

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 B

**DELIBERATE RELEASE OF GMOs FOR ANY OTHER
PURPOSE THAN FOR PLACING ON THE MARKET**

Article 5

1 Articles 6 to 11 shall not apply to medicinal substances and compounds for human use consisting of, or containing, a GMO or combination of GMOs provided that their deliberate release for any purpose other than that of being placed on the market is authorised by Community legislation which provides:

- a for a specific environmental risk assessment in accordance with Annex II and on the basis of the type of information specified in Annex III without prejudice to additional requirements provided for by the said legislation;
- b for explicit consent prior to release;
- c for a monitoring plan in accordance with the relevant parts of Annex III, with a view to detecting the effects of the GMO or GMOs on human health or the environment;
- d in an appropriate manner for requirements relating to treatment of new items of information, information to the public, information on the results of releases, and exchanges of information at least equivalent to those contained in this Directive and in the measures taken in accordance therewith.

2 Assessment of the risks to the environment presented by such substances and compounds shall be carried out in coordination with the national and Community authorities mentioned in this Directive.

3 Procedures ensuring conformity of the specific environmental risk assessment and equivalence with the provisions of this Directive must be provided for by the said legislation, which must refer to this Directive.