

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 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).

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

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.