

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 of genetically modified micro-organisms with a view to protecting human health and the environment.

*Article 2*

For the purposes of this Directive the following definitions shall apply:

- (a) 'micro-organism' means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, and animal and plant cells in culture;
- (b) 'genetically modified micro-organism' (GMM) means a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination; within the terms of this definition:
  - (i) genetic modification occurs at least through the use of the techniques listed in Annex I, Part A;
  - (ii) the techniques listed in Annex I, Part B, are not considered to result in genetic modification;
- (c) 'contained use' means any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment;
- (d) 'accident' means any incident involving a significant and unintended release of GMMs in the course of their contained use which could present an immediate or delayed hazard to human health or the environment;
- (e) 'user' means any natural or legal person responsible for the contained use of GMMs;
- (f) 'notification' means the presentation of the requisite information to the competent authorities of a Member State.

*Article 3*

- 1 Without prejudice to Article 4(1), this Directive shall not apply:
  - a where genetic modification is obtained through the use of the techniques/methods listed in Annex II, Part A; or
  - b for contained uses involving only types of GMMs meeting the criteria listed in Annex II, Part B which establish their safety for human health and the environment. These types of GMMs shall be listed in Annex II, Part C.
- 2 Article 4(3) and (6) and Articles 5 to 11 shall not apply to the transport of GMMs by road, rail, inland waterway, sea or air.
- 3 This Directive shall not apply to the storage, culture, transport, destruction, disposal or use of GMMs which have been placed on the market in accordance with Directive 2001/18/

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EC or pursuant to other Community legislation which provides for a specific environmental risk assessment similar to that laid down in that Directive, provided that the contained use is in accordance with the conditions, if any, of the consent for placing on the market.

#### *Article 4*

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

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

3 The assessment referred to in paragraph 2 shall result in the final classification of the contained uses in four classes applying the procedure set out in Annex III, which will result in the assignment of containment levels in accordance with Article 5:

- Class 1 : activities of no or negligible risk, that is to say activities for which level 1 containment is appropriate to protect human health and the environment.
- Class 2 : activities of low risk, that is to say activities for which level 2 containment is appropriate to protect human health and the environment.
- Class 3 : activities of moderate risk, that is to say activities for which level 3 containment is appropriate to protect human health and the environment.
- Class 4 : activities of high risk, that is to say activities for which level 4 containment is appropriate to protect human health and the environment.

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

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

6 A record of the assessment referred to in paragraph 2 shall be kept by the user and made available in an appropriate form to the competent authority as part of the notification pursuant to Articles 6, 8 and 9 or on request.

#### *Article 5*

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

2 The assessment referred to in Article 4(2) and the containment and other protective measures applied shall be reviewed periodically, and forthwith if:

- a the containment measures applied are no longer adequate or the class assigned to the contained uses is no longer correct; or

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- b there is reason to suspect that the assessment is no longer appropriate judged in the light of new scientific or technical knowledge.

#### *Article 6*

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

#### *Article 7*

Following the notification referred to in Article 6, subsequent class 1 contained use may proceed without further notification. Users of GMMs in class 1 contained uses shall be required to keep the record of each assessment referred to in Article 4(6), which shall be made available to the competent authority on request.

#### *Article 8*

1 For first and subsequent class 2 contained uses to be carried out in premises notified in accordance with Article 6, a notification containing the information listed in Annex V, Part B shall be submitted.

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

However, the applicant may himself request from the competent authority a decision on the grant of a formal authorisation. The decision must be made within a maximum of 45 days from the notification.

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

#### *Article 9*

1 For first and subsequent class 3 or class 4 contained uses to be carried out in premises notified in accordance with Article 6, a notification containing the information listed in Annex V, Part C shall be submitted.

2 A class 3 or higher class of contained use may not proceed without the prior consent of the competent authority, which shall communicate its decision in writing:

- a at the latest 45 days after submission of the new notification, in the case of premises which have been the subject of a previous notification to carry out class 3 or a higher class of contained uses and where any associated consent requirements have been satisfied for the same or a higher class than the contained use with which it is intended to proceed;
- b at the latest 90 days after submission of the notification, in other cases.

#### *Article 10*

1 Member States shall designate the authority or authorities competent to implement the measures which they adopt in application of this Directive and to receive and acknowledge the notifications referred to in Articles 6, 8 and 9.

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2 The competent authorities shall examine the conformity of the notifications with the requirements of this Directive, the accuracy and completeness of the information given, the correctness of the assessment referred to in Article 4(2) and the class of contained uses and, where appropriate, the suitability of the containment and other protective measures, the waste management, and emergency response measures.

3 If necessary, the competent authority may:

- a ask the user to provide further information or to modify the conditions of the proposed contained use or to amend the class assigned to the contained use(s). In this case the competent authority may require that the contained use, if proposed, should not begin, or, if in progress, should be suspended or terminated, until the competent authority has given its approval on the basis of the further information obtained or of the modified conditions of the contained use;
- b limit the time for which the contained use should be permitted or subject it to certain specific conditions.

4 For the purpose of calculating the periods referred to in Articles 8 and 9, any period of time during which the competent authority:

- a is awaiting any further information which it may have requested from the notifier in accordance with point (a) of paragraph 3; or
- b is carrying out a public inquiry or consultation in accordance with Article 12;

shall not be taken into account.

#### *Article 11*

1 If the user becomes aware of relevant new information or modifies the contained use in a way which could have significant consequences in terms of the risks posed by it, the competent authority shall be informed as soon as possible and the notification pursuant to Articles 6, 8 and 9 shall be modified.

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

#### *Article 12*

Where a Member State considers it appropriate, it may provide that the public is to be consulted on aspects of the proposed contained use, without prejudice to Article 18.

#### *Article 13*

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

- a an emergency plan is drawn up for contained uses where failure of the containment measures could lead to serious danger, whether immediate or delayed, to humans outside the premises and/or to the environment, except where such an emergency plan has been drawn up under other Community legislation;
- b information on such emergency plans, including the relevant safety measures to be applied, 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.

2 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 14*

1 Member States shall take the necessary measures to ensure that, in the event of an accident, the user is required immediately to inform the competent authority specified in Article 10 and to provide the following information:

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

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

- a ensure that any measures necessary are taken, and immediately alert any Member States which could be affected by the accident;
- b 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 15*

1 Member States shall be required to:

- a consult with other Member States likely to be affected in the event of an accident on the proposed implementation of emergency plans;
- b inform the Commission as soon as possible of any accident within the scope of this Directive, giving details of the circumstances of the accident, the identity and quantities of the GMMs concerned, the response measures taken and their effectiveness and an analysis of the accident, including recommendations designed to limit its effects and to avoid similar accidents in the future.

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

#### *Article 16*

Member States shall ensure that the competent authority organises inspections and other control measures to ensure that users comply with this Directive.

#### *Article 17*

1 Member States shall send to the Commission, at the end of each year, a summary report on class 3 and class 4 contained uses notified during that year pursuant to Article 9, including the description, purpose and risks of the contained use(s).

2 Every three years, and for the first time on 5 June 2003, Member States shall send the Commission a summary report on their experience with this Directive.

3 Every three years, and for the first time on 5 June 2004, the Commission shall publish a summary based on the reports referred to in paragraph 2.

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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 18*

1 Where its disclosure affects one or more of the items mentioned in Article 4(2) of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information<sup>(1)</sup>, the notifier may indicate the information in the notifications submitted pursuant to this Directive that should be treated as confidential. Verifiable justification must be given in such cases.

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

2 In no case may the following information, when submitted pursuant to Articles 6, 8 or 9, be kept confidential:

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

3 The Commission and the competent authorities shall not divulge to third parties any information deemed to be confidential according to the second subparagraph of paragraph 1 and notified or otherwise provided pursuant to this Directive, and shall protect intellectual property rights relating to the data received.

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

#### *Article 19*

The measures designed to amend non-essential elements of this Directive relating to adapting Annexes II, III, IV and V to technical progress, and to adapting Annex II, Part C, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(2).

#### *Article 20*

1 The Commission shall be assisted by a committee.

2 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

#### *Article 21*

Directive 90/219/EEC, as amended by the acts listed in Annex VI, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time limits for transposition into national law of the Directives set out in Annex VI, Part B.

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References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VII.

*Article 22*

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

*Article 23*

This Directive is addressed to the Member States.

Done at Strasbourg, 6 May 2009.

*For the European Parliament*

*The President*

H.-G. PÖTTERING

*For the Council*

*The President*

J. KOHOUT

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- (1) [OJ L 41, 14.2.2003, p. 26.](#)