COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 29.07.1998
COM(1998) 479 final

95/ 0340 (SYN)

Re-examined 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 c (d)
of the EC Treaty)

EXPLANATORY MEMORANDUM

The proposal for the amendment was adopted by the Commission on 6 December 1995 and submitted to the Council on 28 March 1996.

The Economic and Social Committee adopted its opinion on 10 July 1996.

The European Parliament adopted its first reading of the Proposal to amend Directive 90/219/EEC during the plenary session of 12 March 1997.

The Commission presented on 12 June 1997 an amended Proposal to the Council (COM(97) 240 Final 95/0340 SYN).

The Council adopted a common position on 16 December 1997.

The European Parliament examined the Council's common position at second reading on 16 June 1998 and approved it subject to 34 amendments.

The Commission has examined the amendments approved by the European Parliament after its second reading, incorporating a number of them into the present re-examined Proposal.

The Commission's position on each of the amendments proposed by the European Parliament at second reading is as follows.

The Commission can accept in full amendments 5, 6, 17, 19, 25 and 32. These clarify or further the principles of the Commission Proposal.

In addition the Commission can partially accept amendments 8, 12, 13, and 14. Commentary on these amendments follows:-

Amendment 8 (Article 14b) will be reworded to make clear that the relevant safety measures applicable in an emergency must be supplied to the bodies and authorities likely to be affected by the accident.

Amendment 12 (Article 20a) requires 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 13 (Article 21). The Commission has accepted a IIa comitology procedure which gives flexibility to the Council to adopt different measures to those proposed by the Commission instead of the IIIb 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 regulatory 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.

The Commission can partially accept Amendment 14 (Annex III). The proposed alteration to the procedure for the adoption to technical progress of part B of Annex III is not acceptable by the Commission. The proposed procedure based on 100a of the EC Treaty would not provide sufficient flexibility and could compromise safety and the environmental protection where rapid adaptation of the annex would be required. The more specific reference to Directive 90/679/EEC on the protection of workers from biological agents is acceptable. The addition of an emphasised 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 can accept in principle amendments 2, 18, 20, 21, 28, 33, 34 and 35. Commentary on these amendments follows:-

Amendment 2 (Article 2) would result in the requirement for physical barriers to always be present during waste disposal, this requirement is not appropriate for all cases, for example with cell culture disposal where other specific containment measures such as chemical barriers would be adequate. The Commission can accept that specific containment measures as interpreted by the Directive in Annex IV, should be applied to provide a high level of safety for the general population and the environment.

Amendment 28 (Annex IV table Ic) which seeks to require animal containment in appropriate cages, pens or tanks will be reworded to use the identified types of containment measures in the amendment as examples to prevent uncertainty over the definition of the terms used.

Amendments 18, 20, 21, 33 - 35 seek to reintroduce containment and control measures into the tables of annex IV. This is proposed to clarify that these measures are not accorded a lesser status than those in the tables because they are contained in the preface to the tables. However the preface, and accordingly containment and control contained there in, have equal legal weight to those measures specified in the tables. To clarify this position a footnote will be added to the preface indicating that Member States can incorporate the provisions of the preface into the tables to assist clarity of understanding of requirements for the classes of activity.

The Commission has not accepted amendments 1, 3, 7, 9, 10, 11, 15, 16, 22, 23, 24, 26, 27, 29, 30 and 31. Commentary on these amendments follows:-

Amendment 1 (preamble) 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 3, 7, 10, 16 and 31 have not been accepted by the Commission, because they duplicate provisions already present in Articles 12.2, 13 and 5.6 respectively or present in annex IV.

Amendment 9 (new Article 14a) deals with the issue of liability insurance and is 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.

Amendment 11 (Article 20) seeks to restrict amendments to Annex III by the regulatory committee procedure to part A only. The Commission is unable to accept restriction on the procedure to amend annex III. The proposal that amendments to the risk assessment procedure in Annex III part B must be done in accordance with Article 100A of the Treaty is not acceptable. The legal base of the Directive is Article 130S of the Treaty and such a prescriptive measure would also complicate amendments to the annex to take advantage of increased scientific knowledge.

Amendments 15 and 30 (Annex IV Table Ia & II) seek amend the requirements for surfaces in laboratories. The Commission considers that the requirement that surfaces should be resistant to water, decontamination agents and easy to clean and those for benches are met in the common position. The Commission does not accept the change in specification for floors walls and ceilings at level 3 which is 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.

Amendment 22 (Annex IV Table Ia) This amendment on vector control increases the burden of control measures, by making them requirements at level 1 which by definition has negligible risk, and thus not will not always increase safety levels.

Amendment 23 (Annex IV Table Ib) This amendment seeks to re-establish the Commission proposal, however this change will result standards for glasshouse work in excess of that required for the same level of work in laboratories. At level 1 risk should be minimal and at level 3 Optional would allow application of requirement dependant on risk, accordingly the Commission does not accept this amendment.

Amendment 24 (Annex IV Table Ib) The Commission does not accept this amendment which seeks to re-establish the Commission proposal, because this change will result standards for glasshouse work in excess of that required for the same level of work in laboratories. In the absence of specification the requirements of table 1a applies.

Amendment 26 (Annex IV Table Ic) This requires facilities to be specifically designed for decontamination. This burden is excessive when animals which routinely excrete non GMM class 2 pathogens do not require this.

Amendment 27 (Annex IV Table Ic) The Commission does not accept this amendment because walls are not normally contaminated in animal units and washing at level 3 & 4 is

precautionary, this measure is not merited at level 2. At level 1 work is of minimal risk and preface point xiv still applies. 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 29 (Annex IV Table II) 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.

Re-examined 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 189c paragraph d of the EC Treaty)

COMMON POSITION	RE-EXAMINED PROPOSAL
Article 2 (c)	
(c) 'contained use' shall mean any activity in which micro-organisms are genetically modified or in which such genetically modified micro-organisms are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with the general population and the environment.	(c) 'contained use' shall mean any activity in which micro-organisms are genetically modified or in which such genetically modified micro-organisms are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to provide a high level of safety for the general population and the environment
Article 9 (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 10(2)	
2. A class 3 or higher of contained use may not proceed without the prior written consent of the competent authority:	2. A class 3 or higher of contained use may not proceed without the consent of the competent authority which shall communicate its decision in writing:
(a) at the latest 45 days after submission of the new notification, in the case of premises which have been the subject of a previous notification to carry out class 3 or a higher class of contained uses and where any associated consent requirements have been satisfied for the same or a higher class than the contained use with which it is intended to proceed,	(a) at the latest 45 days after submission of the new notification, in the case of premises which have been the subject of a previous notification to carry out class 3 or a higher class of contained uses and where any associated consent requirements have been satisfied for the same or a higher class than the contained use with which it is intended to proceed,
(b) at the latest 90 days after submission of the notification, in other cases."	(b) at the latest 90 days after submission of the notification, in other cases."

Article 14 (b)

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

Article 20a

Before the ... (*) Annex II, Part B, listing the criteria for inclusion of types of GMMs into Annex II, Part C, shall be adopted by the Council acting by qualified majority on a proposal from the Commission. Amendments to Annex II, Part B, shall be adopted by the Council acting by qualified majority on a proposal from the Commission. * 24 months after the entry into force of this Directive	Within 6 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

1. The Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission. 2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.	1. The Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission. 2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3.(a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee. (b) If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority. If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.	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 three months 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 III par. 3

Procedure	Procedure
5. In order to inform this process the user may firstly take into account relevant community legislation (for example Council Directives 90/679/EEC and 93/88/EEC and classification schemes referring to plant and animal pathogens) and other international and national classification schemes. These schemes concern natural micro-organisms and as such are usually based on the ability of micro-organisms to cause disease to humans, animals or plants and on the severity and transmissibility of the disease likely to be caused.	5. In order to inform this process the user may firstly take into account relevant community legislation in particular Directives 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work as amended by Directive 93/88/EEC and adapted to technical progress by Directive 95/30/EC. International or national classification schemes (e.g. WHO, NIH etc.) and their revisions due to new scientific knowledge and technical progress may also be considered. These 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. 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 5(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 IV Preface (new footnote)

Member States can incorporate general provisions from the preface in the following Tables to assist clarity of requirements.

Table I a (line 10 new)

10	Biohazard signs on the door
	Containment levels
	1 not required
	2 required
	3 required
	4 required

Table I a (line 14)

14 Protective clothing	14 Protective clothing
Containment levels	Containment levels
1 suitable protective clothing	1 suitable protective clothing
2 suitable protective clothing	2 suitable protective clothing
3 suitable protective clothing	3 suitable protective clothing ± foot wear
4 complete change of clothing + foot wear before entry and exit	4 complete change of clothing + foot wear before entry and exit

Table I c (line 2)

2 Animal facilities[1)] separated by lockable doors	2 Animal facilities separated by lockable doors
Containment levels	**Containment levels**
1 optional	1 required
2 required	2 required
3 required	3 required
4 required	4 required

Table I c (line 5) new

5 Animals kept in appropriate containment facilities such as cages pens or tanks
Containment levels
1 required
2 required
3 required
4 required

Table II (line 15) new

15 Biohazard signs should be posted
Containment levels
1 not required
2 required
3 required
4 required

[1)] Animal facility: a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures.

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