Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (repealed)

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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 100a 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 189b of the Treaty[(3)] in the light of the joint text approved on 16 December 1997 by the Conciliation Committee,

(1) Whereas, in their resolution of 1 February 1993 on a Community programme of policy and action in relation to the environment and sustainable development[(4)], the Council and the representatives of the Governments of the Member States, meeting within the Council, approved the general approach and strategy of the programme presented by the Commission, in which the need for risk management of non-agricultural pesticides is emphasised;

(2) Whereas, both when the eighth Amendment[(5)] to Council Directive 76/769/EEC of 27 July 1976, on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of dangerous substances and preparations[(6)] was adopted in 1989 and during the discussion in the Council on Directive 91/414/EEC concerning the placing of plant protection products on the market[(7)], the Council expressed concern at the lack of harmonised Community provisions for biocides, formerly known as non-agricultural pesticides, and invited the Commission to examine the situation in Member States and the possibility for action at Community level;

(3) Whereas biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured products; whereas biocidal products can pose risks to humans, animals and the environment in a variety of ways due to their intrinsic properties and associated use patterns;

(4) Whereas the Commission review showed differences in the regulatory situation in the Member States; whereas such differences may constitute barriers not only to trade in biocidal products but also to trade in products treated with them, thereby affecting the functioning of the internal market; whereas, therefore, the Commission proposed the

development of a framework of rules relating to the placing on the market for use of biocidal products, taking as a condition a high level of protection for humans, animals and the environment; whereas, having regard to the principle of subsidiarity, decisions taken at Community level should be restricted to those necessary for the proper functioning of the common market and to avoid duplication of work by Member States; whereas a directive on biocidal products is the most appropriate way of establishing such a framework;

(5) Whereas the framework of rules should provide that biocidal products should not be placed on the market for use unless they have complied with the relevant procedures of this Directive;

(6) Whereas, to take account of the specific nature of some biocidal products and the risks associated with their proposed use, it is appropriate to provide for simplified authorisation procedures, including registration;

(7) Whereas it is appropriate that the applicant submit dossiers which contain information which is necessary to evaluate the risks that will arise from proposed uses of the product; whereas a common core data set for active substances and for biocidal products in which they are contained is necessary so as to assist both the applicants seeking authorisation and those carrying out the evaluation to decide on the authorisation; whereas, furthermore, specific data requirements need to be elaborated for each of the product types covered by this Directive;

(8) Whereas it is necessary, when biocidal products are being authorised, to make sure that, when properly used for the purpose intended, they are sufficiently effective and have no unacceptable effect on the target organisms such as resistance or unacceptable tolerance, and, in the case of vertebrate animals, unnecessary suffering and pain, and have, in the light of current scientific and technical knowledge, no unacceptable effect on the environment and, in particular, on human or animal health;

(9) Whereas it is necessary to provide common principles for the evaluation and authorisation of biocidal products to ensure a harmonised approach by Member States;

(10) Whereas Member States should not be prevented from imposing additional requirements on the use of biocidal products in so far as these additional requirements are in conformity with Community law and in particular do not run counter to the provisions of this Directive; whereas such provisions are intended to protect the environment and human and animal health by means such as epidemic control and food and feedingstuff protection;

(11) Whereas, in the light of the diversity of both the active substances and the biocidal products concerned, the data and test requirements should suit the individual circumstances and result in an overall risk assessment;

(12) Whereas it is necessary to establish a Community list of active substances permitted for inclusion in biocidal products; whereas a Community procedure must be laid down for assessing whether or not an active substance can be entered in the Community list; whereas the information that interested parties must submit with a view to admission of an active substance to the list has to be specified; whereas active substances on the list

should be reviewed periodically, and, if appropriate, compared with each other under specific conditions, to take account of developments in science and technology;

(13) Whereas, when due account is taken of products which pose only a low risk, their active substances should be incorporated in a specific annex; whereas substances the main use of which is non-pesticidal but which have some minor use as a biocide either directly, or in a product consisting of an active substance and a simple diluent should be incorporated in a separate specific annex;

(14) Whereas when an active substance is evaluated for its entry or otherwise in the relevant annexes of the Directive, it is necessary for such an evaluation to cover, where appropriate, the same aspects as those covered by the evaluation made under Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[(8)] and Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances[(9)] as far as the risk assessment is concerned; whereas, therefore, the risks associated with the production, use and disposal of the active substance and materials treated with it are to be considered in a similar way as they are in the aforementioned legislation;

(15) Whereas it is in the interest of the free circulation of biocidal products, as well as of materials treated with them, that authorisation granted by one Member State should be recognised by other Member States subject to the specific conditions contained in this Directive;

(16) Whereas, while envisaging harmonised provisions for all biocidal product types, including those intended to control vertebrates, the actual use of such types might give rise to concern; whereas therefore Member States should be allowed, subject to the Treaty, to derogate from the principle of mutual recognition for biocidal products falling under three particular types of biocides whenever intended to control particular kinds of vertebrates, in so far as such derogations are justified and do not jeopardise the purpose of this Directive;

(17) Whereas it is therefore desirable that a system for the mutual exchange of information should be established and that Member States and the Commission should make available to each other on request the particulars and scientific documentation submitted in connection with applications for authorisation of biocidal products;

(18) Whereas it should be possible for Member States to authorise, for a limited period of time, biocidal products which do not comply with the abovementioned conditions, especially in the event of an unforeseen danger threatening humans, animals or the environment which cannot be contained by other means; whereas the Community procedure should not prevent Member States from authorising, for a limited period of time for use in their territory, biocidal products containing an active substance not yet entered in the Community list, provided that a dossier meeting Community requirements has been submitted and the Member State concerned believes that the active substance and the biocidal product satisfy the Community conditions set for them;

(19) Whereas it is essential that this Directive help to minimise the number of tests on animals and that testing should be made dependent on the purpose and use of a product;

(20) Whereas close coordination should be ensured with other Community legislation and in particular with Directive 91/414/EEC, the Directives concerned with the protection of water and those concerned with the contained use and deliberate release of genetically modified organisms;

(21) Whereas the Commission is to draw up technical notes for guidance in particular on the implementation of the authorisation procedures, the entry of active substances in the appropriate Annexes, the Annexes relating to data requirements and the Annex dealing with the common principles;

(22) Whereas, in order to ensure that the requirements laid down in respect of authorised biocidal products are satisfied when they are placed on the market, Member States should make provision for appropriate control and inspection arrangements;

(23) Whereas the implementation of this Directive, the adaptation of its Annexes to the development of technical and scientific knowledge and the inclusion of active substances in the appropriate Annexes necessitate close cooperation between the Commission, the Member States and the applicants; whereas, in cases where the procedure of the Standing Committee on Biocidal Products is to be applied, this constitutes a suitable basis for such cooperation;

(24) Whereas an agreement on a *modus vivendi* between the European Parliament, the Council and the Commission concerning the implementing measures for acts adopted in accordance with the procedure laid down in Article 189b of the EC Treaty was reached on 20 December 1994[(10)];

(25) Whereas the Commission will apply the *modus vivendi* to the implementing measures flowing from this Directive that it envisages adopting, including those concerning Annexes IA and IB;

(26) Whereas, since the full implementation of this Directive, and especially the review programme, will not be achieved for several years, Directive 76/769/EEC provides a framework to complement the development of the positive list by limitations of the marketing and use of certain active substances and products or groups thereof;

(27) Whereas the review programme on active substances will need to take account of other work programmes within the framework of other Community legislation concerned with the review or authorisation of substances and products or relevant international Conventions;

(28) Whereas the costs of the procedures associated with the operation of the Directive need to be recovered from those seeking to place, or placing, biocidal products on the market and from those supporting the entries of active substances in the relevant Annexes;

(29) Whereas minimum rules concerning the use of biocidal products at work are laid down under Directives on health and safety at work; whereas it is desirable to develop further rules in this area,

HAVE ADOPTED THIS DIRECTIVE:

(**1**) OJ C 239, 3.9.1993, p. 3, OJ C 261, 6.10.1995, p. 5 and OJ C 241, 20.8.1996, p. 8.

(**2**) OJ C 195, 18.7.1994, p. 70 and OJ C 174, 17.6.1996, p. 32.

(**3**) Opinion of the European Parliament of 18 April 1996 (OJ C 141, 13.5.1996, p. 191), Council common position of 20 December 1996 (OJ C 69, 5.3.1997, p. 13) and Decision of the European Parliament of 13 May 1997 (OJ C 167, 2.6.1997, p. 24). Council Decision of 18 December 1997. Decision of the European Parliament of 14 January 1998.

(**4**) OJ C 138, 17.5.1993, p. 1.

(**5**) OJ L 398, 30.12.1989, p. 19.

(**6**) OJ L 262, 27.9.1976, p. 201. Directive as last amended by Directive 97/16/EC (OJ L 116, 6.5.1997, p. 31).

(**7**) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Directive 96/68/EC (OJ L 277, 30.10.1996, p. 25).

(**8**) OJ L 154, 5.6.1992, p. 1.

(**9**) OJ L 84, 5.4.1993, p. 1.

(**10**) OJ C 102, 4.4.1996, p. 1.