COMMISSION OF THE EUROPEAN COMMUNITIES

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95/0340 (SYN)

Amended proposal for a

COUNCIL DIRECTIVE

amending Directive 90/219/EEC
on the contained use of genetically modified micro-organisms

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

EXPLANATORY MEMORANDUM

Pursuant to Article 189 (a) paragraph 2 of the EC treaty, the Commission submits an amended proposal for a Council Directive amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms. The amended proposal takes account of a number of amendments from the European Parliament adopted at its March 1997 Plenary Session.

In general the Commission cannot accept amendments that seek to limit the information given to the public or the Commission, introduce specific requirements for liability insurance, change the legal basis of the Directive or complicate its operation. However the Commission can accept in full amendments 2, 3, 9, 10, 16, 17, 19, 31, 41, 42, 49 and 56 which clarify or further the principles of the Commission Proposal.

In addition the Commission can partially accept amendments 4, 11, 27, 30 (merged with 29), 37, 38, 39, 43, 47, 48, 54 and 55. Commentary on these amendments follows:-

Amendment 4 (Article 2 (a)) seeks to delete the words "including viruses, viroids, animal and plant cells in culture, but excluding naked nucleic acid molecules.". The Commission accepts the deletion of "but excluding naked nucleic acid molecules", but wishes to retain the other words to assist clarity and maintain the intended scope of the Directive.

Amendment 11 makes a textual change in Article 6 (a) (1) deleting the word risk and adding the plural form of activity. The Commission accepts this but has substituted contained use(s) in place of activities to be consistent with other amendments.

Amendment 27 requires in Article 14 (b) information on safety measures to be included, regional administrative authorities to be informed and a system of co-operation be established to guarantee public informed in detail. The Commission accepts, with rewording, the requirement for information on safety measures which must be relevant to the emergency plans. However the Commission cannot accept that the Directive would require the implementation of a regional system for co-operation within a Member State to guarantee the public are informed in detail. This is under the responsibility of the Member State.

Amendment 30 the restriction of serious damage to public health or the environment in Article 15.1 is not acceptable to the Commission. An accident is defined in Article 2(f) and the proposed wording implies that damage must have occurred, whereas the current definition covers the potential hazard from the accident. The proposed addition of the words "and unintentionally released" added at end of the second indent of Article 15.1 has not been accepted because it restricts the article to not covering accidents by self inoculation (injection). The deletion of the word emergency in the fourth indent of Article 15.1 is already in the Proposal. The replacement of the word avoid with prevent in Article 15.2 is accepted by the Commission.

Amendment 37 (Article 20) seeks to limit the annexes that can be modified by the committee procedure to Annex III par.1 -5 and annexes IV & V. The Commission accepts that annexes I & IIB (should be only amendable by the full procedure. The Commission is unable to accept restriction on the procedure to amend annexes II and III. The restriction on amending annex

II would prevent the operation of the list of types of GMMs shown to be safe for human health and the environment. It would also prevent the rapid modification of annex IIA which lists techniques of genetic modification not leading to a GMM should an, as yet unknown, safety issue indicate the need to further restrict this annex. The exclusion of some parts of annex III would complicate amendments to the annex as a whole.

Amendment 38 requires in Article 20 (a) (new) that within 6 months of implementation of the Directive, following a Commission proposal, the criteria defining GMMs suitable for inclusion into Annex II B shall be made in accordance with Article 100a of the EC Treaty. The Commission has accepted this, but not the suggested Treaty base of 100a since the Directive is made under Article 130S1.

Amendment 39 concerns Article 21. The Commission has accepted a 2a comitology procedure which gives flexibility to the Council to adopt different measures to those proposed by the Commission instead of the 3b procedure contained in the Commission Proposal for the modification of Directive 90/219/EEC. Concerning the report of experience with the Directive the Commission considers that this requirement is present in Article 18.3 and the report will be made available to Parliament. However the proposal in the amendment that the decisions and minutes of the committee are made available to the public is not acceptable to the Commission, since it conflicts with the agreement between the Commission and the European Parliament (applicable from 1.12.1996) on transparency and publicity of committee meetings.

Amendment 43 proposes in Annex III new wording for par.2 a and a specific reference to Directive 90/679/EEC on the protection of workers from biological agents in par. 3. These changes are acceptable to the Commission. The addition of a specific risk assessment procedure for human health is not acceptable to the Commission since the Directive covers human health and the environment. The Commission feels specific guidance of this nature would best be produced in guidance to the Annex. The Commission has accepted text from par. 5a and par. 5b which assist the clarity of the Commission Proposal.

Amendments 47 and 48 (Annex IV Table Ia) amend the requirements for surfaces in laboratories. The Commission accepts that the surfaces should be resistant to water, decontamination agents and easy to clean. The Commission has not accepted the change in specification for floors walls and ceilings which are in excess of the requirements of Directive 90/679/EEC on the protection of workers from biological agents, which also covers GMMs, since this measure is primarily related to worker protection.

Amendments 54 and 55 (Annex IV Table II) amend the requirements for surfaces in facilities for other activities. The Commission accepts that benches, if fitted, should be included at all levels and that the surfaces should be resistant to water and decontamination agents. The Commission has not accepted the change in specification for floors walls and ceilings. The requirement that floors must be resistant at level 2 should remain to be applied on a case by case basis depending on the risk assessment which considers the size of the operation. The alterations at levels 3 and 4 are not required due to the absence of very large scale production of those agents,

The Commission can accept in principle amendments 7, 8, 14, 15, 21, 22, 23, 24, 25, 35 and 68. Commentary on these amendments follows:-

Amendment 7 concerning Article 2 (c) is acceptable with a minor rewording to refer to annex II C.

Amendment 8 links the risk assessment to the containment and control measures in Article 6a, the Commission accepts the principle but has altered the wording to assist clarity.

Amendments 14 and 15 seek to introduce the principle of good microbiological practice and the requirement to review its application in the workplace in Article 6a (2). The Commission accepts the inclusion of the principle in the Directive, but feels that such technical measures are best located in the preface to Annex IV which details the containment and control measures to be applied.

Amendments 21, 22, 23, 24, 25, and 35 introduce the separation of classes 3 and 4 for different notification requirements in Articles 10, 11, 12 and 18, requiring an explicit consent for subsequent activities for class 4 and implicit consent for class 3. The Commission accepts the principle of these amendments to strengthen the administrative controls for high risk work but intends to retain the equal treatment of classes 3 & 4, accordingly making both subject to explicit consent for all uses in Article 10a (3).

Amendment 68 seeks to amend the definition of contained use in Article 2 (c) to avoid possible confusion over the use of the word limit. The Commission accepts the principle of this amendment but proposes to replace "avoid their contact with" by expressing the principle aim of the Directive using the words "provide a high level of safety for".

The Commission has not accepted amendments 1, 6, 12, 13, 18, 20, 26, 28, 32, 33, 34, 36, 40, 44, 45, 46, 50, 51, 52, 53, 57 and 58. Commentary on these amendments follows:-

Amendment 1 proposing to change the legal basis of the Proposal from 130S.1 to 100A is not acceptable to the Commission. Legally, since the scope of Directive 90/219/EEC is not being significantly altered, and it does not impact directly on the functioning of the harmonised market, there is no legal argument to change the legal basis of the Directive from 130S1 to 100A. In addition the change of legal base would prevent Member States from providing in their national legislation containment and control measures which are more stringent than those provided for in the Directive.

Amendments 18 & 20 seek to separate class 3 and 4 activities for different notification requirements are not acceptable because the Commission believes that such a separation would complicate the operation of the Directive and could lead to confusion.

Amendments 44, 45 and 46 which seek to reintroduce the distinction of purpose into the revision of the Directive, are not acceptable to the Commission. The Commission seeks to regulate the activity, for example laboratory work, irrespective of the final purpose for which the work is being undertaken.

Amendments 26, 36, 57 and 58 have not been accepted by the Commission. These amendments seek to limit the information available to the public or aspects of activities that can be subject to public consultation to solely health and environmental protection and emergency plans. The

Commission feels that these restrictions will not improve public confidence in the regulation of this technology.

Amendments 32 and 33 seek to restrict information required to be given to Competent Authorities and the Commission in the event of an accident, to that which presents possible serious damage. Under these amendments the choice of what is covered by health and environmental protection and emergency plans is left with the notifier. These amendments are not acceptable to the Commission.

Amendments 13 and 28 deal with the issue of liability insurance and the provision of financial security and are not acceptable to the Commission. The subject of liability is under consideration by the Commission, which intends to produce a white paper on environmental liability. The Commission wishes to deal with this matter in a horizontal manner to avoid different liability requirements in different Directives.

Amendments 6, 12 and 34 have not been accepted by the Commission because they duplicate provisions present in Article 2(h), 12.2 and duties present in Articles 8, 9 and 10 respectively.

Amendment 40 has not been accepted by the Commission because it produces a duplication of existing text within the same annex, which does not assist the clarity of the text.

Amendments 50 and 51 have not been accepted by the Commission. These amendments increase the burden of control measures, by making them requirements, without the option to decide if they are necessary in all cases. These measures will not always be required and thus not always increase safety levels.

Amendment 52 has not been accepted by the Commission. This precautionary measure should not be specifically required for class 2 activities. The amendment is in excess of the requirements of Directive 90/679/EEC on the protection of workers from biological agents, which covers GMMs, and this measure is primarily related to worker protection.

Amendment 53 is technically invalid since the genetically modified micro-organisms are not required to be in a closed system and as such has not been accepted by the Commission.

Amended Proposal for a

COUNCIL DIRECTIVE

amending Directive 90/219/EEC

on the contained use of genetically modified micro-organisms

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

COMMISSION PROPOSAL	AMENDED PROPOSAL
	Recital 3a (new)
	Whereas the principle of good microbiological practice and the principles of safety and health at work laid down in the relevant Community laws should apply to all activities in which genetically modified micro-organisms are used;
	Recital 4a (new)
	Whereas specific measures should be adopted and used for the control of the disposal of material from the activities of the contained use of genetically modified micro-organisms;
	Article 2(a)
(a) The following words are added at the end of paragraph (a): "including viruses, viroids and animal and plant cells in culture but excluding naked nucleic acid molecules.";	(a) The following words are added at the end of paragraph (a): "including viruses, viroids and animal and plant cells in culture (words deleted)..";
	Article 2(c)
(c) "contained use" shall mean: any operation in which micro-organisms are genetically modified or in which such genetically modified micro-organisms are cultured, stored, used, transported or destroyed [deleted words], and for which physical barriers, or a combination of physical barriers together with chemical and/or biological barriers, are used to limit their contact with the general population and the environment; or any activity in which genetically modified micro-organisms are disposed of, for which physical or chemical or biological barriers, or any combination of these types, are used to limit their contact with the general population and the environment;"	(c) "contained use" shall mean: any operation in which micro-organisms are genetically modified or in which such genetically modified micro-organisms are cultured, stored, used, transported or destroyed [deleted words], and for which physical barriers, or a combination of physical barriers together with chemical and/or biological barriers, are used to provide a high level of safety for the general population and the environment; or any activity in which genetically modified micro-organisms are disposed of, for which physical or chemical or biological barriers, or any combination of these types, are used to provide a high level of safety for the general population and the environment;"

Article 3

This Directive shall not apply where genetic modification is obtained through the use of the techniques or methods listed in Annex II, or for contained-use activities involving other types of genetically modified micro-organisms known to be safe for human health and the environment. Such types of genetically modified micro-organisms and their characteristics are listed in Annex II, Part B	This Directive shall not apply where genetic modification is obtained through the use of the techniques or methods listed in Annex II, or for contained-use activities involving other types of genetically modified micro-organisms known to be safe for human health and the environment. Such types of genetically modified micro-organisms and their characteristics are listed in Annex II, Part B and Part C;

Article 6 (3)

3. The assessment should result in the categorization of the contained-use activities in the following four classes of risk:	3. The assessment shall result in the final categorization of the contained-use activities in the following four classes of risk and serve to determine the level of containment and control measures in accordance with Article 6a:

Article 6 (3a) (new)

	3a. Where there is doubt as to which of two classes of risk is appropriate for the proposed contained-use activity(ies), the higher classification should be assigned until sufficient evidence justifies the use of the lower classification.

Article 6 (4a) (new)

	4a. When assessing the risk entailed in an activity involving genetically modified micro-organisms, the question of disposal shall be taken especially into account. Where appropriate, the necessary safety measures shall be implemented in order to protect human health and the environment.

Article 6a (1)

1. The user shall apply the containment and control measures from the appropriate Table(s) in Annex IV corresponding to the risk class of the activity, so as to keep workplace and environmental exposure to any genetically modified micro-organisms to the lowest reasonably practicable level, and so that a high level of safety is ensured."	1. The user shall apply the containment and control measures from the appropriate Table(s) in Annex IV corresponding to the class of the contained use(s), so as to keep workplace and environmental exposure to any genetically modified micro-organisms to the lowest reasonably practicable level, and so that a high level of safety is ensured."

Article 10(1)

1. For the first and subsequent Class 2 activities to be carried out in premises notified in accordance with Article 8, a notification containing the information listed in Annex V, Part B shall be submitted.	1. For the first and subsequent Class 2 contained use(s) to be carried out in premises notified in accordance with Article 8, a notification containing the information listed in Annex V, Part B shall be submitted.

Article 10 (2a) (new)

	2a. The applicant can, however, himself request a decision on a formal authorization from the competent authority. This decision must be made within a maximum of 45 days from the notification.

Article 10a (2)

2. If no previous notification has been submitted for Class 3 or a higher class of activities, the contained use may not proceed without the consent of the competent authority. The competent authority shall communicate its decision in writing at the latest 90 days after submission of the notification.	2. If no previous notification has been submitted for Class 3 or a higher class of contained use, the contained use may not proceed without the consent of the competent authority. The competent authority shall communicate its decision in writing at the latest 90 days after submission of the notification.

Article 10a (3)

3. If a previous notification has been submitted for Class 3 or a higher class of activities and the associated consent requirements have been satisfied, the contained use may in absence of any indication to the contrary from the competent authority proceed 45 days after submission of the new notification, or earlier with the agreement of the competent authority."	3. If a previous notification has been submitted for Class 3 or a higher class of activities and the associated consent requirements have been satisfied for the same or higher class, the contained use may not proceed without the consent of the competent authority. The competent authority shall communicate its decision in writing at the latest 45 days after submission of the notification.

Article 14 (b)

(b) Information on emergency plans is supplied in an appropriate manner, and without their having to request it, to bodies and authorities liable to be affected by the accident. The information shall be updated at appropriate intervals. It shall also be made publicly available.	(b) Information on emergency plans and relevant safety measures is supplied in an appropriate manner, and without their having to request it, to bodies and authorities liable to be affected by the accident. The information shall be updated at appropriate intervals. It shall also be made publicly available.

Article 15 (2)

	(a) in the second indent, the word "avoid" is replaced by the word "prevent"

Article 16 (1) (a) (new)

In point (a) of paragraph 1 of Article 16, the word "liable" is replaced by the word "likely".

Article 20

In Article 20, the words "Annexes II to V" are replaced by the words "Annexes I to V".	In Article 20, the words "Annexes II to V" are replaced by the words "Annexes II part A, II part C and annexes III to V".

Article 20a (new)

Within six months of the implementation date of this Directive specified in Article 2, the criteria for the inclusion of certain types of genetically modified micro-organisms in Annex II, Part B, shall be laid down in accordance with Article 130S1 of the EC Treaty.

Article 21

3. The Commission shall adopt measures which shall apply immediately. However, if these measures are not in accordance with the opinion of the committee, they shall be communicated by the Commission to the Council forthwith. In that event the Commission may defer application of the measures which it has decided for a period of not more than one month from the date of such communication.

The Council, acting by a qualified majority, may take a different decision within the time-limit referred to in the previous subparagraph.

Annex II part B

B. Types of genetically modified micro-organisms which have been shown to be safe for human health and the environment and which are, therefore, excluded from the Directive:"	B. Criteria establishing the safety of genetically modified micro-organisms to human health and the environment.

Annex II part C (new)

C. Types of genetically modified micro-organisms which meet the criteria listed in part B

Annex III par. 2

2. a. The assessment referred to in Article 6 should be based on the following:	2. The assessment referred to in Article 6 should be based on the following:
(i) the recipient micro-organism;	a. The identification of any potentially harmful effects of the operation in particular any potentially harmful effects caused by:
(ii) the inserted (donated) genetic material;	(i) the recipient micro-organism;
(iii) the vector;	(ii) the inserted (donated) genetic material;
(iv) the donor micro-organism (if the donor micro-organism is used during the operation);	(iii) the vector;
(v) the resulting genetically modified micro-organisms.	(iv) the donor micro-organism (if the donor micro-organism is used during the operation);
b. The severity of the potentially harmful effects.	(v) the resulting genetically modified micro-organisms.
c. The likelihood of the potentially harmful effects being realized.	b. The severity of the potentially harmful effects.
	c. The likelihood of the potentially harmful effects being realized.
Annex III par. 3	
Procedure	Procedure
3. In order to arrive at the categorization of a particular activity, as referred to in Article 6, the user may take into consideration the risk class of the recipient, the vector and, if applicable, donor micro-organism as given in other Community legislation, international or national schemes (e.g. WHO, NIH etc.).	3. In order to arrive at the categorization of a particular activity, as referred to in Article 6, the user may take into consideration the risk class of the recipient, the vector and, if applicable, donor micro-organism as given in other Community legislation, in particular Directives 90/679/EEC[1] on the protection of workers from risks related to exposure to biological agents at work as amended by Directive 93/88/EEC[2] and adapted to technical progress by Directive 95/30/EC[3], International or national schemes (e.g. WHO, NIH etc.) and their revisions due to new scientific knowledge and technical progress may also be considered.
These classification schemes concern natural micro-organisms and are usually based on the ability of micro-organisms to cause disease to humans or animals, and on the severity and transmissibility of the disease likely to be caused. The user may also take into consideration classification schemes referring to plant pathogens (which are usually established on a national basis).	These classification schemes concern natural micro-organisms and are usually based on the ability of micro-organisms to cause disease to humans or

[1] OJ No L 374 31.12.1990 p.1
[2] OJ No L 268 29.10.1993 p. 0071
[3] OJ No L 155 06.07.1995 p. 0041

The above mentioned classification schemes give only a provisional indication of the risk class of the activity and the corresponding set of containment and control measures required.

animals, and on the severity and transmissibility of the disease likely to be caused. Directive 90/679/EEC classifies micro-organisms, as biological agents, into four classes of risk on the basis of potential effects on a healthy human adult. These classes of risk can be used as guidance to the categorization of the contained use activities in the four Classes of risk referred to in Article 6(3). The user may also take into consideration classification schemes referring to plant pathogens (which are usually established on a national basis). The above mentioned classification schemes give only a provisional indication of the risk class of the activity and the corresponding set of containment and control measures required.

Annex III par.5b (new)

5b. Risk assessments for human health and the environment may give rise to different classifications of the contained use. Where this occurs, the final classification will be the higher of the two classifications with its accompanying containment and control measures.

Annex IV Preface (new paragraphs)

As a minimum, in addition to specific safety measures, the following principles of good microbiological practice at work shall invariably apply to genetically modified micro-organisms:

(a) when necessary, tests shall be carried out to ascertain the presence of viable used organisms outside the physical boundaries within which they are primarily contained;

(b) provision shall be made for basic and regular further training of personnel;

(c) biological safety committees or subcommittees shall be set up according to requirements;

(d) internal practical rules of conduct

shall be drawn up and enforced to ensure the safety of personnel.

The application of 'Good microbiological practice' shall be reviewed by the user periodically. The persons employed in this area shall take part in the review, without prejudice to Article 11 of Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work[4].

Table I a (line 3)

3 Surfaces resistant to acids, alkalis, solvents, disinfectants Containment levels 1 yes (bench) 2 yes (bench) 3 yes (bench, floor) 4 yes (bench, floor, ceiling, walls)	3 Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and which are easy to clean Containment levels 1 yes (bench) 2 yes (bench) 3 yes (bench, floor) 4 yes (bench, floor, ceiling, walls)

Table I a (line 12)

12 Washing and decontamination provisions for personnel Containment levels 1 yes 2 yes 3 yes 4 yes	12 Handwashing and decontamination provisions for personnel Containment levels 1 yes 2 yes 3 yes 4 yes

Table II (line 9)

9 Surfaces resistant to acids, alkalis, solvents, disinfectants Containment levels 1 optional 2 optional 3 yes (bench if any, floor) 4 yes (bench, floor, ceiling, walls)	9 Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and which are easy clean Containment levels 1 yes (bench if any) 2 yes (bench if any) 3 yes (bench if any, floor) 4 yes (bench if any, floor,

[4] OJ No. L183, 29.6.1989, p.1.

ceiling, walls)

Table II (line 16)

16	Washing and decontamination provisions for personnel	16 Handwashing and decontamination provisions for personnel
	Containment levels	Containment levels
	1 yes	1 yes
	2 yes	2 yes
	3 yes	3 yes
	4 yes	4 yes

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