

I

(Information)

COUNCIL

COMMON POSITION (EC) No 7/98

adopted by the Council on 16 December 1997

with a view to adopting Council Directive 98/.../EC amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms

(98/C 62/01)

THE COUNCIL OF THE EUROPEAN UNION,

should be in line with international practice and based on an assessment of the risk;

Having regard to the Treaty establishing the European Community, and in particular Article 103s(1) thereof,

Having regard to the proposal from the Commission ⁽¹⁾,Having regard to the opinion of the Economic and Social Committee ⁽²⁾,Acting in accordance with the procedure laid down in Article 189c of the Treaty ⁽³⁾,

(1) Whereas, within the meaning of the Treaty, action by the Community relating to the environment should be based on the principle that preventive action is to be taken and shall have as its objective to preserve, protect and improve the environment and to protect human health;

(2) Whereas contained uses of genetically modified micro-organisms (GMMs) should be classified in relation on the risks they present for human health and the environment; whereas such classification

(3) Whereas in order to ensure a high level of protection the containment and other protective measures applied to a contained use must correspond to the classification of the contained use; whereas in case of uncertainty the appropriate containment and other protective measures for the higher classification should be applied until less stringent measures are justified by appropriate data;

(4) Whereas appropriate measures should be adopted and used for the control of the disposal of material from contained uses of GMMs;

(5) Whereas GMMs which are disposed of without appropriate provisions for specific containment measures to limit their contact with the general population and the environment do not fall within the scope of the present Directive; other Community legislation such as Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms ⁽⁴⁾ may apply;

⁽¹⁾ OJ C 356, 22.11.1997, p. 14.

⁽²⁾ OJ C 295, 7.10.1996, p. 52.

⁽³⁾ Opinion of the European Parliament of 12 March 1997 (OJ C 115, 14.4.1997, p. 59), Council Common Position of 16 December 1997 and Decision of the European Parliament of ... (not yet published in the Official Journal).

⁽⁴⁾ OJ L 117, 8.5.1990, p. 15. Directive as last amended by Commission Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72).

- (6) Whereas exemptions pursuant to this Directive do not entail exemptions pursuant to any other Community legislation that may apply, such as Directive 90/220/EEC;
- (7) Whereas for all activities involving GMMs the principles of good microbiological practice and good occupational safety and hygiene should apply in accordance with relevant Community legislation;
- (8) Whereas the containment and other protective measures applied to contained uses should be reviewed periodically;
- (9) Whereas people employed in contained uses should be consulted in accordance with the requirements of relevant Community legislation, in particular Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) ⁽¹⁾;
- (10) Whereas weaknesses have been identified in Directive 90/219/EEC ⁽²⁾; whereas the administrative procedures and notification requirements should be linked to the risk of the contained uses;
- (11) Whereas Directive 90/219/EEC did not permit sufficient adaptation to technical progress; whereas the technical parts of that Directive need to be adapted to technical progress;
- (12) Whereas the implementation of Directive 90/219/EEC could benefit from the addition of a list of GMMs that are safe for human health and the environment; whereas these GMMs should meet certain criteria in order to establish their safety;
- (13) Whereas, to take account of the pace at which biotechnology is advancing, the nature of the criteria to be developed and the limited scope of this list, it is appropriate for the Council to define and revise these criteria;
- (14) Whereas there is now considerable experience and knowledge of the risks associated with the contained use of GMMs;
- (15) Whereas Directive 90/219/EEC should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 90/219/EEC is hereby amended as follows:

1. Articles 2 to 16 shall be replaced by the following:

'Article 2

For the purposes of this Directive:

- (a) "micro-organism" shall mean any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cells in culture;
- (b) "genetically modified micro-organism" (GMM) shall mean a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Within the terms of this definition:

- (i) genetic modification occurs at least through the use of the techniques listed in Annex I, Part A;
- (ii) the techniques listed in Annex I, Part B, are not considered to result in genetic modification;
- (c) "contained use" shall mean any activity in which micro-organisms are genetically modified or in which such GMMs 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;
- (d) "accident" shall mean any incident involving a significant and unintended release of GMMs in the course of their contained use which could present an immediate or delayed hazard to human health or the environment;

⁽¹⁾ OJ L 374, 31.12.1990, p.1. Directive as last amended by Commission Directive 97/59/EC (OJ L 282, 15.10.1997, p. 33).

⁽²⁾ OJ L 117, 8.5.1990, p. 1. Directive as amended by Commission Directive 94/51/EC (OJ L 297, 18.11.1994, p. 29).

- (e) "user" shall mean any natural or legal person responsible for the contained use of GMMs;
- (f) "notification" shall mean the presentation of the requisite information to the competent authorities of a Member State.

Article 3

Without prejudice to Article 5(1) this Directive shall not apply:

- where genetic modification is obtained through the use of the techniques/methods listed in Annex II, Part A, or
- for contained uses involving only types of GMMs meeting the criteria listed in Annex II Part B which establish their safety to human health and the environment. These types of GMMs shall be listed in Annex II, Part C.

Article 4

Articles 5(3), 5(6) and Articles 6 to 12 shall not apply to the transport of GMMs by road, rail, inland waterway, sea or air.

This Directive shall not apply to the storage, culture, transport, destruction, disposal or use of GMMs which have been placed on the market in accordance with Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (*) or pursuant to other Community legislation, which provides for a specific environmental risk assessment similar to that laid down in the said Directive, provided that the contained use is in accordance with the conditions, if any, of the consent for placing on the market.

(*) OJ L 117, 8.5.1990, p. 15. Directive as last amended by Commission Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72).

Article 5

1. Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the contained use of GMMs.

2. To this end the user shall carry out an assessment of the contained uses as regards the risks to human health and the environment that these contained uses may incur, using as a minimum the elements of assessment and the procedure set out in Annex III, sections A and B.

3. The assessment referred to in paragraph 2 shall result in the final classification of the contained uses in four classes applying the procedure set out in Annex III, which will result in the assignment of containment levels in accordance with Article 6:

Class 1: activities of no or negligible risk, that is to say activities for which level 1 containment is appropriate to protect human health as well as the environment.

Class 2: activities of low risk, that is to say activities for which level 2 containment is appropriate to protect human health as well as the environment.

Class 3: activities of moderate risk, that is to say activities for which level 3 containment is appropriate to protect human health as well as the environment.

Class 4: activities of high risk, that is to say activities for which level 4 containment is appropriate to protect human health as well as the environment.

4. Where there is doubt as to which class is appropriate for the proposed contained use, the more stringent protective measures shall be applied unless sufficient evidence, in agreement with the competent authority, justifies the application of less stringent measures.

5. The assessment referred to in paragraph (2) shall especially take into account the question of disposal. Where appropriate, the necessary safety measures shall be implemented in order to protect human health and the environment.

6. A record of the assessment referred to in paragraph (2) shall be kept by the user and made available in an appropriate form to the competent authority as part of the notification pursuant to Articles 7, 9 and 10 or on request.

Article 6

1. The user shall apply, except to the extent that paragraph 2 of Annex IV allows other measures to be applied, the general principles and the appropriate containment and other protective measures set out in Annex IV corresponding to the class of the contained use, so as to keep workplace and environmental exposure to any GMMs to the lowest reasonably practicable level, and so that a high level of safety is ensured.

2. The assessment referred to in Article 5(2) and the containment and other protective measures applied shall be reviewed periodically, and forthwith if:

- (a) the containment measures applied are no longer adequate or the class assigned to the contained uses is no longer correct, or
- (b) there is reason to suspect that the assessment is no longer adequate as judged in the light of new scientific or technical knowledge.

Article 7

When premises are to be used for the first time for contained uses, the user shall be required to submit to the competent authorities, before commencing such use, a notification containing at least the information listed in Annex V, Part A.

Article 8

Following the notification referred to in Article 7, subsequent class 1 contained use may proceed without further notification. Users of GMMs in class 1 contained uses shall be required to keep the record of each assessment referred to in Article 5(6), which shall be made available to the competent authority on request.

Article 9

1. For first and subsequent class 2 contained uses to be carried out in premises notified in accordance with Article 7, a notification containing the information listed in Annex V, Part B shall be submitted.

2. If the premises have been the subject of a previous notification to carry out class 2 or a higher class of contained uses and any associated consent requirements have been satisfied, the class 2 contained use may proceed immediately following the new notification.

3. If the premises have not been the subject of a previous notification to carry out class 2 or a higher class of contained uses, the class 2 contained use may, in the absence of any indication to the contrary from the competent authority, proceed 45 days after submission of the notification referred to in paragraph 1, or earlier with the agreement of the competent authority.

Article 10

1. For first and subsequent class 3 or class 4 contained uses to be carried out in premises notified in accordance with Article 7, a notification containing the information listed in Annex V, Part C shall be submitted.

2. A class 3 or higher class of contained use may not proceed without the prior written consent of the competent authority:

- (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.

Article 11

1. Member States shall designate the authority or authorities competent to implement the measures which they adopt in application of this Directive and to receive and acknowledge the notifications referred to in Articles 7, 9 and 10.

2. The competent authorities shall examine the conformity of the notifications with the requirements of this Directive, the accuracy and completeness of the information given, the correctness of the assessment referred to in Article 5(2) and the class of contained uses and, where appropriate, the adequacy of the containment and other protective measures, the waste management, and emergency response measures.

3. If necessary, the competent authority may:

- (a) ask the user to provide further information or to modify the conditions of the proposed contained use or to amend the class assigned to the

contained use(s). In this case the competent authority may require that the contained use, if proposed, does not begin, or, if in progress, is suspended or terminated, until the competent authority has given its approval on the basis of the further information obtained or of the modified conditions of the contained use;

- (b) limit the time for which the contained use should be permitted or subject it to certain specific conditions.

4. For the purpose of calculating the periods referred to in Articles 9 and 10, any period of time during which the competent authority:

- is awaiting any further information which it may have requested from the notifier in accordance with paragraph 3(a), or
- is carrying out a public inquiry or consultation in accordance with Article 13

shall not be taken into account.

Article 12

If the user becomes aware of relevant new information or modifies the contained use in a way which could have significant consequences for the risks posed by it, the competent authority shall be informed as soon as possible and the notification pursuant to Articles 7, 9 and 10 shall be modified.

If information subsequently becomes available to the competent authority which could have significant consequences for the risks by the contained use, the competent authority may require the user to modify the conditions of, or suspend or terminate, the contained use.

Article 13

Where a Member State considers it appropriate, it may provide that the public shall be consulted on aspects of the proposed contained use, without prejudice to Article 19.

Article 14

The competent authorities shall ensure that before a contained use commences:

- (a) an emergency plan is drawn up for contained uses where failure of the containment measures could lead to serious danger, whether immediate or delayed, to humans outside the premises and/or to

the environment, except where such an emergency plan has been drawn up under other Community legislation;

- (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.

The Member States concerned shall at the same time make available to other Member States concerned, as a basis for all necessary consultation within the framework of their bilateral relations, the same information as that which is disseminated to their nationals.

Article 15

1. Member States shall take the necessary measures to ensure that, in the event of an accident, the user shall be required to inform immediately the competent authority specified in Article 11 and provide the following information:

- the circumstances of the accident,
- the identity and quantities of the GMMs concerned,
- any information necessary to assess the effects of the accident on the health of the general population and the environment,
- the measures taken.

2. Where information is given pursuant to paragraph 1, the Member States shall be required to:

- ensure that any measures necessary are taken, and alert immediately any Member States which could be affected by the accident,
- collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit the effects thereof.

Article 16

1. Member States shall be required to:

- (a) consult with other Member States, likely to be affected in the event of an accident, on the proposed implementation of emergency plans;

(b) inform the Commission as soon as possible of any accident within the scope of this Directive, giving details of the circumstances of the accident, the identity and quantities of the GMMs concerned, the response measures taken and their effectiveness and an analysis of the accident, including recommendations to limit its effects and avoid similar accidents in the future.

2. The Commission, in consultation with the Member States, shall establish a procedure for the exchange of information pursuant to paragraph 1. It shall also set up and keep at the disposal of the Member States a register of accidents within the scope of this Directive, including an analysis of the causes of the accidents, experience gained and measures taken to avoid similar accidents in the future.'

2. Articles 18, 19 and 20 shall be replaced by the following:

'Article 18

1. Member States shall send to the Commission, at the end of each year, a summary report on class 3 and class 4 contained uses notified during that year pursuant to Article 10 including the description, purpose and risks of the contained use(s).

2. Every three years, Member States shall send the Commission a summary report on their experience with this Directive, the first time being on . . . (*).

3. Every three years, the Commission shall publish a summary based on the reports referred to in paragraph 2, the first time being on . . . (**).

4. The Commission may publish general statistical information on the implementation of this Directive and related matters, as long as it contains no information likely to cause harm to the competitive position of a user.

(*) 54 months after the entry into force of this Directive.

(**) 66 months after the entry into force of this Directive.

Article 19

1. Where its disclosure affects one or more of the items mentioned in Article 3(2) of Council Directive 90/313/EEC of 7 June 1990 on the freedom of access

to information on the environment (***), the notifier may indicate the information in the notifications submitted pursuant to this Directive that should be treated as confidential. Verifiable justification must be given in such cases.

2. The competent authority shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decision.

3. In no case may the following information, when submitted according to Articles 7, 9 or 10, be kept confidential:

- the general characteristics of the GMMs, name and address of the notifier, and location of use,
- class of contained use and measures of containment,
- the evaluation of foreseeable effects, in particular any harmful effects on human health and the environment.

4. The Commission and the competent authorities shall not divulge to third parties any information decided to be confidential according to paragraph 2 and notified or otherwise provided pursuant to this Directive, and shall protect intellectual property rights relating to the data received.

5. If, for whatever reasons, the notifier withdraws the notification, the competent authority must respect the confidentiality of the information supplied.

(***) OJ L 158, 23.6.1990, p. 56.

Article 20

Amendments necessary to adapt Annex II, Part A, and Annexes III to V to technical progress and to adapt Annex II, Part C, shall be decided in accordance with the procedure laid down in Article 21.'

3. The following Article shall be inserted:

'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.'

4. The Annexes are replaced by the Annexes shown in the Annex hereto.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 18 months after the date of its entry into force. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their

official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive enters into force on the day of its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at . . .

For the Council

The President

ANNEX

ANNEX I

PART A

Techniques of genetic modification referred to in Article 2(b)(i) are, *inter alia*:

1. Recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation.
2. Techniques involving the direct introduction into a micro-organism of heritable material prepared outside the micro-organism including micro-injection, macro-injection and micro-encapsulation.
3. Cell fusion or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART B

Techniques referred to in Article 2(b)(ii) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs made by techniques/methods other than techniques/methods excluded by Annex II, PART A:

- (1) *in vitro* fertilisation;
 - (2) natural processes such as: conjugation, transduction, transformation;
 - (3) polyploidy induction.
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ANNEX II

PART A

Techniques or methods of genetic modification yielding micro-organisms to be excluded from the Directive on the condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs other than those produced by one or more of the techniques/methods listed below:

1. Mutagenesis.
2. Cell fusion (including protoplast fusion) of prokaryotic species that exchange genetic material by known physiological processes.
3. Cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions.
4. Self-cloning consisting in the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent) with or without prior enzymic or mechanical steps, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by natural physiological processes where the resulting micro-organism is unlikely to cause disease to humans, animals or plants.

Self-cloning may include the use of recombinant vectors with an extended history of safe use in the particular micro-organisms.

PART B

Criteria establishing the safety of GMMs to human health and the environment:

... (to be completed in accordance with the procedures in Article 20a)

PART C

Types of GMMs which meet the criteria listed in Part B:

... (to be completed in accordance with the procedure in Article 21)

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ANNEX III

PRINCIPLES TO BE FOLLOWED FOR THE ASSESSMENT REFERRED TO IN ARTICLE 5(2)

This Annex describes in general terms the elements to be considered and the procedure to be followed to perform the assessment referred to in Article 5(2). It will be supplemented, as regards in particular section B, by guidance notes to be developed by the Commission in accordance with the procedure set out in Article 21.

These guidance notes shall be completed no later than the ... (*).

A. ELEMENTS OF ASSESSMENT

1. The following should be considered as potentially harmful effects:
 - disease to humans including allergenic or toxic effects,
 - disease to animals or plants,
 - adverse effects resulting from the inability to treat disease or offer effective prophylaxis,
 - adverse effects resulting from establishment or dissemination in the environment,
 - adverse effects resulting from the natural transfer of inserted genetic material to other organisms.
2. The assessment referred to in Article 5(2) should be based on the following:
 - (a) the identification of any potentially harmful effects, in particular those associated with:
 - (i) the recipient micro-organism;
 - (ii) the inserted (donated) genetic material;
 - (iii) the vector;
 - (iv) the donor micro-organism (as long as the donor micro-organism is used during the operation);
 - (v) the resulting GMM;
 - (b) the characteristics of the activity;
 - (c) the severity of the potentially harmful effects;
 - (d) the likelihood of the potentially harmful effects being realised.

B. PROCEDURE

3. The first stage in the assessment process should be to identify the harmful properties of the recipient and, where appropriate, the donor micro-organism, any harmful properties associated with the vector or inserted material, including any alteration in the recipient's existing properties.
4. In general, only GMMs which show the following characteristics would be considered appropriate for inclusion in class 1 as defined in Article 5:
 - (i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants ⁽¹⁾;

(*) 18 months after the entry into force of the Directive.

(¹) This would only apply to animals and plants in the environment likely to be exposed.

- (ii) the nature of the vector and the insert is such that they do not endow the GMM with a phenotype likely to cause disease to humans, animals or plants ⁽¹⁾, or likely to cause adverse effects in the environment;
 - (iii) the GMM is unlikely to cause disease to humans, animals or plants ⁽¹⁾ and is unlikely to have adverse effects on the environment.
5. In order to be informed on this process the user may firstly take into account relevant Community legislation (for example Council Directive 90/679/EEC ⁽²⁾) 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.
6. The hazard identification process carried out in accordance with paragraphs 3 to 5, should lead to the identification of the level of risk associated with the GMM.
7. Selection of the containment and other protective measures should then be made on the basis of the level or risk associated with the GMMs together with consideration of:
- (i) the characteristics of the environment likely to be exposed (e.g. whether in the environment likely to be exposed to the GMMs there are known biota which can be adversely affected by the micro-organisms used in the contained use activity);
 - (ii) the characteristics of the activity (e.g. its scale; nature);
 - (iii) any non-standard operations (e.g. the inoculation of animals with GMMs; equipment likely to generate aerosols).
- Consideration of items (i) to (iii) for the particular activity may increase, reduce or leave unaltered the level of risk associated with the GMM as identified under paragraph 6.
8. The analysis carried out as described above will finally lead to the assignment of the activity to one of the classes described in Article 5(3).
9. The final classification of the contained use should be confirmed by reviewing the completed assessment referred to in Article 5(2).

⁽¹⁾ This would only apply to animals and plants in the environment likely to be exposed.

⁽²⁾ OJ L 374, 31.12.1990, p. 1. Directive as last amended by Commission Directive 97/59/EC (OJ L 282, 15.10.1997, p. 33).

ANNEX IV

CONTAINMENT AND OTHER PROTECTIVE MEASURES

General principles

1. These tables present the normal minimum requirements and measures necessary for each level of containment.

Containment is also achieved through the use of good work practices, training, containment equipment and special installation design. For all activities involving GMMs the principles of good microbiological practice and the following principles of good occupational safety and hygiene, shall apply:

- (i) to keep workplace and environmental exposure to any GMM to the lowest practicable level;
- (ii) to exercise engineering control measures at source and to supplement these with appropriate personal protective clothing and equipment when necessary;
- (iii) to test adequately and maintain control measures and equipment;
- (iv) to test, when necessary, for the presence of viable process organisms outside the primary physical containment;
- (v) to provide appropriate training of personnel;
- (vi) to establish biological safety committees or subcommittees, if required;
- (vii) to formulate and implement local codes of practice for the safety of personnel, as required;
- (viii) where appropriate to display biohazard signs;
- (ix) to provide washing and decontamination facilities for personnel;
- (x) to keep adequate records;
- (xi) to prohibit eating, drinking, smoking, applying cosmetics or the storing of food for human consumption in the work area;
- (xii) to prohibit mouth pipetting;
- (xiii) to provide written standard operating procedures where appropriate to ensure safety;
- (xiv) to have effective disinfectants and specified disinfection procedures available in case of spillage of GMMs;
- (xv) to provide safe storage for contaminated laboratory equipment and materials, when appropriate.

2. The titles of the tables are indicative:

Table I A presents minimum requirements for laboratory activities.

Table I B presents additions to and modifications of Table I A for glasshouse/growth-room activities involving GMMs.

Table I C presents additions to and modifications of Table I A for activities with animals involving GMMs.

Table II presents minimum requirements for activities other than laboratory activities.

In some particular cases, it might be necessary to apply a combination of measures, from Table I A and Table II, of the same level.

In some cases users may, with the agreement of the competent authority, not apply a specification under a particular containment level or combine specifications from two different levels.

In these tables "optional" means that the user may apply these measures on a case-by-case basis, subject to the assessment referred to in Article 5(2).

Table I A

Containment and other protective measures for laboratory activities

	Specifications	Containment levels			
		1	2	3	4
1	Laboratory suite: isolation ⁽¹⁾	Not required	Not required	Required	Required
2	Laboratory: sealable for fumigation	Not required	Not required	Required	Required

Equipment

3	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required (bench)	Required (bench)	Required (bench, floor)	Required (bench, floor, ceiling, walls)
4	Entry to lab via airlock ⁽²⁾	Not required	Not required	Optional	Required
5	Negative pressure relative to the pressure of the immediate surroundings	Not required	Not required	Required except for ⁽³⁾	Required
6	Extract and input air from the laboratory should be HEPA-filtered	Not required	Not required	Required (HEPA) ⁽⁴⁾ — extract air except for ⁽³⁾	Required (HEPA) ⁽⁵⁾ — input and extract air
7	Microbiological safety cabinet/enclosure	Not required	Optional	Required	Required
8	Autoclave	On site	In the building	En suite ⁽⁶⁾	In lab = double-ended

System of work

9	Restricted access	Not required	Required	Required	Required
11	Specific measures to control aerosol dissemination	Not required	Required minimise	Required prevent	Required prevent
13	Shower	Not required	Not required	Optional	Required
14	Protective clothing	Suitable protective clothing	Suitable protective clothing	Suitable protective clothing	Complete change of clothing and footwear before entry and exit
15	Gloves	Not required	Optional	Required	Required
18	Efficient vector control (e.g. for rodents and insects)	Optional	Required	Required	Required

Specifications	Containment levels			
	1	2	3	4

Waste

19	Inactivation of GMMs in effluent from hand-washing sinks or drains and showers and similar effluents	Not required	Not required	Optional	Required
20	Inactivation of GMMs in contaminated material and waste	Optional	Required	Required	Required

Other measures

21	Laboratory to contain its own equipment	Not required	Not required	Optional	Required
23	An observation window or alternative is to be present so that occupants can be seen	Optional	Optional	Optional	Required

(1) Isolation = the laboratory is separated from other areas in the same building or is in a separated building.

(2) Airlock = entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

(3) Activities where transmission does not occur via airborne route.

(4) HEPA = High efficiency particulate air.

(5) Where viruses which are not retained by HEPA filters are used, extra requirements will be necessary for extract air.

(6) With validated procedures, allowing the safe transfer of material into an autoclave outside the lab, and providing an equivalent level of protection.

Table I B

Containment and other protective measures for glasshouses and growth-rooms

The terms "glasshouse" and "growth-room" refer to a structure with walls, a roof and a floor designed and used principally for growing plants in a controlled and protected environment.

All provisions of Table I A shall apply with the following additions/modifications:

Specifications	Containment levels			
	1	2	3	4

Building

1	Greenhouse: permanent structure ⁽¹⁾	Not required	Required	Required	Required
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Equipment

3	Entry via a separated room with two interlocking doors	Not required	Optional	Optional	Required
4	Control of contaminated run-off water	Optional	Minimise ⁽²⁾ run-off	Prevent run-off	Prevent run-off

System of work

6	Measures to control undesired species such as insects, rodents, arthropods	Required	Required	Required	Required
7	Procedures for transfer of living material between the glasshouse/growth-room, protective structure and laboratory will control dissemination of genetically modified micro-organisms	Minimise dissemination	Minimise dissemination	Prevent dissemination	Prevent dissemination

⁽¹⁾ The glasshouse shall consist of a permanent structure with a continuous waterproofed covering, located on a site graded to prevent entry of surface run-off having self-closing lockable doors.

⁽²⁾ Where transmission can occur through the ground.

Table I C

Containment and other protective measures for activities in animal units

All provisions of Table I A shall apply with the following additions/modifications:

Specifications	Containment levels			
	1	2	3	4

Facilities

1	Isolation of animal unit ⁽¹⁾	Optional	Required	Required	Required
2	Animal facilities ⁽²⁾ separated by lockable doors	Optional	Required	Required	Required
3	Animal facilities designed to facilitate decontamination (waterproof and easily washable material (cages, etc.))	Optional	Optional	Required	Required
4	Floor and/or walls easily washable	Optional	Required (floor)	Required (floor and walls)	Required (floor and walls)
6	Filters on isolators or isolated room ⁽³⁾	Not required	Optional	Required	Required

⁽¹⁾ Animal unit: a building, or separate area within a building containing facilities and other areas such as changing rooms, showers, autoclaves, food storage areas, etc.

⁽²⁾ 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.

⁽³⁾ Isolators: transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

Table II

Containment and other protective measures for other activities

Specification	Containment levels				
	1	2	3	4	
General					
1	Viable micro-organisms should be contained in a system which separates the process from the environment (closed system)	Optional	Required	Required	Required
2	Control of exhaust gases from the closed system	Not required	Required, minimise release	Required, prevent release	Required, prevent release
3	Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	Optional	Required, minimise release	Required, prevent release	Required, prevent release
4	Inactivation of bulk culture fluids before removal from the closed system	Optional	Required, by validated means	Required, by validated means	Required, by validated means
5	Seals should be designed so as to minimise or prevent release	No sepecific requirement	Minimise release	Prevent release	Prevent release
6	The controlled area should be designed to contain spillage of the entire contents of the closed system	Optional	Optional	Required	Required
7	The controlled area should be sealable to permit fumigation	Not required	Optional	Optional	Required
Equipment					
8	Entry via airlock	Not required	Not required	Optional	Required
9	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required (bench if any)	Required (bench if any)	Required (bench if any, floor)	Required (bench floor, ceiling, walls)
10	Specific measures to adequately ventilate the controlled area in order to minimise air contamination	Optional	Optional	Optional	Required
11	The controlled area should be maintained at an air pressure negative to the immediate surroundings	Not required	Not required	Optional	Required
12	Extract and input air from the controlled area should be HEPA filtered	Not required	Not required	Required (extract air, optional for input air)	Required (input and extract air)

Specification	Containment levels			
	1	2	3	4

System of work

13	Closed systems should be located within a controlled area	Not required	Optional	Required	Required
14	Access should be restricted to nominated personnel only	Not required	Required	Required	Required
17	Personnel should shower before leaving the controlled area	Not required	Not required	Optional	Required
18	Personnel should wear protective clothing	Required (work clothing)	Required (work clothing)	Required	Complete change before exit and entry

Waste

22	Inactivation of GMMs in effluent from handwashing-sinks and showers or similar effluents	Not required	Not required	Optional	Required
23	Inactivation of GMMs in contaminated material and waste including those in process effluent before final discharge	Optional	Required, by validated means	Required, by validated means	Required, by validated means

ANNEX V

PART A

Information required for the notification referred to in Article 7:

- name of user(s) including those responsible for supervision and safety,
- information on the training and qualifications of the persons responsible for supervision and safety,
- details of any biological committees or subcommittees,
- address and general description of the premises,
- a description of the nature of the work which will be undertaken,
- the class of the contained uses,
- only for class 1 contained uses, a summary of the assessment referred to in Article 5(2) and information on waste management.

PART B

Information required for the notification referred to in Article 9:

- the date of submission of the notification referred to in Article 7,
- the name of the persons responsible for supervision and safety and information on the training and qualification,
- the recipient, donor and/or parental micro-organism(s) used and, where applicable, the host-vector system(s) used,
- the source(s) and the intended function(s) of the genetic material(s) involved in the modification(s),
- identity and characteristics of the GMM,
- the purpose of the contained use including the expected results,
- approximate culture volumes to be used,
- description of the containment and other protective measures to be applied, including information about waste management including the wastes to be generated, their treatment, ultimate form and destination,
- a summary of the assessment referred to in Article 5(2),
- the information necessary for the competent authority to evaluate any emergency response plans if required under Article 14.

PART C

Information required for the notification referred to in Article 10:

- (a) — the date of submission of the notification referred to in Article 7,
 - the name of the persons responsible for supervision and safety and information on the training and qualification;
- (b) — the recipient or parental micro-organism(s) to be used,
 - the host-vector system(s) to be used (where applicable),
 - the source(s) and intended functions(s) of the genetic material(s) involved in the modification(s),
 - identity and characteristics of the GMM,
 - the culture volumes to be used;

- (c) — description of the containment and other protective measures to be applied, including information about waste management including the type and form of wastes to be generated, their treatment, ultimate form and destination,
 - the purpose of the contained use including the expected results,
 - description of the sections of the installation;
 - (d) information about accident prevention and emergency response plans, if any:
 - any specific hazards arising from the location of the installation,
 - the preventive measures applied such as safety equipment, alarm systems and containment methods,
 - procedures and plans for verifying the continuing effectiveness of the containment measures,
 - a description of information provided to workers,
 - the information necessary for the competent authority to evaluate any emergency response plans if required under Article 14;
 - (e) a copy of the assessment referred to in Article 5(2).'
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STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. On 28 March 1996 the Commission submitted to the Council a proposal for a Directive based on Article 130s(1) of the EC Treaty, amending Directive 90/219/EEC.
2. The European Parliament delivered its opinion at first reading on 12 March 1997 while the Economic and Social Committee delivered its opinion on 10 July 1996.
3. Following the opinion of the European Parliament, the Commission submitted an amended proposal to the Council on 13 June 1997.
4. On 16 December 1997 the Council adopted its common position in accordance with Article 189c of the Treaty.

II. AIM

The aim of this Directive is to revise Directive 90/219/EEC to take account of developments in scientific knowledge and experience acquired since the introduction of Directive 90/219/EEC and to simplify the administrative procedures linked to the contained use of genetically modified micro-organisms (hereinafter referred to as 'GMMs') while maintaining a level of protection of the environment and of human health at least equal to that of the Directive in force.

To reach this goal the proposal provides for administrative procedures, rules of notification, and containment and protection measures according to the risk posed by the contained uses of GMMs.

III. ANALYSIS OF THE COMMON POSITION

Supporting the aim stated in section II, the Council's common position includes 28 of the 35 amendments adopted by the European Parliament and incorporated by the Commission in its amended proposal, either verbatim or in substance.

A. Amendments not adopted by the Council

1. *Amendment 68*

The Council preferred to keep the wording ('... to limit their contact ...') contained in Article 2(c) of the original Commission proposal. It furthermore considered that the reference to the various types of barrier was pointless since the various containment measures were set out in detail in Annex IV.

2. *Amendment 15*

This amendment was deemed superfluous inasmuch as 'good microbiological practice' was included in the 'containment and other protective measures', and had to be reviewed periodically within the meaning of Article 6(2), and the relevant Community legislation already provided for staff consultation (see reminder in recital 9 of the common position).

3. *Amendment 17*

This amendment appeared to run counter to the aim of administrative simplification and did not contribute towards enhancing the safety of contained uses.

4. *Amendment 27*

As the safety measures referred to here formed part of the emergency plans, the wording of the amendment could lead to confusion by presenting them as a separate element.

5. *Amendment 38*

While agreeing with the approach of the European Parliament and the Commission as regards the need for a specific provision to define the criteria applicable to the inclusion of types of GMM in Annex II, Part C, and the time limit for carrying this out, the Council considered that in order to take account of the rate at which biotechnology was progressing, the nature of the criteria to be laid down and the limited scope of this list of GMMs, the Council should define and revise these criteria.

6. *Amendment 39*

The Council considered that the type III (b) Committee set up pursuant to Directive 90/219/EEC currently in force and which the Commission had itself adopted in its original proposal, represented the right balance between control over the Annexes subject to this procedure and their rapid adaptation to technical progress.

7. *Amendment 43*

In general, the Council considered that the section on the Annex III procedure needed to be substantially reorganised if there were to be an effective assessment of risks to the environment and to human health and not simply a superposing of risk assessment for human health and risk assessment for the environment. It was therefore necessary to distinguish between the risk identification procedure as such (Annex III, section B, paragraphs 3 to 6, and section A as regards the elements to be taken into account during the assessment) and the classification of the operation in one of the classes described in Article 5 (Annex III, section B, paragraphs 7 to 9).

Moreover, given the quantitative significance of class 1 uses, which in principle involved less costly obligations, the Council deemed it necessary to specify the characteristics of the GMMs which could be put into that class.

B. Amendments made by the Council to the amended proposal

Apart from the changes resulting from the non-incorporation of certain amendments, the Council made some changes to the amended proposal for the sake of clarity and in order to avoid having provisions without any practical effect, or to enhance the level of protection resulting from the Directive. This applies to:

1. *Article 2(g)*, in that the definition of 'significant changes' proposed in it is superfluous in view of the wording of Article 6(2) of the common position;
2. *Article 4, first paragraph*, in which the list of provisions that do not apply to the transport of GMMs has been adjusted to include the provisions relating to the classification of contained uses (Article 5(3) and Article 6);

3. the wording of *Article 5(2) and (3)*, which has been amended to reflect the procedure described in Annex III;
 4. *Article 6(1)*, which by referring to Annex IV, paragraph 2, reflects the possibility of applying to a containment class measures other than those laid down for that class in Annex IV;
 5. *Article 10*, in which the wording of the common position clarifies that prior written consent by the competent authority is necessary for class 3 or class 4 uses also in the case of premises which have already been the subject of notification;
 6. *Article 14(a)*, in which the common position specifies that an emergency plan must be drawn up irrespective of the class and not only for classes 3 and 4;
 7. *Article 19*, the wording of which has been clarified and aligned with Directive 90/313/EEC;
 8. *the transposition date*, set at 18 months after the entry into force of the Directive;
 9. *Annex III*, where in section A, paragraph 1, allergenic or toxic effects have been added to what are to be considered as 'potentially harmful effects' and where more generally the Commission has been asked to develop guidance notes, to supplement the assessment procedure in particular;
 10. *Annex IV*, paragraph 1, where it appeared useful to give a reminder of about 15 safety and hygiene principles to be observed at the workplace;
 11. *Annex V*, where information is to be added on wastes for class 1 and emergency plans for class 2.
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