

Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, as regards the implementing powers conferred on the Commission

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁽²⁾,

Whereas:

- (1) Directive 2001/18/EC of the European Parliament and of the Council⁽³⁾ provides that certain measures are to be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽⁴⁾.
- (2) Decision 1999/468/EC has been amended by Decision 2006/512/EC, which introduced the regulatory procedure with scrutiny for the adoption of measures of general scope and designed to amend non-essential elements of a basic instrument adopted in accordance with the procedure referred to in Article 251 of the Treaty, *inter alia*, by deleting some of those elements or by supplementing the instrument with new non-essential elements.
- (3) In accordance with the statement by the European Parliament, the Council and the Commission⁽⁵⁾ concerning Decision 2006/512/EC, for the regulatory procedure with scrutiny to be applicable to instruments adopted in accordance with the procedure referred to in Article 251 of the Treaty which are already in force, those instruments must be adjusted in accordance with the applicable procedures.
- (4) The Commission should be empowered to adopt the measures necessary for the implementation of Directive 2001/18/EC. Those measures are designed to adapt certain annexes, establish criteria for the notification and fix minimum thresholds. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2001/18/EC, *inter alia*, by supplementing it with new non-essential elements,

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they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

- (5) Directive 2001/18/EC should therefore be amended accordingly.
- (6) Since the amendments made to Directive 2001/18/EC by this Directive are technical in nature and concern committee procedure only, they do not need to be transposed by the Member States. It is therefore not necessary to lay down provisions to that effect,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments

Directive 2001/18/EC is hereby amended as follows:

1. Article 16(2) and (3) shall be replaced by the following:
2. The criteria and information requirements referred to in paragraph 1, as well as any appropriate requirements for a summary of the dossier, shall be established. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted, after consultation of the relevant Scientific Committee, in accordance with the regulatory procedure with scrutiny referred to in Article 30(3). The criteria and information requirements shall be such as to ensure a high level of safety of human health and the environment and shall be based on the available scientific evidence concerning such safety and on experience gained from the release of comparable GMOs.

The requirements set out in Article 13(2) shall be replaced by those adopted in accordance with the first subparagraph, and the procedure set out in Article 13(3), (4), (5) and (6) and Articles 14 and 15 shall apply.
3. Before the regulatory procedure with scrutiny referred to in Article 30(3) is initiated with a view to a decision on criteria and information requirements referred to in paragraph 1, the Commission shall make the proposal available to the public. The public may make comments to the Commission within 60 days. The Commission shall forward any such comments, together with an analysis, to the Committee established pursuant to Article 30.;
2. Article 21(2) shall be replaced by the following:
 2. For products where adventitious or technically unavoidable traces of authorised GMOs cannot be excluded, a minimum threshold may be established below which these products shall not have to be labelled in accordance with paragraph 1.

Threshold levels shall be established according to the product concerned. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 30(3).;
3. Article 21(3) shall be replaced by the following:

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3. For products intended for direct processing, paragraph 1 shall not apply to traces of authorised GMOs in proportions no higher than 0,9 % or lower thresholds, provided that these traces are adventitious or technically unavoidable.

The threshold levels referred to in the first subparagraph may be established. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 30(3).;

4. Article 23(2) shall be replaced by the following:

2. Within 60 days of the date of receipt of the information transmitted by the Member State, a decision shall be taken on the measure taken by that Member State in accordance with the regulatory procedure referred to in Article 30(2). For the purpose of calculating the 60-day period, any period of time during which the Commission is awaiting further information which it may have requested from the notifier or is seeking the opinion of the Scientific Committee or Committees which has or have been consulted shall not be taken into account. The period of time during which the Commission is awaiting the opinion of the Scientific Committee or Committees consulted shall not exceed 60 days.

Likewise, the period of time the Council takes to act in accordance with the regulatory procedure referred to in Article 30(2) shall not be taken into account.;

5. Article 26(2) shall be replaced by the following:

2. Conditions for the implementation of paragraph 1 shall be established, without duplicating or creating inconsistencies with labelling provisions laid down in existing Community legislation. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 30(3). In so doing, account should be taken, as appropriate, of labelling provisions established by Member States in accordance with Community legislation.;

6. Article 27 shall be replaced by the following:

Article 27

Adaptation of annexes to technical progress

The adaptation to technical progress of Sections C and D of Annex II, Annexes III to VI, and Section C of Annex VII, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 30(3).;

7. Article 30(3) shall be replaced by the following:

3. 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.;

8. the first paragraph of Annex II shall be replaced by the following:

This Annex describes in general terms the objective to be achieved, the elements to be considered and the general principles and methodology to be followed to

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perform the environmental risk assessment (e.r.a.) referred to in Articles 4 and 13. Technical guidance notes may be developed in accordance with the regulatory procedure referred to in Article 30(2) in order to facilitate the implementation and explanation of this Annex.;

9. the introductory wording to Annex IV shall be replaced by the following:

This Annex describes in general terms the additional information to be provided in the case of notification for placing on the market and the information for labelling requirements regarding GMOs as or in products to be placed on the market and GMOs exempted under the second subparagraph of Article 2(4). Technical guidance notes, as regards, *inter alia*, the description of how the product is intended to be used, may be developed in accordance with the regulatory procedure referred to in Article 30(2) in order to facilitate the implementation and explanation of this Annex. The labelling requirements for exempted organisms set out in Article 26 shall be met by providing appropriate recommendations for, and restrictions on, use.;

10. the first and second paragraphs of Annex VII shall be replaced by the following:

This Annex describes in general terms the objective to be achieved and the general principles to be followed in the design of the monitoring plan referred to in Article 13(2), Article 19(3) and Article 20. Technical guidance notes may be developed in accordance with the regulatory procedure referred to in Article 30(2) in order to facilitate the implementation and explanation of this Annex.

Article 2

Entry into force

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

Article 3

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 11 March 2008.

For the European Parliament

The President

H.-G. PÖTTERING

For the Council

The President

J. LENARČIČ

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- (1) [OJ C 161, 13.7.2007, p. 45.](#)
- (2) Opinion of the European Parliament of 14 November 2007 (not yet published in the Official Journal) and Council Decision of 3 March 2008.
- (3) [OJ L 106, 17.4.2001, p. 1.](#) Directive as last amended by Regulation (EC) No 1830/2003 ([OJ L 268, 18.10.2003, p. 24.](#))
- (4) [OJ L 184, 17.7.1999, p. 23.](#) Decision as amended by Decision 2006/512/EC ([OJ L 200, 22.7.2006, p. 11.](#))
- (5) [OJ C 255, 21.10.2006, p. 1.](#)