II

(Preparatory Acts)

COMMISSION

Amended proposal for a European Parliament and Council Directive amending Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms [1]

(1999/C 139/10)

COM(1999) 139 final — 98/0072(COD)

(Submitted by the Commission pursuant to Article 189a(2) of the EC Treaty on 25 March 1999)

[1] OJ C 139, 4.5.1998.

ORIGINAL PROPOSAL	AMENDED PROPOSAL
Recital 1	
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, under the Treaty, action by the Community relating to the environment should be based on the principle that preventive action should be taken; whereas the precautionary principle has been taken into account in the drafting of this Directive;
Recital 4a (new)	
	Whereas means shall be sought of providing possibilities to facilitate the control of GMOs or their retrieval in the event of an acute risk;
Recital 5	
Whereas the provisions of the Directive concerning Part B releases of products shall not apply to products under development covered by Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive;	Whereas the provisions of the Directive concerning Part B releases of products shall not apply to products under development covered by Community legislation which provides for a specific environmental risk assessment at least equivalent to that laid down in this Directive;
Recital 5a (new)	
	Whereas the environmental risk assessment of this Directive concerning Part C releases should be a point of reference for products containing, or consisting of, GMOs covered by other Community legislation which should therefore provide for a specific environmental risk assessment at least equivalent to that laid down in this Directive;

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Recital 5b (new)	
	Whereas, for the renewal of consent, all the terms of the original consent may be revised, including those such as monitoring or the fixed period of the consent;
Recital 7	
Whereas it is appropriate that the administrative procedure for granting consents to the placing on the market of GMOs as or in products should become more efficient and more transparent and that consent should only be granted for a fixed period;	Whereas it is appropriate that the administrative procedure for granting consents to the placing on the market of GMOs as or in products should become more efficient and more transparent and that first-time consent should be granted for a fixed period;
Recital 12	
Whereas the Commission may consult any committee it has created with a view to advising it on the ethical implications of biotechnology on general matters which in the view of the Commission may raise ethical concerns;	Whereas the Commission's European Group on Ethics in Science and New Technologies may be consulted with a view to obtaining advice on ethical issues of general nature regarding the deliberate release of GMOs;
Article 2(1)	
1. 'organism' is any biological entity capable of replication or of transferring genetic material;	1. 'organism' is any biological entity, with the exception of humans, capable of replication or of transferring genetic material;
Article 2(3a) (new)	
	(3a) 'unauthorised deliberate release' means any deliberate release of GMOs as or in products for which no authorisation was given;
Article 2(3b) (new)	
	(3b) 'product' means a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market;
Article 2(5)	
5. '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';	5. 'notification' means the presentation of documents containing the requisite information to, and if appropriate, the lodging of samples of the GMO or its genetic materials with, the competent authorities of a Member State. The person making the presentation shall be referred to as 'the notifier';
Article 2(6)	
6. 'environmental risk assessment' means the evaluation of the direct and indirect risks to human health and the environment which the deliberate release of GMOs into the environment may pose;	6. 'environmental risk assessment' means the evaluation of the direct, indirect, immediate or delayed risks to human health and the environment which the deliberate release of GMOs into the environment may pose;

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Article 2(6a) (new)	
	(6a) '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'.
Article 4(3)	
Member States shall ensure that the competent authorities organises inspections and other control measures as appropriate, to ensure compliance with this Directive.	Member States shall ensure that the competent authorities organises inspections and other control measures as appropriate, to ensure compliance with this Directive. In the event of an unauthorised deliberate release of GMOs the Member State concerned shall ensure that necessary measures are taken to terminate the release, to initiate remedial action and to inform other Member States, the Commission and the public.
Article 5	
Articles 6 to 9 shall not apply to any products under development covered by Community legislation which provides for a specific environmental risk assessment similar to that laid down in those Articles.	Articles 6 to 9 shall not apply to any products under development covered by Community legislation which provides for a specific environmental risk assessment at least equivalent to that laid down in Annex II of this Directive.
Article 6b(2)	
2. The notification referred to in paragraph 1 shall include a technical dossier supplying the information specified in Annex III necessary for evaluating any foreseeable risks from the deliberate release of a GMO or combination of GMOs, in particular:	2. The notification referred to in paragraph 1 shall include a technical dossier supplying the information specified in Annex III necessary for evaluating any foreseeable risks from the deliberate release of a GMO or combination of GMOs, in particular:
(a) general information including information on personnel and training,	(a) general information including information on personnel and training,
(b) information relating to the GMO(s),	(b) information relating to the GMO(s),
(c) information relating to the conditions of release and the receiving environment,	(c) information relating to the conditions of release and the receiving environment,
(d) information on the interactions between the GMO(s) and the environment,	(d) information on the interactions between the GMO(s) and the environment,
(e) information on monitoring, control, waste treatment and emergency response plans,	(e) a detailed plan for monitoring in order to identify any relevant direct, indirect, immediate or delayed effects of the GMOs on human health or the environment,
	(f) information on control, remediation, waste treatment and emergency response plans,
(f) a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged.	(g) a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged.

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Article 6d(2)	
2. If information becomes available subsequently to the competent authority which could have significant consequences for the risks posed by the release, the competent authority may require the notifier to modify the conditions of, suspend or terminate the deliberate release.	2. If information becomes available subsequently to the competent authority which could have significant consequences for the risks posed by the release, the competent authority shall evaluate such information and may require the notifier to modify the conditions of, suspend or terminate the deliberate release.
Article 7	
	Without prejudice to the provisions of Article 19, Member States shall make available to the public information on Part B releases of GMOs. To the extent feasible and appropriate, Member States shall inform and consult the public on any aspect of the proposed deliberate release in an adequate, effective and timely manner. Any such public participation procedure shall not exceed 90 days. The Commission shall lay down, pursuant to Article 21, the manner in which this public participation procedure shall take place before . . . [the date foreseen for the transposition of the amending Directive].
Article 8	
	After completion of a release and, thereafter, at the intervals laid down in the consent, the notifier shall inform the competent authority of the result of the release in respect of any risk to human health or the environment, with particular reference to any kind of product that the notifier may intend to notify at a later stage. The summaries of the results of the release, including any data resulting from monitoring, shall be made available to the Commission and the other Member States.
Article 9(2)	
2. The Commission shall immediately forward these summaries to the other Member States, which may, within 30 days, present observations through the Commission or directly.	2. The Commission shall immediately forward these summaries to the other Member States, which may, within 30 days, present observations through the Commission or directly. At their request, Member States shall be permitted to receive a copy of the full notification from the competent authority of the relevant Member State.
Article 10	
Articles 11 to 18 shall not apply to any products covered by Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive.	Articles 11 to 18 shall not apply to any products covered by Community legislation which provides for a specific environmental risk assessment at least equivalent to that laid down in Annex II of this Directive.

ORIGINAL PROPOSAL	AMENDED PROPOSAL
Article 12(3)	
3. The assessment report shall indicate whether the GMO(s) in question should be placed on the market and under which conditions, if any, or whether additional assessment is required.	3. The assessment report shall indicate (i) whether the GMO(s) in question should be placed on the market and under what conditions, if any, (ii) whether the GMO(s) in question shall not be placed on the market or (iii) whether additional assessment is required.
The assessment reports shall be established in accordance with the guidelines laid down in Annex VI.	The assessment reports shall be established in accordance with the guidelines laid down in Annex VI.
Article 12(3a) (new)	
	(3a) In the case referred to in paragraph 3(ii), the competent authority shall inform the notifier that the release does not fulfil the conditions of this Directive and that it is therefore rejected at the same time as it forwards its assessment report to the Commission.
Article 13c(4)	
4. In the absence of any reasoned objection from a Member State or the Commission within 30 days following the date of submission referred to in paragraph 3, the competent authority that received the original notification shall give its consent in writing for the renewal of the original consent and shall inform the other Member States and the Commission thereof. The consent shall be granted for a fixed period of seven years.	4. In the absence of any reasoned objection from a Member State or the Commission within 30 days following the date of submission referred to in paragraph 3, the competent authority that received the original notification shall give its consent in writing for the renewal of the original consent and shall inform the other Member States and the Commission thereof. The period of validity of the consent may be limited as appropriate.
Article 13d(1)	
1. In cases where an objection is raised and maintained in accordance with Article 13(2), 13b(5) or 13c(3), or an additional assessment is required in accordance with Article 12(3), the Commission shall take a decision within three months in accordance with the procedure laid down in Article 21.	1. In cases where an objection is raised and maintained in accordance with Article 13(2), 13b(5) or 13c(3), or an additional assessment is required in accordance with Article 12(3), the Commission shall take a decision within three months in accordance with the procedure laid down in Article 21.
For the purpose of calculating the three month period, any period of time during which the Commission is awaiting further information which it may have requested from the notifier or is seeking the opinion of a Scientific Committee which has been consulted shall not be taken into account.	For the purpose of calculating the three month period, any period of time during which the Commission is awaiting further information which it may have requested from the notifier or is seeking the opinion of a Scientific Committee which has been consulted in accordance with Article 20a(1) shall not be taken into account.

ORIGINAL PROPOSAL	AMENDED PROPOSAL
Article 13e(3)	
3. Consent to the placing on the market of GMOs in or as a product shall be granted for a fixed period of seven years. The notifier may proceed with the placing on the market only when he has received the written consent of the competent authority in accordance with Articles 13, 13b, 13c and 13d, and in conformity with any conditions, including reference to particular ecosystems/environments, required in that consent.	3. Without prejudice to Article 13c(4), consent to the placing on the market of GMOs in or as a product shall be granted for a fixed period of seven years. The notifier may proceed with the placing on the market only when he has received the written consent of the competent authority in accordance with Articles 13, 13b, 13c and 13d, and in conformity with any conditions, including reference to particular ecosystems/environments, required in that consent.
Article 13e(5)	
5. If the competent authority receives additional information pursuant to paragraph 4, it shall immediately inform the Commission and the competent authorities of the other Member States.	5. If the competent authority receives additional information pursuant to paragraph 4, or otherwise, which could have significant consequences for the risks posed by the release, the competent authority shall evaluate such information, and it shall immediately inform the Commission and the competent authorities of the other Member States of the action taken.
Article 16(1)	
1. Where a Member State, as a result of new information or reassessment of existing information, has detailed grounds for considering that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.	1. Where a Member State, as a result of additional information or reassessment of existing information, has detailed grounds for considering that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that product on its territory. In the event of an acute risk, the deliberate release shall be terminated immediately and, as far as possible, the GMOs shall be recovered. In addition, the public shall be informed of the risk posed by the GMOs. The Member State shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.
Article 20a	
The relevant Scientific Committee(s) shall be consulted by the Commission on any matter which is likely to have an effect on human health and/or the environment before the decision procedure referred to in Articles 13d(1) or 16(2) is initiated.	1. The relevant Scientific Committee(s) shall be consulted by the Commission on any matter which is likely to have an effect on human health and/or the environment before the decision procedure referred to in Articles 13d(1) or 16(2) is initiated. The Commission may require the adoption of an opinion by the Scientific Committee(s) within a specified time period.

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	2. The Commission, on its own initiative or at the request of the Council or the European Parliament, may consult its European Group on Ethics in Science and New Technologies with a view to advising it on ethical issues of general nature regarding the release of GMOs.
ANNEX II (A) (1)	
1. Elements which may be considered as potentially harmful effects:	1. Elements which may be considered as potentially harmful effects:
— pathogenicity to humans, animals or plants,	— pathogenicity to humans, animals, plants or microorganisms,
— compromising of prophylactic or therapeutic treatments,	— compromising of prophylactic or therapeutic treatments,
— effects on population dynamics within the receiving environment,	— effects on population dynamics within the receiving environment,
— effects on geochemistry,	— effects on geochemistry,
— the uncontrolled spread of the GMO(s) in the environment and invasion of unrelated ecosystems,	— the uncontrolled spread of the GMO(s) in the environment and invasion of unrelated ecosystems,
— effects resulting from the transfer of the inserted genectic material to other organisms,	— effects resulting from the transfer of the inserted genetic material to other organisms,
— phenotypic and genetic instability.	— phenotypic and genetic instability.
ANNEX II (B) (5)	
5. Application of management strategies for risks from the deliberate release of GMO(s) If for any release the estimated risk for any identified hazard is not an acceptable level, the GMO(s) or the conditions of the release should be modified to reduce the risk.	5. Application of management strategies for risks from the deliberate release of GMO(s) If for any release the estimated risk for any identified hazard is not an acceptable level, the GMO(s) or the conditions of the release shall be modified in such a way as to reduce the risk to an acceptable level.
ANNEX IIIB (G) (4)	
4. Description of monitoring plans and techniques.	4. Description of monitoring plans and techniques and their duration and frequency.
ANNEX IV (A) (5)	
5. information relating to the introduced genetic modification which could be of relevance to the establishment of a possible register of modifications introduced in organisms (species). This may include nucleotide sequences or other type of information which is relevant to the inclusion in such a register.	5. information relating to the introduced genetic modification which is of relevance for the detection and identification of the GMO(s) to facilitate post-marketing control and inspection. This may include nucleotide sequences or other type of information which is relevant to the inclusion in a register regarding the control of GMOs released for placing on the market.

ORIGINAL PROPOSAL	AMENDED PROPOSAL
ANNEX IV (B) (6) (new)	
	6. description of procedures which facilitate the retrieval of the GMOs in the event of an acute risk.
ANNEX VI (5)	
5. A conclusion on whether the GMO(s) in question should be placed on the market in or as (a) product(s) and under which conditions or whether an additional assessment is required on certain aspects. The aspects which require additional assessment should be specified.	5. A conclusion on whether the GMO(s) in question should be placed on the market in or as (a) product(s) and under which conditions, whether the GMO(s) in question shall not be placed on the market or whether an additional assessment is required on certain aspects. The aspects which require additional assessment should be specified. In the case that it has been concluded that the GMO(s) in question shall not be placed on the market, the competent authority shall give reasons for its decision.