



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 22.12.2006
COM(2006) 920 final

2006/0296 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Amending

Directive 2001/18/CE

concerning the deliberate release into the environment of genetically modified organisms, as regards the implementing powers conferred to the Commission

(presented by the Commission)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Amending

Directive 2001/18/CE

concerning the deliberate release into the environment of genetically modified organisms, as regards the implementing powers conferred to the Commission

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 Commission¹,

Having regard to the opinion of the European Economic and Social Committee²,

Having regard to the opinion of the Committee of the Regions³,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁴

Whereas:

- (1) Directive 2001/18/EC of the European Parliament and of the Council⁵ 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 Commission⁶.
- (2) Decision 1999/468/EC has been amended by Decision 2006/512/EC, which introduced a regulatory procedure with scrutiny to be used for the adoption of implementing measures of general scope which seek to amend non-essential elements of a basic instrument adopted in accordance with the procedure referred to in Article 251 of the Treaty, including by deleting some of those elements or by supplementing the instrument by the addition of new non-essential elements.

1

...

2

...

3

...

4

...

5

OJ L 106, 17.4.2001, p. 1–39

6

OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p.

11).

- (3) In accordance with the joint statement of the European Parliament, the Council and the Commission⁷ on Decision 2006/512/EC, instruments which are already in force must be adjusted in accordance with the applicable procedures, so as to replace the regulatory procedure laid down in Article 5 of the Decision 1999/468/EC by the regulatory procedure with scrutiny, wherever there are measures which fall within its scope. That statement indicates a list of instruments that should be adjusted as a matter of urgency, including Directive 2001/18/EC.
- (4) In particular power should be conferred on the Commission 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 and supplement it by the addition of new non essential elements, they should 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 to be made to Directive 2001/18/EC are adjustments of a technical nature which only concern the committee procedures, 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

Directive 2001/18/EC is amended as follows:

(1) In Article 16, paragraphs 2 and 3 are replaced by the following:

"2. The Commission shall establish the criteria and information requirements referred to in paragraph 1 as well as any appropriate requirements for a summary. 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 the information requirements shall be such as to ensure a high level of safety to human health and the environment and be based on the scientific evidence available on such safety and on the experience gained from the release of comparable GMOs.

The requirements set out in Article 13(2) shall be replaced by those adopted above, and the procedure set out in Article 13(3), (4), (5) and (6) and Articles 14 and 15 shall apply.

3. Before the procedure referred to in Article 30(3) for a decision on criteria and information requirements referred to in paragraph 1 is initiated, the Commission shall make the proposal available to the public. The public may make comments to

⁷ OJ C 255, 21.10.2006, p.1

the Commission within 60 days. The Commission shall forward any such comments, together with an analysis, to the Committee set up pursuant to Article 30."

(2) In Article 21, paragraph 2 is replaced by the following:

"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 according to the provision in paragraph 1.

The Commission shall establish the threshold levels 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 27 is 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)."

(4) In Article 30, paragraph 3 is replaced by the following:

"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."

Article 2

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

Article 3

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President