Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast) (Text with EEA relevance)

DIRECTIVE 2009/41/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 6 May 2009

on the contained use of genetically modified micro-organisms

(Recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 175(1) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms[(3)] has been substantially amended several times[(4)]. Since further amendments are to be made, it should be recast in the interests of clarity.

(2) Under the Treaty, action by the Community relating to the environment must be based on the principle that preventive action is to be taken and must have as its objective, among other things, the preservation, protection and improvement of the environment and the protection of human health.

(3) Measures concerning the evaluation and best use of biotechnology with regard to the environment are a priority area on which Community action should concentrate.

(4) The development of biotechnology is such as to contribute to the economic expansion of the Member States. This involves the use of genetically modified micro-organisms (GMMs) in operations of various types and scales.

(5) The contained use of GMMs should be such as to limit their possible negative consequences for human health and the environment, due attention being given to the prevention of accidents and the control of waste.

(6) GMMs which are disposed of without appropriate provisions for specific containment measures to limit their contact with the general population and the environment do not

fall within the scope of this Directive. Other Community legislation such as 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[(5)] may apply.

(7) Micro-organisms, if released into the environment in one Member State in the course of their contained use, may reproduce and spread, crossing national frontiers and thereby affecting other Member States.

(8) In order to bring about the safe development of biotechnology throughout the Community, it is necessary to establish common measures for the evaluation and reduction of the potential risks arising in the course of all operations involving the contained use of GMMs and to set appropriate conditions of use.

(9) The precise nature and scale of risks associated with the contained use of GMMs are not yet fully known and the risk involved must be assessed on a case-by-case basis. In order to evaluate the risk to human health and the environment, it is necessary to lay down requirements for risk assessment.

(10) Contained uses of GMMs should be classified in relation to the risks they present to human health and the environment. Such classification should be in line with international practice and based on an assessment of the risk.

(11) In order to ensure a high level of protection, the containment and other protective measures applied to a contained use must correspond to the classification of the contained use. Where there is any uncertainty, the appropriate containment and other protective measures for the higher classification should be applied until less stringent measures are justified by appropriate data.

(12) For all activities involving GMMs the principles of good microbiological practice and good occupational safety and hygiene should apply in accordance with relevant Community legislation.

(13) Appropriate containment measures should be applied at the various stages of an operation to control emissions and the disposal of material from contained uses of GMMs, and to prevent accidents.

(14) Any person, before undertaking for the first time the contained use of a GMM in a particular installation, should forward a notification to the competent authority so that the authority may satisfy itself that the proposed installation is appropriate for the purposes of carrying out the activity in a manner that does not present a hazard to human health and the environment.

(15) It is also necessary to establish appropriate procedures for the case-by-case notification of specific operations involving the contained use of GMMs, taking account of the degree of risk involved.

(16) In the case of operations involving high risk, the consent of the competent authority should be given.

(17) The containment and other protective measures applied to contained uses should be reviewed periodically.

(18) It may be considered appropriate to consult the public on the contained use of GMMs.

(19) People employed in contained uses should be consulted in accordance with the requirements of relevant Community legislation, in particular Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)[(6)].

(20) Appropriate measures should be taken to inform any person liable to be affected by an accident on all matters relating to safety.

(21) Emergency plans should be established to deal effectively with accidents.

(22) If an accident occurs, the user should immediately inform the competent authority and communicate the information necessary for assessing the impact of that accident and for taking the appropriate action.

(23) It is appropriate for the Commission, in consultation with the Member States, to establish a procedure for the exchange of information on accidents and for the Commission to set up a register of such accidents.

(24) The contained use of GMMs throughout the Community should be monitored, and to this end Member States should supply certain information to the Commission.

(25) In order to be considered safe for human health and the environment, GMMs should meet the list of criteria as defined in Annex II, Part B. To take account of the pace at which biotechnology is advancing, the nature of the criteria to be developed and the limited scope of that list, it is appropriate for the Council to revise those criteria, which should, where necessary, be supplemented by guidance notes to facilitate their application.

(26) The measures necessary for the implementation of this Directive should 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[(7)].

(27) In particular, the Commission should be empowered to adopt the amendments necessary to adapt Annexes II, III, IV and V to technical progress, and to adapt Annex II, Part C. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(28) The new elements introduced into this Directive concern only the committee procedures. They therefore do not need to be transposed by the Member States.

(29) This Directive should be without prejudice to the obligations of the Member States relating to the time limits for transposition into national law of the Directives set out in Annex VI, Part B,

HAVE ADOPTED THIS DIRECTIVE:

(**1**) OJ C 162, 25.6.2008, p. 85.

(**2**) Opinion of the European Parliament of 21 October 2008 (not yet published in the Official Journal) and Council Decision of 30 March 2009.

(**3**) OJ L 117, 8.5.1990, p. 1.

(**4**) See Annex VI, Part A.

(**5**) OJ L 106, 17.4.2001, p. 1.

(**6**) OJ L 262, 17.10.2000, p. 21.

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