

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 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⁽¹⁾ and 70/458/EEC⁽²⁾.

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

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on an official national register of basic material in accordance with Council Directive 1999/105/EC⁽³⁾.

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- (1) 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](#)).
- (2) 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.
- (3) Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material ([OJ L 11, 15.1.2000, p. 17](#)).