Article 13d

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

For the purpose of calculating the three-month period, any period of time during which the Commission is awaiting further information which it may have requested from the notifier or is seeking the opinion of a Scientific Committee which has been consulted shall not be taken into account.

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

Article 13e

1. Once a product has received a written consent, it may be used without further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to.

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

3. Consent to the placing on the market of GMOs in or as a product shall be granted for a fixed period of seven years. The notifier may proceed with the placing on the market only when he has received the written consent of the competent authority in accordance with Articles 13, 13b, 13c and 13d, and in conformity with any conditions, including reference to particular ecosystems/environ-mens, required in that consent.

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

(a) revise the information and conditions specified in the notification dossier,

(b) inform the competent authority,

and

(c) take the measures necessary to protect human health and the environment.

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

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

5. Article 14 is replaced by the following:

'Article 14

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

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

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

'Article 16

1. Where a Member State, as a result of new information or reassessment of existing information, has detailed grounds for considering that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

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

Article 17

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

2. Without prejudice to Article 19, all GMOs which have received written consent for the placing on the market or whose placing on the market was rejected as or in products under this Directive, the assessment reports carried out for these GMOs and the opinion(s) of the Scientific Committees consulted shall be made available to the public. For each product, the GMO or GMOs contained therein and the use or uses shall be clearly specified.

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

Article 18

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

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

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

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

9. Article 20 is replaced by the following:

'Article 20

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

10. The following Article 20a is inserted.

'Article 20a

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

11. Article 21 is replaced by the following:

'Article 21

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

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

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

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

If, on the expiry of a period of three months from the date of referral to the Council, the Council has

not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.'

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

'*Article 22a*

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

Article 22b

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

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

Article 2

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

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

Article 3

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

Article 4

This Directive is addressed to the Member States.

ANNEX I A

TECHNIQUES REFERRED TO IN ARTICLE 2(2)

PART 1

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

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

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

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

PART 2

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

1. *in vitro* fertilization,

2. natural processes such as: conjugation, transduction, transformation,

3. polyploidy induction.

ANNEX I B

TECHNIQUES REFERRED TO IN ARTICLE 3

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

1. mutagenesis,

2. cell fusion (including protoplast fusion) of plant cells where the resulting organisms can also be produced by traditional breeding methods.

ANNEX II

PRINCIPLES FOR THE ENVIRONMENTAL RISK ASSESSMENT

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

1. *Elements which may be considered as potentially harmful effects:*

   — pathogenicity to humans, animals or plants,

   — compromising of prophylactic or therapeutic treatments,

   — effects on population dynamics within the receiving environment,

   — effects on geochemistry,

   — the uncontrolled spread of the GMO(s) in the environment and invasion of unrelated ecosystems,

   — effects resulting from the transfer of the inserted genetic material to other organisms,

   — phenotypic and genetic instability.

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

   — the characteristics of the non-modified organism(s), and of the

   — introduced trait(s) which give rise to the GMO(s),

   — the characteristics of the intended use,

   — the receiving environment, and

   — the interaction between these.

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

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

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

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

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

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

3. *The likelihood of the hazard being realised*

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

4. *Estimation of the risk posed by each identified hazard*

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

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

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

6. *Determination of the overall risk of adverse effects*

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

ANNEX III

INFORMATION REQUIRED IN THE NOTIFICATION

The notification for a deliberate release referred to in Part B or Part C of the Directive is to include, as appropriate, the information set out below in the sub-Annexes.

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

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

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

The term 'higher plants' means plants which belong to the taxonomic groups Gymnospermae and Angiospermae.

ANNEX III A

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

I. GENERAL INFORMATION

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

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

C. Title of the project

II. INFORMATION RELATING TO THE GMO

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

1. Scientific name;
2. Taxonomy;
3. Other names (usual name, strain name, etc.);
4. Phenotypic and genetic markers;
5. Degree of relatedness between donor and recipient or between parental organisms;
6. Description of identification and detection techniques;
7. Sensitivity, reliability (in quantitative terms) and specificity of detection and dentification techniques;
8. Description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors, symbionts and hosts;
9. Potential for genetic transfer and exchange with other organisms;

10. Verification of the genetic stability of the organisms and factors affecting it;

11. Pathological, ecological and physiological traits:

    (a) classification of hazard according to existing Community rules concerning the protection of human health and/or the environment;

    (b) generation time in natural ecosystems, sexual and asexual reproductive cycle;

    (c) information on survival, including seasonability and the ability to form survival structures for example, seeds, spores or sclerotia;

    (d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). Ability to colonise other organisms;

    (e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;

    (f) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.

12. Nature of indigenous vectors:

    (a) sequence;

    (b) frequency of mobilisation;

    (c) specificity;

    (d) presence of genes which confer resistance.

13. History of previous genetic modifications.

B. **Characteristics of the vector**

1. Nature and source of the vector;

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

3. Frequency of mobilisation of inserted vector and/or genetic transfer capabilities and methods of determination;

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

C. **Characteristics of the modified organism**

1. Information relating to the genetic modification:

    (a) methods used for the modification;

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

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

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

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

2. Information on the final GMO:

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

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

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

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

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

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

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

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

(i) health considerations:

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

(ii) product hazards;

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

(iv) capacity for colonisations;

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

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

— communicability,

— infective dose,

— host range, possibility of alteration,

— possibility of survival outside of human host,

— presence of vectors or means of dissemination,

— biological stability,

— antibiotic-resistance patterns,

— allergenicity,

— availability of appropriate therapies.

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

A. **Information on the release**

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

2. Foreseen dates of the release and time planning of the experiment including frequency and duration of releases;

3. Preparation of the site previous to the release;

4. Size of the site;

5. Method(s) to be used for the release;

6. Quantities of GMOs to be released;

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

8. Worker protection measures taken during the release;

9. Post-release treatment of the site;

10. Techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment;

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

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

1. Geographical location and grid reference of the site(s) (in case of notifications under Part C the site(s) of release will be the foreseen areas of use of the product);

2. Physical or biological proximity to humans and other significant biota;

3. Proximity to significant biotopes or protected areas;

4. Size of local population;

5. Economic activities of local populations which are based on the natural resources of the area;

6. Distance to closest areas protected for drinking water and/or environmental purpose;

7. Climatic characteristics of the region(s) likely to be affected;

8. Geographical, geological and pedological characteristics;

9. Flora and fauna, including crops, livestock and migratory species;

10. Description of target and non-target ecosystems likely to be affected;

11. A comparison of the natural habitat of the recipient organism with the proposed site(s) of release;

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

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

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

1. Biological features which affect survival, multiplication and dispersal;

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

3. Sensitivity to specific agents.

B. **Interactions with the environment**

1. Predicted habitat of the GMOs;

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

3. Genetic transfer capability:

   (a) post-release transfer of genetic material from GMOs into organisms in affected ecosystems;

   (b) post-release transfer of genetic material from indigenous organisms to the GMOs;

4. Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the modified organism;

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

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

7. Description of ecosystems to which the GMOs could be disseminated.

C. **Potential environmental impact**

1. Potential for excessive population increase in the environment;

2. Competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s);

3. Identification and description of the target organisms;

4. Anticipated mechanism and result of interaction between the released GMOs and the target organism;

5. Identification and description of non-target organisms which may be affected unwittingly;

6. Likelihood of post-release shifts in biological interactions or in host range;

7. Known or predicted effects on non-target organisms in the environment, impact on population levels of competitors: preys, hosts, symbionts, predators, parasites and pathogens;

8. Known or predicted involvement in biogeochemical processes;

9. Other potentially significant interactions with the environment.

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

A. **Monitoring techniques**

1. Methods for tracing the GMOs, and for monitoring their effects;

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

3. Techniques for detecting transfer of the donated genetic material to other organisms;

4. Duration and frequency of the monitoring.

B. **Control of the release**

1. Methods and procedures to avoid and/or minimize the spread of the GMOs beyond the site of release or the designated area for use;

2. Methods and procedures to protect the site from intrusion by unauthorized individuals;

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

C. **Waste treatment**

1. Type of waste generated;

2. Expected amount of waste;

3. Possible risks;

4. Description of treatment envisaged.

D. **Emergency response plans**

1. Methods and procedures for controlling the GMOs in case of unexpected spread;

2. Methods for decontamination of the areas affected, e.g. eradication of the GMOs;

3. Methods for disposal or sanitation of plants, animals, soils, etc. that were exposed during or after the spread;

4. Methods for the isolation of the area affected by the spread;

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

ANNEX III B

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

A. GENERAL INFORMATION

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

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

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

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

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

D. INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

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

2. Information on the sequences actually inserted/deleted:

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

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

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

   (d) copy number of the insert.

3. Information on the expression of the insert:

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

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

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

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

   (b) dissemination;

   (c) survivability.

5. Genetic stability of the insert.

6. Potential for transfer of genetic material from the genetically modified plants to other organisms.

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

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

9. Potentially significant interactions with non-target organisms.

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

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

E. INFORMATION RELATING TO THE SITE OF RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6, 6a, 6b AND 6c)

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

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

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

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

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

1. Purpose of the release.

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

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

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

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

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

1. Any precautions taken:

   (a) distance(s) from sexually compatible plant species;

   (b) any measures to minimise/prevent pollen or seed dispersal.

2. Description of methods for post-release treatment of the site.

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

4. Description of monitoring plans and techniques.

5. Description of any emergency plans.

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

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

2. Any selective advantage or disadvantage conferred to other sexually compatible plants species, which may result from genetic transfer from the genetically modified plant.

3. Potential environmental impact of the interaction between the genetically modified plant and target organisms (if applicable).

4. Possible environmenal impact resulting from potential interactions with non-target organisms.

ANNEX IV

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

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

1. Name of the product and names of the GMOs contained therein;

2. Name of the manufacturer or distributor and his address in the Community;

3. Specificity of the product, exact conditions of use including, when appropriate, the type of environment and/or the geographical area(s) of the Community for which the product is suited;

4. Type of expected use: industry, agriculture and skilled trades, consumer use by public at large;

5. Information relating to the introduced genetic modification which could be of relevance to the establishment of a possible register of modifications introduced in organisms (species). This may include nucleotide sequences or other type of information which is relevant to the inclusion in such a register.

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

1. Measures to take in case of unintended release or misuse;

2. Specified instructions or recommendations for storage and handling;

3. Estimated production in and/or imports to the Community;

4. Proposed packaging. This must be appropriate so as to avoid unintended release of the GMOs during storage, or at a later stage;

5. Proposed labelling. This must include, at least in summarised form, the information referred to in points A. 1, A. 2, A. 3, B. 1 and B. 2.

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

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

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

ANNEX V

CRITERIA FOR CLASSIFICATION OF RELEASES PROVIDED FOR IN ARTICLE 6

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

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

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

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

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

ANNEX VI

GUIDELINES FOR THE ASSESSMENT REPORTS FORESEEN BY ARTICLE 12

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

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

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

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

4. Identification of any new risks to human health and/or the environment that may arise from the release of the GMO(s) in question as compared to the release of the corresponding non-modified organism(s) based on the risk assessment as described in Annex II;

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

ANNEX VII

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

— human health considerations:

  — potential of the GMOs for pathogenic, toxic or allergenic effects,

  — capacity of the GMOs for colonisation,

  — potential of the GMOs to compromise the efficacy of therapeutic, prophylactic or diagnostic measures;

— environmental considerations:

  — potential of the GMOs to persist and spread in the environment,

  — potential of the GMOs for interactions with target or non-target organisms,

  — potential of the GMOs to affect population dynamics;

— effects resulting from potential horizontal gene transfer;

— phenotypic and genetic stability of the GMOs.