COUNCIL DIRECTIVE 94/43/EC

of 27 July 1994

establishing Annex VI to Directive 91/414/EEC concerning the placing of plant protection products on the market

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1], and in particular Article 18 (1) thereof,

Having regard to the proposal from the Commission,

Whereas Annex VI to Directive 91/414/EEC lays down uniform principles aiming to ensure that the Member States, in deciding on authorizations for plant protection products, apply the requirements of Article 4 (1) (b), (c), (d) and (e) of the Directive in an equivalent manner and at the high level of protection of human and animal health and the environment sought by the Directive;

Whereas it is therefore necessary to lay down detailed principles concerning the evaluation of information on plant protection products supplied by applicants and the decision to be made on authorization on the basis of the results of that evaluation;

Whereas such principles have to be laid down for each of the different requirements provided for in Article 4 (1) (b), (c), (d) and (e);

Whereas, initially, it is desirable to lay down uniform principles for chemical plant protection products only; whereas it therefore remains for the uniform principles for products containing micro-organisms to be laid down in accordance with the same procedure as provided for in Article 18 (1) of the Directive 91/414/EEC;

Whereas the provisions of this Directive on the protection of water are without prejudice to Member States' obligations under the Directives concerning the protection of water, and in particular Directives 75/440/EEC [2], 80/68/EEC [3] and 80/778/EEC [4];

Whereas a review of the abovementioned Directives is necessary and this should be carried out as soon as possible;

Whereas, pending such review, the provisions of this Directive concerning the protection of water are transitional in nature;

Whereas it is important to evaluate the impact of the use of plant protection products on groundwater, but whereas the models currently available do not enable a precise estimate to be made of the foreseeable concentration in such water; whereas it is therefore necessary to re-examine the provisions of Part C, point 2.5.1.2 (b) of Annex VI to Directive 91/414/EEC as soon as models validated at Community level enable such concentration to be estimated precisely,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex VI to Directive 91/414/EEC is hereby established as set out in the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than one year after its entry into force.

[1] OJ No L 230, 19. 8. 1991, p. 1. Directive as amended by Commission Directive 93/71/EEC (OJ No L 221, 31. 8. 1993, p. 27).

[2] Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States (OJ No L 194, 25. 7. 1975, p. 26. Directive as last amended by Directive 91/692/EEC (OJ No L 377, 31. 12. 1991, p. 48).

[3] Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances (OJ No L 20, 26. 1. 1980, p. 43). Directive as last amended by Directive 91/692/EEC (OJ No L 377, 31. 12. 1991, p. 48).

[4] Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption (OJ No L 229, 30. 8. 1980, p. 11). Directive as last amended by Directive 91/692/EEC (OJ No L 377, 31. 12. 1991, p. 48).

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

Article 3

This Directive shall enter into force on the date of its publication in the *Official Journal of the European Communities.*

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 27 July 1994.

For the Council,
The President
Th. WAIGEL

ANNEX

'ANNEX VI

UNIFORM PRINCIPLES FOR EVALUATION AND AUTHORIZATION OF PLANT PRODUCTION PRODUCTS

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A. INTRODUCTION

1. The principles developed in this Annex aim to ensure that evaluations and decisions with regard to authorization of plant protection products, provided they are chemical preparations, result in the implementation of the requirements of Article 4 (1) (b), (c), (d) and (e) of this Directive by all the Member States at the high level of protection of human and animal health and the environment.

2. In evaluating applications and granting authorizations Member States shall:

   (a) — ensure that the dossier supplied is in accordance with the requirements of Annex III, at the latest at the time of finalization of the evaluation for the purpose of decision-making without prejudice, where relevant, to the provisions of Article 13 (1) (a), (4) and (6) of this Directive,

   — ensure that the data submitted are acceptable in terms of quantity, quality, consistency and reliability and sufficient to permit a proper evaluation of the dossier,

   — evaluate, where relevant, justifications submitted by the applicant for not supplying certain data;

   (b) take into account the Annex II data concerning the active substance in the plant protection product, submitted for the purpose of inclusion of the active substance concerned in Annex I, and the results of the evaluation of those data, without prejudice, where relevant, to the provisions of Article 13 (1) (b), (2), (3) and (6) of this Directive;

   (c) take into consideration other relevant technical or scientific information they can reasonably possess with regard to the performance of the plant protection product or to the potentially adverse effects of the plant protection product, its components or its residues.

3. Where in the specific principles on evaluation reference is made to Annex II data, this shall be understood as being the data referred to in point 2 (b).

4. Where the data and information provided are sufficient to permit completion of the evaluation for one of the proposed uses, applications must be evaluated and a decision made for the proposed use.

   Taking account of justifications provided and with the benefit of any subsequent clarifications, Member States shall reject applications for which the data gaps are such that it is not possible to finalize the evaluation and to make a reliable decision for at least one of the proposed uses.

5. During the process of evaluation and decision-making, Member States shall cooperate with the applicants in order to resolve any questions on the dossier quickly or to identify at an early stage any additional studies necessary for a proper evaluation of the dossier, or to amend any proposed conditions for the use of the plant protection product or to modify its nature or its composition in order to ensure full satisfaction of the requirements of this Annex or of this Directive.

   Member States shall normally come to a reasoned decision within 12 months of receiving a technically complete dossier. A technically complete dossier is one that satisfies all the requirements of Annex III.

6. The judgments made by the competent authorities of the Member States during the evaluation and decision-making process must be based on scientific principles, preferably recognized at international level (for example, by the EPPO), and be made with the benefit of expert advice.

B. EVALUATION

1. General principles

1. Having regard to current scientific and technical knowledge, Member States shall evaluate the information referred to in Part A, point 2, and in particular:

   (a) assess the performance in terms of efficacy and phytotoxicity of the plant protection product for each use for which authorization is sought; and

(b) identify the hazards arising, assess their significance and make a judgment as to the likely risks to humans, animals or the environment.

2. In accordance with the terms of Article 4 of this Directive, which *inter alia* specifies that Member States shall have regard to all normal conditions under which the plant protection product may be used, and to the consequences of its use, Member States shall ensure that evaluations carried out have regard to the proposed practical conditions of use and in particular to the purpose of use, the dose, the manner, frequency and timing of applications, and the nature and composition of the preparation. Whenever possible Memeber States shall also take into account the principles of integrated control.

3. In the evaluation of applications submitted, Member States shall have regard to the agricultural, plant health or environmental (including climatic) conditions in the areas of use.

4. In interpreting the results of evaluations, Member States shall take into consideration possible elements of uncertainty in the information obtained during the evaluation, in order to ensure that the chances of failing to detect adverse effects or of under-estimating their importance are reduced to a minimum. The decision-making process shall be examined to identify critical decision points or items of data for which uncertainties could lead to a false classification of risk.

   The first evaluation made shall be based on the best available data or estimates reflecting the realistic conditions of use of the plant protection product.

   This should be followed by a repeat evaluation, taking account of potential uncertainties in the critical data and of a range of use conditions that are likely to occur and resulting in a realistic worst-case approach, to determine whether it is possible that the initial evaluation could have been significantly different.

5. Where specific principles of Section 2 provide for the use of calculation models in the evaluation of a plant protection product, those models shall:

   — make a best possible estimation of all relevant processes involved taking into account realistic parameters and assumptions,

   — be submitted to an analysis as referred to in B, point 1.4,

   — be reliably validated with measurements carried out under circumstances relevant for the use of the model,

   — be relevant to the conditions in the area of use.

6. Where metabolites, degradation or reaction products are referred to in the specific principles, only those that are relevant for the proposed criterion shall be taken into consideration.

2. **Specific principles**

Member States shall, for the evaluation of the data and information submitted in support of applications, and without prejudice to the general principles of Section 1, implement the following principles.

2.1. *Efficacy*

2.1.1. Where the proposed use concerns the control of or protection against an organism, Member States shall evaluate the possibility that this organism could be harmful under the agricultural, plant health and environmental (including climatic) conditions in the area of the proposed use.

2.1.2. Where the proposed use concerns an effect other than the control of or protection against an organism, Member States shall evaluate whether significant damage, loss or inconvenience could occur under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use if the plant protection product were not used.

2.1.3. Member States shall evaluate the efficacy data on the plant protection product as provided for in Annex III having regard to the degree of control or the extent of the effect desired and having regard to the relevant experimental conditions such as: