COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a
COUNCIL DIRECTIVE
amending Directive 90/219/EEC
on the contained use of genetically modified micro-organisms

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. Introduction and Summary

1.1 The need for a revision of Directive 90/219/EEC

Directive 90/219/EEC relating to the contained use of genetically modified micro-organisms was proposed and adopted together with Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms in a horizontal way on the principle that a precautionary approach as regards safety to human health and the environment should be followed in order to ensure that the expected benefits of this technology can develop safely.

The basis for Directive 90/219/EEC was the scientific knowledge of the early 1980s and most particularly the limited experience of that time with industrial applications.

While ensuring that the techniques of genetic modification are used in a responsible way, we must at the same time take into account the wider scientific knowledge and experience gained over the last ten years.

Since the early 1980s the techniques of genetic modification have been used extensively in many research laboratories and industrial facilities worldwide, as a result of which there is now scientific evidence pointing to the safety of many types of activities involving genetically modified micro-organisms, which can, therefore, be carried out safely in contained facilities by applying normal good laboratory practices.

The Commission has mounted an extensive and systematic review of the provisions of Directive 90/219/EEC by taking into account not only the abovementioned scientific knowledge, but also the experience gained with the implementation of this Directive. In carrying out this review the Commission was involved in extensive consultation with interested parties.

The review identified the following main weaknesses in Directive 90/219/EEC:

(i) The classification system for GMMs is not in line with international practice.

(ii) The administrative procedures and notification requirements are not linked to the real risk of activities.

(iii) The administrative procedures for certain classes of activities involving genetically modified micro-organisms are unnecessarily restrictive.

(iv) There is insufficient guidance as to the containment and control measures which should be applied in order to protect human health and the environment.

(v) The flexibility of the Directive is limited as it does not provide for easy adaptation to technical progress of one of its Technical Annexes.

The Commission considers that it is now possible to propose amendments which will address the weaknesses of the Directive, while at the same time continuing to provide the same level of protection for human health and the environment.

Before making this proposal the Commission has taken into consideration corresponding regulations in other parts of the world (e.g. USA, Canada) and international guidelines (NIH, OECD, WHO).

1.2 Main elements of the proposal

In essence the Commission is proposing the following:

(i) The administrative procedures and notification requirements will be linked to the risk of the activities involving GMMs. Four classes of risk will be foreseen as judged in the light of scientific knowledge and international experience.

As a consequence, the current non-risk based differential treatment of operations for administrative purposes will be abolished.

(ii) The administrative procedures will be streamlined where this does not compromise safety.

(iii) The minimum containment and control measures to be applied for each risk class will be further specified, thus ensuring harmonization and adequate environmental protection.

(iv) The possibility for further exemptions of safe genetically modified micro-organisms will be introduced, thus ensuring rapid adaptation to technical progress and avoidance of unjustified administrative burdens on users.

(v) All Annexes will become amendable through a Regulatory Committee procedure, thus enhancing flexibility and permitting timely adaptation of these highly technical parts of the Directive to rapidly advancing scientific and technical progress.

In addition to the abovementioned main modifications, the proposal contains amendments which were considered necessary in order for the text to be consistent and clear. Furthermore, it was considered necessary, to up-date some technical parts of the Directive on the basis of experience and scientific progress.

2. Presentation of changes in the Articles and the Annexes

Article 2

- Paragraph (a)

It has been considered necessary to provide some further technical clarification concerning the definition of "micro-organism".

- Paragraphs (d) and (e) of Directive 90/219/EEC have been deleted, since the distinction between Type A and Type B operations was not based on any identified risk.

- Paragraph (c)

The definition of "contained use" has been modified as regards disposal, so that the disposal of genetically modified micro-organisms originating from contained-use activities can be covered and evaluated under the same Directive that covers the contained use of such GMMS.

Article 3

Given the pace at which the field is advancing, it has been considered appropriate to introduce the possibility for future exemption of types of GMMs other than those specified already in Annex II A once evidence of their safety for human health and the environment becomes available.

Article 4

- Paragraph b

  The use of genetically modified micro-organisms which have been placed on the market following the procedures of Directive 90/220/EEC or of other Community legislation which provides for a specific environmental risk-assessment similar to that laid down in that Directive, will be exempted from Directive 90/219/EEC provided that the contained use of such GMMs is in accordance with the conditions, if any, of the marketing consent or approval given under the abovementioned Community legislation.

  This has been considered necessary in order to avoid a situation where notification would have to be submitted and a risk assessment would have to be carried out in order to proceed in particular premises with uses of GMMs which have already been given consent/approval under Community legislation providing for a specific environmental risk assessment. Such a situation would be unjustified since a full assessment of the approved use(s) of such GMMs would have already been carried out under the abovementioned Community legislation.

Article 5

- Paragraph 3

  Activities involving genetically modified micro-organisms will be subject to a risk assessment which should result in the categorization of activities in four classes of risk. The principles on which the risk assessment should be carried out are outlined in Annex III.

  This has been considered necessary since all internationally accepted guidelines and other Community legislation (Directive 90/679/EEC) foresee classification in four classes of risk. In this way low and high risk genetically modified micro-organisms will no longer be classified in the same group and be subject to the same administrative procedures as is currently the case.

  Given the emphasis of Directive 90/219/EEC on the protection of human health and the environment, which presupposes the application of containment measures commensurate to risk, each risk class will correspond to a particular level of containment. In this way there will be clear provisions as to the minimum containment measures which are appropriate for each risk class, which is not currently the case for low to high risk GMMs.

Article 6

- Paragraph 1

  The user shall apply the containment and control measures which correspond to the risk class of the activity, so that a high level of safety is ensured and exposure to any genetically modified micro-organisms is kept to the lowest practicable level.

Annex IV presents four Tables outlining the normal minimum requirements and measures for each level of containment and for different types of activities. According to international practice these measures correspond to a high level of safety.

Paragraph 2

It has been specified that not only the containment and control measures, but also the risk assessment should be periodically reviewed in the light of new scientific or technical knowledge and in the case of significant changes in the activities.

Articles 8, 9 and 10

These Articles specify the administrative procedures and notification requirements which are considered appropriate for each risk class. More specifically:

Article 8

Class 1 activities will be able to commence immediately following the notification referred to in Article 7, which should include at least the information outlined in Annex VA.

This has been considered appropriate since Class 1 activities are activities of no or negligible risk and there is no justification for a waiting period before commencement of such activities.

The Commission believes that for Class 1 activities safety for human health and the environment is adequately ensured through the corresponding containment and control measures outlined in Annex IV. Furthermore, competent authorities have the right to control at any time the correctness of the risk assessment and the adequacy of safety and emergency response measures as well as the adequacy of waste management according to the provisions of Article 11. For Class 1 activities, control by the competent authorities will be facilitated by the obligation imposed on users to keep records of each assessment.

Article 9

Class 2 activities will be able to commence following submission of the information outlined in Annex VB.

If no previous notification has been submitted for Class 2 or higher class activities, work can only commence 45 days after submission of the notification, or earlier with the agreement of the competent authority. Such a waiting period has been considered necessary, in order for the competent authority to be able to verify if the users are able to carry out the risk assessment and to apply the appropriate containment and control measures.

If, however, a previous notification has been submitted for Class 2 or higher class activities and the associated consent requirements have been satisfied, the new Class 2 activity can commence immediately following a new notification containing the information outlined in Annex VB. This has been considered appropriate since users will have been able to demonstrate earlier their ability to carry out risk assessment and apply the appropriate control and containment measures.

Article 10

Class 3 and Class 4 activities will be able to commence following submission of the information outlined in Annex VC.

If no previous notification has been submitted for the same or higher class activities, the contained use may not proceed without a written consent of the competent authority which should be given within 90 days after submission of the notification. If, however, a previous notification has been submitted for the same or higher class of activities and the associated consent requirements have been satisfied, then the new activity can in the absence of any indication to the contrary, commence 45 days after submission of a new notification containing the information outlined in Annex VC. This has been considered appropriate since users will have been able to demonstrate earlier their ability to carry out risk assessment and apply the appropriate control and containment measures.

Article 11

Competent Authorities appointed by Member States will have the responsibility not only of receiving and acknowledging notifications, but also of examining the correctness of the risk assessment and the assignment of class of the risk. The competent authority may, among others, ask the user to amend the class of risk assigned to the activity(ies) and may require that the contained use, if proposed does not begin or if in progress is halted.

Article 14

Paragraph a

Given the risk-based approach of this proposal, it has been considered necessary to define on the basis of the class of risk the activities for which the drawing up of emergency response plans will be necessary. It has also been considered necessary to further clarify the circumstances under which the drawing-up of emergency response plans will be necessary. It has, therefore, been specified that emergency plans should be drawn up for Class 3 and Class 4 activities where failure of the containment measures could lead to serious danger, immediate or delayed to humans outside the premises and/or to the environment.

Paragraph b

It has been considered necessary to clarify that information on emergency plans should be supplied to bodies and authorities likely to be affected by an accident.

Article 15

Paragraph 1

Given the fact that it might not always be possible to have exact information on the identity and the quantities of GMMs released in the event of an accident, it has been considered necessary to specify that in the event of an accident information should be given on the identity and quantities of the GMMs concerned (i.e. involved in the contained use affected by the accident).

Article 16

Paragraph b

Given the fact that it might not be always possible to have exact information on the identity and the quantities of GMMs released in the event of an accident, it has been considered appropriate to specify that the Commission should be informed of the identity and the quantities of the GMMs concerned (i.e. involved in the contained use affected by the accident).

Article 18

Paragraph 1

Given the new risk-based classification system outlined in Article 5, it is proposed that the summary reports to be submitted to the Commission by Member States should cover Class 3 and Class 4 activities.

Article 19

It has been considered necessary to bring this paragraph in line with the modifications introduced in the body of the Directive and the Annexes, while ensuring that the public has access to information related to safety.

It is, therefore, proposed that in no case may the following information be kept confidential:

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

Article 20

Given the pace at which this field is advancing it is necessary that the technical elements of the Directive (i.e. the Annexes) are easily adaptable to technical progress.

The Commission considers that the possibility for easy adaptation to technical progress should also be introduced for Annex I, since this Annex presents the technical interpretation of the notion described in Article 2(b) and as such it should reflect the state of the art.

It is, therefore, the Commission's proposal that all Annexes be amendable through a Committee procedure.

Annex I

This Annex presents a technical interpretation of the term "genetically modified micro-organism" as defined in Article 2(b).

Part 1 outlines the techniques which according to recent scientific knowledge fall within the notion defined in Article 2(b), while

Part 2 outlines the techniques which according to recent scientific knowledge do not fall within the abovementioned notion.

Annex II

Part A: This part of the Annex has been adapted to technical progress and outlines techniques of genetic modification which should be excluded from the scope of the Directive in accordance with Article 3.

Part B: This part includes types of GMMs which are known to be safe for human health and the environment, and which are excluded from the Directive in accordance with Article 3.

The Commission has at present been able to identify GMMs known to be safe, which are listed in Part A. Given the pace at which this field is advancing it is to be expected that types of GMMs known to be safe will be identified in the future, and will be included in Part B.

Annex III

This Annex outlines the principles according to which the assessment referred to in Article 5 should be carried out.

Paragraph 1 outlines the basic elements of the risk assessment, which are: the identification of potentially harmful effects, their severity and the likelihood of them being realized, while paragraph 2 outlines the effects that can be considered as potentially harmful.

Paragraphs 3, 4 and 5 present a harmonized approach to the categorization of activities and selection of control measures based on already existing classification schemes, the new properties of the GMM, the characteristics of the operation and the characteristics of the environment likely to be exposed.

Annex IV

In order to ensure harmonization and adequate environmental protection it has been considered necessary to further specify and elaborate upon the minimum containment and control measures for each risk class and for different types of activities following a careful examination of national and international practices, as well as the work of CEN in this field.

The result of this analysis has been Annex IV, which presents four Tables outlining minimum containment and control measures for laboratory activities (Table I a, additional measures for glasshouses and growthrooms (Table I b and animal units (Table I c, as well as minimum containment and control measures for other than laboratory activities (Table II).

Annex V

This Annex outlines the information which should be submitted for:

- the first time that activities involving GMMs take place in particular premises (Part A);
- Class 2 activities in particular (Part B);
- Class 3 and Class 4 activities in particular (Part C).

3. Impact on Small and Medium Enterprises (SMEs)

The Commission estimates that the proposed amendment will have a positive impact on small and medium enterprises and their competitiveness for the following reasons:

- The elimination of regulatory redundancies i.e. administrative requirements not justified by safety, will have a positive impact on the competitiveness of SMEs.
- The administrative procedures have been linked to the actual risk of the activities following a classification system which is clear and compatible with other Community legislation (i.e. Directive 90/679/EEC) and international guidelines.
- The proposed classification in four classes of risk is expected to eliminate current unnecessary costs for the management of low risk GMMs which currently fall under Group II.

- The abolition of the non-risk based and rather confusing differential treatment of operations for administrative purposes which currently places additional unjustified burdens on large scale and industrial operations without regard to actual risk leads to the direct linking of administrative burdens to the actual risk of activities and consequently to rationalization of administrative costs.

- The administrative procedures and requirements have been lightened for the vast majority (Class 1 and Class 2) of activities in which SMEs normally engage, and have been brought closer to those currently applied by the main trading partners of the EU. This is expected to lower threshold costs for SMEs developing innovative biotechnology applications and could provide an incentive for joint-venture R&D investment and for the location of production activities in the EU.

- The provision of clear guidance as to the containment and control measures that should be applied depending on the risk of the activities and the clarification of ambiguous technical terms is expected to contribute further to the reduction of the costs of compliance.

Proposal for a

COUNCIL DIRECTIVE

amending Directive 90/219/EEC

on the contained use of genetically modified micro-organisms

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 130s thereof,

Having regard to the proposal from the Commission,

Acting in accordance with the procedure laid down in Article 189c of the Treaty, in cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas, under the Treaty, action by the Community relating to the environment should be based on the principle that preventive action is to be taken and to seek to preserve, protect and improve the environment and to protect human health;

Whereas activities involving genetically modified micro-organisms should be classified in relation to the risks they present; whereas such classification should be in line with international practice; whereas such classification should be based on an assessment of the risk;

Whereas appropriate containment and control measures should be applied to ensure a high level of safety; whereas the containment and control measures should be linked to the risk of the activities;

Whereas the following main weaknesses have been identified in Council Directive 90/219/EEC[1], as amended by Commission Directive 94/51/EC[2]: the classification system is not in line with international practice, the administrative procedures and notification requirements are not linked to the real risk of activities; the administrative procedures for certain classes of activities involving genetically modified micro-organisms are unnecessarily restrictive; there is insufficient guidance as to the containment and control measures which should be applied in order to protect human health and the environment; Directive 90/219/EEC does not permit rapid adaptation to technical progress; technical parts of the Directive need to be adapted to technical progress;

Whereas there is now considerable experience and knowledge of the risks associated with the contained use of genetically modified micro-organisms;

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:

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(1) OJ No L 117, 8.5.1990, p. 1.

(2) OJ No L 297, 18.11.1994, p. 29.

1. Article 2 is amended as follows:

(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.";

(b) In paragraph (b), the references to "Annex I A" in subparagraphs (i) and (ii) are replaced by "Annex I";

(c) Paragraph (c) is replaced by the following:

"(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;"

(d) Paragraphs (d) and (e) are deleted;

(e) The following paragraph (i) is added:

"(i) "significant changes" in the context of Article 6a(2) shall mean changes which could change the result of the risk assessment."

2. Article 3 is replaced by the following:

"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";

3. Article 4 is deleted.

4. Article 5 is amended as follows:

(a) In the first sentence the words "Articles 7 to 12" are replaced by the words "Articles 6a and Articles 8 to 11";

(b) The second sentence is replaced by the following:

"This Directive shall not apply to the storage, culture, transport, destruction, disposal or use of genetically modified micro-organisms which have been placed on the market in accordance with Directive 90/220/EEC or under any other Community legislation, which provides for a specific environmental-risk assessment similar to that laid down in Directive 90/220/EEC, provided always that the contained use is in accordance with the conditions, if any, of the marketing approval or consent."

5. Article 6 is amended as follows:

(a) Paragraphs 2 and 3 are replaced by the following texts:

"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 they may incur, taking due account of the principles set out in Annex III.

3. The assessment should result in the categorization of the contained-use activities in the following four classes of risk:

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 that could be exposed to the genetically modified micro-organisms.

Class 2: Activities of low risk, that is activities for which level 2 containment is appropriate to protect human health as well as the environment that could be exposed to the genetically modified micro-organisms in the absence of containment.

Class 3: Activities of moderate risk, that is activities for which level 3 containment is appropriate to protect human health as well as the environment that could be exposed to the genetically modified micro-organisms in the absence of containment.

Class 4: Activities of high risk, that is activities for which level 4 containment is appropriate to protect human health as well as the environment that could be exposed to the genetically modified micro-organisms in the absence of containment."

(b) In paragraph 4, the words "Articles 8, 9 and 10" is replaced by the words "Articles 8 and 10".

6. The following Article 6a is inserted:

"Article 6a

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."

2. The risk assessment and the containment and control measures applied shall be periodically reviewed forthwith if:

(a) there has been a significant change in the activity(ies) to which the assessment relates; 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."

7. Article 7 is deleted.

8. Articles 8, 9 and 10 are replaced by the following:

"Article 8

When premises are to be used for the first time for activities involving the contained use of genetically modified micro-organisms, the user shall be required to submit to the competent authorities a notification containing at least the information listed in Annex V, Part A.

Article 9

For Class 1 activities to be carried out, no further notification shall be needed. Such activities shall be able to commence immediately following the notification referred to in Article 8. Users of genetically modified micro-organisms in Class 1 activities shall be required to keep the record of each assessment referred to in Article 6(4), which shall be made available to the competent authority on request.

Article 10

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.

2. If no previous notification has been submitted for Class 2 or a higher class of activities, the contained use may, in absence of any indication to the contrary from the competent authority, proceed 45 days after submission of the notification referred to above, or earlier with the agreement of the competent authority.

3. If a previous notification has been submitted for Class 2 activities or higher and the associated consent requirements have been satisfied, the contained use may proceed immediately following the new notification."

9. The following Article 10a is inserted:

"Article 10a

1. For first and subsequent Class 3 or Class 4 activities to be carried out in premises notified in accordance with Article 8, a notification containing the information listed in Annex V, Part C shall be submitted.

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.

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."

10. Article 11 is amended as follows:

(a) The words "Article 8, Article 9(2) and Article 10" in paragraph 1 are replaced by the words "Articles 8, 10 and 10a";

(b) In paragraph 2, the word "classification" is replaced by the words "risk assessment and the class of risk";

(c) In point (a) of paragraph 3, the second sentence is replaced by the following: "In this case the competent authority may require that the contained use, if proposed, does not begin or, if in progress, is halted, 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.";

(d) Paragraphs 4 and 5 are deleted;

(e) In paragraph 6, the words "paragraphs 4 and 5" are replaced by the words "Articles 10 and 10a".

11. Paragraph 1 of Article 12 is replaced by the following:

"1. 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 under Articles 8, 10 and 10a modified."

12. Article 13 is replaced by the following:

"Article 13

Where a Member State considers it appropriate, it may provide that groups or the public shall be consulted on aspects of the proposed contained use, in accordance with Article 19."

13. Article 14 is replaced by the following:

"Article 14

The competent authorities shall ensure that, where necessary, before an activity commences:

(a) An emergency plan is drawn up for Class 3 and Class 4 activities where failure of the containment measures could lead to serious danger, immediate or delayed, to humans outside the premises and/or to the environment.

(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.

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."

14. Paragraph 1 of Article 15 is amended as follows:

(a) In the second indent, the word "released" is replaced by the word "concerned";

(b) In the fourth indent, the word "emergency" is deleted.

15. In point (b) of paragraph 1 of Article 16, the phrase "the identity and quantities of the genetically modified micro-organisms released, the emergency response measures employed and their effectiveness" is replaced by "the identity and quantities of the genetically modified micro-organisms concerned, the response measures employed and their effectiveness".

16. In Article 18, paragraph 1 is replaced by the following:

"1. Member States shall send to the Commission, at the end of each year, a summary report on the Class 3 and Class 4 contained uses notified under Article 10a, including the description, purpose and risks of the activity or activities."

17. In Article 19, paragraph 4 is replaced by the following:

"4. In no case may the following information, when submitted according to Articles 8, 9 or 10, be kept confidential:

-- the characteristics of the genetically modified micro-organisms, name and address of the notifier, and location of use;

-- the level and measures of containment;

-- the evaluation of foreseeable effects, in particular any harmful effects on human health and the environment."

18. In Article 20, the words "Annexes II to V" are replaced by the words "Annexes I to V".

19. The Annexes are amended as 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 by 1 January 1999. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted 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 shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Communities.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President

ANNEX

The Annexes to Directive 90/219/EEC are amended as follows:

1. Former Annex I A becomes Annex I and is amended as follows:

   (a) In Part 1, point (i) is replaced by the following:

   "(i) 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."

   (b) Part 2 is amended as follows:

   (i) In the introductory phrase, the word "DNA" is replaced by the words "nucleic acid", and the following words are added: "made by techniques or methods other than those excluded by Annex II:"

   (ii) Point 2 is replaced by the following:

   "(2) natural processes such as: conjugation, transduction, transformation;"

2. Annex I B is deleted.

3. Annex II is replaced by the following:

"Annex II

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 genetically modified micro-organisms 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, where the resulting micro-organism is unlikely to cause disease to humans, animals or plants;

3. Cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions, where the resulting micro-organism is unlikely to cause disease to humans, animals or plants;

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 phytogenetically 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. The following are non-exhaustive examples of safe host/vector systems:

- E-coli K 12 strains/pBR 322;
- Eukaryotic cells/defective Simian virus 40 (SV 40).

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:"

.....

4. Annex III is replaced by the following:

"Annex III

PRINCIPLES TO BE FOLLOWED FOR THE ASSESSMENT REFERRED TO IN ARTICLE 6

Elements of assessment

1. The following should be considered as potentially harmful effects:
   - disease to humans, 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 transfer of genes to other organisms.

2. a. The assessment referred to in Article 6 should be based on the following:
      (i) the recipient micro-organism;
      (ii) the inserted (donated) genetic material;
      (iii) the vector;
      (iv) the donor micro-organism (if the donor micro-organism is used during the operation);
      (v) the resulting genetically modified micro-organisms.
   b. The severity of the potentially harmful effects.
   c. The likelihood of the potentially harmful effects being realized.

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.).

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

4. The final classification and selection of control measures must be made in the light of:

(i) any harmful properties (see above) which the vector or inserted material might confer on the recipient, or any alteration of the recipient's existing properties;

(ii) the characteristics of the operation (e.g. its nature, scale);

(iii) the characteristics of the environment likely to be exposed to the genetically modified micro-organisms (e.g. whether in the environment likely to be exposed to the genetically modified micro-organisms there are known biota which can be adversely affected by the micro-organisms used in the contained-use activity).

5. The analysis carried out as described under paragraph 4 above may lead to a categorization of the risk of the activity higher or lower than the provisional one. The check foreseen in paragraph 4 should be repeated, until the final classification is stable."

5. Annex IV is replaced by the following:

"Annex IV

Containment and Control Measures

Preface

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

Containment is achieved through the use of good workpractices, containment equipment and special installation design.

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/growthroom activities involving genetically modified micro-organisms (GMMs).

Table I c presents additions to and modifications of Table I a for activities with animals involving genetically modified micro-organisms (GMMs).

Table II presents minimum requirements for other activities than laboratories 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 exceptional cases (e.g. for plant pathogens), it also might be appropriate, following consultation with the Competent Authority not to apply a specification under a particular containment level or to combine specifications from two different levels.

In these Tables:

* no: means not required.
* optional: means that the user should decide on a case-by-case basis, subject to the risk assessment, to what extent these measures are to be applied.
* yes: means required.

Annex IV

Table I a

Containment and Control Measures for Laboratory Activities

Specifications		Containment levels			
		1	2	3	4
	BUILDING				
1	Laboratory suite: isolation[1]	no	no	yes	yes
2	Laboratory: sealable for fumigation	no	no	yes	yes
	EQUIPMENT				
3	Surfaces resistant to acids, alkalis, solvents, disinfectants	yes (bench)	yes (bench)	yes (bench, floor)	yes (bench, floor, ceiling, walls)
4	Entry to lab via airlock[2]	no	no	optional	yes
5	Negative pressure relative to the pressure of the immediate surroundings	no	no	yes except for[4]	yes
6	Extract and input air from the laboratory should be HEPA-filtered	no	no	yes (HEPA)[3] - Extract air except for[4]	yes (HEPA) - Input and extract air
7	Microbiological safety cabinet/enclosure	no	optional	yes	yes
8	Autoclave	on site	in the building	in suite	in lab = double ended
	SYSTEM OF WORK				
9	Restricted access	no	yes	yes	yes
10	Biohazard signs on the door	no	yes	yes	yes
11	Control of aerosol formation	no	yes minimize	yes prevent	yes prevent
12	Washing and decontamination provisions for personnel	yes	yes	yes	yes

(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) HEPA = High Efficiency Particulate Air.

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

Containment and Control Measures for Laboratory Activities

	Specifications	Containment levels			
		1	2	3	4
	SYSTEM OF WORK				
13	Shower	no	no	optional	yes
14	Protective clothing	labcoat	labcoat	suitable protective clothing + foot wear	complete change of clothing + foot wear before entry and exit
15	Gloves	no	optional	yes	yes
16	Test adequately and maintain control measures and equipment	yes	yes	yes	yes
17	Record keeping	yes	yes	yes	yes
18	Efficient vector control (e.g. for rodents and insects)	optional	yes	yes	yes
	WASTE				
19	Inactivation of GMMs in effluent from handwashing sinks or drains and showers if any	no	no	optional	yes
20	Inactivation of GMMs in contaminated material and waste	optional	yes	yes	yes

Annex IV

Table I b

Containment and Control Measures for Glasshouses and Growthrooms

The terms glasshouse and growthroom 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[5]	no	yes	yes	yes
	EQUIPMENT				
2	Surroundings without susceptible plant species	no	optional	yes	yes
3	Entry via a separated room with two interlocking doors	optional	optional	yes	yes
4	Control of contaminated run-off water	optional	minimize[6] run-off	prevent run- off	prevent run-off
	SYSTEM OF WORK				
5	Restricted access	yes (visitors accepted)	yes	yes	yes
6	Measures to control undesired species as insects, rodents, arthropods	yes	yes	yes	yes
7	Procedures for transfer of living material between the glasshouse/growth room, protective structure and laboratory shall prevent dissemination of genetically modified microorganisms	minimize dissemination	minimize dissemination	prevent dissemination	prevent dissemination

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

(6) Where transmission can occur through the ground.

Annex IV

Table I c

Containment and Control 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[7]	optional	yes	yes	yes
2	Animal facilities[8] separated by lockable doors	yes	yes	yes	yes
3	Animal facilities design for decontamination (waterproof and easily washable material (cages, etc.))	optional	optional	yes	yes
4	Floor and/or walls easily washable	yes (floor)	yes (floor)	yes (floor and walls)	yes (floor and walls)
5	Animal containment in appropriate cages, pens or tanks	yes	yes	yes	yes
6	Filters on isolators[9]	no	no	optional	yes

(7) 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.

(8) 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.

(9) isolators: transparent boxes where the animal is contained within or outside a cage.

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Table II

Containment and Control Measures for other Activities

	Specifications	Containment levels			
		1	2	3	4
	GENERAL				
1	Viable micro-organisms should be contained in a system which physically separates the process from the environment (closed system)	no	yes	yes	yes
2	Control of exhaust gases from the closed system	no	yes, minimize release	yes, prevent release	yes, prevent release
3	Control of aerosols during sampling collection, addition of material to a closed system or transfer of material to another closed system	no	yes, minimize release	yes, prevent release	yes, prevent release
4	Inactivation of bulk culture fluids before removal from the closed system	no	yes, by validated means	yes, by validated means	yes, by validated means
5	Seals should be designed so as to minimize or prevent release	no specific requirement	minimize 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	yes	yes
7	The controlled area should be sealable to permit fumigation	no	no	optional	yes
	EQUIPMENT				
8	Entry via airlock	no	no	optional	yes
9	Surfaces resistant to acids, alkalis, solvents, disinfectants	optional	optional	yes (bench if any, floor)	yes (bench, floor, ceiling, walls)
10	The controlled area should be adequately ventilated to minimize air contamination	optional	optional	optional	yes
11	The controlled area should be maintained at an air pressure negative to the immediate surroundings	no	no	optional	yes
12	Extract and input air from the controlled area should be HEPA filtered	no	no	yes (extract air, optional for input air)	yes (input and extract air)

Containment and Control Measures for other Activities

	Specifications	Containment levels			
		1	2	3	4
	SYSTEM OF WORK				
13	Closed systems should be located within a controlled area	no	optional	yes	yes
14	Access should be restricted to nominated personnel only	no	yes	yes	yes
15	Biohazard signs should be posted	no	yes	yes	yes
16	Washing and decontamination provisions for personnel	yes	yes	yes	yes
17	Personnel should shower before leaving the controlled area	no	no	optional	yes
18	Personnel should wear protective clothing	yes (work clothing)	yes (work clothing)	yes	complete change before exit and entry
19	Test adequately and maintain control measures and equipment	yes	yes	yes	yes
20	Record keeping	yes	yes	yes	yes
21	Appropriate training and supervision for personnel	yes	yes	yes	yes
	WASTE				
22	Inactivation of GMMs in effluent from handwashing sinks and showers if any	no	no	optional	yes
23	Inactivation of GMMs in contaminated material and waste	optional	yes	yes	yes
24	Inactivation of GMMs in process effluent before final discharge	optional	yes, by validated means	yes, by validated means	yes, by validated means

6. Annex V is replaced by the following:

"Annex V

PART A

Information required for the notification referred to in Article 8:

- name of user(s) including those responsible for supervision and safety information on their training and qualifications;
- details of any biological committees or subcommittees;
- address of installation;
- general description of the premises;
- a description of the nature of the work which will be undertaken;
- the class of risk of the activities;
- a summary of the risk assessment referred to in Article 6(2) and (3) (only for Class 1 activities).

PART B

Information required for the notification referred to in Article 10:

- the date of submission of the notification referred to in Article 8;
- 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 manipulation(s);
- identity and characteristics of the genetically modified micro-organism(s);
- the purpose of the contained use including the expected results;
- approximate culture volumes to be used;
- description of the containment and control measures to be applied, including information about the wastes to be generated, their treatment, ultimate form and destination;
- a summary of the risk assessment referred to in Article 6(2) and (3).

PART C

Information required for the notification referred to in Article 10a:

(a)
- the date of submission of the notification referred to in Article 8;
- name of the responsible person;

(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 function(s) of the genetic material(s) involved in the manipulation(s);
- identity and characteristics of the genetically modified micro-organism;
- the culture volumes to be used;

(c)
- description of the containment and control measures to be applied, including information about 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:

- the sources of hazards and conditions under which accidents might occur;
- 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 prepared in accordance with Article 14;

(e) a copy of the risk assessment referred to in Article 6(2) and (3).

ANNEX

CONSOLIDATED TEXT WITH AMENDMENTS UNDERLINED

ARTICLE 1

This Directive lays down common measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment.

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, but excluding naked nucleic acid molecules.

(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 1;

(ii) the techniques listed in Annex I, Part 2, 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 genetically modified micro-organisms are cultured, stored, used, transported, destroyed 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 GMMs are disposed of and 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.

(d) 'accident' shall mean any incident involving a significant and unintended release of genetically modified micro-organisms in the course of their contained use which could present an immediate or delayed hazard to human health or the environment;

(e) 'user' shall mean any natural or legal person responsible for the contained use of genetically modified micro-organisms;

(f) 'notification' shall mean the presentation of the requisite information to the competent authorities of a Member State.

(g) 'significant changes' in the context of Article 6 (2) shall mean changes which could change the result of the risk assessment;

ARTICLE 3

This Directive shall not apply where genetic modification is obtained through the use of the techniques/methods listed in Annex II, or for contained use activities involving other types of GMMs known to be safe for human health and the environment. Such types of GMMs and their characteristics shall be listed in Annex II, part B.

ARTICLE 4

Articles 6 to 11 shall not apply to the transport of genetically modified micro-organisms by road, rail, inland waterway, sea or air. This Directive shall not apply to the storage, culture, transport, destruction, disposal or use of genetically modified micro-organisms which have been placed on the market in accordance with Directive 90/220/EEC or under other Community legislation, which provides for a specific environmental risk assessment similar to that laid down in Directive 90/220/EEC, provided that the contained use is in accordance with the conditions, if any, of the marketing approval/consent.

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 genetically modified micro-organisms.

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 they may incur, taking due account of the principles set out in Annex III.

3. Such an assessment should result in the categorisation of the contained use activities in 4 classes of risk:

Class 1:	Activities of no or negligible risk, that is activities for which level 1 containment is appropriate to protect human health as well as the environment that could be exposed to the GMMs in the absence of containment.
Class 2:	Activities of low risk, that is activities for which level 2 containment is appropriate to protect human health as well as the environment that could be exposed to the GMMs in the absence of containment.
Class 3:	Activities of moderate risk, that is activities for which level 3 containment is appropriate to protect human health as well as the environment that could be exposed to the GMMs in the absence of containment.
Class 4:	Activities of high risk, that is activities for which level 4 containment is appropriate to protect human health as well as the environment that could be exposed to the GMMs in the absence of containment.

4. A record of this assessment shall be kept by the user and made available in an appropriate form to the competent authority as part of the notification under Articles 7 and 9 or upon request

ARTICLE 6

5. 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.

6. The risk assessment and the containment and control measures applied shall be periodically reviewed forthwith if:

   a. there has been a significant change in the activity(ies) to which the assessment relates 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 activities involving the contained use of genetically modified micro-organisms, the user shall be required to submit to the competent authorities a notification containing at least the information listed in Annex VA.

ARTICLE 8

For class 1 activities to be carried out no further notification shall be needed. Such activities shall be able to commence immediately following the notification referred to in Article 7. Users of genetically modified micro-organisms in class 1 activities shall be required to keep the record of each assessment referred to in Article 5 (4), which shall be made available to the competent authority on request.

ARTICLE 9

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

2. If no previous notification has been submitted for that or higher class of activities, the contained use may, in absence of any indication to the contrary from the competent authority, proceed 45 days after submission of the notification referred to above, or earlier with the agreement of the competent authority.

3. If a previous notification has been submitted for class 2 activities or higher and the associated consent requirements have been satisfied, the contained use may proceed immediately following the new notification.

ARTICLE 10

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

2. If no previous notification has been submitted for that or 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.

3. If a previous notification has been submitted for the same or 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.

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 Article 7, Article 9 and Article 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 risk assessment and the class of risk and, where appropriate, the adequacy of the waste management, safety, 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 of risk assigned to the activity(ies). In this case the competent authority may require that the contained use, if proposed does not begin, or if in progress is halted, 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 Article 9 and Article 10, any periods 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

1. 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 under Article 7, Article 9 and Article 10 modified.

2. If information becomes available subsequently to the competent authority which could have significant consequences for the risks posed by the contained use, the competent authority may require the user to modify the conditions of, 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 in accordance with Article 19.

ARTICLE 14

The competent authorities shall ensure that, where necessary, before an activity commences:

(a) An emergency plan is drawn up for class 3 and class 4 activities where failure of the containment measures could lead to serious danger, immediate or delayed, to humans outside the premises and/or to the environment.

(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.

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 immediately to inform the competent authority specified in Article 11 and provide the following information:

- the circumstances of the accident,
- the identity and quantities of the genetically modified micro-organisms 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 under paragraph 1, the Member States shall be required to:

- ensure that any medium and long-term measures necessary are taken, and immediately alert any Member State 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 in the 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 genetically modified micro-organisms concerned, the 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 under 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.

ARTICLE 17

Member States shall ensure that the competent authority organizes inspections and other control measures to ensure user compliance with this Directive.

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 under Article 10 including the description, purpose and risks of the activity(ies).

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 in.....

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.

ARTICLE 19

1. The Commission and the competent authorities shall not divulge to third parties any confidential information notified or otherwise provided under this Directive and shall protect intellectual property rights relating to the data received.

2. The notifier may indicate the information in the notifications submitted under this Directive, the disclosure of which might harm his competitive position, that should be treated as confidential. Verifiable justification must be given in such cases.

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

4. In no case may the following information, when submitted according to Articles 7, 8, or 9, be kept confidential:

   - the characteristics of the genetically modified micro-organisms, name and address of the notifier, and location of use;
   - level and measures of containment;
   - the evaluation of foreseeable effects in particular any harmful effects on human health and the environment.

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

ARTICLE 20

Amendments necessary to adapt Annexes I to V to technical progress shall be decided in accordance with the procedure defined in Article 21.

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.

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.

ARTICLE 22

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than ..... They shall forthwith inform the Commission thereof.

ARTICLE 23

This Directive is addressed to the Member States.

ANNEX I

PART 1

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

(i) 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.

(ii) 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;

(iii) cell fusion or hybridization 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 2

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 genetically modified micro-organisms made by techniques/methods other than those excluded by Annex II:

(1) in vitro fertilization;
(2) natural processes such as: conjugation, transduction, transformation;
(3) polyploidy induction.

ANNEX II

A. Techniques/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, where the resulting micro-organism is unlikely to cause disease to humans, animals or plants.

3. Cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions, where the resulting micro-organism is unlikely to cause disease to humans, animals or plants.

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 phytogenetically 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. The following are non-exhaustive examples of safe host/vector systems:

   - E-coli K 12 strains/pBR 322
   - Eukaryotic cells/defective Simian virus 40 (SV 40)

B. Types of GMMs which have been shown to be safe for human health and the environment and which are excluded from the Directive:

(Completly new text)

ANNEX III

PRINCIPLES TO BE FOLLOWED FOR THE ASSESSMENT REFERRED TO IN ARTICLE 5

Elements of assessment

1. The following should be considered as potentially harmful effects:

   - disease to humans, 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 transfer of genes to other organisms.

2. The assessment referred to in Article 5 should be based on the following:

   a) The identification of any potentially harmful effects of the operation, in particular any potentially harmful effects associated with:

      i) the recipient micro-organism
      ii) the inserted (donated) genetic material
      iii) the vector
      iv) the donor micro-organism (if the donor micro-organism is used during the operation)
      v) the resulting GMM

   b) The severity of the potentially harmful effects

   c) The likelihood of the potentially harmful effects being realised.

Procedure

3. In order to arrive at the categorisation of a particular activity, as referred to in Article 5, 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.).
   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). 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.

4. The final classification and selection of control measures must be made in the light of:

i) any harmful properties (see above) which the vector or inserted material might confer on the recipient, or any alteration of the recipient's existing properties;

ii) the characteristics of the operation (e. g. its nature, scale);

iii) the characteristics of the environment likely to be exposed to the GMMs (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).

5. The analysis carried out as described under para. 4 above may lead to a categorisation of the risk of the activity higher or lower than the provisional one. The check foreseen in para. 4 should be repeated, until the final classification is stable.

(New text and Tables)

ANNEX IV

Containment and Control Measures

Preface

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

Containment is achieved through the use of good workpractices, containment equipment and special installation design.

The titles of the Tables are indicative.
Table Ia presents minimum requirements for laboratory activities.
Table Ib presents additions to and modifications of Table Ia for glasshouse/growthroom activities involving genetically modified micro-organisms (GMMs).
Table Ic presents additions to and modifications of Table Ia for activities with animals involving genetically modified micro-organisms (GMMs).

Table II presents minimum requirements for other activities than laboratories 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 exceptional cases (e. g. for plant pathogens), it also might be appropriate, following consultation with the Competent Authority not to apply a specification under a particular containment level or to combine specifications from two different levels.

In these Tables:

- no: means not required
- optional: means that the user should decide on a case by case basis, subject to the risk assessment, to what extent these measures are to be applied.
- yes: means required

Annex IV
Table I a
Containment and Control Measures for Laboratory Activities

Specifications		Containment levels			
		1	2	3	4
	BUILDING				
1	Laboratory suite: isolation[1]	no	no	yes	yes
2	Laboratory: sealable for fumigation	no	no	yes	yes
	EQUIPMENT				
3	Surfaces resistant to acids, alkalis, solvents, disinfectants	yes (bench)	yes (bench)	yes (bench, floor)	yes (bench, floor, ceiling, walls)
4	Entry to lab via airlock[2]	no	no	optional	yes
5	Negative pressure relative to the pressure of the immediate surroundings	no	no	yes except for[4]	yes
6	Extract and input air from the laboratory should be HEPA-filtered	no	no	yes (HEPA)[3] - Extract air except for[4]	yes (HEPA) - Input and extract air
7	Microbiological safety cabinet/enclosure	no	optional	yes	yes
8	Autoclave	on site	in the building	in suite	in lab = double ended
	SYSTEM OF WORK				
9	Restricted access	no	yes	yes	yes
10	Biohazard signs on the door	no	yes	yes	yes
11	Control of aerosol formation	no	yes minimize	yes prevent	yes prevent
12	Washing and decontamination provisions for personnel	yes	yes	yes	yes

(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) HEPA = High Efficiency Particulate Air.

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

Containment and Control Measures for Laboratory Activities

Specifications		Containment levels			
		1	2	3	4
SYSTEM OF WORK					
13	Shower	no	no	optional	yes
14	Protective clothing	labcoat	labcoat	suitable protective clothing + foot wear	complete change of clothing + foot wear before entry and exit
15	Gloves	no	optional	yes	yes
16	Test adequately and maintain control measures and equipment	yes	yes	yes	yes
17	Record keeping	yes	yes	yes	yes
18	Efficient vector control (e.g. for rodents and insects)	optional	yes	yes	yes
WASTE					
19	Inactivation of GMMs in effluent from handwashing sinks or drains and showers if any	no	no	optional	yes
20	Inactivation of GMMs in contaminated material and waste	optional	yes	yes	yes

Annex IV
Table I b
Containment and Control Measures for Glasshouses and Growthrooms

The terms glasshouse and growthroom 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[5]	no	yes	yes	yes
	EQUIPMENT				
2	Surroundings without susceptible plant species	no	optional	yes	yes
3	Entry via a separated room with two interlocking doors	optional	optional	yes	yes
4	Control of contaminated run-off water	optional	minimize[6] run-off	prevent run- off	prevent run-off
	SYSTEM OF WORK				
5	Restricted access	yes (visitors accepted)	yes	yes	yes
6	Measures to control undesired species as insects, rodents, arthropods	yes	yes	yes	yes
7	Procedures for transfer of living material between the glasshouse/growth room, protective structure and laboratory shall prevent dissemination of genetically modified microorganisms	minimize dissemination	minimize dissemination	prevent dissemination	prevent dissemination

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

(6) Where transmission can occur through the ground.

Annex IV
Table I c
Containment and Control 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[7]	optional	yes	yes	yes
2	Animal facilities[8] separated by lockable doors	yes	yes	yes	yes
3	Animal facilities design for decontamination (waterproof and easily washable material (cages, etc.))	optional	optional	yes	yes
4	Floor and/or walls easily washable	yes (floor)	yes (floor)	yes (floor and walls)	yes (floor and walls)
5	Animal containment in appropriate cages, pens or tanks	yes	yes	yes	yes
6	Filters on isolators[9]	no	no	optional	yes

(7) 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.

(8) 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.

(9) isolators: transparent boxes where the animal is contained within or outside a cage.

Annex IV
Table II
Containment and Control Measures for other Activities

	Specifications	Containment levels			
		1	2	3	4
	GENERAL				
1	Viable micro-organisms should be contained in a system which physically separates the process from the environment (closed system)	no	yes	yes	yes
2	Control of exhaust gases from the closed system	no	yes, minimize release	yes, prevent release	yes, prevent release
3	Control of aerosols during sampling collection, addition of material to a closed system or transfer of material to another closed system	no	yes, minimize release	yes, prevent release	yes, prevent release
4	Inactivation of bulk culture fluids before removal from the closed system	no	yes, by validated means	yes, by validated means	yes, by validated means
5	Seals should be designed so as to minimize or prevent release	no specific requirement	minimize 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	yes	yes
7	The controlled area should be sealable to permit fumigation	no	no	optional	yes
	EQUIPMENT				
8	Entry via airlock	no	no	optional	yes
9	Surfaces resistant to acids, alkalis, solvents, disinfectants	optional	optional	yes (bench if any, floor)	yes (bench, floor, ceiling, walls)
10	The controlled area should be adequately ventilated to minimize air contamination	optional	optional	optional	yes
11	The controlled area should be maintained at an air pressure negative to the immediate surroundings	no	no	optional	yes
12	Extract and input air from the controlled area should be HEPA filtered	no	no	yes (extract air, optional for input air)	yes (input and extract air)

Containment and Control Measures for other Activities

	Specifications	Containment levels			
		1	2	3	4
	SYSTEM OF WORK				
13	Closed systems should be located within a controlled area	no	optional	yes	yes
14	Access should be restricted to nominated personnel only	no	yes	yes	yes
15	Biohazard signs should be posted	no	yes	yes	yes
16	Washing and decontamination provisions for personnel	yes	yes	yes	yes
17	Personnel should shower before leaving the controlled area	no	no	optional	yes
18	Personnel should wear protective clothing	yes (work clothing)	yes (work clothing)	yes	complete change before exit and entry
19	Test adequately and maintain control measures and equipment	yes	yes	yes	yes
20	Record keeping	yes	yes	yes	yes
21	Appropriate training and supervision for personnel	yes	yes	yes	yes
	WASTE				
22	Inactivation of GMMs in effluent from handwashing sinks and showers if any	no	no	optional	yes
23	Inactivation of GMMs in contaminated material and waste	optional	yes	yes	yes
24	Inactivation of GMMs in process effluent before final discharge	optional	yes, by validated means	yes, by validated means	yes, by validated means

(Partially Redrafted)

ANNEX V

PART A

Information required for the notification referred to in Article 7:

- name of user(s) including those responsible for supervision, safety and information on their training and qualifications;
- details of any biological committees or subcommittees;
- address of installation;
- general description of the premises;
- a description of the nature of the work which will be undertaken;
- the class of risk of the activities;
- a summary of the risk assessment referred to in Article 5 (3) (only for class 1 activities)

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 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 manipulation(s);
- identity and characteristics of the genetically modified micro-organism(s);
- the purpose of the contained use including the expected results;
- approximate culture volumes to be used;
- description of the containment and control measures to be applied, including information about the wastes to be generated, their treatment, ultimate form and destination;
- a summary of the risk assessment referred to in Article 5 (3).

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;
- name of the responsible person;

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 function(s) of the genetic material(s) involved in the manipulation(s);
- identity and characteristics of the genetically modified micro-organism;

- the culture volumes to be used;

c)
- description of the containment and control measures to be applied, including information about 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:
- the sources of hazards and conditions under which accidents might occur;
- 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 prepared in accordance with Article 14;

e) a copy of the risk assessment referred to in Article 5 (3).

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