

Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast) (Text with EEA relevance)

- Article 1 This Directive lays down common measures for the contained use...
- Article 2 For the purposes of this Directive the following definitions shall...
- Article 3 (1) Without prejudice to Article 4(1), this Directive shall not...
- Article 4 (1) Member States shall ensure that all appropriate measures are...
- Article 5 (1) Save to the extent that point 2 of Annex...
- Article 6 When premises are to be used for the first time...
- Article 7 Following the notification referred to in Article 6, subsequent class...
- Article 8 (1) For first and subsequent class 2 contained uses to...
- Article 9 (1) For first and subsequent class 3 or class 4...
- Article 10 (1) Member States shall designate the authority or authorities competent...
- Article 11 (1) If the user becomes aware of relevant new information...
- Article 12 Where a Member State considers it appropriate, it may provide...
- Article 13 (1) The competent authorities shall ensure that before a contained...
- Article 14 (1) Member States shall take the necessary measures to ensure...
- Article 15 (1) Member States shall be required to:
- Article 16 Member States shall ensure that the competent authority organises inspections...
- Article 17 (1) Member States shall send to the Commission, at the...
- Article 18 (1) Where its disclosure affects one or more of the...
- Article 19 The measures designed to amend non-essential elements of this Directive...
- Article 20 (1) The Commission shall be assisted by a committee.
- Article 21 Directive 90/219/EEC, as amended by the acts listed in Annex...
- Article 22 This Directive shall enter into force on the 20th day...
- Article 23 This Directive is addressed to the Member States.
- Signature

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ANNEX I

PART A

PART B

## ANNEX II

## PART A

## PART B

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

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...

## PART C

## ANNEX III

Principles to be followed for the assessment referred to in Article 4(2)

This Annex describes in general terms the elements to be...

- A. Elements of assessment
  1. The following should be considered as potentially harmful effects:
  2. The assessment referred to in Article 4(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 points...
  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

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1. These tables present the normal minimum requirements and measures necessary...
2. The titles of the tables are indicative:
3. In implementing this Annex, Member States may in addition incorporate...

#### ANNEX V

Information required for the notification referred to in Articles 6, 8 and 9

##### PART A

##### PART B

##### PART C

#### ANNEX VI

##### PART A

Repealed Directive with list of its successive amendments

##### PART B

Time limits for transposition into national law

#### ANNEX VII

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- (1) [OJ C 162, 25.6.2008, p. 85.](#)
- (2) Opinion of the European Parliament of 21 October 2008 (not yet published in the Official Journal) and Council Decision of 30 March 2009.
- (3) [OJ L 117, 8.5.1990, p. 1.](#)
- (4) See Annex VI, Part A.
- (5) [OJ L 106, 17.4.2001, p. 1.](#)
- (6) [OJ L 262, 17.10.2000, p. 21.](#)
- (7) [OJ L 184, 17.7.1999, p. 23.](#)