

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.