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COUNCIL DIRECTIVE

of 23 April 1990

on the deliberate release into the environment of genetically modified organisms

(90/220/EEC)

(OJ L 117, 8.5.1990, p. 15)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Directive 94/15/EC of 15 April 1994	L 103	20	22.4.1994
►**M2**	Commission Directive 97/35/EC of 18 June 1997	L 169	72	27.6.1997

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on the deliberate release into the environment of genetically modified organisms

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THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission [1],

In cooperation with the European Parliament [2],

Having regard to the opinion of the Economic and Social Committee [3],

Whereas, under the Treaty, action by the Community relating to the environment should be based on the principle that preventive action should be taken;

Whereas living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting other Member States; whereas the effects of such releases on the environment may be irreversible;

Whereas the protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release of genetically modified organisms (GMOs) into the environment;

Whereas disparity between the rules which are in effect or in preparation in the Member States concerning the deliberate release into the environment of GMOs may create unequal conditions of competition or barriers to trade in products containing such organisms, thus affecting the functioning of the common market; whereas it is therefore necessary to approximate the laws of the Member States in this respect;

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 should, inasmuch as they concern health, safety, environmental and consumer protection, be based on a high level of protection throughout the Community;

Whereas it is necessary to ensure the safe development of industrial products utilizing GMOs;

Whereas this Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record;

Whereas it is necessary to establish harmonized procedures and criteria for the case-by-case evaluation of the potential risks arising from the deliberate release of GMOs into the environment;

Whereas a case-by-case environmental risk assessment should always be carried out prior to a release;

Whereas the deliberate release of GMOs at the research stage is in most cases a necessary step in the development of new products derived from, or containing, GMOs;

Whereas the introduction of GMOs into the environment should be carried out according to the 'step by step' principle; whereas this means that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken;

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(1) OJ No C 198, 28. 7. 1988, p. 19 and OJ No C 246, 27. 9. 1989, p. 5.
(2) OJ No C 158, 26. 6. 1989, p. 225 and OJ No C 96, 17. 4. 1990.
(3) OJ No C 23, 30. 1. 1989, p. 45.

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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 ecosystems which could be affected by its use;

Whereas it is necessary to establish a Community authorization procedure for the placing on the market of products containing, or consisting of, GMOs where the intended use of the product involves the deliberate release of the organism(s) into the environment;

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

Whereas that notification should contain a technical dossier of information including a full environmental risk assessment, appropriate safety and emergency response, and, in the case of products, precise instructions and conditions for use, and proposed labelling and packaging;

Whereas, after notification, no deliberate release of GMOs should be carried out unless the consent of the competent authority has been obtained;

Whereas the competent authority should give its consent only after it has been satisfied that the release will be safe for human health and the environment;

Whereas it may be considered appropriate in certain cases to consult the public on the deliberate release of GMOs into the environment;

Whereas it is appropriate for the Commission, in consultation with the Member States, to establish a procedure for the exchange of information on deliberate releases of GMOs notified under this Directive;

Whereas it is important to follow closely the development and use of GMOs; whereas a list should be published of all the products authorized under this Directive;

Whereas, when a product containing a GMO or a combination of GMOs is placed on the market, and where such a product has been properly authorized under this Directive, a Member State may not on grounds relating to matters covered by this Directive, prohibit, restrict or impede the deliberate release of the organism in that product on its territory where the conditions set out in the consent are respected; whereas a safeguard procedure should be provided in case of risk to human health or the environment;

Whereas the provisions of this Directive relating to placing on the market of products should not apply to products containing, or consisting of, GMOs covered by other Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive;

Whereas a Committee should be set up to assist the Commission on matters relating to the implementation of this Directive and to its adaptation to technical progress,

HAS ADOPTED THIS DIRECTIVE:

PART A

General provisions

Article 1

1. The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment:

— when carrying out the deliberate release of genetically modified organisms into the environment,

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

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

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Article 2

For the purposes of this Directive:

(1) 'organism' is any biological entity capable of replication or of transferring genetic material;

(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 A Part 1;

(ii) the techniques listed in Annex I A Part 2 are not considered to result in genetic modification;

(3) 'deliberate release' means any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment such as physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment;

(4) 'product' means a preparation 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;

(6) 'notification' means the presentation of documents containing the requisite information to the competent authority of a Member State. The person making the presentation 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';

(8) 'environmental risk assessment' means the evaluation of the risk to human health and the environment (which includes plants and animals) connected with the release of GMOs or products containing GMOs.

Article 3

This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.

Article 4

1. Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs.

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

3. Member States shall ensure that the competent authority organizes inspections and other control measures as appropriate, to ensure compliance with this Directive.

PART B

Deliberate release of GMOs into the environment for research and development purposes or for any other purpose than for placing on the market

Article 5

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, or for any other purpose than for placing on the market, must submit a

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notification to the competent authority referred to in Article 4 (2) of the Member State within whose territory the release is to take place;

(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 or combination of GMOs may pose to human health or the environment, together with the methods used and the bibliographic reference to them and covering, 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 receiving environment,

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

(v) information on monitoring, control, waste treatment and emergency response plans;

(b) a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged;

(3) the competent authority may accept that releases of a combination of GMOs on the same site or of the same GMO on different sites for the same purpose and within a limited period may be notified in a single notification;

(4) the notifier shall include in the notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by him either inside or outside the Community.

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;

(5) in the case of a subsequent release of the same GMO or combination of GMOs previously notified as part of the same research programme, the notifier shall be required to submit a new notification. In this case, the notifier may refer to data from previous notifications or results from previous releases;

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

(a) revise the measures specified in the notification,

(b) inform the competent authority in advance of any modification or as soon as the new information is available,

(c) take the measures necessary to protect human health and the environment.

Article 6

1. On receipt and after acknowledgment of the notification the competent authority shall:

— examine it for compliance with this Directive,

— evaluate the risks posed by the release,

— record its conclusions in writing,
and, if necessary,

— carry out tests or inspections as may be necessary for control purposes.

2. The competent authority, having considered, where appropriate, any comments by other Member States made in accordance with Article 9, shall