# 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 D

## FINAL PROVISIONS

### *Article 25*

### Confidentiality

1 The Commission and the competent authorities shall not divulge to third parties any confidential information notified or exchanged under this Directive and shall protect intellectual property rights relating to the data received.

2 The notifier may indicate the information in the notification submitted under this Directive, the disclosure of which might harm his competitive positionand which should therefore be treated as confidential. Verifiable justification must be given in such cases.

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

4 In no case may the following information when submitted according to Articles 6, 7, 8, 13, 17, 20 or 23 be kept confidential:

— general description of the GMO or GMOs, name and address of the notifier, purpose of the release, location of release and intended uses;

— methods and plans for monitoring of the GMO or GMOs and for emergency response;

— environmental risk assessment.

5 If, for whatever reasons, the notifier withdraws the notification, the competent authorities and the Commission must respect the confidentiality of the information supplied.

### *Article 26*

### Labelling of GMOs referred to in Article 2(4), second subparagraph

1 The GMOs to be made available for operations referred to under Article 2(4), second subparagraph, shall be subject to adequate labelling requirements in accordance with the relevant sections of Annex IV in order to provide for clear information, on a label or in an accompanying document, on the presence of GMOs. To that effect the words ‘This product contains genetically modified organisms’ shall appear either on a label or in an accompanying document.

**[**[F1]2 The Commission is empowered to adopt delegated acts in accordance with Article 29a amending Annex IV by establishing specific labelling requirements referred to in paragraph 1, without duplicating or creating inconsistencies with labelling provisions laid down in existing Union legislation. In so doing, account should be taken, as appropriate, of labelling provisions established by Member States in accordance with Union legislation.**]**

**Textual Amendments**

**F1** Substituted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

## *[F2 Article 26a*

## Measures to avoid the unintended presence of GMOs

1 Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.

[F3 1a As from 3 April 2017 Member States in which GMOs are cultivated shall take appropriate measures in border areas of their territory with the aim of avoiding possible cross-border contamination into neighbouring Member States in which the cultivation of those GMOs is prohibited, unless such measures are unnecessary in the light of particular geographical conditions. Those measures shall be communicated to the Commission.]

2 The Commission shall gather and coordinate information based on studies at Community and national level, observe the developments regarding coexistence in the Member States and, on the basis of the information and observations, develop guidelines on the coexistence of genetically modified, conventional and organic crops.]

**Textual Amendments**

**F2** 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).

**F3** Inserted by Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (Text with EEA relevance).

## *[F3 Article 26b*

## Cultivation

1 During the authorisation procedure of a given GMO or during the renewal of consent/authorisation, a Member State may demand that the geographical scope of the written consent or authorisation be adjusted to the effect that all or part of the territory of that Member State is to be excluded from cultivation. That demand shall be communicated to the Commission at the latest 45 days from the date of circulation of the assessment report under Article 14(2) of this Directive, or from receiving the opinion of the European Food Safety Authority under Article 6(6) and Article 18(6) of Regulation (EC) No 1829/2003. The Commission shall present the demand of the Member State to the notifier/applicant and to the other Member States without delay. The Commission shall make the demand publicly available by electronic means.

2 Within 30 days from the presentation by the Commission of that demand, the notifier/applicant may adjust or confirm the geographical scope of its initial notification/application.

In the absence of confirmation, the adjustment of the geographical scope of the notification/application shall be implemented in the written consent issued under this Directive and, where applicable, the decision issued in accordance with Article 19 of this Directive as well as the decision of authorisation adopted under Articles 7 and 19 of Regulation (EC) No 1829/2003.

The written consent issued under this Directive and, where applicable, the decision issued in accordance with Article 19 of this Directive, as well as the decision of authorisation adopted under Articles 7 and 19 of Regulation (EC) No 1829/2003, shall then be issued on the basis of the adjusted geographical scope of the notification/application.

Where a demand in accordance with paragraph 1 of this Article is communicated to the Commission after the date of circulation of the assessment report under Article 14(2) of this Directive, or after receipt of the opinion of the European Food Safety Authority under Article 6(6) and Article 18(6) of Regulation (EC) No 1829/2003, the timelines set out in Article 15 of this Directive to issue the written consent or, as the case may be, in Articles 7 and 19 of Regulation (EC) No 1829/2003 to submit to the Committee a draft of the decision to be taken, shall be extended by a single period of 15 days regardless of the number of Member States presenting such demands.

3 Where no demand was made pursuant to paragraph 1 of this Article, or where the notifier/applicant has confirmed the geographical scope of its initial notification/application, a Member State may adopt measures restricting or prohibiting the cultivation in all or part of its territory of a GMO, or of a group of GMOs defined by crop or trait, once authorised in accordance with Part C of this Directive or with Regulation (EC) No 1829/2003, provided that such measures are in conformity with Union law, reasoned, proportional and non-discriminatory and, in addition, are based on compelling grounds such as those related to:

a environmental policy objectives;
b town and country planning;
c land use;
d socioeconomic impacts;
e avoidance of GMO presence in other products without prejudice to Article 26a;
f agricultural policy objectives;
g public policy.

Those grounds may be invoked individually or in combination, with the exception of the ground set out in point (g) which cannot be used individually, depending on the particular circumstances of the Member State, region or area in which those measures will apply, but shall, in no case, conflict with the environmental risk assessment carried out pursuant to this Directive or to Regulation (EC) No 1829/2003.

4 A Member State which intends to adopt measures pursuant to paragraph 3 of this Article shall first communicate a draft of those measures and the corresponding grounds invoked to the Commission. This communication may take place before the GMO authorisation procedure under Part C of this Directive or under Regulation (EC) No 1829/2003 has been completed. During a period of 75 days starting from the date of such communication:

a the Member State concerned shall refrain from adopting and implementing those measures;
b the Member State concerned shall ensure that operators refrain from planting the GMO or GMOs concerned; and
c the Commission may make any comments it considers appropriate.

On expiry of the 75-day period referred to in the first subparagraph, the Member State concerned may, for the whole duration of the consent/authorisation and as from the date of entry into force of the Union authorisation, adopt the measures either in the form originally proposed, or as amended to take account of any non-binding comments received from the Commission. Those measures shall be communicated to the Commission, the other Member States and the authorisation holder without delay.

Member States shall make publicly available any such measure to all operators concerned, including growers.

5 Where a Member State wishes all or part of its territory to be reintegrated into the geographical scope of the consent/authorisation from which it was previously excluded pursuant to paragraph 2, it may make a request to that effect to the competent authority which issued the written consent under this Directive or to the Commission if the GMO has been authorised under Regulation (EC) No 1829/2003. The competent authority which has issued the written consent or the Commission, as the case may be, shall amend the geographical scope of the consent or of the decision of authorisation accordingly.

6 For the purposes of an adjustment of the geographical scope of the consent/authorisation of a GMO under paragraph 5:

a for a GMO which has been authorised under this Directive, the competent authority which has issued the written consent shall amend the geographical scope of the consent accordingly and inform the Commission, the Member States and the authorisation holder once this is complete;

b for a GMO which has been authorised under Regulation (EC) No 1829/2003, the Commission shall amend the decision of authorisation accordingly, without applying the procedure set out in Article 35(2) of that Regulation. The Commission shall inform the Member States and the authorisation holder accordingly.

7 Where a Member State has revoked measures taken pursuant to paragraphs 3 and 4, it shall notify the Commission and the other Member States without delay.

8 Measures adopted under this Article shall not affect the free circulation of authorised GMOs as, or in, products.

**Textual Amendments**

**F3** Inserted by Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (Text with EEA relevance).

*Article 26c*

**Transitional measures**

1 From 2 April 2015 until 3 October 2015, a Member State may demand that the geographical scope of a notification/application submitted, or of an authorisation granted, under this Directive or Regulation (EC) No 1829/2003 before 2 April 2015 be adjusted. The Commission shall present the demand of the Member State to the notifier/applicant and to the other Member States without delay.

2 Where the notification/application is pending and the notifier/applicant has not confirmed the geographical scope of its initial notification/application within 30 days from the

communication of the demand referred to in paragraph 1 of this Article, the geographical scope of the notification/application shall be adjusted accordingly. The written consent issued under this Directive and, where applicable, the decision issued in accordance with Article 19 of this Directive as well as the decision of authorisation adopted under Articles 7 and 19 of Regulation (EC) No 1829/2003 shall then be issued on the basis of the adjusted geographical scope of the notification/application.

3 Where the authorisation has already been granted and the authorisation holder has not confirmed the geographical scope of the authorisation within 30 days from the communication of the demand referred to in paragraph 1 of this Article, the authorisation shall be modified accordingly. For a written consent under this Directive, the competent authority shall amend the geographical scope of the consent accordingly and shall inform the Commission, the Member States, and the authorisation holder once this is complete. For an authorisation under Regulation (EC) No 1829/2003, the Commission shall amend the decision of authorisation accordingly, without applying the procedure set out in Article 35(2) of that Regulation. The Commission shall inform the Member States and the authorisation holder accordingly.

4 Where no demand was made pursuant to paragraph 1 of this Article, or where a notifier/applicant or, as the case may be, an authorisation holder has confirmed the geographical scope of its initial application or, as the case may be, authorisation, paragraphs 3 to 8 of Article 26b shall apply mutatis mutandis.

5 This Article is without prejudice to the cultivation of any authorised GMO seeds and plant propagating materials which were planted lawfully before the cultivation of the GMO is restricted or prohibited in the Member State.

6 Measures adopted under this Article shall not affect the free circulation of authorised GMOs as, or in, products.**]**

**Textual Amendments**

**F3** Inserted by Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (Text with EEA relevance).

## *[F1 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).**]**

**Textual Amendments**

**F1** Substituted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

*Article 28*

**Consultation of Scientific Committee(s)**

1 In cases where an objection as regards the risks of GMOs to human health or to the environment is raised by a competent authority or the Commission and maintained in accordance with Article 15(1), 17(4), 20(3) or 23, or where the assessment report referred to in Article 14 indicates that the GMO should not be placed on the market, the relevant Scientific Committee(s) shall be consulted by the Commission, on its own initiative or at the request of a Member State, on the objection.

2 The relevant Scientific Committee(s) may also be consulted by the Commission, on its own initiative or at the request of a Member State, on any matter under this Directive that may have an adverse effect on human health and the environment.

3 The administrative procedures laid down in this Directive shall not be affected by paragraph 2.

*Article 29*

**Consultation of Committee(s) on Ethics**

1 Without prejudice to the competence of Member States as regards ethical issues, the Commission shall, on its own initiative or at the request of the European Parliament or the Council, consult any committee it has created with a view to obtaining its advice on the ethical implications of biotechnology, such as the European Group on Ethics in Science and New Technologies, on ethical issues of a general nature.

This consultation may also take place at the request of a Member State.

2 This consultation is conducted under clear rules of openness, transparency and public accessibility. Its outcome shall be accessible to the public.

3 The administrative procedures provided for in this Directive shall not be affected by paragraph 1.

*I[F4] Article 29a*

**Exercise of the delegation**

1 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2 The power to adopt delegated acts referred to in Article 16(2), Article 21(2) and (3), Article 26(2) and Article 27 shall be conferred on the Commission for a period of five years from 26 July 2019. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3 The delegations of power referred to in Article 16(2), Article 21(2) and (3), Article 26(2) and Article 27 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision.

It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4 Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[(1)].

5 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6 A delegated act adopted pursuant to Article 16(2), Article 21(2) and (3), Article 26(2) and Article 27 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.**]**

**Textual Amendments**

**F4** Inserted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

*Article 30*

**Committee procedure**

1 The Commission shall be assisted by a committee.

2 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.

[F5]3 . . . . . .

**Textual Amendments**

**F5** Deleted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

*Article 31*

**Exchange of information and reporting**

1 Member States and the Commission shall meet regularly and exchange information on the experience acquired with regard to the prevention of risks related to the release and the placing on the market of GMOs. This information exchange shall also cover experience gained from the implementation of Article 2(4), second subparagraph, environmental risk assessment, monitoring and the issue of consultation and information of the public.

Where necessary, guidance on the implementation of Article 2(4), second subparagraph, may be provided by the committee established under Article 30(1).

2 The Commission shall establish one or several register(s) for the purpose of recording the information on genetic modifications in GMOs mentioned in point A No 7 of Annex IV. Without prejudice to Article 25, the register(s) shall include a part which is accessible to the public. The detailed arrangements for the operation of the register(s) shall be decided in accordance with the procedure laid down in Article 30(2).

3 Without prejudice to paragraph 2 and point A No 7 of Annex IV,

a Member States shall establish public registers in which the location of the release of the GMOs under part B is recorded.

b Member States shall also establish registers for recording the location of GMOs grown under part C, *inter alia* so that the possible effects of such GMOs on the environment may be monitored in accordance with the provisions of Articles 19(3)(f) and 20(1). Without prejudice to such provisions in Articles 19 and 20, the said locations shall:

— be notified to the competent authorities, and

— be made known to the public

in the manner deemed appropriate by the competent authorities and in accordance with national provisions.

4 Every three years, Member States shall send the Commission a report on the measures taken to implement the provisions of this Directive. This report shall include a brief factual report on their experience with GMOs placed on the market in or as products under this Directive.

5 Every three years, the Commission shall publish a summary based on the reports referred to in paragraph 4.

6 The Commission shall send to the European Parliament and the Council, in 2003 and thereafter every three years, a report on the experience of Member States with GMOs placed on the market under this Directive.

7 When submitting this report in 2003, the Commission shall at the same time submit a specific report on the operation of part B and part C including an assessment of:

a all its implications, particularly to take account of the diversity of European ecosystems and the need to complement the regulatory framework in this field;

b the feasibility of various options to improve further the consistency and efficiency of this framework, including a centralised Community authorisation procedure and the arrangements for the final decision making by the Commission;

c whether sufficient experience has accumulated on the implementation of part B differentiated procedures to justify a provision on implicit consent in these procedures and on part C to justify the application of differentiated procedures; and

d the socioeconomic implications of deliberate releases and placing on the market of GMOs.

8 The Commission shall send to the European Parliament and the Council every year, a report on the ethical issues referred to in Article 29(1); this report may be accompanied, if appropriate, by a proposal with a view to amending this Directive.

*Article 32*

**Implementation of the Cartagena Protocol on biosafety**

1 The Commission is invited to bring forward as soon as possible and in any case before July 2001 a legislative proposal for implementing in detail the Cartagena Protocol on biosafety. The proposal shall complement and, if necessary, amend the provisions of this Directive.

2 This proposal shall, in particular, include appropriate measures to implement the procedures laid down in the Cartagena Protocol and, in accordance with the Protocol, require Community exporters to ensure that all requirements of the Advance Informed Agreement Procedure, as set out in Articles 7 to 10, 12 and 14 of the Cartagena Protocol, are fulfilled.

*Article 33*

**Penalties**

Member States shall determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive. Those penalties shall be effective, proportionate and dissuasive.

*Article 34*

**Transposition**

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 17 October 2002. They shall forthwith inform the Commission thereof.

When Member States adopt these measures they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

2 Member States shall communicate to the Commission the texts of the main provisions of domestic law which they adopt in the field covered by this Directive.

*Article 35*

**Pending notifications**

1 Notifications concerning placing on the market of GMOs as or in products received pursuant to Directive 90/220/EEC, and in respect of which the procedures of that Directive have not been completed by 17 October 2002 shall be subject to the provisions of this Directive.

2 By 17 January 2003 notifiers shall have complemented their notification in accordance with this Directive.

*Article 36*

**Repeal**

1 Directive 90/220/EEC shall be repealed on 17 October 2002.

2 References made to the repealed Directive shall be construed as being made to this Directive and should be read in accordance with the correlation table in Annex VIII.

*Article 37*

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

*Article 38*

This Directive is addressed to the Member States.

**(1)** **[**[F4]OJ L 123, 12.5.2016, p. 1.**]**

**Textual Amendments**

**F4** Inserted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).