Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

1998/0072(COD) - 12/03/2001 - Final act

PURPOSE: to protect human health in view of the deliberate release into the environment of genetically modified organisms and the placing on the market of products either completely or partially genetically modified.

COMMUNITY MEASURE: Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

CONTENT: in accordance with the joint text approved by the Conciliation Committee, the Council formally adopted the directive (with the abstention of the Italian and the French delegates). This directive concerns the experimental release of GMOs (for research and development purposes) as well as the placing of GMOs on the market. In accordance with the precautionary principle, the new directive requires that an environmental risk assessment be carried out before the authorisation procedure. Furthermore, the directive foresees the identification and the elimination of GMOs which contain genes resistent to antibiotiques used in medical and veterinary treatments.

This elimination will take place before the end of 2004 in the case of GMOs on the market and before tne end of 2008 in the case of GMOs authorised for experimental research. GMOs cannot be released on a voluntary basis, into the environment or on the market, except in the case of the provisions in part B of the directive (deliberate release of GMOs for any other purpose than for placing on the market) or in part C (placing on the market of GMOs as or in products). Each part is characterised by a standard procedure according to which the principal competent authority (which,in the Member State, has received notification) gives its authorisation to voluntary release or placing on the market. Only one competent national authority is accredited to give an authorisation in the framework of the standard procedure in part B; however, all competent authorities participate in the differentiated procedure (simple) foreseen in part B and the standard procedure in part C. As regards placing on the market, which concerns all the Member States, authorisation is prohibited except in the case of possible objections or if a decision is taken by the committee procedure and the main competent authority does not oppose the plan to place GMOs as or in products on the market. Such authorisation is given after a large consultation (public, scientific committees) and for a maximum of 10 years for the first authorisation. After 10 years, a new request must be presented which, in principle, is subject to the same deadline of 10 years. The authorisation defines obligations relating to monitoring and labelling. Labelling is obligatory for all stages of the placing on the market and the label must indicate clearly that 'the product contains genetically modified organisms'. Thresholds may be established for each product below which products containing accidental or inevitable technical traces of GMOs need not be labelled. In addition to labelling requirements, provisions relating to the traceability of GMOs allow competent authorities to follow GMOs at all stages on the market. The directive provides for the obligatory public consultation for part B and C, both for the standard and the differentiatedprocedures. With regard to part B, information on all releases and their location, is accessible to the public via public registers. Member States shall also establish registers for recording the location of GMOs grown under part C. These are made known to the public in the manner deemed appropriate by the competent authorities and in accordance with the national provision. In part B, the standard procedure is supplemented by a differentiated procedure concerning, for example, obligations regarding information and deadlines, by which and after the obligatory consultation of scientifc committees and the public, a committee defines differentiated procedures which may apply in the case of releases fulfilling certain security criteria. The decisions of the committee are taken by a regulatory committee procedure. Additional procedures are foreseen for the renewing of authorisation, the treatment of authorisations granted in the framework of the directive in force as well as the monitoring and the treatment of new information and objections to GMOs which have already been authorised. The requirements contained in part C are not applicable to products authorised by other Community legislation which, from the point of view of evaluation and risk management, monitoring - where appropriate - labelling, public information and the safeguard clause, is 'equivalent' to the directive in question. A similar derogation relating to the provisions of part B is applicable to medicinal substances.

ENTRY INTO FORCE: 17.04.2001.

DEADLINE FOR TRANSPOSTION: 17.10.2001.