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

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission[(1)],

Having regard to the opinion of the Economic and Social Committee[(2)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty, in the light of the joint text approved by the Conciliation Committee on 20 December 2000[(3)],

Whereas:

(1) The Report of the Commission on the Review of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms[(4)], adopted on 10 December 1996, identified a number of areas where improvement is needed.

(2) There is a need for clarification of the scope of Directive 90/220/EEC and of the definitions therein.

(3) Directive 90/220/EEC has been amended. Now that new amendments are being made to the Directive, it is desirable, for reasons of clarity and rationalisation, that the provisions in question should be recast.

(4) Living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting other Member States. The effects of such releases on the environment may be irreversible.

(5) The protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release into the environment of genetically modified organisms (GMOs).

(6) Under the Treaty, action by the Community relating to the environment should be based on the principle that preventive action should be taken.

(7) It is necessary to approximate the laws of the Member States concerning the deliberate release into the environment of GMOs and to ensure the safe development of industrial products utilising GMOs.

(8) The precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it.

(9) Respect for ethical principles recognised in a Member State is particularly important. Member States may take into consideration ethical aspects when GMOs are deliberately released or placed on the market as or in products.

(10) For a comprehensive and transparent legislative framework, it is necessary to ensure that the public is consulted by either the Commission or the Member States during the preparation of measures and that they are informed of the measures taken during the implementation of this Directive.

(11) Placing on the market also covers import. Products containing and/or consisting of GMOs covered by this Directive cannot be imported into the Community if they do not comply with its provisions.

(12) Making GMOs available to be imported or handled in bulk quantities, such as agricultural commodities, should be regarded as placing on the market for the purpose of this Directive.

(13) The content of this Directive duly takes into account international experience in this field and international trade commitments and should respect the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. As soon as possible, and in any case before July 2001, the Commission should, in the context of the ratification of the Protocol, submit the appropriate proposals for its implementation.

(14) Guidance on the implementation of provisions related to the definition of the placing on the market in this Directive should be provided by the Regulatory Committee.

(15) When defining 'genetically modified organism' for the purpose of this Directive, human beings should not be considered as organisms.

(16) The provisions of this Directive should be without prejudice to national legislation in the field of environmental liability, while Community legislation in this field needs to be complemented by rules covering liability for different types of environmental damage in all areas of the European Union. To this end the Commission has undertaken to bring forward a legislative proposal on environmental liability before the end of 2001, which will also cover damage from GMOs.

(17) This Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record.

(18) It is necessary to establish harmonised procedures and criteria for the case-by-case evaluation of the potential risks arising from the deliberate release of GMOs into the environment.

(19) A case-by-case environmental risk assessment should always be carried out prior to a release. It should also take due account of potential cumulative long-term effects associated with the interaction with other GMOs and the environment.

(20) It is necessary to establish a common methodology to carry out the environmental risk assessment based on independent scientific advice. It is also necessary to establish common objectives for the monitoring of GMOs after their deliberate release or placing on the market as or in products. Monitoring of potential cumulative long-term effects should be considered as a compulsory part of the monitoring plan.

(21) Member States and the Commission should ensure that systematic and independent research on the potential risks involved in the deliberate release or the placing on the market of GMOs is conducted. The necessary resources should be secured for such research by Member States and the Community in accordance with their budgetary procedures and independent researchers should be given access to all relevant material, while respecting intellectual property rights.

(22) The issue of antibiotic-resistance genes should be taken into particular consideration when conducting the risk assessment of GMOs containing such genes.

(23) The deliberate release of GMOs at the research stage is in most cases a necessary step in the development of new products derived from, or containing GMOs.

(24) The introduction of GMOs into the environment should be carried out according to the 'step by step' principle. This means that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken.

(25) No GMOs, as or in products, intended for deliberate release are to be considered for placing on the market without first having been subjected to satisfactory field testing at the research and development stage in ecosystems which could be affected by their use.

(26) The implementation of this Directive should be carried out in close liaison with the implementation of other relevant instruments such as Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[(5)]. In this context the competent authorities concerned with the implementation of this Directive and of those instruments, within the Commission and at national level, should coordinate their action as far as possible.

(27) Concerning the environmental risk assessment for part C, risk management, labelling, monitoring, information to the public and safeguard clause, this Directive should be a point of reference for GMOs as or in products authorised by other Community legislation which should therefore provide for a specific environmental risk assessment, to be 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 laid down 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. To this end it

is necessary to provide for cooperation with the Community and Member State bodies mentioned in this Directive for the purpose of its implementation.

(28) It is necessary to establish a Community authorisation procedure for the placing on the market of GMOs, as or in products, where the intended use of the product involves the deliberate release of the organism(s) into the environment.

(29) The Commission is invited to conduct a study which should contain an assessment of various options to improve further the consistency and efficiency of this framework, particularly focusing on a centralised authorisation procedure for the placing on the market of GMOs within the Community.

(30) For sectoral legislation, monitoring requirements may have to be adapted to the product concerned.

(31) Part C of this Directive does not apply to products covered by Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[(6)], provided that it includes an environmental risk assessment equivalent to that provided for by this Directive.

(32) Any person, before undertaking a deliberate release into the environment of a GMO, or the placing on the market of GMOs, as or in products, where the intended use of the product involves its deliberate release into the environment, is to submit a notification to the national competent authority.

(33) That notification should contain a technical dossier of information including a full environmental risk assessment, appropriate safety and emergency response, and, in the case of products, precise instructions and conditions for use, and proposed labelling and packaging.

(34) After notification, no deliberate release of GMOs should be carried out unless the consent of the competent authority has been obtained.

(35) A notifier should be able to withdraw his dossier at any stage of the administrative procedures laid down in this Directive. The administrative procedure should come to an end when a dossier is withdrawn.

(36) Rejection of a notification for the placing on the market of a GMO as or in products by a competent authority should be without prejudice to the submission of a notification of the same GMO to another competent authority.

(37) An agreement should be reached at the end of the mediation period when no objections remain.

(38) Rejection of a notification following a confirmed negative assessment report should be without prejudice to future decisions based on the notification of the same GMO to another competent authority.

(39) In the interests of the smooth functioning of this Directive, Member States should be able to avail themselves of the various provisions for the exchange of information and experience before having recourse to the safeguard clause in this Directive.

(40) In order to ensure that the presence of GMOs in products containing, or consisting of, genetically modified organisms is appropriately identified, the words 'This product contains genetically modified organisms' should appear clearly either on a label or in an accompanying document.

(41) A system should be designed using the appropriate committee procedure, for the assignment of a unique identifier to GMOs, taking into account relevant developments in international fora.

(42) It is necessary to ensure traceability at all stages of the placing on the market of GMOs as or in products authorised under part C of this Directive.

(43) It is necessary to introduce into this Directive an obligation to implement a monitoring plan in order to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs as or in products after they have been placed on the market.

(44) Member States should be able, in accordance with the Treaty, to take further measures for monitoring and inspection, for example by official services, of the GMOs as or in products placed on the market.

(45) Means should be sought for providing possibilities for facilitating the control of GMOs or their retrieval in the event of severe risk.

(46) Comments by the public should be taken into consideration in the drafts of measures submitted to the Regulatory Committee.

(47) The competent authority should give its consent only after it has been satisfied that the release will be safe for human health and the environment.

(48) The administrative procedure for granting consents for the placing on the market of GMOs as or in products should be made more efficient and more transparent and first-time consent should be granted for a fixed period.

(49) For products for which consent has been granted for a fixed period a streamlined procedure should apply as regards the renewal of consent.

(50) The existing consents granted under Directive 90/220/EEC have to be renewed in order to avoid disparities between consents granted under that Directive and those pursuant to this Directive and in order to take full account of the conditions of consent under this Directive.

(51) Such renewal requires a transitional period during which existing consents granted under Directive 90/220/EEC remain unaffected.

(52) When a consent is renewed, it should be possible to revise all the conditions of the original consent, including those related to monitoring and the time limitation of the consent.

(53) Provision should be made for consultation of the relevant Scientific Committee(s) established by Commission Decision 97/579/EC[(7)] on matters which are likely to have an impact on human health and/or the environment.

(54) The system of exchange of information contained in notifications, established under Directive 90/220/EEC, has been useful and should be continued.

(55) It is important to follow closely the development and use of GMOs.

(56) When a product containing a GMO, as or in products, is placed on the market, and where such a product has been properly authorised under this Directive, a Member State may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive. A safeguard procedure should be provided in case of risk to human health or the environment.

(57) The Commission's European Group on Ethics in Science and New Technologies should be consulted with a view to obtaining advice on ethical issues of a general nature regarding the deliberate release or placing on the market of GMOs. Such consultations should be without prejudice to the competence of Member States as regards ethical issues.

(58) Member States should be able to consult any committee they have established with a view to obtaining advice on the ethical implications of biotechnology.

(59) The measures necessary for the implementation of this Directive are to be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(8)].

(60) The information exchange set up under this Directive should also cover experience gained with the consideration of ethical aspects.

(61) In order to increase the effective implementation of the provisions adopted under this Directive it is appropriate to provide for penalties to be applied by Member States, including in the event of release or placing on the market contrary to the provisions of this Directive, particularly as a result of negligence.

(62) A report to be issued every three years by the Commission, taking into account the information provided by Member States, should contain a separate chapter regarding the socioeconomic advantages and disadvantages of each category of GMOs authorised for placing on the market, which will take due account of the interest of farmers and consumers.

(63) The regulatory framework for biotechnology should be reviewed so as to identify the feasibility of improving further the consistency and efficiency of that framework. Procedures may need to be adapted so as to optimise efficiency, and all options which might achieve that should be considered,

HAVE ADOPTED THIS DIRECTIVE:

(**1**) OJ C 139, 4.5.1998, p. 1.

(**2**) OJ C 407, 28.12.1998, p. 1.

(**3**) Opinion of the European Parliament of 11 February 1999 (OJ C 150, 28.5.1999, p. 363), Council Common Position of 9 December 1999 (OJ C 64, 6.3.2000, p. 1) and Decision of the European Parliament of 12 April 2000 (OJ C 40, 7.2.2001, p. 123). Decision of the European Parliament of 14 February 2001 and Decision of the Council of 15 February 2001.

(**4**) OJ L 117, 8.5.1990, p. 15. Directive as last amended by Commission Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72).

(**5**) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 1999/80/EC (OJ L 210, 10.8.1999, p. 13).

(**6**) OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).

(**7**) OJ L 237, 28.8.1997, p. 18.

(**8**) OJ L 184, 17.7.1999, p. 23.