

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 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.

[^{F12} [^{F2}The Commission is empowered to adopt delegated acts in accordance with Article 29a in order to supplement this Directive by establishing the criteria and information requirements referred to in paragraph 1, as well as any appropriate requirements for a summary of the dossier, after consultation of the relevant Scientific Committee. 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.

[^{F23} Before adopting delegated acts pursuant to paragraph 2, 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 experts referred to in Article 29a(4).]]

Textual Amendments

- F1** 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.](#)
- F2** 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 \(Text with EEA relevance\).](#)