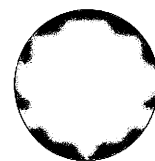




European Communities



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**** I**

REPORT

drawn up on behalf of the Committee on the Environment,
Public Health and Consumer Protection

on the proposal from the Commission to the Council
(COM/88/160 - C2-73/88) for a directive on the
deliberate release to the environment of genetically
modified organisms

Rapporteur : Mr Gerhard SCHMID

4412 . 221

PE 128.472/fin.

A Series: Reports - B series: Motions for Resolutions, Oral Questions.

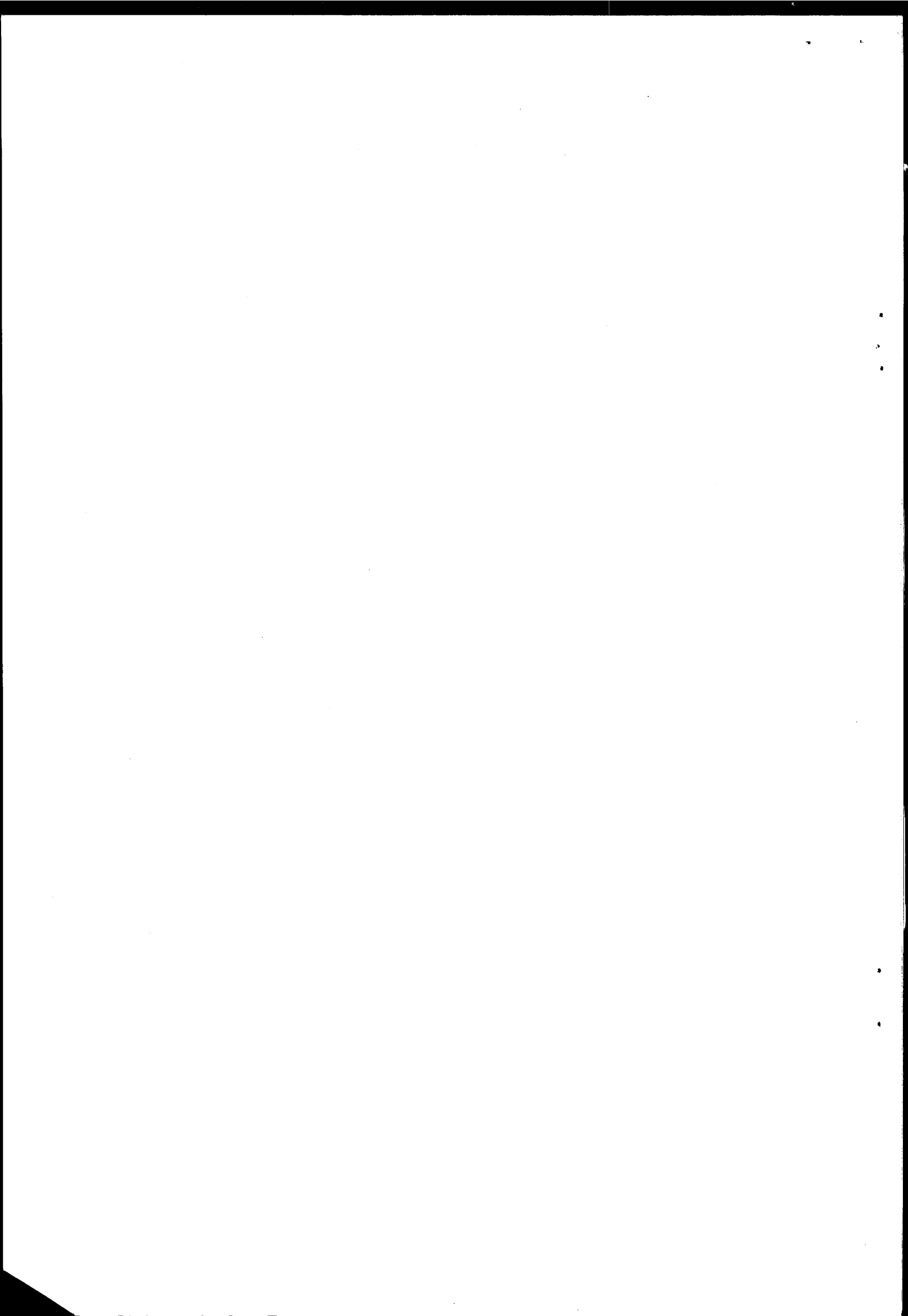
***** = Consultation procedure requiring a single reading

****I** = Cooperation procedure (first reading)

- C Series: Documents received from other Institutions (e.g. Consultations)

****II** = Cooperation procedure (second reading) which requires the votes of the majority of the Members of Parliament

******* = Parliamentary assent which requires the votes of the majority of the current Members of Parliament



By letter of 9 June 1988, the President of the Council of the European Communities requested the European Parliament, pursuant to Article 100a of the EEC Treaty, to deliver an opinion on the proposal from the Commission of the European Communities to the Council for a directive on the deliberate release to the environment of genetically modified organisms.

On 16 June 1988, the President of the European Parliament referred this proposal to the Committee on the Environment, Public Health and Consumer Protection as the Committee responsible and to the Committee on Energy, Research and Technology for its opinion.

At its meeting of 26 February 1988, the Committee on the Environment, Public Health and Consumer Protection appointed Mr Gerhard SCHMID, rapporteur.

At its meeting of 2 March 1989 the Committee decided to ask the Committee on Legal Affairs and Citizens' Rights for its opinion on the appropriate legal basis for the proposed directive.

The Committee on the Environment, Public Health and Consumer Protection considered the Commission's proposal and the draft report at its meetings of 11 July 1988, 2 March 1989, 31 March 1989 and 26 April 1989.

At this last meeting the Committee adopted the report by 15 votes to 0, with 3 abstentions.

The following took part in the vote:

Mrs WEBER, chairman; Mr SCHLEICHER, vice-chairman, Mr PEREIRA, vice-chairman; Mr SCHMID, rapporteur; Mrs BELO (deputizing for Mr CANO PINTO), Mrs BLOCH von BLOTTNITZ, Mr BOMBARD, Mrs DIEZ DE RIVERA, Mr ELLIOTT (deputizing for Mr HUGHES), Mr V. GARCIA (deputizing for Mr LACERDA DE QUEIROZ), Mr GRAZIANI, Mrs GREDAL, Mr HÄRLIN (deputizing for Mr ROELANTS du VIVIER), Mr van der LEK, (deputizing for Mrs HAMMERICH), Mrs LENTZ-CORNETTE, Mr MUNTINGH, Ms TONGUE, Mr VALVERDE.

The opinion of the Committee on Legal Affairs and Citizens' Rights is annexed to this report. The opinion of the Committee on Energy, Research and Technology will be published separately.

The report was tabled on 28 April 1989.

The deadline for tabling amendments to this report will be indicated in the draft agenda for the part-session at which it will be debated.

C O N T E N T S

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The Committee on the Environment, Public Health and Consumer Protection hereby submits to the European Parliament the following amendments to the Commission proposal, together with a draft legislative resolution and explanatory statement.

Proposal for a Council directive on the deliberate release to the environment of genetically modified organisms

Text proposed by the Commission of the European Communities

Amendments adopted by the Committee on the Environment, Public Health and Consumer Protection

Citations and recitals

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty Establishing the European Economic Community and in particular Article 100 A thereof,

Having regard to the proposal of the Commission,

Having regard to the opinion of the European Parliament,

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

Whereas disparity between the regulation of the deliberate release to the environment of genetically modified organisms which are in effect or in preparation in the Member States may create unequal conditions of competition and thus directly affect the functioning of the common market; whereas it is therefore necessary to approximate the laws of the Member States in this regard, as provided for in Article 100 A of the Treaty;

AMENDMENT No. 1

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty Establishing the European Economic Community and in particular Articles 130r and 130s thereof,

unchanged

unchanged

unchanged

AMENDMENT No. 2

To read :
Whereas the existing regulations on the deliberate release of GMOs which are in effect in the Member States do not provide adequate protection of the environment everywhere in the Community;

AMENDMENT No 3

To read :

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 shall, inasmuch as they concern health, safety, environmental and consumer protection, take a high level of protection as a base and provide, despite existing differences in economies of the Member States, for equal standards of protection throughout the Community;

Whereas it is therefore necessary to provide Community regulation in order to preserve, protect and improve the quality of the environment and to contribute towards protecting human health;

Third and fourth recitals unchanged

AMENDMENT No. 4

Delete

Whereas it is necessary to ensure the development of industrial products utilizing genetically modified organisms which do not cause harm to human health or the environment; whereas the new biotechnology promises improvements in health and the environment by developing more precise agricultural inputs for protection and nutrition and more effective treatment of wastes;

Sixth recital unchanged

AMENDMENT No 5

To read :

Whereas new techniques of genetic modification are defined in Article 2(2) and Annex I of this Directive; whereas those techniques which have conventionally been used with crop plants and livestock with an excellent safety record are not covered by the definition of Article 2 (2) or Annex I;

Whereas, given the uncertainty about the real risks and the irreversibility of deliberate releases of GMOs, a high level of environmental protection shall be adopted until scientific knowledge has increased our understanding;

AMENDMENT No. 6

Insert new recital 7a:

Whereas for any deliberate release the social desirability of its goals shall be demonstrated as well as the absence of better alternatives to attain them;

Eighth and ninth recitals unchanged

AMENDMENT N . 7

Insert new recital 9a:

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 all the ecosystems which could be affected by its use;

Tenth recital unchanged

AMENDMENT No 8

To read :

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

Whereas no deliberate release of GMOs shall be carried out without the previous explicit authorisation of the competent authorities;

AMENDMENT No. 9

Insert new recital 11a:

Whereas no deliberate release shall be authorised by a competent authority unless it is proven and verified to have no negative impact on the environment and humans;

Twelfth recital unchanged

AMENDMENT No. 10

Insert new recital 12a:

Whereas the consequences of a deliberate release, information on potential hazards and measures to be taken have to be communicated on an active basis to the concerned persons without a request being made; and whereas wider public information must also be foreseen as well as adequate formal and informal consultation procedures;

Thirteenth recital unchanged

AMENDMENT No. 11

Delete

Whereas when a product containing a genetically modified organism or a combination of them is placed on the market where the intended use of that product involves its deliberate release to the environment, and where such a product has been properly notified and endorsed under this Directive, a Member State may not prohibit, restrict or impede the deliberate release of this organism on their territory under the conditions set out in the notification, except under the specific conditions of safeguard procedure, in case of a serious risk to human health or the environment,

Text proposed by the Commission of
the European Communities

Amendments adopted by the Committee
on the Environment, Public Health
and Consumer Protection

AMENDMENT No. 12

NOTE: THIS AMENDMENT APPLIES TO THE
WHOLE OF THE COMMISSION TEXT

In the whole text the word
'notification' shall be replaced by
the word 'application for
authorization', the word 'notify'
shall be replaced by the word 'apply
for authorization', the word
'notifier' shall be replaced by the
word 'applicant' and the word
'endorsement' shall be replaced by
'authorization'.

Part A : General provisions

Article 1

Article 1

1. The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect the health of the general population and the environment in relation with:

- the deliberate release of genetically modified organisms to the environment,
- the placing on the market of products containing or consisting of genetically modified organisms intended for subsequent deliberate release to the environment.

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

AMENDMENT No. 13

Delete first sentence and replace with:

1. The objective of this
Directive is to lay down
standards, and the
administrative procedures in
order to protect human health
and the environment in
relation with:
(rest unchanged)

2. unchanged

Article 2

AMENDMENT No. 14

For the purpose of this Directive:

1. **Organism** includes multicellular and unicellular organisms. It also includes subcellular entities capable of replication or biological activity.

AMENDMENT No 15

Delete Article 2(2) and replace by:

2. Genetically modified organism is an organism in which the genetic material has been altered in a way that does not occur naturally by mating and natural recombination under normal physiological conditions

3. unchanged

4. unchanged

AMENDMENT No 16

Delete Article 2(5) and replace by:

5. Placing on the market means supplying or making available to third persons for the purpose of deliberate release.

6. unchanged

7. unchanged

For the purpose of this Directive:

1. **Organism** includes multicellular and unicellular organisms. It also includes subcellular entities capable of replication.
2. **Genetically modified organism** (hereinafter referred to as GMO) is an organism in which the genetic material is altered in a way that passes the natural barriers of mating and recombination. Annex I indicates the techniques by which such genetic alterations can be obtained.
3. **Deliberate release** means any intentional introduction in the environment of a GMO or a combination of GMOs without provisions for containment such as special procedures, equipment and installations, or facilities that provide physical barriers to prevent their spread into the environment.
4. **Product** means a preparation or formulation 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 for the purpose of sale or commercial distribution.
6. **Notification** means the documents whereby the person who is to carry out a deliberate release of a GMO or a combination of GMOs for the purpose of research and development, or to place a product on the market presents the requisite information to the competent authority of a Member State. This person 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'.

AMENDMENT No 17

Insert a new Article 2(8)

8. 'Authorisation' means: The explicit permission to be given by a competent authority to carry out a release.

AMENDMENT No 18

Add new Article 2(9)

- 9 'Applicant' means: The legal or natural person requesting authorisation and assuming legal responsibility for a deliberate release of GMOs.

Article 3

AMENDMENT No. 19

Delete Article 3(1) and replace by:

1. Member States shall adopt the provisions necessary to ensure that all persons carrying out the deliberate release or placing on the market of GMO(s) shall take all measures reasonably practicable to control any risk of harm to people and the environment.

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

1. Member States shall adopt the provisions necessary to ensure that all persons carrying out a deliberate release or placing on the market of GMOs shall take all measures necessary and shall carry out all previous necessary experiments and tests to control any risk of harm to people and the environment.

2. unchanged

AMENDMENT No 20

Insert a new Article 3(3) :

3. The deliberate release of a GMO shall be subject to express authorization by the competent authority. Under no circumstances shall the release of pathogenic GMOs or of GMOs more able than the parental organism to compete successfully in the natural environment be permissible.

AMENDMENT No. 21

Insert a new Article 3(4) :

4. In respect of releases of GMOs, the Member States shall introduce absolute-liability arrangements and make appropriate indemnification mandatory.

AMENDMENT No. 22

Insert a new Article 3(5) :

5. The Member States shall ensure that effective penalties are imposed for infringements of national rules deriving from this Directive.

AMENDMENT No. 23

Insert a new Article 3(6) :

6. The Member States shall ensure that notice of planned releases is given to the inhabitants of the areas concerned.

Part B: Deliberate release of genetically modified organisms for research and development purposes

Article 4

AMENDMENT No. 24

Article 4(2)(a) first indent, add:

'as well as information on the donor, vector/insert, recipient or parental organisms.'

Article 4

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, must submit a notification to the competent authority specified in Article 3 (2) of the Member State within whose territory the release is to take place before carrying out the release.

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(s) may pose to people or the environment, together with the methods used and the bibliographic reference to them and covering, in particular:

- identification and characteristics of the GMO(s),
- the location of the area where the deliberate release is to be carried out and the predominant meteorological, social, environmental and agricultural characteristics of the area,
- the purpose and conditions of the release, including the quantity of the GMO(s) to be released, the size of the area affected, and the duration of the release,
- all other information necessary for risk assessment,

AMENDMENT No 25

Article 4(2)(a) second indent, add:

'and justification for the choice of location.'

AMENDMENT No 26

Article 4(2)(a), third indent, add:

'and full justification for the chosen parameters'.

AMENDMENT No 27

Article 4(2)(a), last indent, delete first two lines (methods ... for) and replace by:

- methods for monitoring both the GMO(s) and the inserted genetic sequence and proposed techniques for' (rest unchanged)

AMENDMENT No 28

Article 4(2)(a), insert new indent at the end:

- Justification of the social desirability of the objective of the proposed deliberate release and assessment of possible alternatives to attain the same objective.

Article 4(2)(b) and Article 4(3), 4(4) and 4(5) unchanged.

AMENDMENT No 29

Delete Article 4(6) and replace by:

6. In the event of any modification of the deliberate release of GMO(s) which could have consequences with regard to the risks for people or the environment or if new information has become available on such risks, either while the notification is being examined by the competent authorities or after the endorsement, the notifier shall:

- (a) revise the measures specified in Article 4 (2),
- (b) inform the competent authority of the modification, in advance or as soon as the new information is available, in so far as it affects the information contained in the notification.

6. The applicant has an obligation to notify as soon as possible the competent authority of any new information relevant to the proposed deliberate release either while the application is examined by the competent authority or after the deliberate release has been authorized.'

AMENDMENT No 30

Insert new Article 4(7):

7. Under no circumstances may an applicant proceed with a deliberate release unless he has received written authorization from the competent authority.

Article 5

(See overleaf)

AMENDMENT No 31

Delete Article 5 and replace by:

Article 5

1. The competent authority shall:
 - evaluate the risk posed by the release in the light of the notifier's risk assessment,
 - state its conclusions in writing,
and, if necessary,
 - ask the notifier to provide further information or verification tests, explaining the reasons for it,
 - carry out such tests as may be necessary for control purposes.
2. The competent authority shall respond to the notification within 90 days of its receipt, either deciding on its endorsement or indicating the further information required or measures to be taken.
3. If the competent authority is not satisfied with the conditions of the proposed release, it may ask the notifier to modify such conditions of the release so as to bring it into compliance with Article 3 of this Directive.
4. The notifier may proceed with the release only when he has received the endorsement of the competent authority, subject to any conditions required in this endorsement.
5. The Member States may provide for derogations from the provisions under Articles 4 and 5 (1) to 5 (4) and 6 for deliberate releases carried out by or under the responsibility of a public authority which is designated as a competent authority according to Article 3 (2). This derogation does not affect the obligation to assess the risk posed by the release concerned nor the obligation to submit information to the Commission as required in Article 7.

1. Before taking any decision the competent authority shall
 - examine the information provided and its completeness and its conformity with this directive, and request further information if appropriate,
 - carry out a full risk assessment of the proposed deliberate release as well as an evaluation of the social costs and benefits
 - publish the application and actively inform the public
2. The competent authority must decide within nine months from the date of the application whether the proposed deliberate release can be authorized and if so, what conditions must be imposed on the release. The competent authority must state its decision, with full justification, in writing and make this document publicly available.
3. A competent authority cannot authorize a deliberate release unless the following conditions have been fulfilled:
 - the deliberate release is proven and verified to have no negative impact on the environment and human health
 - all the appropriate tests that can be carried out in containment have been completed
 - the social desirability of the objective of the release as well as the benefit of the

- particular release are demonstrated
- the type of the release is such as to enable full control, extermination or recall of the released organisms, should this prove necessary
 - full and appropriate insurance coverage for the particular deliberate release has been provided for by the applicant
- 4 Approval should only be granted for a specified limited time period, after which, if an extension is requested, the applicant must submit the necessary information to enable the competent authority to review the compliance of the deliberate release with the requirements of this Directive, and specifically those outlined under 5(3).

Articles 6 and 7 unchanged

Part C: Placing on the market of products
containing or consisting of genetically modified organisms

Article 8

AMENDMENT No. 32

To read:

Articles 9 to 16 of this Directive do not apply to :

- medicinal products,
- veterinary products,
- foodstuffs, feedingstuffs and their additives,
- plants and animals produced or used in agriculture, horticulture, forestry, husbandry and fisheries, the reproductive material thereof and the products containing these organisms,
- or to any products covered by Community legislation which includes a specific risk assessment.

1. The placing on the market of genetically modified organisms shall be subject to authorization.

2. Until 1 January 1994, official authorization shall be given only where it has been demonstrated that the organisms in question are recoverable.

AMENDMENT No 33

Add a new Article 8(3):

3. The obligation to comply with the provisions of this directive does not exempt the applicant from the obligation to comply with other product legislation in force.

Article 9

Article 9

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 they are 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, and an assessment of any risks for man and/or the environment related to the GMO(s) contained in the product,
- 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 any risk to man and/or the environment, he may propose not to comply with one or more of the requirements of Annex III.B.

2. Subject to the agreement of the competent authority, the notifier may refer in this notification to data or experiences from releases of the same GMO(s) previously notified at the research and development level.

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. If new information has become available with regard to the risks of the product to people or the environment, either before or after the endorsement, the notifier shall:

- revise the measures specified in Article 9 (1), and
- inform the competent authority immediately.

AMENDMENT No 34

Delete Article 9(1), 9(2) and 9(3) and replace by:

1. Before a GMO or a combination of GMOs is placed on the market as or in a product the manufacturer or the importer to the Community shall submit a request for authorization to the competent authority of each Member State where the product is to be placed on the market or affect its environment.

The request for authorization must include at least the following information:

- all information required under Article 4(2)
- all experimental data obtained from the research and development stage
- proof and results of gradually scaled-up experimental releases carried out in the Community in all the ecosystems which could be affected by the product's use
- the proposed 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.

Article 9(4) unchanged

AMENDMENT No 35

Delete Article 9(5) and replace by:

5. The applicant has an obligation to inform as soon as possible the competent authority of any new information relevant to the

proposed deliberate release of a product either while the application is examined by the competent authority or after the deliberate release has been authorized.

AMENDMENT No. 36

Insert new Article 9(6)

6. Under no circumstances can a manufacturer or importer proceed with a market testing or placing on the market of a product consisting of or containing a GMO anywhere in the Community unless he has received written authorization from the relevant competent authorities.

Article 10

Paragraph 1 unchanged

AMENDMENT No. 37

2. The competent authority may ask the notifier for additional information or suggest further tests to carry out or changes in the conditions of placing on the market so as to bring these conditions into compliance with the Directive.

2. The competent authority may ask the notifier for additional information or insist on further tests to carry out or changes in the conditions of placing on the market so as to bring these conditions into compliance with the Directive.

AMENDMENT No. 38

Insert a new paragraph 10(2)(a)

2(a) Before taking any decision the competent authority shall

- examine the information provided and its completeness and its conformity with this directive, and request further information if appropriate,
- carry out a full risk assessment of the proposed deliberate release as well as an evaluation of the social costs and benefits of the marketing of the product
- publish the application and actively inform the public

Article 10(3) and 10(4) unchanged

AMENDMENT No 39

Insert new Article 10(5):

(See Overleaf)

5. A competent authority cannot authorize the marketing of a product unless the following conditions have been fulfilled:

- the procedure of consultation with the Commission and other Member States has been satisfactorily completed according to the procedures laid down in Article 11

- the product is proven and verified to have no negative impact on the environment and human health

- all the appropriate tests in containment and experimental releases have been completed satisfactorily

- the social desirability of the product as well as the lack of alternative ways to achieve the desired effect are demonstrated

- full and appropriate insurance coverage for product liability has been provided for by the manufacturer or importer

Article 11

Paragraphs 1 to 3 unchanged

AMENDMENT No 40

4. Should it not be possible for the competent authorities concerned to reach an agreement, and should any competent authority feel, on the basis of scientific evidence, that the placing on the market of the product may pose risks to people or the environment, within this period of three months, the Commission shall take a decision in accordance with the procedure laid down in Article 20.

Delete

AMENDMENT No. 41

5. When the competent authority that received the original notification has provided satisfactory response to the requests of the other competent authorities, or if no suggestions have been made within the 60-day period, or when the Commission has taken a favourable decision in the case of Art. 11.4, it shall endorse the notification so that the product may be placed on the market.

Delete

Article 11(6) and (7) unchanged

Article 12 unchanged

Article 13

AMENDMENT No. 42

The Member States may not, on grounds relating to the notification and endorsement 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.

Delete

Article 14

AMENDMENT No. 43

1. Whereas a Member State has evidence that a product which has been properly notified and endorsed under this Directive constitutes a serious risk to people or the environment, it may provisionally restrict or prohibit the use 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.

Delete

2. The Commission shall take a decision on the matter, within 3 months following the procedure laid down in Article 20.

Delete

Articles 15 to 17 unchanged

Article 18

AMENDMENT No. 44

According to the procedure laid down in Article 20, the Commission shall adapt the annexes of this Directive to technical progress by :

Delete

- amending new techniques to be covered or deleting as appropriate
- amending the notification requirements set out in Annexes II and III to take into account the potential hazard of the GMO(s).

Article 19

AMENDMENT No. 45

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

1. The Commission shall be assisted by a Committee of an advisory nature composed of the representatives of the Member States and chaired by the representative of the Commission. The representatives of the Member States shall preferably be scientists specializing in appropriate subjects and shall be responsible for informing and communicating with the general public in their own countries through their representative organizations.

2. The Commission shall function in accordance with the procedures laid down in Article 20.

2. unchanged

Article 20

AMENDMENT NO. 46

Where the procedure laid down in this Article is followed, 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, if necessary by taking a vote. The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to have its position recorded in the minutes. The Commission shall take the utmost account of the opinion delivered by the Committee. It shall inform the Committee of the manner in which its opinion has been taken into account.

Delete

ANNEX I

AMENDMENT NO. 47

Genetically modified organisms are organisms which can be obtained by such techniques as recombinant DNA, micro-injection, macroinjection, microencapsulation, nuclear and organel transplantation or genetic manipulation of viruses.

Delete

ANNEX II

AMENDMENT NO. 48

Not all points included will apply to every case. It is to be expected, therefore, that individual notification will address only the particular issues 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.

Delete paragraph 2 and 3 of the introduction.

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 II (contd.)

AMENDMENT NO. 49

Annex II, Point 3(b),
Second indent

Annex II, Point 3(b)
Second indent

- Geographical, geological and
pedological characteristics

- Geographical, geological,
hydrological and pedological
characteristics

ANNEX III

AMENDMENT NO. 50

Annex III.B

Annex III.B (Line 1)

B. The following information shall be
provided, when relevant, in addition
to that of Annex III.A, in accordance
with Article 9.

Delete 'when relevant'

DRAFT LEGISLATIVE RESOLUTION

embodying the opinion of the European Parliament on the proposal from the Commission to the Council for a directive on the deliberate release to the environment of genetically modified organisms

The European Parliament,

- having regard to the proposal from the Commission to the Council(1),
 - having been consulted by the Council pursuant to Article 100a of the EEC Treaty (Doc. C 2-73/88),
-
- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinions of the Committee on Energy, Research and Technology and the Committee on Legal Affairs and Citizens' Rights (Doc. A 2 - 142/89);
1. Approves the Commission proposal subject to Parliament's amendments and in accordance with the vote thereon;
 2. Calls on the Commission to amend its proposal accordingly, pursuant to Article 149(3) of the EEC Treaty;
 3. Calls on the Council to incorporate Parliament's amendments in the common position that it adopts in accordance with Article 149(2)(a) of the EEC Treaty;
 4. Calls on the Council to notify Parliament should it intend to depart from the text approved by Parliament;
 5. Instructs its President to forward this opinion to the Council and Commission.

(1) OJ No. C 198, 28.7.1988, p. 19 - COM/88/160 - SYN 131

EXPLANATORY STATEMENT1. THE NEED FOR A DIRECTIVE1.1 Possible risks associated with releases

The debate on the risk potential of genetically modified organisms has been under way since the Asilomar conference in 1973. Risk assessments have been based on assumptions, since long-term findings are not available and microorganism ecology is a largely unexplored area, but have led to the introduction of research safety standards involving physical and biological containment measures.

Releases involve a deliberate policy of not ensuring containment. Major ecological changes may be brought about by releasing exotic organisms in a biotope, the following being instructive cases in point :

- the fungus *Endothia*, accidentally released in North America around the turn of the century, within 40 years wiped out the American chestnut, over an area of one million square kilometres, as a characteristic species in the Appalachian oak and chestnut forests;
- the bacterium *Xanthomonas campestris* pv. *citri*, introduced from Japan, has threatened the entire citrus fruit crop in Texas and Florida on a number of occasions;
- the Nile perch, released into Lake Victoria in central Africa, has radically diminished the population of all other fish species there.

The scientific debate has now revealed four possible hazards :

- a disrupted ecological balance,
- unintentional introduction of new pathogenic sources,
- unpredicted exchange of genetic material with related species,
- contraction of the genetic pool.

1.2. Releases - the cross-frontier dimension

The impact of accidents in conventional scientific installations is localized and temporary. Releasing a viable and hazardous organism that does not occur naturally may be an irreversible operation with global implications, which is why national regulation is no longer effective.

1.3. Member State regulations

In Ireland, Greece, Italy, Spain and Portugal, the release of genetically modified organisms is not governed by specific regulations.

No ban on releases exists in Belgium, Luxembourg, the United Kingdom, France or the Netherlands; such operations are subject to oversight. There is no common legal framework or safety philosophy, however; depending on the country

concerned, committees and regulatory planning bodies have been set up and voluntary notification arrangements introduced.

Releases are banned in Denmark and the Federal Republic of Germany; the authorities may make exceptions and give their approval.

To sum up, then, 10 of the 12 Member States lack adequate regulations.

1.4 Level of scientific knowledge

A release is defined as the introduction into the environment of organisms or nucleic acids (viruses) capable of replication. The size, speed of dispersal and viability period of the organism concerned, together with the degree to which growth and replication are human-dependent and the recoverability of the biological material released into the environment are risk assessment factors.

Accordingly, organisms can be classified as :

- viruses
- microorganisms
- plants :
 - (a) wild herbs
 - (b) useful plants
- animals
 - (a) small animals (e.g. insects, worms)
 - (b) large wild animals (living independently of man)
 - (c) domestic animals (dependent on man).

In the course of the scientific debate, assessment of the risk associated with the release of genetically modified organisms ranges from 'non-existent' to 'impact unlikely, but with potentially serious consequences'. For the time being, it is quite impossible to formulate generalized scientific statements on the effects of introducing new species into a biotope; this is particularly true as regards microorganisms and viruses.

2. REQUIREMENTS TO BE MET BY A DIRECTIVE

2.1. Case-by-case authorization

A complete ban on releases, extending to releases for research purposes, would not be advisable; nor would it enjoy majority political backing. The current level of scientific knowledge does not allow criteria for authorizing releases to be laid down wholesale. The answer, then, is to introduce a mandatory authorization procedure and case-by-case evaluation. A genuine common standard for the European Community could only be based on a licensing procedure regulated at Community level. The Treaty provides no proper legal basis for this - unless we are willing to confer the relevant powers upon democratically unaccountable committees of experts or upon the Commission, which is beyond adequate parliamentary oversight. In the circumstances, the narrowly defined procedure for consultation between the Member States proposed by the Commission is the next best solution.

2.2. Product moratorium

There is no need at present to authorize product releases on a huge scale on the Community's internal market. We do not possess sufficient knowledge to

authorize such releases in a responsible manner; nor is it the case that there are licensable products which it is vital to bring to market. Except for research purposes, therefore, no releases should be permitted in the Community over the next five years; the Member States should be allowed to make exceptions where the recoverability of the organisms concerned has been demonstrated or where, in the case of vaccines, there is no other way to produce a medical application.

2.3. Recoverability and ban on releases

A clear distinction must be made in a directive on releases between recoverable and irrecoverable organisms, there being a marked difference in safety requirements in this connection. According to current scientific knowledge, organisms are assumed to be recoverable in connection with domestic animals and useful plants which do not propagate or intercross with wild species and whose ability to compete successfully in the biosphere is not enhanced by genetic modification.

An effective directive which permits releases, provided that certain conditions are met, must also lay down what is not under any circumstances permissible.

3. CRITICISM OF THE COMMISSION DRAFT

The Commission draft fails to meet the key requirements for a directive. The following points in particular invite criticism :

- No provision has been made for absolute-liability arrangements or penalties for infringing the directive;
- The distinction between research and application is spurious;
- Under the draft, the Member State authority itself would be able to decide which information it could keep confidential;
- The section on placing on the market exempts many products, while amendments to the Directives governing the bringing to market of the products concerned, in respect of genetically modified organisms, have not been submitted;
- A directive on the transport of GMOs has not been submitted;
- The directive presupposes that Member State authorities are staffed by suitably qualified personnel, whereas, as can be demonstrated, this is not the case at present in every Member State;
- The Commission draft, unlike current national regulations, does not provide for the inhabitants of an area where an experimental release is to take place to be given notice thereof.

OPINION

OF THE COMMITTEE ON LEGAL AFFAIRS AND CITIZENS' RIGHTS

Letter from the Chairman of the Committee on Legal Affairs and Citizens' Rights to Mrs Beate WEBER, Chairman of the Committee on the Environment, Public Health and Consumer Protection

Brussels, 21 April 1989

Subject: The proposals from the Commission to the Council for a Council Directive on the contained use of genetically modified micro-organisms and on the deliberate release to the environment of genetically modified organisms

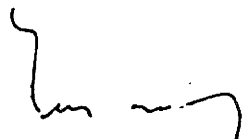

Dear Mrs Weber,

At its meeting of 18 to 20 April 1989, the Committee on Legal Affairs and Citizens' Rights examined the legal basis of two proposals for directives concerning, respectively, the contained use of genetically modified microorganisms and the deliberate release of genetically modified organisms (Doc. C2-73/88 = COM(88) 160 final).

Following an introductory statement by its duty-rapporteur on legal basis questions, Mr BARZANTI, and a comprehensive exchange of views, the Committee took the view that the current disparity of national provisions, legislative and otherwise, regulating the contained use of GMMs and the deliberate release of GNOs could have significant repercussions on the production costs of products using GMMs and GNOs, and hence distort conditions of competition within the Community. The Committee also noted that, as regards the adoption of harmonizing measures which have as their object both the establishment and functioning of the internal market and the protection of the environment, Article 100a, and particularly its third and fourth paragraphs, is a lex specialis as compared with Article 130s, and should be chosen in preference to this latter, in line with the decided cases of the Court of Justice.

In these circumstances the Committee decided¹ :

- by 11 votes to 1, that Article 100a is the correct legal basis for the proposed directive on the contained use of genetically modified microorganisms, and
- unanimously, that Article 100a is the correct legal basis for the proposed directive on the deliberate release to the environment of genetically modified organisms.

¹ The following were present for the vote : Lady ELLES, Chairman; Mr BARZANTI, duty-rapporteur; Mr BRU PURON, Mr COT, Mr DE VRIES (replacing Mr DONNEZ), Mr GARCIA AMIGO, Mr HOON, Mr JANSSEN VAN RAAY, Mr MALANGRE, Mr MUNCH (replacing Mr SARIDAKIS), Mr SANTOS MACHADO (replacing Mr CASINI), Mr WEDEKIND (replacing Mrs FONTAINE), and Mr WIJSENBEEK.



"Frankly, I think we'll regret introducing these organisms into the environment."

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