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

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:

— the choice of the crop or cultivar,

— the agricultural and environmental (including climatic) conditions,

— the presence and density of the harmful organism,

— the development stage of crop and organism,

— the amount of the plant protection product used,

— if required on the label, the amount of adjuvant added,

— the frequency and timing of the applications,

— the type of application equipment.

2.1.4. Member States shall evaluate the performance of the plant protection product in a range of agricultural, plant health and environmental (including climatic) conditions likely to be encountered in practice in the area of proposed use and in particular:

(i) the level, consistency and duration of the effect sought in relation to the dose in comparison with a suitable reference product or products and an untreated control;

(ii) where relevant, effect on yield or reduction of loss in storage, in terms of quantity and/or quality, in comparison with a suitable reference product or products and an untreated control.

Where no suitable reference product exists, Member States shall evaluate the performance of the plant protection product to determine whether there is a consistent and defined benefit under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use.

2.1.5. Where the product label includes requirements for use of the plant protection product with other plant protection products and/or with adjuvants as a tank mix, Member States shall make the evaluations referred to in points 2.1.1 to 2.1.4 in relation to the information supplied for the tank mix.

Where the product label includes recommendations for use of the plant protection product with other plant protection products and/or with adjuvants as a tank mix, Member States shall evaluate the appropriateness of the mix and of its conditions of use.

2.2. *Absence of unacceptable effects on plants or plant products*

2.2.1. Member States shall evaluate the degree of adverse effects on the treated crop after use of the plant protection product according to the proposed conditions of use in comparison, where relevant, with a suitable reference product or products, where they exist, and/or an untreated control.

(a) This evaluation will take into consideration the following information:

(i) the efficacy data provided for in Annex III;

(ii) other relevant information on the plant protection product such as nature of the preparation, dose, method of application, number and timing of applications;

(iii) all relevant information on the active substance as provided for in Annex II, including mode of action, vapour pressure, volatility and water solubility;

(b) This evaluation will include:

(i) the nature, frequency, level and duration of observed phytotoxic effects and the agricultural, plant health and environmental (including climatic) conditions that affect them;

(ii) the differences between main cultivars with regard to their sensitivity to phytotoxic effects;

(iii) the part of the treated crop or plant products where phytotoxic effects are observed;

(iv) the adverse impact on the yield of the treated crop or plant products in terms of quantity and/or quality;

(v) the adverse impact on treated plants or plant products to be used for propagation, in terms of viability, germination, sprouting, rooting and establishment;

(vi) where volatile products are concerned, the adverse impact on adjacent crops.

2.2.2. Where the available data indicate that the active substance or significant metabolites, degradation and reaction products persist in soils and/or in or on plant substances in significant quantities after use of the plant protection product according to the proposed conditions of use, Member States shall evaluate the degree of adverse effects on subsequent crops. This evaluation will be carried out as specified in point 2.2.1.

2.2.3. Where the product label includes requirements for use of the plant protection product with other plant protection products or with adjuvants as a tank mix, the evaluation as specified in point 2.1.1 will be carried out in relation to the information supplied for the tank mix.

2.3. *Impact on vertebrates to be controlled*

Where the proposed use of the plant protection product aims to have an effect on vertebrates, Member States shall evaluate the mechanism by which this effect is obtained and the observed effects on the behaviour and health of the target animals; when the intended effect is to kill the target animal they shall evaluate the time necessary to obtain the death of the animal and the conditions under which death occurs.

This evaluation will take into consideration the following information:

(i) all relevant information as provided for in Annex II and the results of the evaluation thereof, including the toxicological and metabolism studies;

(ii) all relevant information on the plant protection product as provided for in Annex III, including toxicological studies and efficacy data.

2.4. *Impact on human or animal health*

2.4.1. arising from the plant protection product

2.4.1.1. Member States shall evaluate operator exposure to the active substance and/or to toxicologically relevant compounds in the plant protection product likely to occur under the proposed conditions of use (including in particular dose, application method and climatic conditions) using by preference realistic data on exposure and, if such data are not available, a suitable, validated calculation model.

(a) This evaluation will take into consideration the following information:

(i) the toxicological and metabolism studies as provided for in Annex II and the results of the evaluation thereof including the acceptable operator exposure level (AOEL). The acceptable operator exposure level is the maximum amount of active substance to which the operator may be exposed without any adverse health effects. The AOEL is expressed as milligrams of the chemical per kilogram body weight of the operator. The AOEL is based on the highest level at which no adverse effect is observed in tests in the most sensitive relevant animal species or, if appropriate data are available, in humans;

(ii) other relevant information on the active substances such as physical and chemical properties;

(iii) the toxicological studies provided for in Annex III, including where appropriate dermal absorption studies;

(iv) other relevant information as provided for in Annex III such as:

— composition of the preparation,

— nature of the preparation,

— size, design and type of packaging,

— field of use and nature of crop or target,

— method of application including handling, loading and mixing of product,

— exposure reduction measures recommended,

— protective clothing recommendations,

— maximum application rate,

— minimum spray application volume stated on the label,

— number and timing of applications;

(b) This evaluation shall be made for each type of application method and application equipment proposed for use of the plant protection product as well as for the different types and sizes of containers to be used, taking account of mixing, loading operations, application of the plant protection product and cleaning and routine maintenance of application equipment.

2.4.1.2. Member States shall examine information relating to the nature and characteristics of the packaging proposed with particular reference to the following aspects:

— the type of packaging,

— its dimensions and capacity,

— the size of the opening,

— the type of closure,

— its strength, leakproofness and resistance to normal transport and handling,

— its resistance to and compatibility with the contents.

2.4.1.3. Member States shall examine the nature and characteristics of the protective clothing and equipment proposed with particular reference to the following aspects:

— obtainability and suitability,

— ease of wearing taking into account physical stress and climatic conditions.

2.4.1.4. Member States shall evaluate the possibility of exposure of other humans (bystanders or workers exposed after the application of the plant protection product) or animals to the active substance and/or to other toxicologically relevant compounds in the plant protection product under the proposed conditions of use.

This evaluation will take into consideration the following information:

(i) the toxicological and metabolism studies on the active substance as provided for in Annex II and the results of the evaluation thereof, including the acceptable operator exposure level;

(ii) the toxicological studies provided for in Annex III, including where appropriate dermal absorption studies;

(iii) other relevant information on the plant protection product as provided for in Annex III such as:

— re-entry periods, necessary waiting periods or other precautions to protect humans and animals,

— method of application, in particular spraying,

— maximum application rate,

— maximum spray application volume,

— composition of the preparation,

— excess remaining on plants and plant products after treatment,

— further activities whereby workers are exposed.

2.4.2. Arising from residues

2.4.2.1. Member States shall evaluate the specific information on toxicology as provided for in Annex II and in particular:

— the determination of an acceptable daily intake (ADI),

— the identification of metabolites, degradation and reaction products in treated plants or plant products,

— behaviour of residues of the active substance and its metabolites from the time of application until harvest, or in the case of post-harvest uses, until outloading of stored plant products.

2.4.2.2. Prior to evaluating the residue levels in the reported trials or in products of animal origin Member States shall examine the following information:

— data on the proposed good agricultural practice, including data on application as provided for in Annex III and proposed pre-harvest intervals for envisaged uses, or withholding periods or storage periods, in the case of post-harvest uses,

— nature of the preparation,

— analytical methods and the residue definition.

2.4.2.3. On the basis of suitable statistical models Member States shall evaluate the residue levels observed in the reported trials. This evaluation shall be made for each proposed use and shall take into consideration:

(i) the proposed conditions of use of the plant protection product;

(ii) the specific information on residues in or on treated plants, plant products, food and feed as provided for in Annex III and the distribution of residues between edible and non-edible parts;

(iii) the specific information on residues in or on treated plants, plant products, food and feed as provided for in Annex II and the results of the evaluation thereof;

(iv) the realistic possibilities of extrapolating data from one crop to another.

2.4.2.4. Member States shall evaluate the residue levels observed in products of animal origin, taking into consideration the information provided for in Annex III, Part A, point 8.4 and residues resulting from other uses.

2.4.2.5. Member States shall estimate the potential exposure of consumers through diet and, where relevant, other ways of exposure, using a suitable calculation model. This evaluation will take account, where relevant, of other sources of information such as other authorized uses of plant protection products containing the same active substance or which give rise to the same residues.

2.4.2.6. Member States shall, where relevant, estimate the exposure of animals, taking into account the residue levels observed in treated plants or plant products intended to be fed to animals.

2.5. *Influence on the environment*

2.5.1. Fate and distribution in the environment

In the evaluation of the fate and distribution of the plant protection product in the environment, Member States shall have regard to all aspects of the environment, including biota, and in particular to the following:

2.5.1.1. Member States shall evaluate the possibility of the plant protection product reaching the soil under the proposed conditions of use; if this possibility exists they shall estimate the rate and the route of degradation in the soil, the mobility in the soil and the change in the total concentration (extractable and non-extractable (*)) of the active substance and of relevant metabolites, degradation and reaction products that could be expected in the soil in the area of envisaged use after use of the plant protection product according to the proposed conditions of use.

This evaluation will take into consideration the following information:

(i) the specific information on fate and behaviour in soil as provided for in Annex II and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— molecular weight,

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

— volatilization rate,

— dissociation constant,

— photodegradation rate and identity of breakdown products,

— hydrolysis rate in relation to pH and identity of breakdown products;

(iii) all information on the plant protection product as provided for in Annex III, including the information on distribution and dissipation in soil;

(iv) where relevant, other authorized uses of plant protection products in the area of proposed use containing the same active substance or which give rise to the same residues.

(*) Non-extractable residues (sometimes referred to as "bound" or "non-extracted" residues) in plants and soils are defined as chemical species originating from pesticides used according to good agricultural practice that cannot be extracted by methods which do not significantly change the chemical nature of these residues. These non-extractable residues are not considered to include fragments through metabolic pathways leading to natural products.

2.5.1.2. Member States shall evaluate the possibility of the plant protection product reaching the groundwater under the proposed conditions of use; if this possibility exists, they shall estimate, using a suitable calculation model validated at Community level, the concentration of the active substance and of relevant metabolites, degradation and reaction products that could be expected in the groundwater in the area of envisaged use after use of the plant protection product according to the proposed conditions of use.

As long as there is no validated Community calculation model, Member States shall base their evaluation especially on the results of mobility and persistance in soil studies as provided for in Annexes II and III.

This evaluation will also take into consideration the following information:

(i) the specific information on fate and behaviour in soil and water as provided for in Annex II and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— molecular weight,

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

— volatilization rate,

— hydrolysis rate in relation to pH and identity of breakdown products,

— dissociation constant;

(iii) all information on the plant protection product as provided for in Annex III, including the information on distribution and dissipation in soil and water;

(iv) where relevant, other authorized uses of plant protection products in the area of envisaged use containing the same active substance or which give rise to the same residues;

(v) where relevant, data on dissipation including transformation and sorption in the saturated zone;

(vi) where relevant, data on the procedures for drinking water abstraction and treatment in the area of envisaged use;

(vii) where relevant, monitoring data on the presence or absence of the active substance and relevant metabolites, degradation or reaction products in groundwater as a result of previous use of plant protection products containing the same active substance or which give rise to the same residues; such monitoring data shall be interpreted in a consistent scientific way.

2.5.1.3. Member States shall evaluate the possibility of the plant protection product reaching surface water under the proposed conditions of use; if this possibility exists they shall estimate, using a suitable calculation model validated at Community level, the short-term and long-term predicted concentration of the active substance and of metabolites, degradation and reaction products that could be expected in the surface water in the area of envisaged use after use of the plant protection product according to the proposed conditions of use.

If there is no validated Community calculation model, Member States shall base their evaluation especially on the results of mobility and persistence in soil studies and the information on run-off and drift as provided for in Annexes II and III.

This evaluation will also take into consideration the following information:

(i) the specific information on fate and behaviour in soil and water as provided for in Annex II and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— molecular weight,

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

— volatilization rate,

— hydrolysis rate in relation to pH and identity of breakdown products,

— dissociation constant;

(iii) all relevant information on the plant protection product as provided for in Annex III, including the information on distribution and dissipation in soil and water;

(iv) possible routes of exposure:

— drift,

— run-off,

— overspray,

— discharge via drains,

— leaching,

— deposit in the atmosphere;

(v) where relevant, other authorized uses of plant protection products in the area of envisaged use containing the same active substance or which give rise to the same residues;

(vi) where relevant, data on the procedures for drinking water abstraction and treatment in the area of envisaged use.

2.5.1.4. Member States shall evaluate the possibility of the plant protection product being dissipated in the air under the proposed conditions of use; if this possibility exists they shall make the best possible estimation, using where appropriate a suitable, validated calculation model, of the concentration of the active substance and of relevant metabolites, degradation and reaction products that could be expected in the air after use of the plant protection product according to the proposed conditions of use.

This evaluation will take into consideration the following information:

(i) the specific information on fate and behaviour in soil, water and air as provided for in Annex II and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— vapour pressure,

— solubility in water,

— hydrolysis rate in relation to pH and identity of breakdown products,

— photochemical degradation in water and air and identity of breakdown products,

— octanol/water partition coefficient;

(iii) all relevant information on the plant protection product as provided for in Annex III, including the information on distribution and dissipation in air.

2.5.1.5. Member States shall evaluate the procedures for destruction or decontamination of the plant protection product and its packaging.

2.5.2. Impact on non-target species

When calculating toxicity/exposure ratios Member States shall take into consideration toxicity to the most sensitive relevant organism used in the tests.

2.5.2.1. Member States shall evaluate the possibility of exposure of birds and other terrestrial vertebrates to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the extent of the short-term and long-term risk to be expected for these organisms, including their reproduction, after use of the plant protection product according to the proposed conditions of use.

(a) This evaluation will take into consideration the following information:

(i) the specific information relating to toxicological studies on mammals and to the effects on birds and other non-target terrestrial vertebrates, including effects on reproduction, and other relevant information concerning the active substance as provided for in Annex II and the results of the evaluation thereof;

(ii) all relevant information on the plant protection product as provided for in Annex III, including the information on effects on birds and other non-target terrestrial vertebrates;

(iii) where relevant, other authorized uses of plant protection products in the area of envisaged use containing the same active substance or which give rise to the same residues;

(b) This evaluation will include:

(i) the fate and distribution, including persistence and bioconcentration, of the active substance and of relevant metabolites, breakdown and reaction products in the various parts of the environment after application of the plant protection product;

(ii) the estimated exposure of the species likely to be exposed at the time of application or during the period that residues are present, taking into account all relevant routes of exposure such as ingestion of the formulated product or treated food, predation on invertebrates, feeding on vertebrate prey, contact by overspraying or with treated vegetation;

(iii) a calculation of the acute, short-term and, where necessary, long-term toxicity/exposure ratio. The toxicity/exposure ratios are defined as respectively the quotient of LD_{50}, LC_{50} or non-observable effects of concentration (NOEC) expressed on an active substance basis and the estimated exposure expressed in mg/kg body weight.

2.5.2.2. Member States shall evaluate the possibility of exposure of aquatic organisms to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the degree of short-term and long-term risk to be expected for aquatic organisms after use of the plant protection product according to the proposed conditions of use.

(a) This evaluation will take into consideration the following information:

(i) the specific information relating to the effects on aquatic organisms as provided for in Annex II and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

— volatilization rate,

— KOC,

— biodegradation in aquatic systems and in particular the ready biodegradability,

— photodegradation rate and identity of breakdown products,

— hydrolysis rate in relation to pH and identity of breakdown products;

(iii) all relevant information on the plant protection product as provided for in Annex III and in particular the effects on aquatic organisms;

(iv) where relevant, other authorized uses of plant protection products in the area of envisaged use, containing the same active substance or which give rise to the same residues;

(b) This evaluation will include:

(i) the fate and distribution of residues of the active substance and of relevant metabolites, breakdown and reaction products in water, sediment or fish;

(ii) a calculation of the acute toxicity/exposure ratio for fish and Daphnia. This ratio is defined as the quotient of respectively acute LC_{50} or EC_{50} and the predicted short-term environmental concentration;

(iii) a calculation of the algal growth inhibition/exposure ratio for algae. This ratio is defined as the quotient of the EC_{50} and the predicted short-term environmental concentration;

(iv) a calculation of the long-term toxicity/exposure ratio for fish and Daphnia. The long-term toxicity/exposure ratio is defined as the quotient of the NOEC and the predicted long-term environmental concentration;

(v) where relevant, the bioconcentration in fish and possible exposure of predators of fish, including humans;

(vi) if the plant protection product is to be applied directly to surface water, the effect on the change of surface water quality, such as pH or dissolved oxygen content.

2.5.2.3. Member States shall evaluate the possibility of exposure of honeybees to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the short-term and long-term risk to be exptected for honeybees after use of the plant protection product according to the proposed conditions of use.

(a) This evaluation will take into consideration the following information:

(i) the specific information on toxicity to honeybees as provided for in Annex II and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

— photodegradation rate and identity of breakdown products,

— mode of action (e. g. insect growth regulating activity);

(iii) all relevant information on the plant protection product as provided for in Annex III, including the toxicity to honeybees;

(iv) where relevant, other authorized uses of plant protection products in the area of envisaged use, containing the same active substance or which give rise to the same residues;

(b) This evaluation will include:

(i) the ratio between the maximum application rate expressed in grammes of active substance per hectare and the contact and oral LD_{50} expressed in µg of active substance per bee (hazard quotients) and where necessary the persistence of residues on or, where relevant, in the treated plants;

(ii) where relevant, the effects on honeybee larvae, honeybee behaviour, colony survival and development after use of the plant protection product according to the proposed conditions of use.

2.5.2.4. Member States shall evaluate the possibility of exposure of beneficial arthropods other than honeybees to the plant protection product under the proposed conditions of use; if this possibility exists they will assess the lethal and sublethal effects on these organisms to be expected and the reduction in their activity after use of the plant protection product according to the proposed conditions of use.

This evaluation will take into consideration the following information:

(i) the specific information on toxicity to honeybees and other beneficial arthropods as provided for in Annex II and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

— photodegradation rate and identity of breakdown products,

— mode of action (e. g. insect growth regulating activity);

(iii) all relevant information on the plant protection product as provided for in Annex III such as:

— effects on beneficial arthropods other than bees,

— toxicity to honeybees,

— available data from biological primary screening,

— maximum application rate,

— maximum number and timetable of applications;

(iv) where relevant, other authorized uses of plant protection products in the area of envisaged use, containing the same active substance or which give rise to the same residues.

2.5.2.5. Member States shall evaluate the possibility of exposure of earthworms and other non-target soil macro-organisms to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the degree of short-term and long-term risk to be expected to these organisms after use of the plant protection product according to the proposed conditions of use.

(a) This evaluation will take into consideration the following information:

(i) the specific information relating to the toxicity of the active substance to earthworms and to other non-target soil macro-organisms as provided for in Annex II and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— solubility in water,

— octanol/water partition coefficient,

— Kd for adsorption,

— vapour pressure,

— hydrolysis rate in relation to pH and identity of breakdown products,

— photodegradation rate and identity of breakdown products,

— DT_{50} and DT_{90} for degradation in the soil;

(iii) all relevant information on the plant protection product as provided for in Annex III, including the effects on earthworms and other non-target soil macro-organisms;

(iv) where relevant, other authorized uses of plant protection products in the area of envisaged use, containing the same active substance or which give rise to the same residues;

(b) This evaluation will include:

(i) the lethal and sublethal effects,

(ii) the predicted initial and long-term environmental concentration,

(iii) a calculation of the actue toxicity/exposure ratio (defined as the quotient of LC_{50} and predicted initial environmental concentration) and of the long-term toxicity/exposure ratio (defined as the quotient of the NOEC and predicted long-term environmental concentration),

(iv) where relevant, the bioconcentration and persistence of residues in earthworms.

2.5.2.6. Member States shall, where the evaluation carried out under Part B, point 2.5.1.1, does not exclude the possibility of the plant protection product reaching the soil under the proposed conditions of use, evaluate the impact on microbial activity such as the impact on nitrogen and carbon mineralization processes in the soil after use of the plant protection product according to the proposed conditions of use.

This evaluation will take into consideration the following information:

(i) all relevant information on the active substance, including the specific information relating to the effects of non-target soil micro-organisms as provided for in Annex II and the results of the evaluation thereof;

(ii) all relevant information on the plant protection product as provided for in Annex III, including the effects on non-target soil micro-organisms;

(iii) where relevant, other authorized uses of plant protection products in the area of proposed use, containing the same active substance or which give rise to the same residues;

(iv) all available information from biological primary screening.

2.6. *Analytical methods*

Member States shall evaluate the analytical methods proposed for post-registration control and monitoring purposes, to determine:

2.6.1. for formulation analysis:

the nature and quantity of the active substance(s) in the plant protection product and, where appropriate, any toxicologically, ecotoxicologically or environmentally significant impurities and co-formulants.

This evaluation will take into consideration the following information:

(i) the data on analytical methods as provided for in Annex II and the results of the evaluation thereof;

(ii) the data on analytical methods as provided for in Annex III and in particular:

— the specificity and linearity of the proposed methods,

— the importance of interferences,

— the precision of the proposed methods (intra-laboratory repeatability and inter-laboratory reproducibility);

(iii) the limit of detection and determination of the proposed methods for impurities.

2.6.2. for residue analysis:

the residues of the active substance, metabolites, breakdown or reaction products resulting from authorized uses of the plant protection product and which are of toxicological, eco-toxicological or environmental significance.

This evaluation will take into consideration the following information:

(i) the data on analytical methods as provided for in Annex II and the results of the evaluation thereof;

(ii) the data on analytical methods as provided for in Annex III and in particular:

— the specificity of the proposed methods,

— the precision of the proposed methods (intra-laboratory repeatability and inter-laboratory reproducibility),

— the recovery rate of the proposed methods at appropriate concentrations;

(iii) the limit of detection of the proposed methods;

(iv) the limit of determination of the proposed methods.

2.7. *Physical and chemical properties*

2.7.1. Member States shall evaluate the actual active substance content of the plant protection product and its stability during storage.

2.7.2. Member States shall evaluate the physical and chemical properties of the plant protection product and in particular:

— where a suitable FAO specification exists, the physical and chemical properties addressed in that specification,

— where no suitable FAO specification exists, all the relevant physical and chemical properties for the formulation as referred to in the "Manual on the development and use of FAO specifications for plant protection products".

This evaluation will take into consideration the following information:

(i) the data on the physical and chemical properties of the active substance as provided for in Annex II and the results of the evaluation thereof;

(ii) the data on the physical and chemical properties of the plant protection product as provided for in Annex III.

2.7.3. Where proposed label claims include requirements or recommendations for use of the plant protection product with other plant protection products or adjuvants as a tank mix, the physical and chemical compatibility of the products in the mixture must be evaluated.

C. DECISION-MAKING

1. General principles

1. Where appropriate, Member States shall impose conditions or restrictions with the authorizations they grant. The nature and severity of these measures must be selected on the basis of, and be appropriate to, the nature and extent of the expected advantages and the risks likely to arise.

2. Member States shall ensure that, where necessary, decisions taken with respect to the granting of authorizations take account of the agricultural, plant health or environmental (including climatic) conditions in the areas of envisaged use. Such considerations may result

in specific conditions and restrictions of use, and, where necessary, in authorization being granted for some but not other areas within the Member State in question.

3. Member States shall ensure that the authorized amounts, in terms of rates and number of applications, are the minimum necessary to achieve the desired effect even where higher amounts would not result in unacceptable risks to human or animal health or to the environment. The authorized amounts must be differentiated according to, and be appropriate to, the agricultural, plant health or environmental (including climatic) conditions in the various areas for which an authorization is granted. However, the rates and the number of applications may not give rise to undesirable effects such as the development of resistance.

4. Member States shall ensure that decisions respect the principles of integrated control if the product is intended to be used in conditions where these principles are relied on.

5. Since the evaluation is to be based on data concerning a limited number of representative species, Member States shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species.

6. Before issuing an authorization, Member States shall ensure that the label of the product:

   — fulfils the requirements of Article 16 of this Directive,

   — also contains the information on protection of users required by Community legislation on worker protection,

   — specifies in particular the conditions or restrictions under which the plant protection product may or may not be used as referred to in points 1, 2, 3, 4 and 5 above.

   The authorization shall mention the particulars indicated in Article 6 (2) (g) and (h), (3) and (4) of Council Directive 78/631/EEC of 26 June 1978 on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides) [1] and in Article 16 (g) and (h) of Directive 91/414/EEC.

7. Before issuing authorizations, Member States shall:

   (a) ensure that the proposed packaging is in accordance with the provisions of Directive 78/631/EEC;

   (b) ensure that:

      — the procedures for destruction of the plant protection product,

      — the procedures for neutralization of the adverse effects of the product if it is accidentally dispersed, and

      — the procedures for the decontamination and destruction of the packagings,

      are in accordance with the relevant regulatory provisions.

8. No authorization shall be granted unless all the requirements referred to in Section 2 are satisfied. However:

   (a) when one or more of the specific decision-making requirements referred to in Part C, points 2.1, 2.2, 2.3 or 2.7, are not fully satisfied, authorizations shall be granted only where the advantages of the use of the plant protection product under the proposed conditions of use outweight the possible adverse effects of its use. Any restrictions on use of the product relating to non-compliance with some of the aforementioned requirements must be mentioned on the label, and non-compliance with the requirements referred to in point 2.7 must not compromise proper use of the product. These advantages can be in terms of:

      — advantages for and compatibility with integrated control measures or organic farming,

      — facilitating strategies to minimize the risk of development of resistance,

[1] OJ L 206, 29. 7. 1978, p. 13. Directive as last amended by Directive 92/32/EEC (OJ L 154, 5. 6. 1992, p. 1).

— the need for a greater diversity of types of active substances or biochemical modes of action, e.g. for use in strategies to avoid accelerated breakdown in the soil,

— reduced risk for operators and consumers,

— reduced contamination of the environment and reduced impact on non-target species;

(b) where the criteria referred to in Part C, point 2.6, are not fully satisfied because of limitations in current analytical science and technology, authorization shall be granted for a limited period if the methods submitted prove adequate for the purposes intended. In this case the applicant shall be given a time limit in which to develop and submit analytical methods that are in accordance with the criteria referred to above. The authorization will be reviewed on expiry of the time limit accorded to the applicant;

(c) where the reproducibility of the submitted analytical methods referred to in Part C, point 2.6, has only been verified in two laboratories, an authorization shall be granted for one year to permit the applicant to demonstrate the reproducibility of those methods in accordance with agreed criteria.

9. Where an authorization has been granted according to the requirements provided for in this Annex, Member States may, by virtue of Article 4 (6):

(a) define, where possible, preferably in close co-operation with the applicant, measures to improve the performance of the plant protection product, and/or

(b) define, where possible, in close co-operation with the applicant, measures to reduce further the exposure that could occur during and after use of the plant protection product.

Member States shall inform applicants of any measures identified under (a) or (b) and shall invite applicants to provide any supplementary data and information necessary to demonstrate peformance or potential risks arising under the changed conditions.

2. Specific principles

The specific principles shall apply without prejudice to the general principles referred to in Section 1.

2.1. *Efficacy*

2.1.1. Where the proposed uses include recommendations for the control of or protection against organisms which are not considered to be harmful on the basis of experience acquired or scientific evidence under normal agricultural, plant health and environmental (including climatic) conditions in the areas of proposed use or where the other intended effects are not considered to be beneficial under those conditions, no authorization shall be granted for those uses.

2.1.2. The level, consistency and duration of control or protection or other intended effects must be similar to those resulting from the use of suitable reference products. If no suitable reference product exists, the plant protection product must be shown to give a defined benefit in terms of the level, consistency and duration of control or protection or other intended effects under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use.

2.1.3. Where relevant, yield response when the product is used and reduction of loss in storage must be quantitatively and/or qualitatively similar to those resulting from the use of suitable reference products. If no suitable reference product exists, the plant protection product must be shown to give a consistent and defined quantitative and/or qualitative benefit in terms of yield response and reduction of loss in storage under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use.

2.1.4. Conclusions as to the performance of the preparation must be valid for all areas of the Member State in which it is to be authorized, and must hold for all conditions under which its use is proposed, except where the proposed label specifies that the preparation is intended for use in certain specified circumstances (e.g. light infestations, particular soil types or particular growing conditions).

2.1.5. Where proposed label claims include requirements for use of the preparation with other specified plant protection products or adjuvants as a tank mix, the mixture must achieve the desired effect and comply with the principles referred to in points 2.1.1 to 2.1.4.

Where proposed label claims include recommendations for use of the preparation with specified plant protection products or adjuvants as a tank mix, Member States shall not accept the recommendations unless they are justified.

2.2. *Absence of unacceptable effects on plants or plant products*

2.2.1. There must be no relevant phytotoxic effects on treated plants or plant products except where the proposed label indicates appropriate limitations of use.

2.2.2. There must be no reduction of yield at harvest due to phytotoxic effects below that which could be obtained without the use of the plant protection product, unless this reduction is compensated for by other advantages such as an enhancement of the quality of the treated plants or plant products.

2.2.3. There must be no unacceptable adverse effects on the quality of treated plants or plant products, except in the case of adverse effects on processing where proposed label claims specify that the preparation should not be applied to crops to be used for processing purposes.

2.2.4. There must be no unacceptable adverse effects on treated plants or plant products used for propagation or reproduction, such as effects on viability, germination, sprouting, rooting and establishment, except where proposed label claims specify that the preparation should not be applied to plants or plant products to be used for propagation or reproduction.

2.2.5. There must be no unacceptable impact on succeeding crops, except where proposed label claims specify that particular crops, which would be affected, should not be grown following the treated crop.

2.2.6. There must be no unacceptable impact on adjacent crops, except where proposed label claims specify that the preparation should not be applied when particular sensitive adjacent crops are present.

2.2.7. Where proposed label claims include requirements for use of the preparation with other plant protection products or adjuvants, as a tank mix, the mixture must comply with the principles referred to in points 2.2.1 to 2.2.6.

2.2.8. The proposed instructions for cleaning the application equipment must be both practical and effective so that they can be applied with ease so as to ensure the removal of residual traces of the plant protection product which could subsequently cause damage.

2.3. *Impact on vertebrates to be controlled*

An authorization for a plant protection product intended to eliminate vertebrates shall be granted only when:

— death is synchronous with the extinction of consciousness, or

— death occurs immediately, or

— vital functions are reduced gradually without signs of obvious suffering.

For repellant products, the intended effect shall be obtained without unnecessary suffering and pain for the target animals.

2.4. *Impact on human or animal health*

2.4.1. arising from the plant protection product

2.4.1.1. No authorization shall be granted if the extent of operator exposure in handling and using the plant protection product under the proposed conditions of use, including dose and application method, exceeds the AOEL.

Moreover, the conditions of the authorization shall be in compliance with the limit value established for the active substance and/or toxicologically relevant compound(s) of the product in accordance with Council Directive 80/1107/EEC of 27 November 1980 on the protection of workers from the risks related to exposure to chemical, physical and biological agents at

work (1) and in accordance with Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (sixth special directive within the meaning of Article 16 (2) of Directive 89/39/EEC) (2).

2.4.1.2. Where the proposed conditions of use require use of items of protective clothing and equipment, no authorization shall be granted unless those items are effective and in accordance with the relevant Community provisions and are readily obtainable by the user and unless it is feasible to use them under the circumstances of use of the plant protection product, taking into account climatic conditions in particular.

2.4.1.3. Plant protection products which because of particular properties or if mishandled or misused could lead to a high degree of risk must be subject to particular restrictions such as restrictions on the size of packaging, formulation type, distribution, use or manner of use. Moreover, plant protection products which are classified as very toxic may not be authorized for use by non-professional users.

2.4.1.4. Waiting and re-entry safety periods or other precautions must be such that the exposure of bystanders or workers exposed after the application of the plant protection product does not exceed the AOEL levels established for the active substance or toxicologically relevant compound(s) in the plant protection product nor any limit values established for those compounds in accordance with the Community provisions referred to in point 2.4.1.1.

2.4.1.5. Waiting and re-entry safety periods or other precautions must be established in such a way that no adverse impact on animals occurs.

2.4.1.6. Waiting and re-entry periods or other precautions to ensure that the AOEL levels and limit values are respected must be realistic; if necessary special precautionary measures must be prescribed.

2.4.2. arising from residues

2.4.2.1. Authorizations must ensure that residues occurring reflect the minimum quantities of the plant protection product necessary to achieve adequate control corresponding to good agricultural practice, applied in such a manner (including pre-harvest intervals or withholding periods or storage periods) that the residues at harvest, slaughter or after storage, as appropriate, are reduced to a minimum.

2.4.2.2. Where no Community maximum residue limit (MRL) (**) or provisional MRL (at national or at Community level) exists, Member States shall establish a provisional MRL in accordance with Article 4 (1) (f) of this Directive; conclusions as to the levels fixed must be valid for all circumstances which could influence the residue levels in the crop such as timing of application, application rate and frequency or manner of use.

(1) OJ L 327, 3. 12. 1980, p. 8. Directive as last amended by Directive 88/642/EEC (OJ L 356, 24. 12. 1988, p. 74).
(2) OJ L 196, 26. 7. 1990, p. 1. Directive as amended by Directive 97/42/EC (OJ L 179, 8. 7. 1997, p. 4).
(**) A Community MRL will mean an MRL established pursuant to Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables (1), Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals (2), Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin (3), Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal orgin (4), Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables (5) or Council Directive 91/132/EEC of 4 March 1991 amending Directive 74/63/EEC on undesirable substances and products in feedingstuffs (6).

(1) OJ L 340, 9. 12. 1976, p. 26. Directive as last amended by Directive 97/41/EC (OJ L 184, 12. 7. 1997, p. 33).
(2) OJ L 221, 7. 8. 1986, p. 37. Directive as last amended by Directive 97/41/EC (OJ L 184, 12. 7. 1997, p. 33).
(3) OJ L 221, 7. 8. 1986, p. 43. Directive as last amended by Directive 97/41/EC (OJ L 184, 12. 7. 1997, p. 33).
(4) OJ L 224, 18. 8. 1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 749/97 (OJ L 110, 26. 4. 1997, p. 24).
(5) OJ L 350, 14. 12. 1990, p. 71. Directive as amended by Directive 97/41/EC (OJ L 184, 12. 7. 1997, p. 33).
(6) OJ L 66, 13. 3. 1991, p. 16.

2.4.2.3. Where the new circumstances under which the plant protection product is to be used do not correspond to those under which a provisional MRL (at national or at Community level) was established previously, Member States shall not grant an authorization for the plant protection product unless the applicant can provide evidence that its recommended use will not exceed that MRL or unless a new provisional MRL has been established by the Member State or the Commission in accordance with Article 4 (1) (f) of this Directive.

2.4.2.4. Where a Community MRL exists Member States shall not grant an authorization for the plant protection product unless the applicant can provide evidence that its recommended use will not exceed that MRL, or unless a new Community MRL has been established in accordance with the procedure provided for in the relevant Community legislation.

2.4.2.5. In the cases referred to in points 2.4.2.2 and 2.4.2.3, each application for an authorization must be accompanied by a risk assessment taking into account worst-case potential exposure of consumers in the Member State concerned on the basis of good agricultural practice.

Taking into account all registered uses, the proposed use cannot be authorized if the best possible estimate of dietary exposure exceeds the ADI.

2.4.2.6. Where the nature of residues is affected during processing, a separate risk assessment may need to be carried out under the conditions provided for in point 2.4.2.5.

2.4.2.7. Where the treated plants or plant products are intended to be fed to animals, residues occurring shall not have an adverse effect on animal health.

2.5. *Influence on the environment*

2.5.1. Fate and distribution in the environment

2.5.1.1. No authorization shall be granted if the active substance and, where they are of significance from the toxicological, ecotoxicological or environmental point of view, metabolites and breakdown or reaction products, after use of the plant protection product under the proposed conditions of use:

— during tests in the field, persist in soil for more than one year (i.e. $DT_{90} >$ 1 year and $DT_{50} >$ 3 months), or

— during laboratory tests, form non-extractable residues in amounts exceeding 70 % of the initial dose after 100 days with a mineralization rate of less than 5 % in 100 days,

unless it is scientifically demonstrated that under field conditions there is no accumulation in soil at such levels that unacceptable residues in succeeding crops occur and/or that unacceptable phytotoxic effects on succeeding crops occur and/or that there is an unacceptable impact on the environment, according to the relevant requirements provided for in points 2.5.1.2, 2.5.1.3, 2.5.1.4 and 2.5.2.

2.5.1.2. No authorization shall be granted if the concentration of the active substance or of relevant metabolites, degradation or reaction products in groundwater, may be expected to exceed, as a result of use of the plant protection product under the proposed conditions of use, the lower of the following limit values:

(i) the maximum permissible concentration laid down by Council Directive 80/778/EEC [1] of 15 July 1980 relating to the quality of water intended for human consumption, or

(ii) the maximum concentration laid down by the Commission when including the active substance in Annex I, on the basis of appropriate data, in particular toxicological data, or, where that concentration has not been laid down, the concentration corresponding to one tenth of the ADI laid down when the active substance was included in Annex I

unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

[1] 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).

2.5.1.3. No authorization shall be granted if the concentration of the active substance or of relevant metabolites, breakdown or reaction products to be expected after use of the plant protection product under the proposed conditions of use in surface water:

— exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, the values fixed by 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 (1), or

— has an impact deemed unacceptable on non-target species, including animals, according to the relevant requirements provided for in point 2.5.2.

The proposed instructions for use of the plant protection product, including procedures for cleaning application equipment, must be such that the likelihood of accidental contamination of surface water is reduced to a minimum.

2.5.1.4. No authorization shall be granted if the airborne concentration of the active substance under the proposed conditions of use is such that either the AOEL or the limit values for operators, bystanders or workers as referred to in Part C, point 2.4.1, are exceeded.

2.5.2. Impact on non-target species

2.5.2.1. Where there is a possibility of birds and other non-target terrestrial vertebrates being exposed, no authorization shall be granted if:

— the acute and short-term toxicity/exposure ratio for birds and other non-target terrestrial vertebrates is less than 10 on the basis of LD_{50} or the long-term toxicity/exposure ratio is less than 5, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact occurs after use of the plant protection product according to the proposed conditions of use;

— the bioconcentration factor (BCF, related to fat tissue) is greater than 1, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable effects occur — directly or indirectly — after use of the plant protection product according to the proposed conditions of use.

2.5.2.2. Where there is a possibility of aquatic organisms being exposed, no authorization shall be granted if:

— the toxicity/exposure ratio for fish and Daphnia is less than 100 for acute exposure and less than 10 for long-term exposure, or

— the algal growth inhibition/exposure ratio is less than 10, or

— the maximum bioconcentration factor (BCF) is greater than 1 000 for plant protection products containing active substances which are readily biodegradable or greater than 100 for those which are not readily biodegradable,

unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact on the viability of exposed species (predators) occurs — directly or indirectly — after use of the plant protection product according to the proposed conditions of use.

2.5.2.3. Where there is a possibility of honeybees being exposed, no authorization shall be granted if the hazard quotients for oral or contact exposure of honeybees are greater than 50, unless it is clearly established through an appropriate risk assessment that under field conditions there are no unacceptable effects on honeybee larvae, honeybee behaviour, or colony survival and development after use of the plant protection product according to the proposed conditions of use.

2.5.2.4. Where there is a possibility of beneficial arthropods other than honeybees being exposed, no authorization shall be granted if more than 30 % of the test organisms are affected in lethal or sublethal laboratory tests conducted at the maximum proposed application rate, unless it is clearly established through an appropriate risk assessment that under field conditions there is no unacceptable impact on those organisms after use of the plant protection product according to the proposed conditions of use. Any claims for selectivity and proposals for use in integrated pest management systems shall be substantiated by appropriate data.

(1) OJ No L 194, 25. 7. 1975, p. 34. Directive as last amended by Directive 91/692/EEC (OJ No L 377, 31. 12. 1991, p. 48).

2.5.2.5. Where there is a possibility of earthworms being exposed, no authorization shall be granted if the acute toxicity/exposure ratio for earthworms is less than 10 or the long-term toxicity/exposure ratio is less than 5, unless it is clearly established through an appropriate risk assessment that under field conditions earthworm populations are not at risk after use of the plant protection product according to the proposed conditions of use.

2.5.2.6. Where there is a possibility of non-target soil micro-organisms being exposed, no authorization shall be granted if the nitrogen or carbon mineralization processes in laboratory studies are affected by more than 25 % after 100 days, unless it is clearly established through an appropriate risk assessment that under field conditions there is no unacceptable impact on microbial activity after use of the plant protection product according to the proposed conditions of use, taking account of the ability of micro-organisms to multiply.

2.6. *Analytical methods*

The methods proposed must reflect the state of the art. The following criteria must be met in order to permit validation of the analytical methods proposed for post-registration control and monitoring purposes:

2.6.1. for formulation analysis:

the method must be able to determine and to identify the active substance(s) and where appropriate any toxicologically, ecotoxicologically or environmentally significant impurities and co-formulants;

2.6.2. for residue analysis:

(i) the method must be able to determine and confirm residues of toxicological, ecotoxicological or environmental significance;

(ii) the mean recovery rates should be between 70 % and 110 % with a relative standard deviation of ≤ 20 %;

(iii) the repeatability must be less than the following values for residues in foodstuffs:

Residue level mg/kg	Difference mg/kg	Difference in %
0,01	0,005	50
0,1	0,025	25
1	0,125	12,5
> 1		12,5

Intermediate values are determined by interpolation from a log-log graph;

(iv) the reproducibility must be less than the following values for residues in foodstuffs:

Residue level mg/kg	Difference mg/kg	Difference in %
0,01	0,01	100
0,1	0,05	50
1	0,25	25
> 1		25

Intermediate values are determined by interpolation from a log-log graph;

(v) in the case of residue analysis in treated plants, plant products, foodstuffs, feedingstuffs or products of animal origin, except where the MRL or the proposed MRL is at the limit of determination, the sensitivity of the methods proposed must satisfy the following criteria:

Limit of determination in relation to the proposed provisional or Community MRL:

MRL (mg/kg)	limit of determination (mg/kg)
> 0,5	0,1
0,5 – 0,05	0,1 – 0,02
< 0,05	LMR × 0,5

2.7. *Physical and chemical properties*

2.7.1. Where an appropriate FAO specification exists, that specification must be met.

2.7.2. Where no appropriate FAO specification exists, the physical and chemical properties of the product must meet the following requirements

(a) Chemical properties:

Throughout the shelf-life period, the difference between the stated and the actual content of the active substance in the plant protection product must not exceed the following values:

Declared content in g/kg or g/l at 20 °C	Tolerance
up to 25	± 15 % homogeneous formulation
	± 25 % non-homogeneous formulation
more than 25 up to 100	± 10 %
more than 100 up to 250	± 6 %
more than 250 up to 500	± 5 %
more than 500	± 25 g/kg or ± 25 g/l

(b) Physical properties:

The plant protection product must fulfil the physical criteria (including storage stability) specified for the relevant formulation type in the "Manual on the development and use of FAO specifications for plant protection products".

2.7.3. Where the proposed label claims include requirements or recommendations for use of the preparation with other plant protection products or adjuvants as a tank mix and/or where the proposed label includes indications on the compatibility of the preparation with other plant protection products as a tank mix, those products or adjuvants must be physically and chemically compatible in the tank mix.'