

Brussels, 1. XII 1989

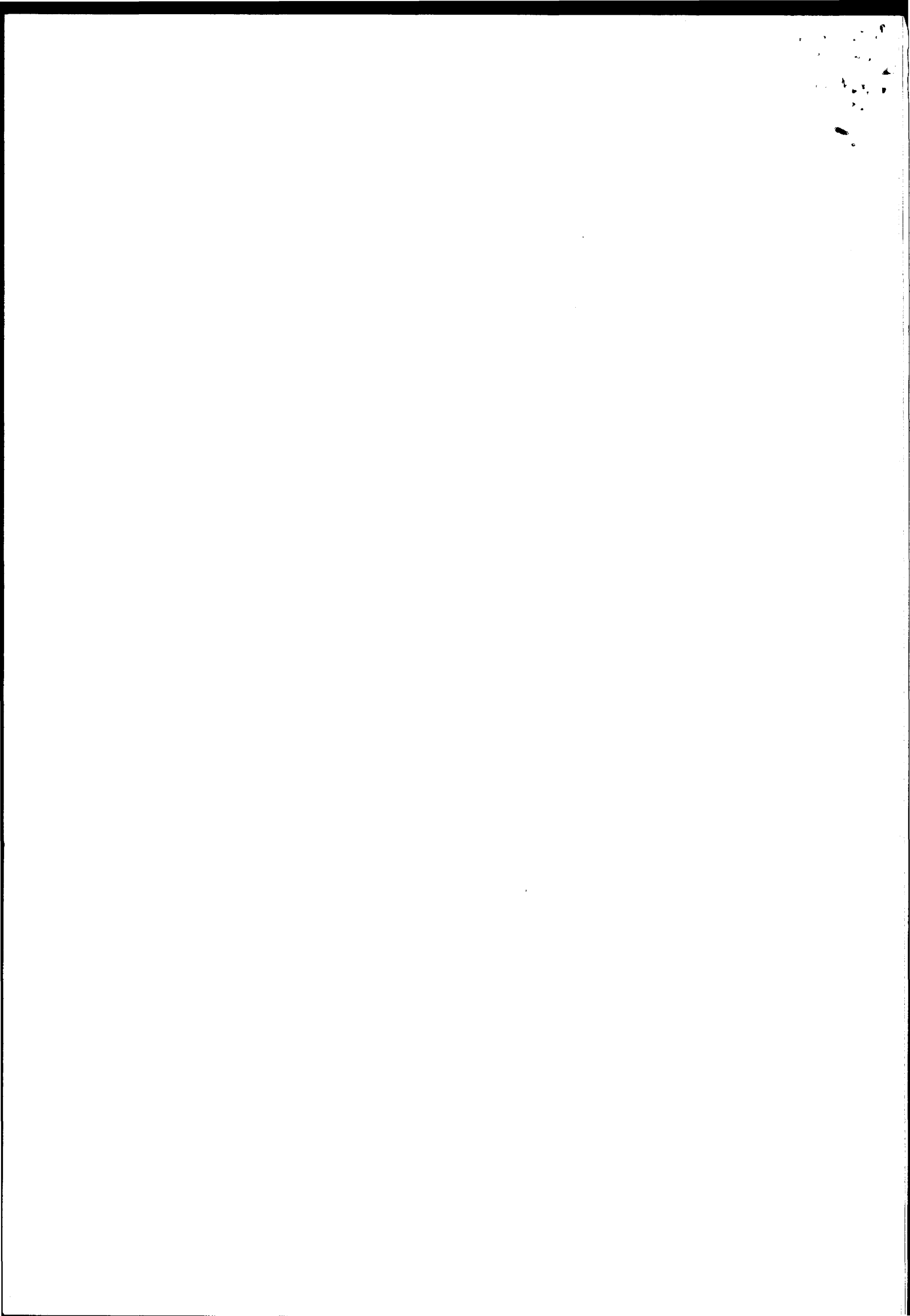
9644/89

RESTREINT

ENV 200
SAN 128
PRO-COOP 164

4412.221

COMMON POSITION
ADOPTED BY THE COUNCIL ON 3.0. XI. 1989
WITH A VIEW TO THE ADOPTION OF THE DIRECTIVE
ON THE DELIBERATE RELEASE INTO THE ENVIRONMENT
OF GENETICALLY MODIFIED ORGANISMS



COUNCIL DIRECTIVE
of
on the deliberate release into the environment
of genetically modified organisms

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

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

In co-operation with the European Parliament ⁽²⁾,

Having regard to the Opinion of the Economic and Social Committee ⁽³⁾,

(1) OJ No C 198, 28.7.1988, p. 19.

(2) Opinion delivered on 25 May 1989 (not yet published in the Official Journal) and Decision of (not yet published in the Official Journal).

(3) OJ No C 23, 30.1.1989, p. 45.

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

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

Whereas disparity between the rules which are in effect or in preparation in the Member States concerning the deliberate release into the environment of GMOs may create unequal conditions of competition or barriers to trade in products containing such organisms, thus affecting the functioning of the common market; whereas it is therefore necessary to approximate the laws of the Member States in this respect;

Whereas measures for the approximation of the provisions of the Member States which have as their object the establishment and functioning of the internal market should, inasmuch as they concern health, safety, environmental and consumer protection, be based on a high level of protection throughout the Community;

Whereas it is necessary to ensure the safe development of industrial products utilizing GMOs;

Whereas this Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record;

Whereas it is necessary to establish harmonized procedures and criteria for the case by case evaluation of the potential risks arising from the deliberate release of GMOs into the environment;

Whereas a case by case environmental risk assessment should always be carried out prior to a release;

Whereas the deliberate release of GMOs at the research stage is in most cases a necessary step in the development of new products derived from, or containing, GMOs;

Whereas the introduction of GMOs into the environment should be carried out according to the "step by step" principle; whereas this means that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken;

Whereas no product containing, or consisting of, GMOs and intended for deliberate release shall be considered for placing on the market without it first having been subjected to satisfactory field testing at the research and development stage in ecosystems which could be affected by its use;

Whereas it is necessary to establish a Community authorisation procedure for the placing on the market of products containing, or consisting of, GMOs where the intended use of the product involves the deliberate release of the organism(s) into the environment;

Whereas any person, before undertaking a deliberate release into the environment of a GMO, or the placing on the market of a product containing, or consisting of, GMOs, where the intended use of that product involves its deliberate release into the environment, shall submit a notification to the national competent authority;

Whereas that notification should contain a technical dossier of information including a full environmental risk assessment, appropriate safety and emergency response, and, in the case of products, precise instructions and conditions for use, and proposed labelling and packaging;

Whereas, after notification, no deliberate release of GMOs should be carried out unless the consent of the competent authority has been obtained;

Whereas the competent authority should give its consent only after it has been satisfied that the release will be safe for human health and the environment;

Whereas it may be considered appropriate in certain cases to consult the public on the deliberate release of GMOs into the environment;

Whereas it is appropriate for the Commission, in consultation with the Member States, to establish a procedure for the exchange of information on deliberate releases of GMOs notified under this Directive;

Whereas it is important to follow closely the development and use of GMOs; whereas a list should be published of all the products authorized under this Directive;

Whereas, when a product containing a GMO or a combination of GMOs is placed on the market, and where such a product has been properly authorized under this Directive, a Member State may not on grounds relating to matters covered by this Directive, prohibit, restrict or impede the deliberate release of the organism in that product on its territory where the conditions set out in the consent are respected; whereas a safeguard procedure should be provided in case of risk to human health or the environment;

Whereas the provisions of this Directive relating to placing on the market of products should not apply to products containing, or consisting of, GMOs covered by other Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive;

Whereas a Committee should be set up to assist the Commission on matters relating to the implementation of this Directive and to its adaptation to technical progress,

HAS ADOPTED THIS DIRECTIVE:

PART A: GENERAL PROVISIONS

Article 1

1. The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment:
 - when carrying out the deliberate release of genetically modified organisms into the environment,
 - when placing on the market products containing, or consisting of, genetically modified organisms intended for subsequent deliberate release into the environment.
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:

- (i) genetic modification occurs at least through the use of the techniques listed in Annex I A Part 1;
 - (ii) the techniques listed in Annex I A Part 2 are not considered to result in genetic modification;
- (3) "deliberate release" means any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment such as physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment;
 - (4) "product" means a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market;
 - (5) "placing on the market" means supplying or making available to third parties;

- (6) "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";
- (7) "use" means the deliberate release of a product which has been placed on the market. The persons carrying out this use will be referred to as "users";
- (8) "environmental risk assessment" means the evaluation of the risk to human health and the environment (which includes plants and animals) connected with the release of GMOs or products containing GMOs.

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 or placing on the market of GMOs.
2. Member States shall designate the competent authority or authorities responsible for carrying out the requirements of this Directive and its Annexes.
3. Member States shall ensure that the competent authority organizes inspections and other control measures as appropriate, to ensure compliance with this Directive.

PART B: DELIBERATE RELEASE OF GMOs INTO
THE ENVIRONMENT FOR RESEARCH AND
DEVELOPMENT PURPOSES OR FOR ANY OTHER PURPOSE THAN
FOR PLACING ON THE MARKET

Article 5

Member States shall adopt the provisions necessary to ensure that:

- (1) any person, before undertaking a deliberate release of a GMO or a combination of GMOs for the purpose of research and development, or for any other purpose than for placing on the market, 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 shall include:
 - (a) a technical dossier supplying the information specified in Annex II necessary for evaluating the foreseeable risks, whether immediate or delayed, which the GMO or combination of GMOs may pose to human health or the environment, together with the methods used and the bibliographic reference to them and covering, 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 receiving environment,

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

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

(b) 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 may accept that releases of a combination of GMOs on the same site or of the same GMO on different sites for the same purpose and within a limited period, may be notified in a single notification;

(4) the notifier shall include in the 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 him either inside or outside the Community.

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;

- (5) in the case of a subsequent release of the same GMO or combination of GMOs previously notified as part of the same research programme, the notifier shall be required to submit a new notification. In this case, the notifier may refer to data from previous notifications or results from previous releases;
- (6) in the event of any modification of the deliberate release of GMOs or a combination of GMOs which could have consequences with regard to the 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 or after that authority has given its written consent, the notifier shall immediately:
- (a) revise the measures specified in the notification,
 - (b) 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.

Article 6

1. On receipt and after acknowledgment of the notification the competent authority shall:

- examine it for compliance with this Directive,
- evaluate the risks posed by the release,
- record its conclusions in writing,

and, if necessary,

- carry out tests or inspections as may be necessary for control purposes.

2. The competent authority, having considered, where appropriate, any comments 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.

3. 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,
or
- is carrying out a public enquiry or consultation in accordance with Article 7

shall not be taken into account.

4. 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.

5. If the competent authority considers that sufficient experience has been obtained of releases of certain GMOs, it may submit to the Commission a request for the application of simplified procedures for releases of such types of GMOs. The Commission shall, in accordance with the procedures laid down in Article 21, establish appropriate criteria and take a decision accordingly on each application. The criteria shall be based on safety to human health and the environment and on the evidence available on such safety.

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

Article 7

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

Article 8

After completion of a release, the notifier shall send to the competent authority the result of the release in respect of any risk to human health or the environment, with particular reference to any kind of product that the notifier intends to notify at a later stage.

Article 9

1. The Commission shall set up a system of exchange of the information contained in the notifications. The competent authorities shall send to the Commission, within thirty days of its receipt, a summary of each notification received. 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 thirty days, ask for further information or 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 6(2).

PART C : PLACING ON THE MARKET OF PRODUCTS CONTAINING GMOs

Article 10

1. Consent may only be given for the placing on the market of products containing, or consisting of, GMOs, provided that:

- written consent has been given to a notification under Part B or if a risk analysis has been carried out based on the elements outlined in that Part;
- the products comply with the relevant Community product legislation;
- the products comply with the requirements of this Part of this Directive, concerning the environmental risk assessment.

2. 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.

3. Not later than 12 months after notification of this Directive, the Commission, in accordance with the procedure laid down in Article 21, shall establish a list of Community legislation covering the products referred to in paragraph 2. This list will be re-examined periodically and, as necessary, revised in accordance with the said procedure.

Article 11

1. Before a GMO or a combination of GMOs are placed on the market as or in a product, the manufacturer or the importer to the Community shall submit a notification to the competent authority of the Member State where such product is to be placed on the market for the first time. This notification shall contain :

- the information required in Annex II, extended as necessary to take into account the diversity of sites of use of the product, including information on data and results obtained from research and developmental releases concerning the ecosystems which could be affected by the use of the product and an assessment of any risks for human health and the environment related to the GMOs or a combination of GMOs contained in the product, including information obtained from the research and development stage on the impact of the release on human health and the environment;
- the conditions for the placing on the market of the product, including specific conditions of use and handling and a proposal for labelling and packaging which should comprise at least the requirements laid down in Annex III.

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 III B.

2. 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.

3. 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.

4. Each new product which, containing or consisting of the same GMO or combination of GMOs, is intended for a different use, shall be notified separately.

5. The notifier may proceed with the release only when he has received the written consent of the competent authority in accordance with Article 13, and in conformity with any conditions, including reference to particular ecosystems/environments, required in that consent.

6. 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 :

- revise the information and conditions specified in paragraph 1,
- inform the competent authority, and
- take the measures necessary to protect human health and the environment.

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, giving particular attention to the environmental risk assessment and the recommended precautions related to the safe use of the product.

2. At the latest 90 days after receipt of the notification, the competent authority shall:

either

(a) forward the dossier to the Commission with a favourable opinion,

or

(b) inform the notifier that the proposed release does not fulfil the conditions of this Directive and that it is therefore rejected.

3. In the case referred to in paragraph 2(a), the dossier forwarded to the Commission shall include a summary of the notification together with a statement of the conditions under which the competent authority proposes to consent to the placing on the market of the product.

The format of this summary shall be established by the Commission in accordance with the procedure laid down in Article 21.

In particular where the competent authority has acceded to the request of the notifier, under the terms of the last subparagraph of Article 11(1), not to comply with some of the requirements of Annex III.B., it shall at the same time inform the Commission thereof.

4. If the competent authority receives additional information pursuant to Article 11(6), it shall immediately inform the Commission and the other Member States.

5. 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.

Article 13

1. On receipt of the dossier referred to in Article 12(3), the Commission shall immediately forward it to the competent authorities of all Member States together with any other information it has collected pursuant to this Directive and advise the competent authority responsible for forwarding the document of the distribution date.

2. The competent authority, in the absence of any indication to the contrary from another Member State within 60 days following the distribution date referred to in paragraph 1, shall give its consent in writing to the notification so that the product can be placed on the market and shall inform the other Member States and the Commission thereof.

3. In cases where the competent authority of another Member State raises an objection - for which the reasons must be stated - and should it not be possible for the competent authorities concerned to reach an agreement within the period specified in paragraph 2, the Commission shall take a decision in accordance with the procedure laid down in Article 21.

4. Where the Commission has taken a favourable decision, the competent authority that received the original notification shall give consent in writing to the notification so that the product may be placed on the market and shall inform the other Member States and the Commission thereof.

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

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

Article 14

Member States shall take all necessary measures to ensure that products containing, or consisting of, GMOs will be placed on the market only if their labelling and packaging is that specified in the written consent referred to in Articles 12 and 13.

Article 15

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

Article 16

1. Where a Member State has justifiable reasons to consider 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, it 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

The Commission shall publish in the Official Journal of the European Communities a list of all the products receiving final written consent under this Directive. For each product, the GMO or GMOs contained therein and the use or uses shall be clearly specified.

Article 18

1. Member States shall send to the Commission, at the end of each year, a brief factual report on the control of the use of all products placed on the market under this Directive.

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

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

PART D: FINAL PROVISIONS

Article 19

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

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

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

4. In no case may the following information when submitted according to Articles 5 or 11 be kept confidential:

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

- methods and plans for monitoring of the GMO or GMOs and for emergency response;
- the evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.

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

Article 20

According to the procedure laid down in Article 21, the Commission shall adapt Annexes II and III to technical progress in particular by amending the notification requirements to take into account the potential hazard of the GMOs.

Article 21

The Commission shall be assisted by a Committee composed by the representatives of the Member States and chaired by the representative of the Commission.

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 3 months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 22

1. Member States and the Commission shall meet regularly and exchange information on the experience acquired with regard to the prevention of risks related to the release of GMOs into the environment.
2. Every three years, Member States shall send the Commission a report on the measures taken to implement the provisions of this Directive, the first time being on 1 September 1992.
3. Every three years, the Commission shall publish a summary based on the reports referred to in paragraph 2, the first time being in 1993.

Article 23

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before ... (+).

(+) 18 months from the date of adoption of this Directive.

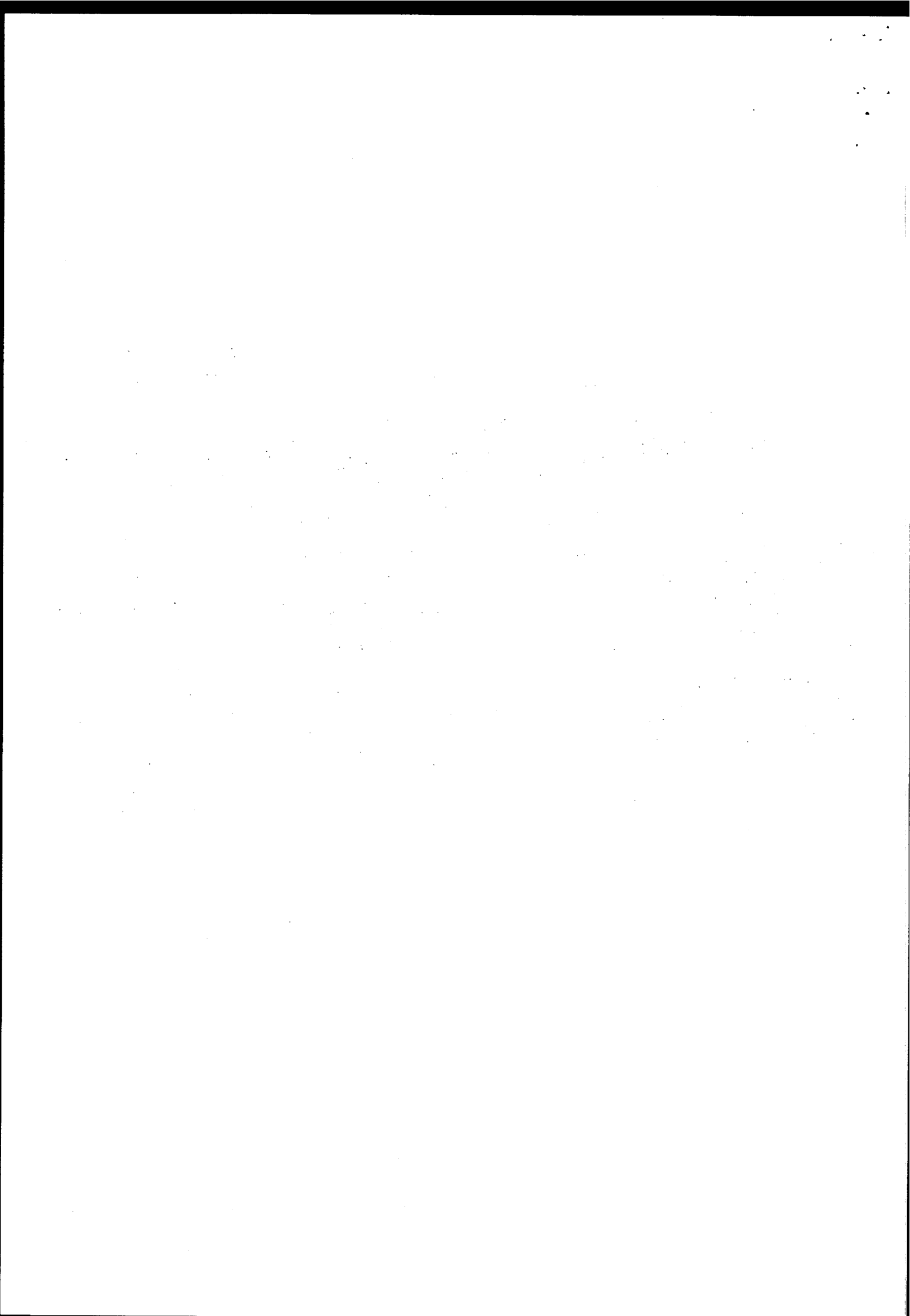
2. Member States shall immediately inform the Commission of all laws, regulations and administrative provisions adopted in implementation of this Directive.

Article 24

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President



TECHNIQUES REFERRED TO IN ARTICLE 2(2)

Part 1 Techniques of genetic modification referred to in Article 2(2)(i)
are inter alia

- (1) Recombinant DNA techniques using vector systems as previously covered by Council Recommendation 82/472/EEC.
- (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 hybridization 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.

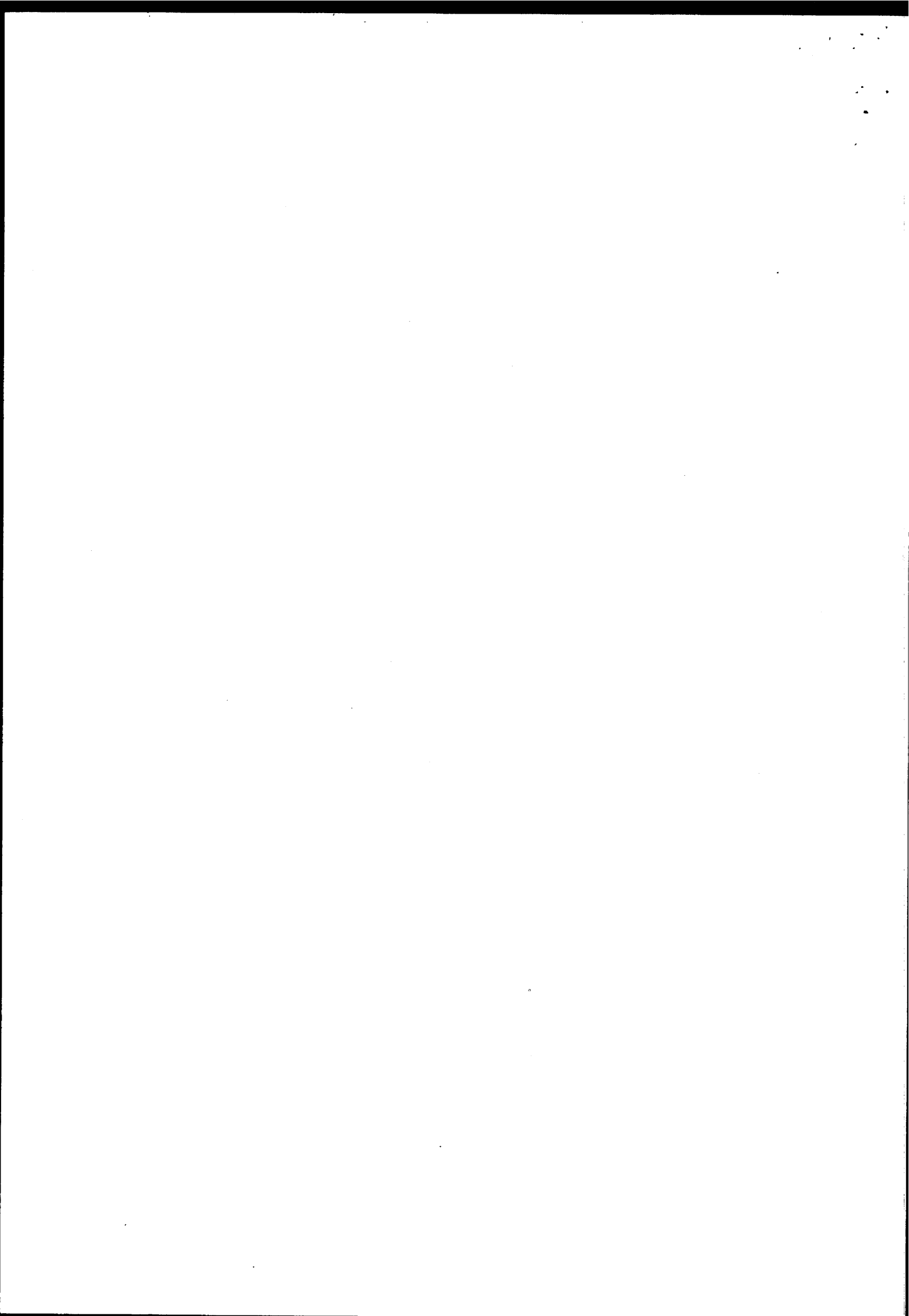
Part 2 Techniques referred to in Article 2(2)(ii) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant DNA molecules or GMOs, are:

- (1) in vitro fertilization,
 - (2) conjugation, transduction, transformation or any other natural process,
 - (3) polyploidy induction.
-

TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques of genetic modification to be excluded from this Directive, on condition that they do not involve the use of GMOs as recipient or parental organisms, are:

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



INFORMATION REQUIRED IN THE NOTIFICATION

The notifications for a deliberate release referred to in Article 5 and for placing on the market referred to in Article 11 must provide the information set out below.

Not all the points included will apply to every case. It is to be expected, therefore, that individual notifications will address only the particular subset of considerations that are appropriate to individual situations. In each case where it is not technically possible or it does not appear necessary to give the information, the reasons shall be stated.

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.

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

I. GENERAL INFORMATION

A. NAME AND ADDRESS OF THE NOTIFIER

B. INFORMATION ON PERSONNEL AND TRAINING

- (1) Name of person(s) responsible for planning and carrying out the release including those responsible for supervision, monitoring and safety, in particular, name and qualifications of the responsible scientist;
- (2) Information on training and qualifications of personnel involved in carrying out the release.

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, cultivar 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. Potential for genetic transfer and exchange with other organisms;
10. Verification of the genetic stability of the organisms and factors affecting it;
11. Pathological, ecological and physiological traits:
 - (a) classification of hazard according to existing Community rules concerning the protection of human health and/or the environment;
 - (b) generation time in natural ecosystems, sexual and asexual reproductive cycle;
 - (c) information on survival, including seasonability and the ability to form survival structures e.g.: seeds, spores or sclerotia;
 - (d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). Ability to colonize other organisms;

- (e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;
- (f) involvement in environmental processes: primary production, nutrient turn-over, 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 mobilization of inserted vector and/or genetic transfer capabilities and methods of determination;
4. Information on the degree to which the vector is limited to the DNA required to perform the intended function.

C. Characteristics of the modified organism:

1. Information relating to the genetic modification;
 - (a) Methods used for the modification
 - (b) Methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;
 - (c) Description of the insert and/or vector construction;
 - (d) Purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;
 - (e) Sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.

2. Information on the final GMO:

- (a) Description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;
- (b) Structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;
- (c) Stability of the organism in terms of genetic traits;
- (d) Rate and level of expression of the new genetic material. Method and sensitivity of measurement;
- (e) Activity of the expressed protein(s);
- (f) Description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;
- (g) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
- (h) History of previous releases or uses of the GMO;
- (i) Health and considerations:
 - (i) toxic or allergenic effects of the non-viable GMOs and/or their metabolic products;
 - (ii) product hazards;
 - (iii) comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
 - (iv) capacity for colonization;
 - (v) if the organism is pathogenic to humans who are immunocompetent:
 - diseases caused and mechanism of pathogenicity including invasiveness and virulence,
 - communicability,
 - infective dose,
 - host range, possibility of alteration,
 - possibility of survival outside of human host,
 - presence of vectors or means of dissemination,
 - biological stability,
 - antibiotic-resistance patterns,
 - allergenicity,
 - availability of appropriate therapies.

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

A. Information on the release:

1. Description of the proposed deliberate release, including the purpose(s) and foreseen products;
2. Foreseen dates of the release and time planning of the experiment including frequency and duration of releases;
3. Preparation of the site previous to the release;
4. Size of the site;
5. Method(s) to be used for the release;
6. Quantities of GMOs to be released;
7. Disturbance on the site (type and method of cultivation, mining, irrigation, or other activities);
8. Worker protection measures taken during the release;
9. Post-release treatment of the site;
10. Techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment;
11. Information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

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

1. Geographical location and grid reference of the site(s) (in case of notifications under Part C the site(s) of release will be the foreseen areas of use of the product);
2. Physical or biological proximity to humans and other significant biota;
3. Proximity to significant biotopes or protected areas;
4. Size of local population;
5. Economic activities of local populations which are based on the natural resources of the area;
6. Distance to closest areas protected for drinking water and/or environmental purpose;
7. Climatic characteristics of the region(s) likely to be affected;
8. Geographical, geological and pedological characteristics;
9. Flora and fauna, including crops, livestock and migratory species;
10. Description of target and non-target ecosystems likely to be affected;
11. A comparison of the natural habitat of the recipient organism with the proposed site(s) of release;
12. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

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

A. Characteristics affecting survival, multiplication and dissemination:

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

B. Interactions with the environment:

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

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:

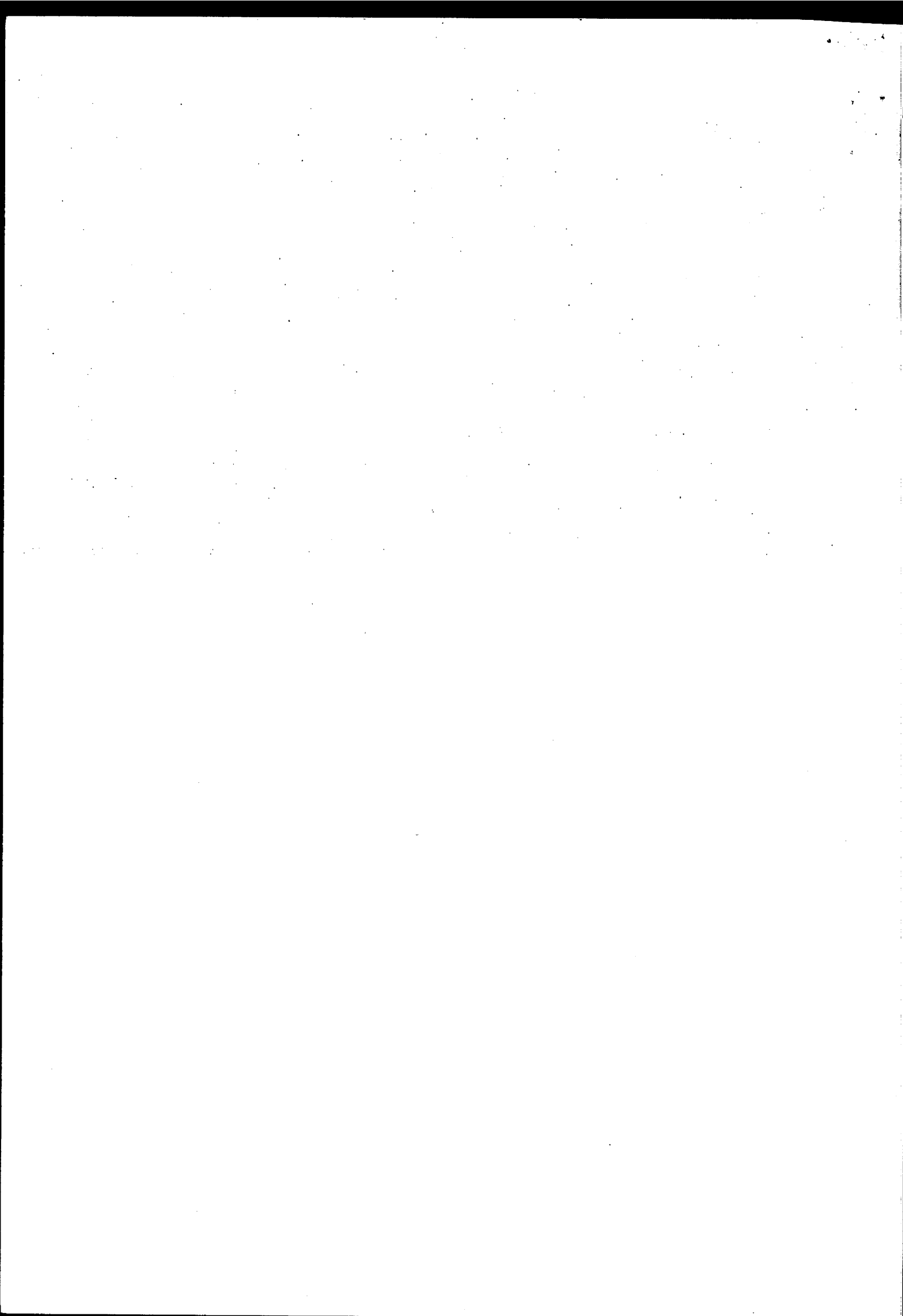
1. Methods and procedures to avoid and/or minimize the spread of the GMOs beyond the site of release or the designated area for use;
2. Methods and procedures to protect the site from intrusion by unauthorized individuals;
3. Methods and procedures to prevent other organisms from entering the site.

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.



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 II:
1. Name of the product and names of GMOs contained therein;
 2. Name of the manufacturer or distributor and his address in the Community;
 3. Specificity of the product, exact conditions of use including, when appropriate, the type of environment and/or the geographical area(s) of the Community for which the product is suited;
 4. Type of expected use: industry, agriculture and skilled trades, consumer use by public at large.

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

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