# Council Directive of 23 April 1990 on the contained use of genetically modified micro-organisms (90/219/EEC) (repealed)

This Directive lays down common measures for the contained
use
For the purposes of this Directive: (a) 'micro-organism' shall
mean
Without prejudice to Article 5(1) this Directive shall not apply:
Article 5(3) and 5(6) and Articles 6 to 12 shall not
(1) Member States shall ensure that all appropriate measures are
(1) The user shall apply, except to the extent that
When premises are to be used for the first time
Following the notification referred to in Article 7, subsequent
class
(1) For first and subsequent class 2 contained uses to
(1) For first and subsequent class 3 or class 4
(1) Member States shall designate the authority or authorities competent
If the user becomes aware of relevant new information or
Where a Member State considers it appropriate, it may provide
The competent authorities shall ensure that before a contained use
(1) Member States shall take the necessary measures to ensure
(1) Member States shall be required to:
Member States shall ensure that the competent authority
organizes inspections
(1) Member States shall send to the Commission, at the
(1) Where its disclosure affects one or more of the
Amendments necessary to adapt Annex II, Part A, and Annexes
Before 5 December 2000 Annex II, Part B, listing the
(1) The Commission shall be assisted by a committee.
Member States shall bring into force the laws, regulations and
This Directive is addressed to the Member States.

ANNEX I

PART A

PART B

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### ANNEX II

### PART A

### PART B

Criteria establishing the safety of GMMs for human health and...

- 1. INTRODUCTION
- 2. GENERAL CRITERIA
  - 2.1. Strain verification/authentication
  - 2.2. Documented and established evidence of safety
  - 2.3. Genetic stability
- 3. SPECIFIC CRITERIA
  - 3.1. Non-pathogenic
    - 3.1.1. Non-toxigenic
    - 3.1.2. Non-allergenic
  - 3.2. No harmful adventitious agents
  - 3.3. Transfer of genetic material
  - 3.4. Safety for the environment in the event of a significant...

Guidance notes supplementing part B of Annex II to Directive...

### INTRODUCTION

- 1. GENERAL CRITERIA
  - 1.1. Strain verification/authentication
  - 1.2. Documented and established safety
  - 1.3. Genetic stability
- 2. SPECIFIC CRITERIA
  - 2.1. Non-pathogenic
    - 2.1.1. Non-toxigenic
    - 2.1.2. Non-allergenic
  - 2.2. No harmful adventitious agents
  - 2.3. Transfer of genetic material
  - 2.4. Safety for the environment in the event of an escape...
    - 2.4.1. Organism survival
    - 2.4.2. Dispersal
    - 2.4.3. Organism establishment in the environment
    - 2.4.4. Transfer of genetic material

### APPENDIX 1

Definitions of terms used in this document

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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... These guidance notes shall be completed no later than 5...

### A. ELEMENTS OF ASSESSMENT

- 1. The following should be considered as potentially harmful effects:
- 2. The assessment referred to in Article 5(2) should be based...

### B. PROCEDURE

- 3. The first stage in the assessment process should be to...
- 4. In general, only GMMs which show the following characteristics would...
- 5. In order to obtain the necessary information to implement this...
- 6. The hazard identification process carried out in accordance with paragraphs...
- 7. Selection of the containment and other protective measures should then...
- 8. The analysis carried out as described above will finally lead...
- 9. The final classification of the contained use should be confirmed...

### ANNEX IV

## CONTAINMENT AND OTHER PROTECTIVE MEASURES

### General principles

- 1. These tables present the normal minimum requirements and measures necessary...
- 2. The titles of the tables are indicative:
- 3. Member states may, in implementing this Annex, incorporate in addition...
- Table I Containment and other protective measures for laboratory activities
- Table I **C**ontainment and other protective measures for glasshouses and growth-rooms
- Table I Containment and other protective measures for activities in animal units...
- Table II Containment and other protective measures for other activities

ANNEX V

PART A

PART B

PART C

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- (1) OJ No C 198, 28. 7. 1988, p. 9 and OJ No C 246, 27. 9. 1989, p. 6.
- (2) OJ No C 158, 26. 6. 1989, p. 122 and OJ No C 96, 17. 4. 1990.
- (3) OJ No C 23, 30. 1. 1989, p. 45.
- (4) OJ No C 328, 7. 12. 1987, p. 1.