COMMISSION OF THE EUROPEAN COMMUNITIES

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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

(presented by the Commission pursuant to Article 189 a (2)
of the EC-Treaty)

EXPLANATORY MEMORANDUM

Pursuant to Article 189a paragraph 2 of the Treaty, the Commission submits an 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 (GMOs). The amended Proposal takes account of a number of amendments from the European Parliament adopted at its Plenary Session on 11 February 1999.

In general the Commission cannot accept amendments that seek to change the balance of the safety net built into the Commission Proposal or which are not in line with the basic principles of the Directive such as the case by case analysis. However, the Commission can accept Amendments 1, 3 to 6, 11, 12, 14 to 17, 20, 25 to 27, 29, 31, 32, 35, 38, 39, 42 to 44, 53, 54, 57, 58, 60, 62, 64 to 66, 89, 92 and 94 either fully or in principle. In addition the Commission can partially accept Amendments 9, 33 and 34. Comments on these amendments are as follows.

Amendments 1, 14, 38, 64, 66 and 92 seek to establish means to facilitate the identification, control and retrieval of GMOs. The Commission agrees to the principle to strengthen administrative control within the Directive. It has accepted these amendments in so far as they do not complicate the operation of the Directive or duplicate provisions already present in the Commission Proposal and has amended Article 2 (5) and Annex IV accordingly and introduced the new recital 4a.

Amendments 3 and 94 strengthen the link of this Directive to product legislation and thus ensure a comprehensive environmental risk assessment throughout the legislative framework concerning biotechnology. Therefore, the Commission has accepted these amendments in principle and reworded Articles 5, 10 and the corresponding recital 5, and introduced the new recital 5a.

Amendment 4, which is fully acceptable to the Commission, confirms in the new recital 5b that all conditions, including monitoring and time limitation may be revised prior to the renewal of consent.

Amendments 5 and 42 delete the reference to the fixed 7 year time limitation of consent in recital 7 and Article 13c, both of which concern the renewal of consent. The Commission can accept an optional time limitation for the renewal of consent and has reworded recital 7 and Articles 13c and 13e accordingly.

Amendments 6 and 54 are acceptable in so far as they confirm that the Council and the European Parliament may request the Commission to consult the Ethical Committee in order to obtain advice on general ethical concerns related to the release of GMOs (recital 12 and Article 20a). The Commission, however, cannot agree to link this consultation to the decision-making on the placing on the market of individual GMOs or to a time limit for delivering an Opinion by the Ethical Committee.

Amendment 9 clarifies the definition of "organism" in Article 2 (1), which does not cover human beings. The second part of this amendment substantially duplicates the first part and is, therefore, not acceptable.

Amendments 11, 12, 15 and 16 change the definition of "environmental risk assessment" and introduce new definitions into Article 2 with a view to clarifying the objective and the text of the Directive. The Commission supports these clarifications. However, Amendments 11 and 15 have been reworded to make them consistent with the text of the Commission Proposal.

Amendments 17, 57 and 62 highlight the precautionary approach as a basis for the approval process. The Commission strongly supports the principle behind these amendments, but is of the opinion that the Directive as a whole reflects the precautionary principle. Accordingly the Commission has addressed this issue in recital 1 which encompasses the framework within which the Directive operates.

Amendment 20 introduces an obligation for Member States and requires that necessary measures are taken in the event of an unauthorised release of GMOs. The amendment also requires that other Member States, the Commission and the public be informed. The Commission accepts the principle of this amendment and has reworded Article 4 (3) accordingly.

Amendments 25 and 26 require that information on remediation plans and details of the monitoring plans are included in the notification dossier for Part B releases (Article 6b (2)). The Commission accepts these amendments in principle, since they clarify the information requirements concerning part B releases.

Amendments 27, 29 and 32 concerning the public consultation for experimental releases is acceptable in principle. The Commission has reworded Article 7 in order to align it with the provisions of the Aarhus Convention relating to public participation in decision-making in environmental matters.

Amendment 31 clarifies that the competent authorities of Member States have to evaluate all additional information which becomes available after consent has been granted. The Commission strongly supports this amendment, which provides a useful clarification in Article 6d (2).

Amendment 33 is partially acceptable insofar as it specifies that reports on releases and the intervals that should be applied to such reports are set out in the authorisation. The Commission has also included in Article 8 that the summaries of the results should be circulated to the Member States (Amendment 35). The Commission strongly supports the principle behind this amendment, since it will promote the link between Part B and Part C of the Directive and contribute towards harmonisation. The reference to long term consequences in Amendment 33 is covered in Articles 6b and 6d of the amended Commission Proposal.

Amendment 34, part 1 amends Article 9 (2) providing an opportunity for Member States to request full dossiers on experimental releases. The Commission accepts this amendment, since it will assist harmonisation of the regulatory assessment and control but clarifies that the dossier should be provided by the competent authorities of the relevant Member State. The second part of Amendment 34 would enable Member States to stop the clock for comments on experimental

releases in other Member States. This, however, would not be practical within the procedures of the Directive and is therefore not acceptable.

Amendment 39 (Article 12 (3)) specifies further the content of the risk assessment report by introducing the requirement to indicate that the GMO in question is not to be placed on the market. The Commission accepts this change and additionally has introduced a new paragraph 3a in Article 12 and reworded Annex VI, paragraph 5 in order to make the text consistent with this amendment.

Amendment 43 addresses the need for termination of the release of a GMO and, in the event of an acute risk, the recovering of GMOs released as far as possible. A requirement to inform the public is also included in this amendment. Amendment 53 replaces the word "new" in Article 16 with the word "additional", which seeks to ensure that Member States take decisions regarding provisional restrictions of use of a certain GMO in line with best available knowledge. The Commission accepts the principle behind these amendments and has reworded Article 16 accordingly.

Amendment 44 clarifies the circumstances when the Scientific Committees may be consulted by the Commission and sets a time limit for such consultations. The Commission agrees in principle that the procedure for the consultation of the relevant Scientific Committees can be clarified further and that in certain cases a specific time limit for delivering an Opinion could be appropriate. Articles 13d and 20a were, therefore, amended accordingly.

Amendment 58 introduces the element "pathogenicity to micro-organisms" in the chapter of potentially harmful effects in Annex II on the principles of the environmental risk assessment. This is a useful clarification and the Commission, therefore, supports this amendment.

Amendment 60 introduces a requirement in Annex II that the release of a GMO should be halted and as far as possible reversed if the estimated risk is not acceptable. It may only be carried out after the conditions have been modified in such a way as to reduce the risks significantly. This amendment mainly duplicates provisions of Articles 13e and 16. However, the Commission has reworded Annex II, Part B, paragraph 5 in order to strengthen the risk assessment methodology.

Amendment 65 specifies that the information submitted by the notifier concerning the monitoring plan shall include information on duration and frequency of the monitoring. This amendment clarifies the information requirement laid down in Annex III B, Part G, paragraph 4 and the Commission supports this amendment fully.

Amendment 89 clarifies that the competent authorities may require the notifier to modify the conditions of, suspend or terminate the deliberate release of GMOs and to take any remedial action under Article 13e (5). The Commission accepts this amendment in principle. It clarifies the duties of the competent authorities following receipt of additional information concerning the potential risks posed by the release of a GMO and Article 13e has been amended accordingly, taking into account the changes which have been accepted in line with Amendments 31 and 43.

The Commission cannot accept Amendments 2, 7, 8, 10, 13, 19, 21-24, 28, 30, 37, 40, 41, 45, 46, 48-52, 55, 59, 61, 63, 67, 68, 73, 75, 79, 84, 86, 87, 90, 91, 95, 96 and 101. Commentary on these amendments is as follows.

Amendments 2 and 22 seek to delete Article 5 and the corresponding recital, which allow the relevant Part B releases to be covered by specific product legislation containing an environmental risk assessment equivalent to that laid down in Directive 90/220/EEC. These amendments are not acceptable to the Commission, since this Article promotes the link between releases for purposes of research and development and product releases.

Amendments 7 and 95 propose a new recital and a provision concerning environment liability rules. The Commission prefers to deal with this matter in a horizontal manner in order to avoid different liability requirements in different Directives and intends to produce a White Paper on environmental liability. These amendments are, therefore, not acceptable.

Amendments 8, 30, 48, 49, 50, 52, 63 and 87 are not acceptable because these represent duplication of other amendments or provisions in the text of the Commission Proposal. They do not assist the clarity of the text.

Amendment 10 is not acceptable since it would significantly enlarge the scope of the Directive to cover "non-living" elements and chemical DNA.

Amendment 13 seeks to introduce an exemption to the definition of placing on the market. While acknowledging the intention to clarify further the definition of the placing on the market in line with the current practice, the Commission feels that the explicit mentioning of one exemption might cause legal uncertainty about the scope of the Directive. Amendment 40 is not consistent with Article 1 of the Commission Proposal and would lead to a lack of clarity. Accordingly, it is also not acceptable.

Amendments 19, 21 and 51 propose the inclusion of provisions concerning the import and export of GMOs. These amendments are not acceptable to the Commission, since they would prejudge the final text of a Biosafety Protocol, which is being negotiated in the framework of the Convention on Biological Diversity.

Amendment 23 has not been accepted by the Commission. It would increase the time periods that Competent Authorities have to review Category I applications and thus places additional burdens on notifiers without increasing safety, since Category I releases meet specific criteria based on safety and familiarity.

Amendment 24 seeks to introduce implicit consent for Category I experimental releases. The Commission considers that an explicit written consent is more appropriate in all cases of releases and has, therefore, not accepted this amendment.

Amendment 28 limits the notifier's choice of appropriate application procedure and is, therefore, not acceptable.

Amendments 37 and 67 address the labelling of GMOs. The labelling policy of the Commission implies that all GMOs covered by Directive 90/220/EEC must be labelled. In cases where the presence of GMOs, mixed with conventional produce, cannot be excluded but there is no evidence of any such presence of GMOs, the "may contain" label is allowed. This possibility, which intends to facilitate operations in early stages of the production chain, is without prejudice to the requirements of the Novel Foods Regulation which ensures that the final consumer is always and affirmatively informed about any presence of GMOs or their modified products in foods and food ingredients. The proposed amendments, therefore, neither improve the information offered to final consumer, nor do they offer any added value to flexibility and the development of information exchange throughout the production chain.

Amendments 41, 45, and 46 seek to replace the 7 year time limitation by a 12 year time limitation for first-time consents. The principle of time-limited consent will allow all information to be reassessed and make it possible to alter the consent conditions so that they reflect the state of scientific knowledge at that time. The Commission cannot accept these amendments because it considers that the period of 7 years is the optimum time needed to reassess a GMO and to re-examine the initial consent conditions. The fixed period of 12 years would be too long for such a review. Amendment 75 requires the 12 year period for first-time consents also in specific product legislation and is not acceptable either.

Amendment 55 proposes changes in the IIIb comitology procedure. The involvement of the European Parliament in the comitology procedure is currently subject to the 'modus vivendi' and will be formalised in a specific decision on the new comitology. This amendment is not acceptable to the Commission at this stage.

Amendments 59, part I and 61 seek to introduce the evaluation of socio-economic aspects as a basic principle into the environmental risk assessment. The basis of the Directive is the protection of the environment and human health. Therefore, the Commission cannot accept the inclusion of socio-economic aspects as a general principle into the scientific evaluation of risks of a GMO on a case by case basis. Amendment 59, part II does not clarify further the Commission Proposal and is also not acceptable.

Amendments 68 and 101 seek to change the criteria in Annex V which determine the GMOs which can be classified into Category I of Part B releases. It is proposed that certain types of GMOs be excluded from Category I on a general basis. These amendments are not acceptable, since they do not follow the case by case principle and the structure of Annex V. According to the Commission Proposal, certain GMOs may be classified on a case by case basis into Category I, if they meet specific criteria of safety and familiarity.

Amendments 73 and 90 have not been accepted by the Commission. These amendments propose a general ban for certain types of GMOs in Directive 90/220/EEC. However, one basic principle of the Directive is that a comprehensive scientific risk assessment is carried out on a case by case basis. A general ban of certain types of GMOs is not consistent with this principle and does not improve the general balance in the Directive. The Commission is of the opinion that the current practice of a case by case based risk assessment thoroughly evaluates the effects and consequences of the insertion of antibiotic resistance genes into a GMO.

Amendment 79 seeks to exempt pharmaceutical products for human use containing or consisting

of GMOs from the scope of Directive 90/220/EEC provided that they are covered by Community legislation, which provides for an equivalent risk assessment. The Commission cannot accept this amendment, since it would go further than Articles 5 and 10 of the Directive, which allow such products only to be removed from the administrative procedures of the Directive and not from the general provisions.

Amendment 84 addresses scientific uncertainties and the need for close co-operation between scientists and policy-makers. This recital is not specifically linked to the legal text of the Directive and is not acceptable to the Commission.

Amendment 86 proposes that a notifier may take legal action, if the competent authority does not respond within the time period set out in the proposed Directive. This amendment is not acceptable, since this issue is covered by the national legal protection regimes, which apply in any case.

Amendment 91 has not been accepted by the Commission, since it is not consistent with the principle of the case by case analysis. It seeks to introduce a general obligation for the Member States and the Commission to ensure that, when consenting to a deliberate release, measures are taken to prevent gene transfer from GMOs to other organisms.

Amendment 96 seeks to introduce in a recital a political statement addressing the creation of a centralised procedure at Community level for the release of GMOs. This amendment is not linked to the legal text and is not acceptable to the 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
(presented by the Commission pursuant to Article 189a paragraph 2 of the EC Treaty)

COMMISSION 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;

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;

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

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:	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.

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

1. 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.

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.	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.

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.
	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 genetic 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)	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.	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.

ANNEX IV (B) (6) (new)

	6. description of procedures which facilitate the retrieval of the GMOs in the event of an acute risk.

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.

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