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)

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

General principles

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Repealed Directive with list of its successive amendments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

(**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.