EUROPEAN COMMUNITIES (AUTHORIZATION, PLACING ON THE MARKET, USE AND CONTROL OF PLANT PROTECTION PRODUCTS) (AMENDMENT) (NUMBER 2) REGULATIONS 1997

I, Joe Walsh, Minister for Agriculture and Food, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), for the purpose of giving further effect to Council Directive No 91/414/EEC of 15 July 19911, and for the purposes of giving effect to Council Directive 97/57/EC of 27 September 1997 2 hereby make the following Regulations:
1 O.J. No. L230/l 19/8/1991
2 O.J. No. L265/87 27/9/1997

REG 1

1. (1) These Regulations may be cited as the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No 2) Regulations, 1997.
(2) The collective citation "the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 1997" shall include these Regulations.
(3) These Regulations shall come into operation on the first day of January 1998.

REG 2

Interpretation
2. (1) In these Regulations—
"the principal Regulations" means the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 1997;
(2) In these Regulations, unless otherwise indicated—
(a) a reference to a Regulation is a reference to a Regulation of these Regulations,
(b) a reference to a paragraph or subparagraph is a reference to a paragraph or subparagraph of the provision in which the reference occurs,
(c) a reference to a Schedule is a reference to a Schedule of the principal Regulations as amended by these Regulations.
(3) A word or expression that is used in the Directive of 1991 or in any Commission Directive or Regulation of the European Communities mentioned in these Regulations has, unless the contrary intention appears, the meaning in these Regulations that it has in the Directive or Regulation concerned.

REG 3

Amendments
3. Regulations 5 and 6 of The European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) Regulations (S.I. No. 200 of 1995) are hereby revoked.

REG 4

4. Annex VI, as set out in Part 5 of the First Schedule to the principal Regulations is hereby replaced by the text set out in Part I of the Schedule to these Regulations.

REG 5

5. Part 2 of the Second Schedule to the principal Regulations is hereby replaced by the text set out in Part 2 of the Schedule to these Regulations.

SCHEDULE
PART I
Annex VI
(Annex VI to the Directive of 1991, as amended by Council Directive 97/57/EC of 22 September 1997)
UNIFORM PRINCIPLES FOR EVALUATION AND AUTHORISATION OF PLANT PROTECTION PRODUCTS
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A INTRODUCTION

1 The principles developed in this Annex are intended to ensure that evaluations and decisions with regard to the authorization of plant protection products, provided they are chemical preparations, result in the implementation of the requirements of Article 4 (1) (b), (c), (d) and (e) of the Directive of 1991, by the competent authority, in a manner that achieves a high level of protection of human and animal health and the environment.

2 In evaluating applications and granting authorizations the competent authority shall:

(a) • without prejudice to the provisions of subparagraph (3) (a) of Regulation 8 and paragraph (3) of Regulation 10 of the principal Regulations, 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,

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

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

(b) without prejudice, where relevant, to the provisions of subparagraphs (3) (b) and (5) (a) of Regulation 8 and paragraphs (1) and (2) of Regulation 10 of the principal Regulations, 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; and

(c) take into consideration other relevant technical or scientific information that it possesses 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 shall be evaluated and a decision made for the proposed use.

Taking account of justifications provided and with the benefit of any subsequent clarifications, the competent authority shall reject applications for which the data gaps are such that it is not

possible to finalise 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, the competent authority shall co-operate with applicants, to resolve any questions relating to the dossier quickly, to identify at an early stage any additional studies necessary for a proper evaluation of the dossier, 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 the Regulations.

The competent authority 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 HI.

6 The judgements made by the competent authority during the evaluation and decision making process shall be based on scientific principles, preferably recognized at international level (for example, by the EPPO), and be made with the benefit of the expert advice available to it.

B EVALUATION

1 General principles

1.1 Having regard to current scientific and technical knowledge, the competent authority 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 authorisation is sought, and

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

1.2 In accordance with the terms of Article 4 of the Directive of 1991, 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, the competent authority 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 the competent authority shall also take into account the principles of integrated control.

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

1.4 In interpreting the results of evaluations, the competent authority 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 underestimating 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 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 the range of use conditions that are likely to occur, resulting in a realistic worst case approach, to determine whether it is possible that the initial evaluation could have been significantly different.
1.5 Where the 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, and
• be relevant to the conditions in the area of use.
1.6 Where metabolites, degradation or reaction products are referred to in the specific principles, only those that are relevant for the criterion concerned shall be taken into account.
2 Specific principles
The competent authority shall, for the evaluation of the data and information submitted in support of applications, and without prejudice to the general principles of Section I, implement the following principles.
2.1 Efficacy
2.1.1 Where the proposed use concerns the control of or protection against an organism, the competent authority 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, the competent authority 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 The competent authority shall evaluate the efficacy data on the plant protection product as provided for in Annex Hl 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, and

• the type of application equipment.
2.1.4 The competent authority 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; and
(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, the competent authority 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, the competent authority 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, the competent authority 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 The competent authority 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; and
(iii) all relevant information on the active substance as provided for in Annex H, 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 main cultivates 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; and
(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 debris in significant quantities after use of the plant protection product according to the proposed conditions of use, the competent authority shall evaluate the degree of adverse effects on subsequent crops. This evaluation shall 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 2.2.1 shall 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 is intended to have an effect on vertebrates, the competent authority 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 it 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; and
(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 The competent authority 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 shall 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; and
(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 The competent authority shall examine, the 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, and
• its resistance to and compatibility with the contents.
2.4.1.3 The competent authority shall examine the nature and characteristics of the protective clothing and equipment proposed with particular reference to the following aspects
• obtainability and suitability, and
• ease of wearing taking into account physical stress and climatic conditions.
2.4.1.4 The competent authority 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 shall take into consideration the following

information:
(i) the toxicological and metabolism studies on the active substance as provided for in Annex H 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; and
(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, and
• further activities whereby workers are exposed.
2.4.2 arising from residues
2.4.2.1 The competent authority shall evaluate the specific information on toxicology as provided for in Annex H and in particular
• the determination of an acceptable Daily intake (ADD,
• the identification of metabolites, degradation and reaction products in treated plants or plant products, and
• 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 out-loading of stored plant products.
2.4.2.2 Prior to evaluating the residue levels in the reported trials or in products of animal origin, the competent authority shall examine the following information—
• data on the proposed good agricultural practice, including data on application as provided for in Annex Hl 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, and
• analytical methods and the residue definition.
2.4.2.3 On the basis of suitable statistical models the competent authority shall evaluate the residue levels observed in the trials reported. 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; and
(iv) the realistic possibilities of extrapolating data from one crop to another.
2.4.2.4 The competent authority shall evaluate the residue levels observed in products of animal origin, taking into consideration the

information provided for in Annex Hl, Part A, point 8.4 and residues resulting from other uses.

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

2.4.2.6 The competent authority 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, the competent authority shall have regard to all aspects of the environment, including biota, and in particular to the following:

2.5.1.1 The competent authority shall evaluate the possibility that the plant protection product may reach the soil under the proposed conditions of use; if this possibility exists it shall estimate the rate and the route of degradation in the soil, mobility in the soil and the change in the total concentration (extractable and non-extractable3) 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.

3 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.

This evaluation shall take into consideration the following information:

(i) the specific information on fate and behaviour in soil as provided for in Annex D 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,
• photo-degradation 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; and

(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 The competent authority shall evaluate the possibility that the plant protection product may reach ground water under the proposed conditions of use; if this possibility exists, it 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 ground water in the area of envisaged use after use of the plant protection product according to the proposed conditions of use. If there is not a validated Community calculation model, the competent authority shall base its evaluation on the results of studies on mobility and persistence in soil as provided for in Annexes II and III.

This evaluation shall 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 Hl, 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 and reaction products in ground water 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 The competent authority shall evaluate the possibility that the plant protection product may reach surface water under the proposed conditions of use; if this possibility exists it 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 not a validated Community calculation model, the competent authority shall base its evaluation on the results of the studies on mobility and persistence in soil and the information on runoff and drift as provided for in Annexes II and III.
This evaluation shall also take into consideration the following information:
(i) the specific information on fate and behaviour in soil and water as provided for in Annex D 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 via 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; and
(vi) where relevant, data on the procedures for drinking water abstraction and treatment in the area of envisaged use.
2.5.1.4 The competent authority shall evaluate the possibility that the plant protection product may be dissipated in the air under the proposed conditions of use; if this possibility exists it 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 shall 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 The competent authority 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 the competent authority shall take into consideration toxicity to the most sensitive relevant organism used in the tests.
2.5.2.1 The competent authority 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 it shall evaluate the extent of the short-term and long-term risks to be expected for these organisms, including reproductive effects, after use of the plant protection product according to the proposed conditions of use.
(a) This evaluation shall 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 H 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; and
(iii) where relevant, other authorised 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 shall 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 ratios. The toxicity/exposure ratios are defined as, respectively,. the quotient of LD50, LC90 or non-observable effect concentration (NOEC) expressed on an active substance basis and the estimated exposure expressed in mg/kg body weight.

2.5.2.2 The competent authority shall evaluate the possibility that exposure of aquatic organisms to the plant protection product may occur under the proposed conditions of use; if this possibility exists it shall evaluate the degree of short-term and long-term risks to be expected for aquatic organisms after use of the plant protection product according to the proposed conditions of use.

(a) This evaluation shall 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,
• photo degradation 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 shall 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 ratios for fish and Daphnia. These ratios are defined as the quotient of respective acute LC50 or EC50 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 EC50 and the predicted short-term environmental concentration;

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

(v) where relevant, bio-concentration in fish and possible exposure

of predators of fish, including humans; and
(vi) if the plant protection product is to be applied directly to surface water, effects on surface water quality, such as pH or dissolved oxygen content.
2.5.2.3 The competent authority shall evaluate the possibility that exposure of honeybees may occur to the plant protection product under the proposed conditions of use; if this possibility exists it shall evaluate the short-term and long-term risks to be expected for honeybees after use of the plant protection product according to the proposed conditions of use.
(a) This evaluation shall 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, photo-degradation 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 toxicity to honeybees; and
(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 shall include:
(i) the ratios between the maximum application rate expressed in grams of active substance per hectare and the contact and oral LC50 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; and
(ii) where relevant, 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 The competent authority 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 it shall assess expected lethal and sub-lethal effects on these organisms and the reduction in their activity after use of the plant protection product according to the proposed conditions of use.
This evaluation shall 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,
• photo-degradation 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 The competent authority 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 it shall evaluate the degree of short-term and long-term risks to be expected to these organisms after use of the plant protection product according to the proposed conditions of use.
(a) This evaluation shall 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 H 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,
• photo-degradation rate and identity of breakdown products,
• DT50 and DT90 for degradation in the soil;
(iii) all relevant information on the plant protection product as provided for in Annex HI, including the effects on earthworms and other non-target soil macro-organisms; and
(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 shall include:
(i) lethal and sub-lethal effects;
(ii) predicted initial and long-term environmental concentration;
(iii) a calculation of the acute toxicity/exposure ratio (defined as the quotient of LC50 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); and
(iv) where relevant, bio-concentration and the persistence of residues in earthworms.
2.5.2.6 The competent authority 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 impact on microbial activity such as 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 shall take into consideration the following information:

(i) all relevant information on the active substance, including the specific information relating to the effects on 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; and

(iv) all available information from biological primary screening.

2.6 Analytical methods

The competent authority 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 shall take into consideration the following information:

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

(iî) data on analytical methods as provided for in Annex III, in particular

• the specificity and linearity of the proposed methods,

• the importance of interference's,

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

(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, ecotoxicological or environmental significance.

This evaluation shall take into consideration the following information:

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

(ii) data on analytical methods as provided for in Annex III, 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; and
(iv) the limit of determination of the proposed methods.
2.7 Physical and chemical properties
2.7.1 The competent authority shall evaluate the actual content of the active substance in the plant protection product and its stability during storage.
2.7.2 The competent authority 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 shall take into consideration the following information:
(i) data on the physical and chemical properties of the active substance as provided for in Annex II and the results of the evaluation thereof; and
(ii) 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 shall be evaluated.
C DECISION-MAKING
1 General principles
1 Where appropriate, the competent authority shall impose conditions or restrictions on authorizations which it grants. The nature and severity of these measures shall 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 The competent authority shall ensure that, where necessary, decisions taken with respect to the granting of authorizations take account of the agricultural, plant health and environmental (including climatic) conditions in the areas of envisaged use. Such considerations may result in specific conditions and restrictions on use, and, where necessary, may result in authorization being granted for some but not other areas within the territory of the state.
3 The competent authority 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 shall be differentiated according to, and be appropriate to the agricultural, plant health and environmental (including climatic) conditions in the various areas for which an authorization is granted. However, the rates and the number of applications shall not give rise to undesirable effects such as the development of resistance.

4 The competent authority shall ensure that decisions taken 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, the competent authority 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, the competent authority shall ensure that the label of the product—

• fulfils the requirements of Regulation 24 of the principal Regulations,

• 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 specified in subparagraphs (2) (g), (ii), (iii), and (iv) and subparagraphs (i) and (j) of Regulation 24 of the principal Regulations.

7 Before issuing authorizations, the competent authority shall:

(a) ensure that the proposed packaging is in accordance with the provisions of Regulation 23 of the principal Regulations; and

(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,

• the procedures for the decontamination and destruction of the packaging,

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 outweigh the possible adverse effects of its use. Any restrictions on use of the product relating to non-compliance with some of the aforementioned requirements shall be mentioned on the label, and non-compliance with the requirements referred to in point 2.7 shall 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,
• 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 shall 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, the competent authority may, by virtue of subparagraph (6) (b) of Regulation 19 of the principal Regulations:
(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.
The competent authority 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
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 shall be similar to those resulting from the use of suitable reference products. If no suitable reference product exists, the plant protection product shall 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 shall 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 shall 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 shall be valid for all areas of the territory of the state, and shall 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 shall 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 other specified plant protection products or adjuvants as a tank mix, the competent authority shall not accept the recommendations unless they are justified.

2.2 Absence of unacceptable effects on plants or plant products

2.2.1 There shall 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 shall 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 shall 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 shall 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 shall 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 shall 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 shall 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 shall 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 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 of 27 November 1980 on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work " and Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work 5 .
4 O.J. No. L327/8 3/12/1980. Directive as last amended by Direction 88/642/EEC O.J. No. L 356/74 24/12/1988
5 O.J. No. L196/1 26/7/1990. Directive as last amended by Directive 97/42/EC O.J. No. L179/4 8/7/1997
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, shall 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 shall not be authorized for use by non-professional users.

2.4.1.4 Waiting and re-entry safety periods or other precautions shall 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 provisions referred to in point 2.4.1.1.

2.4.1.5 Waiting and re-entry safety periods or other precautions shall 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 shall be realistic; if necessary special precautionary measures shall be prescribed.

2.4.2 arising from residues

2.4.2.1 Authorizations shall 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)6 or provisional MRL (at national or at Community level) exists, the competent authority shall establish a provisional MRL in accordance with subparagraph (1) (c) of Regulation 13, subparagraph (2) (b) of Regulation 15 or subparagraph (3) (b) of Regulation 18 of the principal Regulations; conclusions as to the levels fixed shall 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.

6 A Community MRL means an MRL established pursuant to Council Directive 76/895/EEC of 23 November 1976 on the fixing of maximum levels for pesticide residues in or on fruit or vegetables (O.J. No. L340/26 9/12/1976), Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in or on cereals (O.J. No. L221/37 7/8/1986), Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in or on foodstuffs of animal origin (O.J. No. L221/43 7/8/1986), 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 origin (O.J. No. L224/1 18/8/1990), Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in or on certain products of plant origin, including fruit and vegetables

(O.J, No. L350/71 14/12/1990), or Council Directive 91/132/EEC of 4 March 1991 amending Directive 74/63/EEC on undesirable substances and products in feedingstuffs (O.J. No. L66/16 13/3/1991).
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, the competent authority shall not grant an authorization for the plant protection product unless the applicant can provide evidence that the recommended use will not result in the MRL being exceeded, or unless a new provisional MRL has been established by the competent authority, or by the Commission in accordance with Article 4(1)(f) of the Directive of 1991.
2.4.2.4 Where a Community MRL exists the competent authority shall not grant an authorisation for the plant protection product unless the applicant can provide evidence that the recommended use will not result in the MRL being exceeded, or unless a new Community MRL has been established in accordance with the procedures 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 shall be accompanied by a risk assessment, taking into account worst case potential exposure of consumers in the territory of the state, on the basis of good agricultural practice.
Taking into account all registered uses, the proposed use shall not be authorized if the best possible estimate of dietary exposure exceeds the acceptable Daily intake (ADD.
2.4.2.6 Where the nature of residues is affected during processing, a separate risk assessment may 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. DT50 > 1 year and DT90 > 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, in accordance with 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 ground water, 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 of 15 July 1980 7 relating to the quality of water intended for human consumption; or
7 O.J. No. L229/11 30/8/1980
(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 1;
unless it is scientifically demonstrated that under the relevant field conditions the lower concentration is not exceeded.
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 8 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States, or
8 O.J. No. L194/34 25/7/1975
• 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, shall 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 arid 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 LD90 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 bio-concentration factor (BCF, related to fat tissue) is greater than I, 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 authorisation 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 bio-concentration factor (BCF) is greater than 1000 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 sub-lethal 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.
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 shall reflect the state of the art. The following criteria shall 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 shall be suitable for the determination and identification of 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 shall be suitable for the determination and confirmation of residues of toxicological, ecotoxicological or environmental significance;

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

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

Residue level
mg/kgDifference
mg/kgDifference
in %0010.005500.10.0252510.12512.5 >112.5

Intermediate values are determined by interpolation from a log-log graph; (iv) reproducibility shall be less than the following values for residues in foodstuffs:

Residue level
mg/kgDifference
mg/kgDifference
in %0.010.011000.10.055010.2525 >125

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 shall satisfy the following criteria:

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

MRL
(mg/kg)limit of determination
(mg/kg)>0.50.10.5 - 0.050.1 - 0.02 <0.05MRL x 0.5

2.7 Physical and chemical properties

2.7.1 Where an appropriate FAO specification exists, that

specification shall be met.
2.7.2 Where no appropriate FAO specification exists, the physical and chemical properties of the product shall 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 shall not exceed the following values:

Declared content in g/kg or g/l at 20°CToleranceup 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 shall 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 shall be physically and chemically compatible in the tank mix.
PART 2
FORMAT AND PRESENTATION OF DOCUMENTATION
1 The format for the presentation of the documentation referred in paragraph (2) of Regulation 8 of the principal Regulations is that described in the "Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2)", as amended from time to time9
9 European Commission Document 1663/VI/94 Rev 7.6, 31 October, 1997
2 Those guidelines should be adapted as necessary in the case of documentation submitted in support for applications for the authorization of plant protection products.
3 Where in accordance with Regulation 10 of the principal Regulations, it is claimed that the particular tests or study reports be protected, the owner of the tests or studies concerned must be indicated. Where ownership is shared, all of the joint owners must be identified.
4 Where in accordance with subparagraphs (1) (a) and (3) (a) of Regulation 10 of the principal Regulations, agreement to the use of information submitted by other parties is claimed, an original signed and notarized letter, confirming such agreement, and submitted by the owner of the information, must be provided. Each such letter must include the following information:
(i) the identity of those to whom agreement for the use of

information submitted has been granted;
(ii) the purposes for which such agreement has been granted (a particular product, a group of products, or all relevant products); and
(iii) the period for which the agreement given is valid.
5 In the case of existing active substances being reviewed for possible inclusion in Annex I, or being reviewed in the context of applications for authorization of preparations in accordance with Regulation 18 of the principal Regulations, where the information qualifies for protection pursuant to Regulation 10 of the principal Regulations, the following must be provided:
(i) for each test and study referred to in subparagraph (1) (c) of Regulation 10 of the principal Regulations, a list of the Member States in which one or more preparations containing the active substance was on the market on 24 July 1993, and the dates on which authorization of the first such preparation was granted by each such Member State in the case of preparations placed on the market prior to 2 December 1985 in Ireland and prior to 6 October 1986 in the UK, the dates of first placing on the market and the date of expiry of the period of protection for each Member State;
(ii) for each test and study referred to in subparagraph (1) (b) of Regulation 10 of the principal Regulations, a statement that the test or study was generated for the purposes of achieving inclusion in Annex I or has not been previously submitted to the competent authorities of any of the Member States for the authorization of a plant protection product;
(iii) for each test and study referred to in subparagraph (3) (b) of Regulation 10 of the principal Regulations, the identity of the first Member State to authorize the preparation, the date of authorization and the date of expiry of the period of protection for the Community; and
(iv) for each test and study referred to in subparagraph (3) (c) of Regulation 10 of the principal Regulations, a list of the Member States in which the preparation was authorized, and the dates on which such authorization was granted by each such Member State in the case of preparations placed on the market prior to 2 December 1985 in Ireland and prior to 6 October 1986 in the UK, the dates of first placing on the market and the date of expiry of the period of protection for each Member State.
GIVEN under my Official Seal, this 20th day of November, 1997
Joe Walsh,
Minister for Agriculture and Food

Explanatory Note
These Regulations, amend the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 1997 (S.I. No. 139 of 1994, S.I. No. 200 of 1995, S.I. No. 159 of 1996 and S.I. No. 290 of 1997).
The amendments, inter alia, specify revised criteria, in particular revised evaluation and decision making rules, to be applied in the

examination of applications for the authorization of plant protection products. .