COMMISSION OF THE EUROPEAN COMMUNITIES

COM(93)117 final

Brussels, 20 April 1993

Proposal for a

COUNCIL DIRECTIVE

establishing Annex VI of

Directive 91/414/EEC

concerning the placing of plant protection products

on the market.

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market requires in article 4 inter alia that Member States shall not authorize a plant protection product unless a number of requirements mentionned in paragraph (1) (b), (c), (d) and (e) are satisfied, pursuant to the uniform principles provided for in Annex VI.

   Moreover, according to articles 18 and 23 of the Directive, the uniform principles shall be adopted by the Council, acting by a qualified majority on a proposal from the Commission, within one year from the date of notification of the Directive.

2. The uniform principles aim to ensure that all Member States, in making decisions with respect to authorization of plant protection products will apply the requirements of Article 4 in an equivalent manner and at the high level of protection of human and animal health and of the environment seeked by the Directive.

   In this context the Commission would in particular underline that the proposal has taken into consideration current Community legislation with regard to protection of water and in particular drinking water given the concerns expressed during the negociation of Directive 91/414/EEC in the Council and Parliament. The Commission has however the intetion to start a re-examination of Directive 80/778/EEC relating to the quality of water intended for human consumption. Where the result of this examination would lead to a Commission proposal amending this Directive, or other Community regulatory provisions on water contamination by plant protection products, the Commission

will examine immediately the consequences thereof with regard to the necessity of a corresponding amendment of the present proposal, or, where the present proposal would already have been adopted by the Council, the necessity of amending the relevant provisions of Annex VI by the procedures provided therefor in Articles 18 and 19 of Directive 91/414/EEC.

3. The Commission considers that, as the uniform principles are addressed in the first instance to the public authorities in the Member States in charge of plant protection products authorization, these principles should concentrate on the aspects of the evaluation of the data submitted by applicants according to Article 13 of the Directive and of decision making on the basis of these evaluations.

The Commission is however of the opinion that for a proper realisation of the objectives mentionned under point 2 above, the provisions of Annex III should be further defined in order to ensure that evaluations can be made on the basis of a data package developped according to the current state of scientific and technological knowledge. Therefore it is the Commission's intention to define, according to the procedure provided thereto in the Directive, Annex III in such a way that it shall include:

- the parameters to decide when particular studies or information are required;

- the parameters to decide when particular studies or information are not required;

- the experimental protocols that have to be used to generate the required data.

4. This proposal conceives the uniform principles in 3 parts :

1) a general introduction identifies the aims of the uniform principles, the data that have to be taken into account for the evaluation and decision making and the procedures to evaluate data in order to come to a decision;

2) the principles concerning the evaluation of the available data, composed of some general principles and some more specific principles for each of the elements provided for in Article 4(1) (b), (c), (d) and (e);

3) the principles concerning the decision making with respect to authorization of plant protection products, also composed of some general principles and some more specific principles for each of the elements provided for in Article 4 (1) (b), (c), (d) and (e).

5. The Commission has developped this proposal on the basis of highest technical expertise available in the Member States with regard to evaluation and decision making on plant protection products.

However, with regard to certain items such as impact of plant protection products on non-target plants and on non-target aquatic flora as well as fate of plant protection products in air, it has appeared that more experience is required before detailed principles on evaluation and decision making can be developped. The Commission will follow the technical and scientific progress in these fields and as soon as possible introduce more detailed rules concerning these areas according to the procedures provided for in the Directive.

6. In certain cases the use of calculation models is provided in this proposal. However at this moment it is not possible for the Commission to provide models which are harmonised throughout the Community or to identify all the conditions under which certain specified models should be used. This is particularly the case for the models concerning operator exposure and fate and behaviour of plant protection products in the environment.

   It is the intention of the Commission to follow very closely the further developments in this area and to promote, where possible and within its possibilities, further harmonization. Meanwhile the uniform principles provide for some general requirements for the models that are to be used.

7. The present proposal concerns the uniform principles for evaluation and authorization of chemical plant protection products since currently and in the near future almost all the plant protection products that are placed or will be placed on the market are chemical preparations. As soon as possible similar provisions with regard to preparations containing micro-organisms or viruses will be developed.

8. This proposal is expected to have a negligle impact on the Community budget.

9. The proposal is unlikely to have negative impact on business, including SME.

Proposal for a

COUNCIL DIRECTIVE

establishing Annex VI of

Directive 91/414/EEC

concerning the placing of plant protection products

on the market

THE COUNCIL OF THE EUROPEAN COMMUNITIES

Having regard to the Treaty establishing the European Economic 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 of the Commission;

---

(1) OJ N° L 230, 19.08.1991, p. 1.

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

Whereas therefor it is necessary to lay down detailed principles concerning the evaluation of the information submitted by applicants for a plant protection product and concerning the decision making on basis of the results of this evaluation, in view of granting the authorization;

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);

HAS ADOPTED THIS DIRECTIVE :

Article 1

The Annex VI of Directive 91/414/EEC is established by the Annex to the present Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 25 July 1993 at the latest.

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 a reference shall be laid down by the Member States.

Article 3

This Directive is adressed to the Member States.

ANNEX

UNIFORM PRINCIPLES FOR EVALUATION AND AUTHORIZATION OF PLANT PROTECTION PRODUCTS

CONTENTS

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 developped in this Annex aim to ensure that evaluations and decisions with regard to authorization of plant protection products result in the implementation of the requirements of Article 4 (1) (b), (c), (d) and (e) by all the Member States at a high level of protection for man, animals and the environment seeked by the Directive.

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

a) - be assured that the dossier supplied is in accordance to 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, of the provisions of article 13(1) (a), (4) and (6);

- be assured that the data submitted are acceptable in terms of extent, 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 data of Annex II concerning the active substance(s) in the plant protection product which were submitted for the purpose of inclusion of the active substance concerned in Annex I and the results of the evaluation of this information, without prejudice, where relevant, of the provisions of article 13.(1) (b), (2), (3) and (6);

c) take into consideration other relevant technical or scientific information made avalaible to them 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 data of Annex II, this shall be understood as being the data referred to under point 2(b).

4. Where the data and information provided is 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(s) for which the data are sufficient.

Taking account of justifications provided and with the benefit of any necessary clarifications, Member States shall reject applications made, where the data gaps are such that it is not possible to finalize the evaluation and to perform a reliable decision making 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 solve where necessary any questions on the dossier in an early stage or to identify, in an early stage additional studies that would be necessary for a proper evaluation of the dossier, or to amend any proposed conditions of its envisaged use or to modify the nature or the composition of the plant protection product in order to ensure full satisfaction of the requirements of this Annex or of the Directive.

Member States shall come to a justified decision normally at the latest 12 months after a technically complete dossier is available for the Member State. A technically complete dossier is a dossier that satisfies all the requirements of Annex III.

6. The evaluation and decision making process involves judgments which must be based on sound scientific principles 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 under 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 man, animals or the environment.

2. In the evaluation of applications submitted, in accordance with the terms of Article 4, which inter alia specify that Member States 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.

This must include in particular the purpose of use, the dose, the manner, frequency and timing of applications, 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 the envisaged 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 are minimised. 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.

At first the evaluation shall be based on the best available data or estimates reflecting the realistic conditions of use of the plant protection product, and will result in a realistic worst case approach. 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, to determine whether it is possible that the initial estimation could have been significantly different.

5. Where specific principles of part B section 2 provide for the use of calculation models in the evaluation of a plant protection product, these 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 under part 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 the proposed use.

2. Specific principles

Member States shall, for the evaluation of the data and information submitted in support of applications, implement the following principles.

2.1. Efficacy

2.1.1 Where the proposed use concerns the control of or the 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 another effect than the control of or the protection against an organism, Member States shall evaluate if significant damage, loss or inconvenience could occur under the agricultural, plant health and environmental (including climatic) conditions in the area of the proposed use if the plant protection product would not be 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, duration and consistency of control or protection or other intended effects in comparison with suitable reference products and an untreated control;

(ii) where relevant the yield response or reduction of loss in storage in terms of quantity and/or quality in comparison with suitable reference products and an untreated control.

A suitable reference product is defined as an authorized plant protection product which has proved a sufficient performance in practice under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use. In general, formulation type, mode of action, working spectrum and method of application should be close to those of the tested plant protection product.

Where no suitable reference product exists, Member States shall evaluate the performance of the plant protection product to determine if 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 proposed label claims include recommendations for use of the plant protection product with other plant protection products as a tank mix, Member States shall make the evaluations referred to under points 2.1.1 to 2.1.4 above for the tank mix.

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 suitable reference products 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, application rate, 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 these;**

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

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

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

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

(vi) where highly volatile herbicides, active at a very low dose, 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 plants or plant products, after use of the plant protection product according to the proposed conditions of use, Member States shall evaluate the degree of adverse effects on succeeding crops. This evaluation will be carried out as specified under point 2.2.1 above.

2.2.3 Where proposed label claims include recommendations for use of the plant protection product with other plant protection products as a tank mix, the evaluation as specified under point 2.2.1 above will be carried out 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 effects on the behaviour 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 effects on the behaviour of the animal during this period.

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 the 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 and application method) of the plant protection product using by preference realistic data on exposure and, where relevant, a suitable 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. The Acceptable Operator Exposure Level is the amount of active substance absorbed by the operator and which will not lead to 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 no-effect level in the most sensitive species or, if appropriate data are available, in man.

(ii) other relevant information on the active substances such as vapour pressure and volatility;

(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
- container size and design
- 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
- 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 of application equipment.

2.4.1.2 Member States shall evaluate the suitability of the packaging, including closures in terms of its strength, leakproofness, resistance to normal transport and handling and the safety of the fastenings for children.

2.4.1.3 Member States shall evaluate the effectiveness of protective clothing and equipement to be worn or used by those handling and using plant protection products; they shall evaluate also if these items are readily obtainable and if they can be worn with ease, taking into account physical stress and relevant 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;

(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
- minimum spray application volume
- composition of the preparation
- dislodgeable residues
- 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 breakdown and reaction products and of metabolites in treated plants or plant products
- behaviour of residue of the active substance and its metabolites from the time of application until harvest or outloading of stored 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 witholding 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 Member States shall evaluate the residue levels 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;

(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;

2.4.2.4 Member States shall evaluate the residue levels in products of animal origin, taking into consideration the information provided for in Annex III, Part A, point 8.4.

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 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 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 compartments of the environment, including biota, and in particular to the following compartments :

2.5.1.1 **Member States shall evaluate the possibility for the plant protection product to reach the soil under the proposed conditions of use; if this possibility exists they shall evaluate the rate and the route of degradation in the soil, the mobility in the soil and the change of 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 the soil as provided for in Annex II and the results of the evaluation thereof;**

(*) 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 are unextracted by methods which do not significantly change the chemical nature of these residues. These non-extractable residues are considered to exclude fragments through metabolic pathways leading to natural products.

(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 relevant 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.

2.5.1.2 Member States shall evaluate the possibility for the plant protection product to reach the ground water under the proposed conditions of use; if the possibility exists that the plant protection product can reach the ground water they shall estimate, using where appropriate a suitable calculation model, the concentration of the active substance and of relevant metabolites, degradation and reaction products that could be expected in the ground water in or from the areas 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 the fate and behaviour in the soil and in 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) 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.

2.5.1.3 Member States shall evaluate the possibility for the plant protection product to reach surface water under the proposed conditions of use ; if this possibility exists they shall estimate, using where appropriate a suitable calculation model, the short term and long term predicted environmental concentration of the active substance and of relevant metabolites, degradation and reaction products after use of the plant protection product according to the proposed conditions of use.

This evaluation will take into consideration, where relevant, the following information:

(i) the specific information on fate and behaviour in the soil and in 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
- atmospheric deposition;

(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 for the plant protection product to be dissipated in the air under the proposed conditions of use; if this possibility exists they shall estimate, using where appropriate a suitable calculation model, 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 the fate and behaviour in the soil, water and in 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 suitability of the procedures for destruction or decontamination of the plant protection product and its packaging.

2.5.2. Impact on non-target species

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 degree of short term and long term risk, including on the reproduction, to be expected for 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 toxicological studies on mammals and to the effects on birds and other non-target terrestrial vertebrates including effects on the reproduction and other relevant information on 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, degradation and reaction products in the relevant compartments of the environment after application of the plant protection product;

(ii) the estimated exposure of the species likely to be at risk 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, inhalation or grooming;

(iii) a calculation of the acute, short term and, where necessary, long term toxicity/exposure ratio. The toxicity/exposure ratio's are defined as respectively the quotient of LD_{50}, LC_{50} or 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
- Kd for adsorption
- 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, degradation and reaction products in water, sediment or aquatic organisms;

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

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

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

(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 expected 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 in gramme of active substance per hectare and the contact and oral LD_{50} in μg 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 lethal and sublethal effects on these organisms to be expected 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 Annexe III such as :**

- **the effects on beneficial arthropods other than bees**
- **the toxicity to honeybees**
- **available data from biological primary screening in summary form**
- **the maximum application rate;**

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

2.5.2.5 Member States shall evaluate the possibility of exposure of earthworms and other soil non-target 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 soil non-target 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 soil non-target 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 acute 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) 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 for the plant protection product to reach the soil under the proposed conditions of use, evaluate the impact on the microbial activity such as the impact on the nitrogen and carbon mineralisation 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 on soil non-target 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 soil non-target 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.

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 or ecotoxicologically significant impurities and co-formulants;

2.6.2 for residue analysis :

the residues of the active substance, metabolites, degradation or reaction products, resulting from authorized uses of the plant protection product, and which are of 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 provided for in Annex III and in particular :

- the specificity of the proposed methods

- the recovery rate of the proposed methods

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

(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 content of the active substance in 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 FAO specification exists for the active substance contained in the plant protection product, the physical and chemical properties addressed in these specifications;

- where no FAO specification exists for the active substance contained in the plant protection product, 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 :

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

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

2.7.3 **Where proposed label claims include recommendations for use of the plant protection product with other plant protection products 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. Member States shall impose, where appropriate, conditions or restrictions with authorizations granted. 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 decisions, taken with respect to the granting of authorizations, take, where necessary, 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 numbers 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 amounts to be used may not give rise to undesirable effects such as the development of resistance.

4. Member States shall ensure that decisions take, whenever possible, into account the principles of integrated control.

5. Member States shall ensure that the authorization implies an approval of the label provided for a plant protection product, being established according to the requirements of Article 16. Moreover, the label shall contain the information on protection of users required from the implementation of Community legislation on worker protection. In particular the label shall contain the conditions or restrictions under which the plant protection product may be used or may not be used as identified under points (1), (2), (3) or (4) above.

6. Member States shall ensure that the authorization implies an approval of the proposed packaging and of the proposed procedures for destruction or decontamination of the plant protection product and its packaging.

The packaging must be designed in accordance with the provisions of article 15 and fulfil the requirements of the tests made in accordance with the provisions of Annex III part A point 4.

The proposed procedures for destruction or decontamination of the plant protection product and its packaging must be both practical and effective.

7. No authorization shall be granted unless all the requirements as referred to under part C section 2 are satisfied. However :

a) when one or more of the specific decision making requirements as referrred to under part C points 2.1, 2.2, 2.3 or 2.7 are not satisfied, authorizations shall be granted only where the advantages of the use of the plant protection product under the proposed conditions of use outweigh the possible adverse effects of its use. These advantages can be in terms of :

- advantages for and compatibity with integrated control measures or organic farming;

- facilitating strategies to minimize the risk of development of resistance;

- the need for a greater diversity of types of active substances or biochemical modes of action such as for the 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 as referred to under part C point 2.6 are not satisfied because of limitations in current analytical science and technology, an authorization shall be granted for a limited period if the methods submitted have been justified as being adequate for the purposes intended. In this case a time limit shall be given to the applicant in order to develop and submit analytical methods that are in accordance with the criteria as referred to above. The authorization will be reviewed at the expiry of the time limit accorded to the applicant.

8. Member States may, where an authorization has been granted according to the requirements provided for in this Annex in close cooperation with the applicant :

a) identify, where possible, measures to improve the performance of the plant protection product, and/or

b) identify, where possible, measures to reduce further the exposure that could occur 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 performance or potential risks arising under the changed conditions.

2. Specific principles

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 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 these conditions, no authorization shall be granted for these uses.

2.1.2 The level, duration, and consistency of control or protection or other intended effects must be similar to those resulting from 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, duration and consistency 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 and reduction of loss in storage, in terms of quantity and/or quality, must be at a similar level as that resulting from use of suitable reference products. If no suitable reference product exists, the plant protection product must be shown to give a consistent and defined benefit in terms of, where relevant, yield response and reduction of loss in storage in terms of quantity and/or quality under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use.

2.1.4 Conclusions as to 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, particular growing conditions).

2.1.5 Where proposed label claims include recommendations for use of the preparation with other plant protection products as a tank mix, the principles referred to in points 2.1.1 to 2.1.4 above must be satisfied for the preparation applied in the mixture.

2.2 Absence of unacceptable effects on plants or plant products

2.2.1 There must be absence of 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 below that which could be obtained without the use of the plant protection product, unless at the same time, the quality of the treated plants or plant products is capable of being enhanced.

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 unaceptable adverse impact on treated plants or plant products used for propagation, 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.

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 recommendations for use of the preparation with other plant protection products as a tank mix, the principles referred to in points 2.2.1 to 2.2.6 above must be satisfied for the preparation applied in the mixture.

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

2.3. **Impact on vertebrates to be controlled**

The intended effect on vertebrates to be controlled shall be obtained without unneccessary suffering and pain for these 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 Acceptable Operator Exposure Level (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 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 on the protection of workers from the risks related to exposure to carcinogens at work[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 these items are effective, readily obtainable to the user and unless it is feasible to use them under the circumstances of use of the plant protection product.

2.4.1.3 Plant protection products, which because of particular properties and, if mishandled or misused, could lead to a high degree of risk must be subject to particular restrictions such as the size of packaging or formulation type, the distribution, the use or the manner of use. Moreover, plant protection products which are classified as very toxic may not be supplied to nor used by non professional users.

---

(1) O.J. N° L 327, 03.12.80, p.8

(2) O.J. N° L 196, 26.07.90, p. 1

2.4.1.4 Waiting and re-entry 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 the Limit values where they were established for these compounds according to the Community provisions as referred to under point 2.4.1.1 above.

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

2.4.1.6 Waiting and re-entry periods or other precautions ensuring that the AOEL levels and Limit values are respected must be realistic; if necessary special precautionary measures must be foreseen.

2.4.2 Arising from residues

2.4.2.1 Residues occuring should reflect minimum quantities of the plant protection product necessary to achieve adequate pest control, applied in such a manner (including the largest feasable pre-harvest intervals or withholding periods or storage periods) that the residues at harvest, collection, slaughter or after storage, as appropriate, are as low as practicable.

2.4.2.2 Member States shall, where no Community MRL(*) nor a provisionnal MRL (at national or at Community level) exists establish a provisional MRL; 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 or manner of use.

2.4.2.3 Member States shall, where the good agricultural practice or the 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, not grant an authorisation for the plant protection product unless the applicant can provide evidence that this MRL will not be exceeded by the recommended use of it or unless a new provisional MRL is established.

(*) A Community MRL will mean a 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, Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals (1), 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(2) , 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(3) or Council Directive 91/132/EEC of 4 March 1991 amending Directive 74/63/EEC on undesirable substances and products in animal nutrition(4) ; it is envisaged that the data for the establisment of such levels will be available after a period not normaly exceeding 3 years.

---

(1) O.J. N° L. 221, 07.08.86, p. 37

(2) O.J. N° L. 221, 07.08.86, p. 43

(3) O.J. N° L. 350, 14.12.90, p. 71

(4) O.J. N° L. 66, 13.03.91, p. 16

2.4.2.4 Member States shall, where a Community MRL exists not grant an authorisation for the plant protection product unless the applicant can provide evidence that this MRL will not be exceeded by the recommended use of it.

2.4.2.5 In the cases referred to under points 2.4.2.2 and 2.4.2.3 above, each application for an authorisation must be accompanied by a risk assessment taking into account worst case potential exposure of consumers in the Member State concerned.

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

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

2.4.2.7 When the treated plants or plant products are intended to be fed to animals, residues occuring 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 toxicological or environmental significance, metabolites, degradation or reaction products after use under the proposed conditions of use of the plant protection product,

- persist in soil for more than one year (i.e. DT_{90} > 1 year and DT_{50} > 3 months) or

- form bound residues in amounts exceeding 50 % of initial dose after 30 days or 70 % after 100 days connected with mineralisation rate less than 5 % within 100 days

This does not apply if 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 part C 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 water intended for human consumption, as defined by Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption(1), may be expected, without special treatment, not to comply with the provisions of that Directive after use of the plant protection product under the proposed conditions of use

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

---

(1) O.J. N°. L. 229, 30.08.80, p.11

- 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 Directive 75/440/EEC of 16 June 1975 concerning the quality 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 part C 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 minimized.

2.5.1.4 The airborne concentration of the active substance should be such that with respect to the realistic conditions of use neither the AOEL nor Limit values for operators, bystanders or workers as referred to under part C point 2.4.1. are exceeded.

(1) O.J. N°. L. 194, 25.07.75, p. 34

2.5.2. Impact on non-target species

2.5.2.1 If there is a possibility of exposure for birds and other non-target terrestrial vertebrates 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, and the long term toxicity/exposure ratio is less than 5 unless it is cleary 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 - directly or indirectly - occur after use of the plant protection product according to the proposed conditions of use.

2.5.2.2 If there is a possibility of exposure for aquatic organisms 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 chronic exposure, unless it is clearly established through an appropriate risk assessment that under field conditions the viability of aquatic species is not threatened after use of the plant protection product according to the proposed conditions of use;

- the algal growth inhibition/exposure ratio is less than 10 unless it is clearly established through an appropriate risk assessment that under field conditions the viability of algae is not threatened after use of the plant protection product according to the proposed conditions of use;

- the maximum bioconcentration factor (BCF) is greater than 1000 for plant protection products which are readily biodegradable or greater than 100 for those which are not readily biodegradable, unless it is cleary established through an appropriate risk assessment that under field conditions no unacceptable impact on the viability of exposed species, directly and indirectly (predators), occurs after use of the plant protection product according to the proposed conditions of use.

2.5.2.3 If there is a possibility of exposure for honeybees, 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, colony survival and development after use of the plant protection product according to the proposed conditions of use.

2.5.2.4 If there is a possibility of exposure of beneficial arthropods other than honeybees no authorization shall be granted unless it is clearly established through an appropriate risk assessment that under field conditions there is no unacceptable impact on these organisms, taking into account their ability to recover, after use of the plant protection product according to the proposed conditions of use.

If there is a possibility of exposure of beneficial arthropods other than honeybees no authorization for use in integrated pest management systems 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 these 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.

2.5.2.5 If there is a possibility of exposure for earthworms, no authorization shall be granted if the acute toxicity/exposure ratio for earthworms is less than 10 and 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 If there is a possibility of exposure of soil non-target micro-organisms no authorization shall be granted if the nitrogen and carbon mineralisation 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 the microbial activity after use of the plant protection product according to the proposed conditions of use.

2.6 Analytical methods

To enable the validition of the analytical methods proposed for post-registration control and monitoring purposes, the following criteria must be met :

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 or ecotoxicologically significant impurities and co-formulants.

2.6.2 for residue analysis :

(i) the method must be able to determine and confirm residues of toxicological 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 :

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 :

Residu 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 methods proposed must satisfy the following criteria :

Proposed, provisional or Community MRL mg/kg	Limit of Determination mg/kg
> 5	0.5
5 - 0.5	0.5 - 0.1
0.5 - 0.05	0.1 - 0.02
< 0.05	MRL X 0.5

2.7 **Physical and chemical properties**

2.7.1 **Where a FAO specification exists for the active substance contained in the plant protection product, these specifications must be met.**

2.7.2 **Where no FAO specification exists for the active substance contained in the plant protection product the physical and chemical properties must meet the following :**

a) Chemical properties :

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

Content(*)	Tolerance
< 25 g/kg or g/l	±15 %
25 - 100 g/kg or g/l	±10 %
100 - 250 g/kg or g/l	±6 %
250 - 500 g/kg or g/l	±5 %
> 500 g/kg or g/l	±25 g/kg or g/l

(*) in each range the upper limit is not included

b) Physical properties :

The plant protection product must fulfill 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 proposed label claims include recommendations for use of the preparation with other plant protection products 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, these products must be physically and chemically compatible in the tank mix.

ISSN 0254-1475

COM(93) 117 final

DOCUMENTS

EN **03 05**

Catalogue number : CB-CO-93-154-EN-C

ISBN 92-77-54006-0

Office for Official Publications of the European Communities
L-2985 Luxembourg