Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

PART B

DELIBERATE RELASE OF GMOs FOR ANY OTHER PURPOSE THAN FOR PLACING ON THE MARKET

Article 5

1 Articles 6 to 11 shall not apply to medicinal substances and compunds for human use consisting of, or containing, a GMO or combination of GMOs provided that their deliberate release for any purpose other than that of being placed on the market is authorised by Community legislation which provides:

a for a specific environmental risk assessment in accordance with Annex II and on the basis of the type of information specified in Annex III without prejudice to additional requirements provided for by the said legislation;

b for explicit consent prior to release;

c for a monitoring plan in accordance with the relevant parts of Annex III, with a view to detecting the effects of the GMO or GMOs on human health or the environment;

d in an appropriate manner for requirements relating to treatment of new items of information, information to the public, information on the results of releases, and exchanges of information at least equivalent to those contained in this Directive and in the measures taken in accordance therewith.

2 Assessment of the risks to the environment presented by such substances and compounds shall be carried out in coordination with the national and Community authorities mentioned in this Directive.

3 Procedures ensuring conformity of the specific environmental risk assessment and equivalence with the provisions of this Directive must be provided for by the said legislation, which must refer to this Directive.

Article 6

Standard authorisation procedure

1 Without prejudice to Article 5, any person must, before undertaking a deliberate release of a GMO or of a combination of GMOs, submit a notification to the competent authority of the Member State within whose territory the release is to take place.

2 The notification referred to in paragraph 1 shall include:

a a technical dossier supplying the information specified in Annex III necessary for carrying out the environmental risk assessment of the deliberate release of a GMO or combination of GMOs, 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 potential receiving environment,

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

(v) a plan for monitoring in accordance with the relevant parts of Annex III in order to identify effects of the GMO(s) on human health or the environment,

(vi) information on control, remediation methods, waste treatment and emergency response plans,

(vii) a summary of the dossier;

b the environmental risk assessment and the conclusions required in Annex II, section D, together with any bibliographic reference and indications of the methods used.

3 The notifier may refer to data or results from notifications previously submitted by other notifiers, provided that the information, data and results are non confidential or these notifiers have given their agreement in writing, or may submit additional information he considers relevant.

4 The competent authority may accept that releases of the same GMO or of a combination of GMOs on the same site or on different sites for the same purpose and within a defined period may be notified in a single notification.

5 The competent authority shall acknowledge the date of receipt of the notification and, having considered, where appropriate, any observations by other Member States made in accordance with Article 11, 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 that notification is therefore rejected.

6 For the purpose of calculating the 90 day period referred to in paragraph 5, no account shall be taken of any periods of time during which the competent authority:

a is awaiting further information which it may have requested from the notifier, or

b is carrying out a public inquiry or consultation in accordance with Article 9; this public inquiry or consultation shall not prolong the 90 day period referred to in paragraph 5 by more than 30 days.

7 If the competent authority requests new information it must simultaneously give its reasons for so doing.

8 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.

9 Member States shall ensure that no material derived from GMOs which are deliberately released in accordance with part B is placed on the market, unless in accordance with part C.

Article 7

Differentiated procedures

1 If sufficient experience has been obtained of releases of certain GMOs in certain ecosystems and the GMOs concerned meet the criteria set out in Annex V, a competent authority may submit to the Commission a reasoned proposal for the application of differentiated procedures to such types of GMOs.

2 Following its own initiative or at the latest 30 days following the receipt of a competent authority's proposal, the Commission shall,

a forward the proposal to the competent authorities, which may, within 60 days, present observations and at the same time;

b make available the proposal to the public which may, within 60 days, make comments; and

c consult the relevant Scientific Committee(s) which may, within 60 days give an opinion.

3 A decision shall be taken on each proposal in accordance with the procedure laid down in Article 30(2). This decision shall establish the minimum amount of technical information from Annex III necessary for evaluating any foreseeable risks from the release, in particular:

a information relating to the GMO(s);

b information relating to the conditions of release and the potential receiving environment;

c information on the interactions between the GMO(s) and the environment;

d the environmental risk assessment.

4 This decision shall be taken within 90 days of the date of the Commission's proposal or of receipt of the competent authority's proposal. This 90 day period shall not take into account the period of time during which the Commission is awaiting the observations of competent authorities, the comments of the public or the opinion of Scientific Committees, as provided for in paragraph 2.

5 The decision taken under paragraphs 3 and 4 shall provide that the notifier may proceed with the release only when he has received the written consent of the competent authority. The notifier shall proceed with the release in conformity with any conditions required in this consent.

The decision taken under paragraphs 3 and 4 may provide that releases of a GMO or of a combination of GMOs on the same site or on different sites for the same purpose and within a defined period may be notified in a single notification.

6 Without prejudice to paragraphs 1 to 5, Commission Decision 94/730/EC of 4 November 1994 establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6(5) of Council Directive 90/220/EEC[(1)] shall continue to apply.

7 Where a Member State decides to make use or not of a procedure established in a decision taken in accordance with paragraphs 3 and 4 for releases of GMOs within its territory, it shall inform the Commission thereof.

Article 8

Handling of modifications and new information

1 In the event of any modification of, or unintended change to, the deliberate release of a GMO or of a combination of GMOs which could have consequences with regard to risks for human health and the environment after the competent authority has given its written consent, or if new information has become available on such risks, either while the notification is being examined by the competent authority of a Member State or after that authority has given its written consent, the notifier shall immediately:

a take the measures necessary to protect human health and the environment;

b inform the competent authority in advance of any modification or as soon as the unintended change is known or the new information is available;

c revise the measures specified in the notification.

2 If information becomes available to the competent authority referred to in paragraph 1 which could have significant consequences with regard to risks for human health and the environment or under the circumstances described in paragraph 1, the competent authority shall evaluate such information and make it available to the public. It may require the notifier to modify the conditions of, suspend or terminate the deliberate release and shall inform the public thereof.

Article 9

Consultation of and information to the public

1 Member States shall, without prejudice to the provisions of Articles 7 and 25, consult the public and, where appropriate, groups on the proposed deliberate release. In doing so, Member States shall lay down arrangements for this consultation, including a reasonable time-period, in order to give the public or groups the opportunity to express an opinion.

2 Without prejudice to the provisions of Article 25:

— Member States shall make available to the public information on all part B releases of GMOs in their territory;

— the Commission shall make available to the public the information contained in the system of exchange of information pursuant to Article 11.

Article 10

Reporting by notifiers on releases

After completion of a release, and thereafter, at any intervals laid down in the consent on the basis of the results of the environmental risk assessment, 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, where appropriate, particular reference to any kind of product that the notifier intends to notify at a later stage. The format for the presentation of this result shall be established in accordance with the procedure laid down in Article 30(2).

Article 11

Exchange of information between competent authorities and the Commission

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 30 days of its receipt, a summary of each notification received under Article 6. The format of this summary shall be established and modified if appropriate in accordance with the procedure laid down in Article 30(2).

2 The Commission shall, at the latest 30 days following their receipt, forward these summaries to the other Member States, which may, within 30 days, present observations through the Commission or directly. At its request, a Member State shall be permitted to receive a copy of the full notification from the competent authority of the relevant Member State.

3 The competent authorities shall inform the Commission of the final decisions taken in compliance with Article 6(5), including where relevant the reasons for rejecting a notification, and of the results of the releases received in accordance with Article 10.

4 For the releases of GMOs referred to in Article 7, once a year Member States shall send a list of GMOs which have been released on their territory and a list of notifications that were rejected to the Commission, which shall forward them to the competent authorities of the other Member States.

(**1**) OJ L 292, 12.11.1994, p. 31.