

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.