

Directive 2001/18/EC of the European Parliament and of the Council  
of 12 March 2001 on the deliberate release into the environment of  
genetically modified organisms and repealing Council Directive 90/220/EEC

PART C

**PLACING ON THE MARKET OF GMOs AS OR IN PRODUCTS**

*Article 12*

**Sectoral legislation**

1 Articles 13 to 24 shall not apply to any GMO as or in products as far as they are authorised by Community legislation which provides for a specific environmental risk assessment carried out in accordance with the principles set out in Annex II and on the basis of information specified in Annex III without prejudice to additional requirements provided for by the Community legislation mentioned above, and for requirements as regards risk management, labelling, monitoring as appropriate, information to the public and safeguard clause at least equivalent to that laid down in this Directive.

2 As far as Council Regulation (EEC) No 2309/93 is concerned, Articles 13 to 24 of this Directive shall not apply to any GMO as or in products as far as they are authorised by that Regulation provided that a specific environmental risk assessment is carried out in accordance with the principles set out in Annex II to this Directive and on the basis of the type of information specified in Annex III to this Directive without prejudice to other relevant requirements as regards risk assessment, risk management, labelling, monitoring as appropriate, information to the public and safeguard clause provided by Community legislation concerning medicinal products for human and veterinary use.

3 Procedures ensuring that the risk assessment, requirements regarding risk management, labelling, monitoring as appropriate, information to the public and safeguard clause are equivalent to those laid down in this Directive shall be introduced, in a Regulation of the European Parliament and of the Council. Future sectoral legislation based on the provisions of that Regulation shall make a reference to this Directive. Until the Regulation enters into force, any GMO as or in products as far as they are authorised by other Community legislation shall only be placed on the market after having been accepted for placing on the market in accordance with this Directive.

4 During evaluation of the requests for the placing on the market of the GMOs referred to in paragraph 1, the bodies established by the Community under this Directive and by Member States for the purpose of implementing this Directive shall be consulted.

*<sup>F1</sup>Article 12a*

**Transitional measures for adventitious or technically unavoidable presence of  
genetically modified organisms having benefited from a favourable risk evaluation**

1 Placing on the market of traces of a GMO or combination of GMOs in products intended for direct use as food or feed or for processing shall be exempted from Articles 13 to 21 provided that they meet the conditions referred to in Article 47 of Regulation (EC) No

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1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed<sup>(1)</sup>.

2 This Article shall be applicable for a period of three years after the date of application of Regulation (EC) No 1829/2003.]

#### Textual Amendments

- F1** Inserted by [Regulation \(EC\) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed \(Text with EEA relevance\)](#).

### Article 13

#### Notification procedure

1 Before a GMO or a combination of GMOs as or in products is placed on the market, a notification shall be submitted to the competent authority of the Member State where such a GMO is to be placed on the market for the first time. The competent authority shall acknowledge the date of receipt of the notification and immediately forward the summary of the dossier referred to in paragraph 2(h) to the competent authorities of the other Member States and the Commission.

The competent authority shall without delay examine whether the notification is in accordance with paragraph 2 and shall, if necessary, ask the notifier for additional information.

When the notification is in accordance with paragraph 2, and at the latest when it sends its assessment report in accordance with Article 14(2), the competent authority shall forward a copy of the notification to the Commission which shall, within 30 days of its receipt, forward it to the competent authorities of the other Member States.

2 The notification shall contain:

- a the information required in Annexes III and IV. This information shall take into account the diversity of sites of use of the GMO as or in a product and shall include information on data and results obtained from research and developmental releases concerning the impact of the release on human health and the environment;
- b the environmental risk assessment and the conclusions required in Annex II, section D;
- c the conditions for the placing on the market of the product, including specific conditions of use and handling;
- d with reference to Article 15(4), a proposed period for the consent which should not exceed ten years;
- e a plan for monitoring in accordance with Annex VII, including a proposal for the time-period of the monitoring plan; this time-period may be different from the proposed period for the consent;
- f a proposal for labelling which shall comply with the requirements laid down in Annex IV. The labelling shall clearly state that a GMO is present. The words ‘this product contains genetically modified organisms’ shall appear either on a label or in an accompanying document;
- g a proposal for packaging which shall comprise the requirements laid down in Annex IV;
- h a summary of the dossier. The format of the summary shall be established in accordance with the procedure laid down in Article 30(2).

If on the basis of the results of any release notified under part B, or on other substantive, reasoned scientific grounds, a notifier considers that the placing on the market and use of a GMO as or in a product do not pose a risk to human health and the environment, he may propose to the competent authority not to provide part or all of the information required in Annex IV, section B.

3 The notifier shall include in this notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by the notifier either inside or outside the Community.

4 The notifier may also refer to data or results from notifications previously submitted by other notifiers or submit additional information he considers relevant, provided that the information, data and results are non-confidential or these notifiers have given their agreement in writing.

5 In order for a GMO or combination of GMOs to be used for a purpose different from that already specified in a notification, a separate notification shall be submitted.

6 If new information has become available with regard to the risks of the GMO to human health or the environment, before the written consent is granted, the notifier shall immediately take the measures necessary to protect human health and the environment, and inform the competent authority thereof. In addition, the notifier shall revise the information and conditions specified in the notification.

#### *Article 14*

#### **Assessment report**

1 On receipt and after acknowledgement of the notification in accordance with Article 13(2), the competent authority shall examine it for compliance with this Directive.

2 Within 90 days after receipt of the notification the competent authority shall:

- prepare an assessment report and send it to the notifier. A subsequent withdrawal by the notifier shall be without prejudice to any further submission of the notification to another competent authority;
- in the case referred to in paragraph 3(a), send its report, together with the information referred to in paragraph 4 and any other information on which it has based its report, to the Commission which shall, within 30 days of its receipt, forward it to the competent authorities of the other Member States.

In the case referred to paragraph 3(b), the competent authority shall send its report, together with the information referred to in paragraph 4 and any other information on which it has based its report, to the Commission no earlier than 15 days after sending the assessment report to the notifier and no later than 105 days after receipt of the notification. The Commission shall, within 30 days of its receipt, forward the report to the competent authorities of the other Member States.

3 The assessment report shall indicate whether:

- a the GMO(s) in question should be placed on the market and under which conditions; or
- b the GMO(s) in question should not be placed on the market.

The assessment reports shall be established in accordance with the guidelines laid down in Annex VI.

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4 For the purpose of calculating the 90 day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier shall not be taken into account. The competent authority shall state the reasons in any request for further information.

### *Article 15*

#### **Standard procedure**

1 In the cases referred to in Article 14(3), a competent authority or the Commission may ask for further information, make comments or present reasoned objections to the placing on the market of the GMO(s) in question within a period of 60 days from the date of circulation of the assessment report.

Comments or reasoned objections and replies shall be forwarded to the Commission which shall immediately circulate them to all competent authorities.

The competent authorities and the Commission may discuss any outstanding issues with the aim of arriving at an agreement within 105 days from the date of circulation of the assessment report.

Any periods of time during which further information from the notifier is awaited shall not be taken into account for the purpose of calculating the final 45 day period for arriving at an agreement. Reasons shall be stated in any request for further information.

2 In the case referred to in Article 14(3)(b), if the competent authority which prepared the report decides that the GMO(s) should not be placed on the market, the notification shall be rejected. This decision shall state the reasons.

3 If the competent authority which prepared the report decides that the product may be placed on the market, in the absence of any reasoned objection from a Member State or the Commission within 60 days following the date of circulation of the assessment report referred to in Article 14(3)(a) or if outstanding issues are resolved within the 105 day period referred to in paragraph 1, the competent authority which prepared the report shall give consent in writing for placing on the market, shall transmit it to the notifier and shall inform the other Member States and the Commission thereof within 30 days.

4 The consent shall be given for a maximum period of ten years starting from the date on which the consent is issued.

For the purpose of approval of a GMO or a progeny of that GMO intended only for the marketing of their seeds under the relevant Community provisions, the period of the first consent shall end at the latest ten years after the date of the first inclusion of the first plant variety containing the GMO on an official national catalogue of plant varieties in accordance with Council Directives 70/457/EEC<sup>(2)</sup> and 70/458/EEC<sup>(3)</sup>.

In the case of forest reproductive material, the period of the first consent shall end at the latest ten years after the date of the first inclusion of basic material containing the GMO on an official national register of basic material in accordance with Council Directive 1999/105/EC<sup>(4)</sup>.

## Article 16

### Criteria and information for specified GMOs

1 A competent authority, or the Commission on its own initiative, may make a proposal on criteria and information requirements to be met for the notification, by way of derogation from Article 13, for the placing on the market of certain types of GMOs as or in products.

[<sup>F2</sup> 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.]

#### Textual Amendments

- F2** Substituted by [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.](#)

## Article 17

### Renewal of consent

1 By way of derogation from Articles 13, 14 and 15, the procedure set out in paragraphs 2 to 9 shall be applied to the renewal of:

- a consents granted under part C; and
- b before 17 October 2006 of consents granted under Directive 90/220/EEC for placing on the market of GMOs as or in products before 17 October 2002,

2 At the latest nine months before the expiry of the consent, for the consents referred to in paragraph 1(a), and before 17 October 2006, for the consents referred to in paragraph 1(b), the notifier under this Article shall submit a notification to the competent authority which received the original notification, which shall contain:

- a a copy of the consent to the placing on the market of the GMOs;
- b a report on the results of the monitoring which was carried out according to Article 20. In the case of consents referred to in paragraph 1(b), this report shall be submitted when the monitoring was carried out;

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- c any other new information which has become available with regard to the risks of the product to human health and/or the environment; and
- d as appropriate, a proposal for amending or complementing the conditions of the original consent, *inter alia* the conditions concerning future monitoring and the time limitation of the consent.

The competent authority shall acknowledge the date of receipt of the notification and when the notification is in accordance with this paragraph it shall without delay forward a copy of the notification and its assessment report to the Commission, which shall, within 30 days of their receipt, forward them to the competent authorities of the other Member States. It shall also send its assessment report to the notifier.

3 The assessment report shall indicate whether:

- a the GMO(s) should remain on the market and under which conditions; or
- b the GMO(s) should not remain on the market.

4 The other competent authorities or the Commission may ask for further information, make comments, or present reasoned objections within a period of 60 days from the date of circulation of the assessment report.

5 All comments, reasoned objections and replies shall be forwarded to the Commission which shall immediately circulate them to all competent authorities.

6 In the case of paragraph 3(a) and in the absence of any reasoned objection from a Member State or the Commission within 60 days from the date of circulation of the assessment report, the competent authority which prepared the report shall transmit to the notifier the final decision in writing and shall inform the other Member States and the Commission thereof within 30 days. The validity of the consent should not, as a general rule, exceed ten years and may be limited or extended as appropriate for specific reasons.

7 The competent authorities and the Commission may discuss any outstanding issues with the aim of arriving at an agreement within 75 days from the date of circulation of the assessment report.

8 If outstanding issues are resolved within the 75 day period referred to in paragraph 7, the competent authority which prepared the report shall transmit to the notifier its final decision in writing and shall inform the other Member States and the Commission thereof within 30 days. The validity of the consent may be limited as appropriate.

9 Following a notification for the renewal of a consent in accordance with paragraph 2, the notifier may continue to place the GMOs on the market under the conditions specified in that consent until a final decision has been taken on the notification.

#### *Article 18*

### **Community procedure in case of objections**

1 In cases where an objection is raised and maintained by a competent authority or the Commission in accordance with Articles 15, 17 and 20, a decision shall be adopted and published within 120 days in accordance with the procedure laid down in Article 30(2). This decision shall contain the same information as in Article 19(3).

For the purpose of calculating the 120 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 which has been consulted

in accordance with Article 28 shall not be taken into account. The Commission shall state reasons in any request for further information and inform the competent authorities of its requests to the notifier. The period of time during which the Commission is awaiting the opinion of the Scientific Committee shall not exceed 90 days.

The period of time that the Council takes to act in accordance with the procedure laid down in Article 30(2) shall not be taken into account.

2 Where a favourable decision has been taken, the competent authority which prepared the report shall give consent in writing to the placing on the market or to the renewal of the consent, shall transmit it to the notifier and shall inform the other Member States and the Commission thereof within 30 days following the publication or notification of the decision.

### Article 19

#### Consent

1 Without prejudice to requirements under other Community legislation, only if a written consent has been given for the placing on the market of a GMO as or in a product may that product be used without further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to.

2 The notifier may proceed with the placing on the market only when he has received the written consent of the competent authority in accordance with Articles 15, 17 and 18, and in conformity with any conditions required in that consent.

3 The written consent referred to in Articles 15, 17 and 18 shall, in all cases, explicitly specify:

- a the scope of the consent, including the identity of the GMO(s) to be placed on the market as or in products, and their unique identifier;
- b the period of validity of the consent;
- c the conditions for the placing on the market of the product, including any specific condition of use, handling and packaging of the GMO(s) as or in products, and conditions for the protection of particular ecosystems/environments and/or geographical areas;
- d that, without prejudice to Article 25, the notifier shall make control samples available to the competent authority on request;
- e the labelling requirements, in compliance with the requirements laid down in Annex IV. The labelling shall clearly state that a GMO is present. The words 'This product contains genetically modified organisms' shall appear either on a label or in a document accompanying the product or other products containing the GMO(s);
- f monitoring requirements in accordance with Annex VII, including obligations to report to the Commission and competent authorities, the time period of the monitoring plan and, where appropriate, any obligations on any person selling the product or any user of it, *inter alia*, in the case of GMOs grown, concerning a level of information deemed appropriate on their location.

4 Member States shall take all necessary measures to ensure that the written consent and the decision referred to in Article 18, where applicable, are made accessible to the public and that the conditions specified in the written consent and the decision, where applicable, are complied with.

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## Article 20

### Monitoring and handling of new information

1 Following the placing on the market of a GMO as or in a product, the notifier shall ensure that monitoring and reporting on it are carried out according to the conditions specified in the consent. The reports of this monitoring shall be submitted to the Commission and the competent authorities of the Member States. On the basis of these reports, in accordance with the consent and within the framework for the monitoring plan specified in the consent, the competent authority which received the original notification may adapt the monitoring plan after the first monitoring period.

2 If new information has become available, from the users or other sources, with regard to the risks of the GMO(s) to human health or the environment after the written consent has been given, the notifier shall immediately take the measures necessary to protect human health and the environment, and inform the competent authority thereof.

In addition, the notifier shall revise the information and conditions specified in the notification.

3 If information becomes available to the competent authority which could have consequences for the risks of the GMO(s) to human health or the environment, or under the circumstances described in paragraph 2, it shall immediately forward the information to the Commission and the competent authorities of the other Member States and may avail itself of the provisions in Articles 15(1) and 17(7) where appropriate, when the information has become available before the written consent.

When the information has become available after the consent has been given, the competent authority shall within 60 days after receipt of the new information, forward its assessment report indicating whether and how the conditions of the consent should be amended or the consent should be terminated to the Commission which shall, within 30 days of its receipt, forward it to the competent authorities of the other Member States.

Comments or reasoned objections to further placing on the market of the GMO or on the proposal for amending the conditions of the consent shall, within 60 days following the circulation of the assessment report, be forwarded to the Commission which shall immediately forward them to all competent authorities.

The competent authorities and the Commission may discuss any outstanding issues with the aim of arriving at an agreement within 75 days from the date of circulation of the assessment report.

In the absence of any reasoned objection from a Member State or the Commission within 60 days following the date of circulation of the new information or if outstanding issues are resolved within 75 days, the competent authority which prepared the report shall amend the consent as proposed, shall transmit the amended consent to the notifier and shall inform the other Member States and the Commission thereof within 30 days.

4 So as to ensure its transparency, the results of the monitoring carried out under part C of the Directive shall be made publicly available.



## Article 21

### Labelling

1 Member States shall take all necessary measures to ensure that at all stages of the placing on the market, the labelling and packaging of GMOs placed on the market as or in products comply with the relevant requirements specified in the written consent referred to in Articles 15(3), 17(5) and (8), 18(2) and 19(3).

[<sup>F22</sup> 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).]

[<sup>F23</sup> 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).]

#### Textual Amendments

- F2** Substituted by [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.](#)

## Article 22

### Free circulation

Without prejudice to Article 23, Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive.

## Article 23

### Safeguard clause

1 Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that

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Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory.

The Member State shall ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including information to the public.

The Member State shall immediately inform the Commission and the other Member States of actions taken under this Article and give reasons for its decision, supplying its review of the environmental risk assessment, indicating whether and how the conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based.

[<sup>F2</sup> 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.]

#### Textual Amendments

- F2** Substituted by [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.](#)

### Article 24

#### Information to the public

1 Without prejudice to Article 25, upon receipt of a notification in accordance with Article 13(1), the Commission shall immediately make available to the public the summary referred to in Article 13(2)(h). The Commission shall also make available to the public assessment reports in the case referred to in Article 14(3)(a). The public may make comments to the Commission within 30 days. The Commission shall immediately forward the comments to the competent authorities.

2 Without prejudice to Article 25, for all GMOs which have received written consent for placing on the market or whose placing on the market was rejected as or in products under this Directive, the assessment reports carried out for these GMOs and the opinion(s) of the Scientific Committees consulted shall be made available to the public. For each product, the GMO or GMOs contained therein and the use or uses shall be clearly specified.

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- (1) [<sup>F1</sup>OJ L 268, 18.10.2003, p. 1.]
- (2) Council Directive 70/457/EEC of 29 September 1970 on the common catalogue of varieties of agricultural plant species (OJ L 225, 12.10.1970, p. 1). Directive as last amended by Directive 98/96/EC (OJ L 25, 1.2.1999, p. 27).
- (3) Council Directive 70/458/EEC of 29 September 1970 on the marketing of vegetable seed (OJ L 225, 12.10.1970, p. 7). Directive as last amended by Directive 98/96/EC.
- (4) Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material (OJ L 11, 15.1.2000, p. 17).

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#### Textual Amendments

- F1** Inserted by Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance).