COMMISSION OF THE EUROPEAN COMMUNITIES

COM (89) 408 final -SYN 131

Brussels, 1 August 1989

MODIFIED PROPOSAL FOR A COUNCIL DIRECTIVE ON THE DELIBERATE RELEASE TO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS

(presented by the Commission pursuant to the third paragraph of Article 149 of the EEC Treaty)

EXPLANATORY MEMORANDUM

1. In May 1988, the Commission submitted a proposal for a Council Directive on the Deliberate release to the Environment of Genetically modified organisms (COM(88) 160 final - SYN 131), under Article 100A of the Treaty.

2. After a first reading the European Parliament adopted an opinion on the above proposal for a Directive on 25 May 1989, approving a number of amendments to the text proposed by the Commission. In its legislative resolution the European Parliament called on the Commission to amend its proposal accordingly, pursuant to Article 149(3) of the EEC Treaty.

3. The Commission, having considered the amendments approved by the European Parliament, agreed to incorporate a number of them in a modified proposal in as far as they are within the spirit of the Commission's original proposal and serve to clarify it.

4. In the explanatory memorandum of its original proposal for this directive (COM (88) 160 final) the Commission recognised that the intentional release of organisms having a combination of traits that nature may have never produced increases uncertainty as regards the behaviour of the organisms and the possibility of a deleterious impact of the environment, and that it was therefore necessary to proceed with releases of GMOs in a careful manner, and only under conditions of human and environmental safety which are as high as reasonably practical. A case-by-case approach to the evaluation and approval of releases was therefore proposed by the Commission.

5. Within the framework of this approach (endorsed by the European Parliament in its opinion) the limited modifications now being made to the original proposal clarify the provisions for risk assessment and approval for the deliberate release, as well as the implementation and control measures. In addition, given the rapid scientific developments in the field of biotechnology, a clearer definition of genetically modified organisms is provided.

MODIFIED PROPOSAL FOR A COUNCIL DIRECTIVE ON THE DELIBERATE RELEASE TO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS

The Commission, on the basis of the Opinion delivered by the European Parliament in its first reading on 25.5.89, modifies its original Proposal for a Council Directive on the Deliberate release of GMOs (O.J. C 198, 28.7.88) pursuant to Article 149(3) of the EEC Treaty, as follows: -

RECITALS

A new recital 9a to be inserted:

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;

A new recital 12a to be inserted:

"Whereas, after notification, no deliberate release of GMOs shall be carried out unless the consent of the competent authorities has been obtained".

A new recital 12b to be inserted:

"Whereas a competent authority shall only give its consent after it has been satisfied that the release will have no negative impact on the environment and humans".

Article 2

Article 2.2. to be replaced by the following: -

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 Part 1.

ii) The techniques listed in Annex I Part 2, are not considered to result in genetic modification.

Article 3

A new Article 3.3. to be added:

Member States shall ensure that the competent authority organizes inspections and other control measures as

appropriate, to ensure compliance with this Directive, and shall ensure that effective penalties are imposed for infringement of this Directive.

A new Article 3.4. to be added:

Member States shall ensure that adequate information is provided in advance of a planned release to the inhabitants of the areas concerned.

Article 4

Article 4.6. to be replaced by the following:

In the event of any modification of the deliberate release of GMOs which could have consequences with regard to the risks for man 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 consent for the release has been obtained, the notifier shall immediately:

a) revise the measures specified in the notification and adopt all measures necessary to protect human health and the environment.

b) notify the competent authority of the new information available and/or of the modifications of the release in advance of such modifications being undertaken.

Article 5.4. to be replaced by the following: -

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

Article 17.4. to be replaced by the following: -

The Commission and the competent authorities shall not divulge to third Parties any confidential information notified or exchanged under this Directive.

Annex I to be replaced by the following: -

Annex I

Part 1. Techniques of genetic modification referred to in Article 2, paragraph 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 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, paragraph 2, ii) which are not considered to result in genetic modification, on condition that they do not involve the use of r-DNA molecules or GMOs.

1) In vitro fertilisation.

2) Conjugation, transduction, transformation or any other natural process.

3) Polyploidy induction.

Annex II.3. (b)

3rd indent to be replaced by:

- geographical, geological, hydrological and pedological characteristics.

II

(Preparatory Acts)

COMMISSION

Modified proposal for a Council Directive on the deliberate release to the environment of genetically modified organisms (1)

COM(89) 408 final — SYN 131

(Submitted by the Commission pursuant to Article 149 (3) of the EEC Treaty on 23 August 1989)

(89/C 246/06)

The Commission, on the basis of the opinion delivered by the European Parliament in its first reading on 25 May 1989, modifies its original proposal for a Council Directive on the deliberate release of GMOs pursuant to Article 149 (3) of the EEC Treaty, as follows:

A new recital 9a is inserted:

'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;'

A new recital 12a is inserted:

'Whereas, after notification, no deliberate release of GMOs shall be carried out unless the consent of the competent authorities has been obtained'

A new recital 12b is inserted:

'Whereas a competent authority shall only give its consent after it has been satisfied that the release will have no negative impact on the environment and humans'

Article 2.2. is replaced by the following:

'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 Part 1;

(ii) the techniques listed in Annex I Part 2, are not considered to result in genetic modification.'

A new Article 3.3. is added:

'3. Member States shall ensure that the competent authority organizes inspections and other control measures as appropriate, to ensure compliance with this Directive, and shall ensure that effective penalties are imposed for infringement of this Directive.'

A new Article 3.4. is added:

4. Member States shall ensure that adequate information is provided in advance of a planned release to the inhabitants of the areas concerned.'

Article 4.6. is replaced by the following:

'6. In the event of any modification of the deliberate release of GMOs which could have consequences with regard to the risks for man 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 consent for the release has been obtained, the notifier shall immediately:

(a) revise the measures specified in the notification and adopt all measures necessary to protect human health and the environment;

(1) OJ No C 198, 28. 7. 1988, p. 19.

(b) notify the competent authority of the new information available and/or of the modifications of the release in advance of such modifications being undertaken.'

Article 5.4. is replaced by the following:

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

Article 17.4 is replaced by the following:

'4. The Commission and the competent authorities shall not divulge to third parties any confidential information notified or exchanged under this Directive.'

Annex I is replaced by the following:

'ANNEX I

PART I

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 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 r-DNA molecules or GMOs.

1. In vitro fertilization

2. Conjugation, transduction, transformation or any other natural process.

3. Polyploidy induction.

Annex II.3.(b), 3rd indent is replaced by:

'— geographical, geological, hydrological and pedological characteristics.'

Modified proposal for a Council Directive on the contained use of genetically modified micro-organisms (1)

COM(89) 409 final — SYN 131

(Submitted by the Commission pursuant to Article 149 (3) of the EEC Treaty on 23 August 1989)

(89/C 246/07)

The Commission, on the basis of the opinion delivered by the European Parliament on 24 May 1989, modified its original proposal for a Council Directive on the contained use of OGM pursuant to Article 149 (3) of the EEC Treaty, as follows:

Third recital is amended as follows:

'Whereas under the Treaty, action by the Community relating to the environment shall be based on the principle that preventive action shall be taken and shall have the objective to preserve, protect and improve the quality of the environment and to contribute towards protecting human health.'

Eighth recital is amended as follows:

'Whereas it is therefore necessary to approximate legislation in the Member States establishing a common legislative framework for the evaluation and the reduction of the potential risks arising in the course of the contained use of genetically modified micro-organisms in research, development, manu-

(1) OJ No C 198, 28. 7. 1988, p. 9.

(b) notify the competent authority of the new information available and/or of the modifications of the release in advance of such modifications being undertaken.'

Article 5.4. is replaced by the following:

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

Article 17.4 is replaced by the following:

'4. The Commission and the competent authorities shall not divulge to third parties any confidential information notified or exchanged under this Directive.'

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Third recital is amended as follows:

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Eighth recital is amended as follows:

'Whereas it is therefore necessary to approximate legislation in the Member States establishing a common legislative framework for the evaluation and the reduction of the potential risks arising in the course of the contained use of genetically modified micro-organisms in research, development, manu-

(1) OJ No C 198, 28. 7. 1988, p. 9.

facture, storage, transport, waste treatment and disposal in order to enable the safe development of biotechnology throughout the Community.'

Ninth recital is amended as follows:

'Whereas the precise nature and scale of risks associated with genetically modified micro-organisms are not fully known and the hazards involved must be assessed case by case; whereas particular attention must be given to operations using certain genetically modified micro-organisms.'

Tenth recital is amended as follows:

'Whereas genetically modified micro-organisms must be classified in relation to their hazard; whereas in the absence, at present of specifications necessary for allocation in these classes it seems appropriate to develop criteria for classification; whereas to evaluate hazard for human health and the environment it is necessary to lay down essential requirements for risk assessment and appropriate conditions of use.'

Twelfth recital is replaced by:

'Whereas a permanent inventory of information related to the contained use of GMOs within each Member State is necessary in order to monitor the contained use of GMOs and to trace the origin of any negative effects or accidents that might arise.'

Thirteenth recital is replaced by:

'Whereas any person, before undertaking for the first time the contained use of genetically modified micro-organisms, in a particular installation must forward to the competent authority a notification with information allowing the authority to ensure that the proposed installation is appropriate to carry out an activity in a manner that does not present a danger to man and the environment.'

The Sixteenth recital is amended as follows:

'Whereas, if an accident occurs, the user must immediately inform the competent authority and communicate the information necessary for assessing the impact of that accident; whereas in the case of an accident that could pose a threat to human health and the environment, the competent authority must immediately inform the public.'

A new Article 4.5. is added:

'5. The results of the risk-assessment cannot be considered as confidential. A summary of the risk-assessment, excluding strictly confidential information, shall be made available to the public.'

Article 6 is replaced by the following:

'Article 6

When a particular installation is to be used for the first time for operations involving the contained use of genetically modified micro-organisms, the user shall be required to submit to the competent authorities, before commencing such use a notification containing at least the information listed in Annex IVA. A separate notification shall be made for first use of GMMs in Group I and Group II respectively.'

Article 7 is replaced by the following:

'Article 7

1. Users of genetically modified mirco-organisms classified in Group I non-industrial scale operations shall be required to keep records of the work carried out which shall be available to the competent authority on request.

2. Users of genetically modified micro-organisms classified in Group I industrial scale operations shall, before commencing the contained use, be required to submit to the competent authorities a notification containing the information listed in Annex IV B. The information shall be sufficient to enable the competent authority to assess the correctness of the classification.'

Article 8 is replaced by the following:

'Article 8

1. Users of genetically modified micro-organisms classified in Group II non-industrial scale operations shall, before commencing the contained use, be required to submit to the competent authorities a notification containing the information listed in Annex IV C.

2. Users of genetically modified micro-organisms classified in Group II in industrial scale operations shall, before commencing the contained use, be required to submit to the competent authorities a notification containing:

— information on the genetically modified micro-organism(s),

— information on personnel and training,

— information on the installation,

— information on waste management,

— information on accident prevention and emergency response plans,

— the safety assessment referred to in Article 4,

the details of which are listed in Annex IV D.'

Article 9 is replaced by the following:

'Article 9

1. Member States shall designate the authority or authorities competent to implement the measures which they adopt in application of this Directive and to receive and acknowledge the notifications referred to in Article 6, Article 7 (2) and Article 8.

2. The Competent Authorities shall examine the conformity of the notifications with the requirements of this Directive, the accuracy and completeness of the information given, the correctness of the classification and, where appropriate, the adequacy of the waste management, safety, and emergency response measures, and provide for adequate information and consultation of the public, where necessary.

3. If necessary, the competent authority may:

(a) ask the user to provide further information or to modify the conditions of the proposed contained use. In this case, the proposed contained use cannot proceed until the competent authority has given its approval on the basis of the further information obtained or of the modified conditions of the contained use;

(b) limit the time for which the contained use should be permitted or subject it to certain specific conditions.

4. In the case of first-time use in an installation as referred to in Article 6:

— where such use involves GMMs in Group I, the contained use may, in the absence of any indication to the contrary from the competent authority, proceed 90 days after submission of the notification, or earlier with the agreement of the competent authority,

— where such use involves GMMs in Group II, the contained use may not proceed without the consent of the competent authority. The competent authority shall communicate its decision in writing at the latest 90 days after submission of the notification.

5. (a) Operations notified under Article 7 (2) and Article 8 (1), may, in the absence of any indication to the contrary from the competent authority, proceed 60 days after submission of the notification, or earlier with the agreement of the competent authority;

(b) Operations notified under Article 8 (2) may not proceed without the consent of the competent authority.

The competent authority shall communicate its decision in writing at the latest 90 days after submission of the notification.

6. For the calculation of the periods referred to in paragraphs 4 and 5 above, the periods during which the competent authority:

— is awaiting any further information which it may have requested from the notifier in accordance with paragraph 3a of this Article

or

— is carrying out a public enquiry or consultation in accordance with Article 11.2.

shall not be taken into account.'

Article 10 is replaced by the following:

'Article 10

1. The user has an obligation to inform as soon as possible the competent authority of any relevant new information or modification of the contained use, or of any change in the category of genetically modified micro-organisms used and to modify accordingly the notification submitted under Articles 6, 7 and 8.

2. If information becomes available subsequently to the competent authority by whatever means indicating that there may be consequences for the risks posed by the contained use or for the conditions under which the contained use should be carried out, the competent authority must re-examine the notification and may require the user to provide additional information, modify the conditions of, suspend or terminate the contained use.'

Article 11 is replaced by:

'Article 11

1. The competent authorities shall ensure that, where necessary, before an operation commences:

(a) an emergency plan is drawn up to deal with biological hazards outside the installation in the event of an accident and the emergency services are aware of the hazards and informed thereof in writing and that the emergency services are adequately trained and equipped for dealing with such accidents;

(b) information on safety measures and on the correct behaviour to adopt in the case of an accident is supplied in an appropriate manner, and without their having to request it, to persons liable to be affected by the accident. The information shall be repeated and updated at appropriate intervals. It shall also be made publicly available, together with the summary of the proposed project.

The Member States concerned shall at the same time make available to other Member States concerned, as a basis for all necessary consultation within the framework of their bilateral relations, the same information as that which is disseminated to their own nationals.

2. Where the competent auhtority considers it appropriate, it may consult groups or the public on any aspect of the proposed contained use.

Article 12 is replaced by:

'Article 12

1. Member States shall take the necessary measures to ensure that, in the event of an accident, the user shall be required immediately to inform the competent authority specified in Article 9 and provide the following information:

— the circumstances of the accident,

— the identity and quantities of the genetically modified micro-organism(s) released,

— any information necessary to assess the effects of the accident on the health of the general population and the environment,

— the emergency measures taken,

— subsequent steps taken to avoid future accidents.

2. The Member States shall be required to:

— ensure that any emergency, medium and long-term measures necessary are taken, and immediately alert any Member States which could be affected by the accident,

— collect, where possible, the information necessary for a full analysis of the accident and ensure that measures are taken to avoid similar accidents in the future and to limit the effects thereof.'

Article 13.1. point (c) is modified as follows:

'(c) inform the Commission as soon as possible of any accident within the scope of this Directive, giving details of the circumstances of the accident, the identity and quantities of the genetically modified micro-organisms released, the emergency response measures employed and their effectiveness, and an analysis of the accident including requirements to limit its effects and avoid similar accidents in the future.'

A new Article 14a is inserted:

'Article 14a

1. The Commission and the competent authorities shall not divulge to third parties any confidential information notified or otherwise provided under this Directive.

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

3. The competent auhtority shall decide, after prior 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 be kept confidential.

— description of the GMMs, name and address of the notifier, purpose of the contained use, and location of use;

— methods and plans for monitoring of the GMMs and for emergency response;

— the evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.'

COMMISSION OF THE EUROPEAN COMMUNITIES

HIGHER EDUCATION IN THE EUROPEAN COMMUNITY — STUDENT HANDBOOK

This Student Handbook has been prepared, for the assistance of students and their advisers, to bring together in all Community languages the basic information needed by those considering a period of higher education in another Member State.

The Handbook contains an entry for each of the Member States of the Community. Each entry consists of two main sections, a descriptive text and annexes. The text gives general information on the structure of the higher education system, its institutions and the types of qualifications obtainable, on admission conditions and application procedures, and on fees, language requirements, and grants, as well as an indication of important social elements such as social security, counselling, accommodation, etc. The annexes to each country entry contain a list of addresses of organizations and institutions from which further information and/or application forms may be obtained, a bibliography of national information material, in most cases a table of subjects taught at each institution, and a glossary per national entry for the explanation of terms that have not been translated. Special provisions of the universities to facilitate study for disabled students are mentioned in the text and in some of the tables.

In addition to the national entries, the Handbook contains separate entries for the College of Europe at Bruges and the European University Institute at Florence.

Furthermore, the Handbook gives information in a special chapter on the cooperation of universities in the framework of the newly created Erasmus programme of the EC. All higher education projects accepted into the programme during the first selection round 1987/88 are listed, broken down by subject areas.

The last chapter gives a survey of Naric, the network of national information centres for the recognition of diplomas, certificates and periods of study which is being coordinated and supported by the Commission.

470 pp.

Published in: ES, DA, DE, GR, EN, FR, IT, NL, PT.

Catalogue number: CB-49-87-713-EN-C ISBN: 92-825-7633-7

Price (excluding VAT) in Luxembourg:

ECU 17.25 — IRL 13.50 — UKL 11.95 — BFR 750

OFFICE FOR OFFICIAL PUBLICATIONS OF THE EUROPEAN COMMUNITIES
L-2985 Luxembourg

88-40