COUNCIL DIRECTIVE 97/57/EC

of 22 September 1997

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, by the judgment of the Court of Justice of the European Communities of 18 June 1996 [2], Council Directive 94/43/EC [3] of 27 July 1994, establishing Annex VI to Directive 91/414/EEC, was annulled;

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 that 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 possible to lay down at this stage uniform principles for chemical plant protection products only; whereas therefore it 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 Directive 91/414/EEC; whereas such approach is in line with Directive 91/414/EEC, and in particular Article 23 (2) thereof;

Whereas in particular for all plant protection products a high level of protection for all groundwater must be satisfied under the conditions of use which will be laid down in the authorization; whereas therefore it must be provided that plant protection products may only be authorized when it is adequately demonstrated that their use in accordance with the conditions to be laid down in the authorization will not lead to concentrations of the active substance or of relevant metabolites, degradation or reaction products in groundwater which exceed the lower of the limit values for groundwater referred to in this Directive; whereas this applies as well for plant protection products containing active substances, already on the market two years after notification of Directive 91/414/EEC, which means that for such products an authorization can be granted only where it is adequately demonstrated that, under the new conditions of use which will be laid down in the authorization, the expected concentrations resulting exclusively from the new use will not exceed the lower of the limit values referred to in this Directive;

Whereas the provisions of this Directive concerning the protection of water, including the provisions related to monitoring, are without prejudice to Member States' obligations under the Directives concerned, and in particular Directives 75/440/EEC [4], 80/68/EEC [5] and 80/778/EEC [6];

Whereas a review of the abovementioned directives is in progress, and where necessary will have to be followed by an adaptation of this Directive;

Whereas a short implementation period is justified given that in the light of the decision of the Court of Justice of the European Communities of 18 June 1996 only those provisions concerning groundwater have been reviewed,

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.

[1] OJ L 230, 19. 8. 1991, p. 1. Directive as last amended by Commission Directive 96/68/EC (OJ L 277, 30. 10. 1996, p. 25).

[2] Judgment of 18 June 1996, Parliament/Council, C-303/94, ECR p. I-2943.

[3] OJ L 227, 1. 9. 1994, p. 31.

[4] 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 L 194, 25. 7. 1975, p. 26). Directive as last amended by Directive 91/692/EEC (OJ L 377, 31. 12. 1991, p. 48).

[5] Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances (OJ L 20, 26. 1. 1980, p. 43). Directive as last amended by Directive 91/692/EEC (OJ L 377, 31. 12. 1991, p. 48).

[6] Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption (OJ L 229, 30. 8. 1980, p. 11). Directive as last amended by Directive 91/692/EEC (OJ L 377, 31. 12. 1991, p. 48).

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 October 1997.

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, 22 September 1997.

For the Council

The President

F. BODEN

ANNEX

'ANNEX VI

UNIFORM PRINCIPLES FOR EVALUATION AND AUTHORIZATION OF PLANT PROTECTION PRODUCTS

CONTENTS

A. **INTRODUCTION**

B. **EVALUATION**

1. **General principles**

2. **Specific principles**

2.1. Efficacy

2.2. Absence of unacceptable effects on plants or plant products

2.3. Impact on vertebrates to be controlled

2.4. Impact on human or animal health

2.4.1. arising from the plant protection product

2.4.2. arising from residues

2.5. Influence on the environment

2.5.1. Fate and distribution in the environment

2.5.2. Impact on non-target species

2.6. Analytical methods

2.7. Physical and chemical properties

C. **DECISION-MAKING**

1. **General principles**

2. **Specific principles**

2.1. Efficacy

2.2. Absence of unacceptable effects on plants or plant products

2.3. Impact on vertebrates to be controlled

2.4. Impact on human or animal health

2.4.1. arising from the plant protection product

2.4.2. arising from residues

2.5. Influence on the environment

2.5.1. Fate and distribution in the environment

2.5.2. Impact on non-target species

2.6. Analytical methods

2.7. Physical and chemical properties

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, results 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 judgements 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 harzards 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 Member 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 priciples

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: