COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 1 August 1989

MODIFIED PROPOSAL FOR A COUNCIL DIRECTIVE ON THE CONTAINED USE OF GENETICALLY MODIFIED MICRO-ORGANISMS

Presented by the Commission pursuant to Article 149(3) of the EEC Treaty

EXPLANATORY MEMORANDUM

1. In May 1988, the Commission submitted a proposal for a Council Directive on the Contained use of Genetically modified micro-organisms (COM(88) 160 final - SYN 131).

2. After a first reading the European Parliament adopted an opinion on the above proposal for a Directive on 24 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 installations carrying out work with genetically modified microorganisms should do this in a manner which prevents or minimises any potential risk to man and the environment, and the use of OGM should be undertaken with the degree of security (control) commensurate with the potential risk involved. The Commission's proposal differentiated to a certain extent between degrees of risk involved in various operations by taking into account both the type of operation and the type of OGM used.

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 provide further differentiation in the procedure foreseen in relation to the degree of potential risk of the contained uses involved, as well as as further clarification of the provisions foreseen in case of accident. Confidentiality provisions are introduced to safegard commercially sensitive information, accompanied by wider information provisions for none confidential information as well as an option for wider consultation.

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The Commission, on the basis of the Opinion delivered by the European Parliament on 24.5.89, modified its original Proposal for a Council Directive on the Contained Use of OGM (O.J. C 198, 28.7.88) pursuant to Article 149(3) of the EEC Treaty, as follows: -

RECITALS

Third recital to be 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 to be 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, manufacture, storage, transport, waste treatment and disposal in order to enable the safe development of biotechnology throughout the Community.

Ninth recital to be 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 to be 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 to be 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 to be 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 to be 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.

Article 4

A new Article 4.5. to be added:

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, to be replaced by the following text: -

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, to be replaced by the following text: -

1. Users of genetically modified micro-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 IVB. The information shall be sufficient to enable the competent authority to assess the correctness of the classification.

Article 8, to be replaced by the following text: -

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 IVC.

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 IVD.

Article 9, to be replaced by the following text: -

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 paragraph 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 paragraph 2 and Article 8 paragraph 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 paragraph 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, to be replaced by the following text:

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, text to be replaced by: -

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 authority considers it appropriate, it may consult groups or the public on any aspect of the proposed contained use.

Article 12, text to be replaced by:

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), to be 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 to be inserted: -

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 authority 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.