



COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMUNICATION FROM THE COMMISSION
TO THE EUROPEAN PARLIAMENT

pursuant to the first subparagraph of Article 189 c (b) of the EC-Treaty

Common position of the Council on the Proposal for a Council Directive
amending Directive 90/219/EEC on the contained use of genetically
modified micro-organisms

I. PROCEDURE

The Proposal (COM(95)640 final 95/0340 SYN) was presented to the Council on 28 March 1996 (co-operation procedure under Article 130S1 of the Treaty).

The Economic and Social Committee adopted its Opinion on 10 July 1996 (OJ C295 of 7 October 1996).

The European Parliament gave its Opinion in its first reading during the plenary session of 12 March 1997 (OJ C 115 of 14 April 1997).

Following the Opinion of the European Parliament and pursuant to Article 189 (a) paragraph 2 of the EC treaty, the Commission adopted an amended Proposal on 12 June 1997 (COM(97) 240 Final 95/0340 SYN).

The Council formally adopted its common position on 16.12.1997.

II. PURPOSE

Directive 90/219/EEC covers all work with GMMs in contained facilities (laboratories and industrial facilities). The objective of the Directive was to safeguard human health and the environment and provide a common basis for regulation of this new technology throughout the EU.

The Directive was adopted in April 1990. However, it was based on the scientific knowledge of the early 1980's and was perceived to have some weaknesses as soon as 1991.

The main elements of the Commission Proposal designed to revise Directive 90/219/EEC to technical progress, are:

- i. the administrative procedures and notification requirements will be linked to the risk of the activities involving GMMs, which will be classified into four risk groups and streamlined where this does not compromise safety;
- ii. the minimum containment and control measures to be applied to each of the four classes of risk are specified, and the possibility for future adaptations to technical progress will be simplified.

The Commission Proposal retains the regulation of genetically modified micro-organisms based on the precautionary principle.

III. COMMISSION POSITION ON THE COUNCIL COMMON POSITION

1. GENERAL COMMENTS

The Commission accepted thirty five of the fifty seven amendments proposed by the European Parliament in the first reading either totally, partially or in principle. They were incorporated in the amended Proposal of 12 June 1997 (COM(97) 240 Final 95/0340 SYN).

Twenty nine of the amendments have been incorporated in the common position either in principle, entirety or in part.

The Commission considers that the common position does not alter the basic technical approach and aims of the Proposal whilst some aspects of the text have been clarified and strengthened.

- the disposal of waste is specifically taken into account;
- in cases of doubt of the classification of an activity, the more stringent safety measures are applied;
- the administrative control has been reinforced by the requirement to obtain explicit consent for all class 3 and class 4 work with GMMs;
- the requirement for emergency plans has been extended to all cases where failure of containment could lead to serious danger, and
- the containment and control measures have been strengthened by the incorporation of a requirement to apply the principles of good occupational safety and hygiene.

The Commission however **does not accept** the proposed new Article 20a which excludes the European Parliament from the procedure to establish and modify Annex IIB which affects the scope of the Directive, nor Article 21 which remains with the IIb Regulatory Committee procedure instead of the IIa procedure foreseen by the Commission in its amended Proposal following the first Opinion of the European Parliament.

Due to the process of redrafting, in some instances it is the principle of the amendment and not the exact wording which has been retained in the common position.

2. DETAILED COMMENTS

- a) Parliamentary amendments accepted by the Commission in the amended Proposal and **which have been incorporated** in the common position

References to recitals and articles refer to those numbered in the common position.

- recital on the application of the principles of good microbiological practice (Recital 7, **amendment 2**)
- recital on specific measures on waste disposal (Recital 4a, **amendment 3**)
- recital on consultation of employees according to Directive 90/679/EEC (Recital 9, **amendment 15**)
- deletion of part of definition of micro-organism (Article 2a, **amendment 4**)
- reference to Annex II parts B and C (Article 3, **amendment 7**)
- reference to the risk assessment determining containment measures in accordance with Article 6 (Article 5.3, **amendment 8**)
- provision that if in doubt between two classification levels, highest to be used (Article 5.3a, **amendment 9**)
- provision for waste disposal to be taken especially into account (Article 5.3b, **amendment 10**)
- reference to contained use instead of activity (Article 6.1, **amendment 11**)
- reference to contained uses instead of activities (Article 9.1, **amendment 16**)
- reference to contained uses instead of activities (Article 10.1, **amendment 19**)
- reference to subsequent class 4 activities requiring a consent (Article 10.2, **amendments 21, 22, 23, 24, 25 and 35**)
- reference to Member States likely to be affected rather than liable (Article 16.1a, **amendment 31**)
- reference to annexes amendable by regulatory committee procedure (Article 20, **amendment 37**)
- provision for annex II B to detail criteria for GMMs to be included in Annex IIC (Annex II part B, **amendment 41**)
- provision for annex II C to form a list of GMMs that meet the criteria in annex IIB (Annex II part C, **amendment 42**)
- reference to the identification of potentially harmful effects and Directives 90/679/EEC and 93/88/EEC (Annex III, **amendment 43**)
- reference to the principles of good microbiological practice (Annex IV, **amendment 14**)
- reference to handwashing facilities (Annex IV preface, **amendments 49 and 56**)

- reference to resistance to water and decontamination agents (Annex IV Table Ia, line 3, **amendments 47 and 48**)
 - ~~reference to resistance to water and decontamination agents (Annex IV Table II line 9, **amendments 54 and 55**)~~
- b) Parliamentary amendments accepted, in total or in part, by the Commission in the amended Proposal but which **have not been incorporated** in the common position
- amendment to the definition of contained use (Article 2c, **amendment 68**)
 - ability for notifier to request a decision within 45 days (Article 9.2a, **amendment 17**)
 - addition of the words relevant safety measures to emergency plans supplied to bodies affected by an accident (Article 14b, **amendment 27**)
 - replace “avoid” by “prevent” similar accidents (Article 15.2, **amendment 30**)
 - a full 130S1 procedure instead of Council procedure to establish and modify Annex IIB (Article 20a, **amendment 38**)
 - use a IIa comitology procedure for the Regulatory Committee in place of a IIIb procedure (Article 21, **amendment 39**)
- c) New elements introduced by Council in the common position with respect to the amended Proposal. Changes detailed in section (A) and (B) are not repeated. Only significant changes are highlighted, alterations to take account of renumbering are not detailed in the following text.

Article 19.1

Specific exclusion from disclosure, after justification, is made for items mentioned in Article 3(2) of Directive 90/313/EEC on the freedom of access to information on the environment to accommodate concerns on national security.

Article 20a

Adopts a “simplified” Council procedures under Article 145 of the Treaty for the adoption and amendment of Annex IIB.

Article 21

Retains the IIIb Regulatory Committee for the amendment of Annexes IIC to V instead of the IIa procedure proposed in the amended Commission Proposal.

IV. CONCLUSION

The Commission considers that whilst the common position text of the Council should be technically acceptable, the Commission cannot join the unanimous position of the Council to exclude the European Parliament from the process of adopting or modifying of Annex IIB which affects the scope of the Directive.