COMMISSION DIRECTIVE 94/37/EC

of 22 July 1994

amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1], as last amended by Commission Directive 93/71/EEC [2], and in particular Article 18 (2) thereof,

Whereas Annexes II and III to Directive 91/414/EEC lay down the requirements for the dossier to be submitted by applicants respectively for the inclusion of an active substance in Annex I and for the authorization of a plant protection product;

Whereas it is necessary to indicate in Annexes II and III to the applicants, as precisely as possible, any details on the required information, such as the circumstances, conditions and technical protocols under which certain data have to be generated; whereas these provisions should be introduced as soon as available in order to permit applicants to use them in the preparation of their dossier;

Whereas greater precision can now be given to the data requirements concerning the identity, physical and chemical properties and further on the active substance, provided for in sections 1, 2 and 3 of Part A of Annex II;

Whereas greater precision can now be given to the data requirements concerning the identity, physical, chemical and technical properties and other general information on the plant protection product, provided for in sections 1 to 4 of Part of Annex III;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 91/414/EEC is amended as follows:

1. In Part A of Annex II, the sections headed '1. Identity of the active substance', '2. Physical and chemical properties of the active substance' and '3. Further information on the active substance' are replaced by Annex I hereto;

2. In Part A of Annex III, the sections headed '1. Identity of the plant protection product', '2. Physical, chemical and technical properties of the plant protection product', '3. Data on application' and '4. Further information on the plant protection product' are replaced by Annex II hereto.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 July 1995. They shall immediately inform the Commission thereof.

When Member States adopt these measures, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

This Directive shall enter into force on 1 August 1994.

Done at Brussels, 22 July 1994.

For the Commission

René STEICHEN

Member of the Commission

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[1] OJ No L 230, 19. 8. 1991, p. 1.
[2] OJ No L 221, 31. 8. 1993, p. 27.

ANNEX I

1. **Identity of the active substance**

The information provided must be sufficient to identify with precision each active substance, to define it in terms of its specification and to characterize it as to its nature. The information and data referred to, unless otherwise specified, are required for all active substances.

1.1. *Applicant (name, address, etc.)*

The name and address of the applicant (permanent Community address) must be provided as must the name, position, telephone and telefax number of the appropriate person to contact.

Where, in addition, the applicant has an office, agent or representative in the Member State to which the application for inclusion in Annex I is submitted, and if different, in the Rapporteur Member State appointed by the Commission, the name and address of the local office, agent or representative must be provided, as must the name, position, telephone and telefax number of the appropriate person to contact.

1.2. *Manufacturer (name, address, including location of plant)*

The name and address of the manufacturer or manufacturers of the active substance must be provided as must the name and address of each manufacturing plant in which the active substance is manufactured. A contact point (preferably a central contact point, to include name, telephone and telefax number) must be provided, with a view to providing updating information and responding to queries arising, regarding manufacturing technology, processes and the quality of product (including where relevant, individual batches). Where following inclusion of the active substances in Annex I, there are changes in the location or number of manufacturers, the information required must again be notified to the Commission and the Member States.

1.3. *Common name proposed or ISO-accepted, and synonyms*

The ISO common name, or proposed ISO common name and where relevant, other proposed or accepted common names (synonyms), including the name (title) of the nomenclature authority concerned, must be provided.

1.4. *Chemical name (IUPAC and CA nomenclature)*

The Chemical name as given in Annex I to Directive 67/548/EEC, or, if not included in this Directive, in accordance with both IUPAC and CA nomenclature, must be provided.

1.5. *Manufacturer's development code number(s)*

Code numbers used to identify the active substance, and where available, formulations containing the active substance, during development work, must be reported. For each code number reported, the material to which it relates, the period for which it was used, and the Member States or other countries in which it was used and is being used, must be stated.

1.6. *CAS, EEC and CIPAC numbers (if available)*

Chemical Abstracts, EEC (EINECS or ELINCS), and CIPAC numbers, where they exist, must be reported.

1.7. *Molecular and structural formula, molecular mass*

The molecular formula, molecular mass and structural formula of the active substance, and where relevant, the structural formula of each stereo and optical isomer present in the active substance, must be provided.

1.8. *Method of manufacture (synthesis pathway) of the active substance*

The method of manufacture, in terms of the identity of the starting materials, the chemical pathways involved, and the identity of by-products and impurities present in the final product, must be provided, for each manufacturing plant. Generally process engineering information is not required.

Where the information provided relates to a pilot plant production system, the information required must again be provided once industrial scale production methods and procedures have stabilized.

1.9. *Specification of purity of the active substance in g/kg*

The minimum content in g/kg of pure active substance (excluding inactive isomers) in the manufactured material used for production of formulated products, must be reported.

Where the information provided relates to a pilot plant production system, the information required must again be provided to the Commission and the Member States once industrial scale production methods and procedures have stabilized, if production changes result in a changed specification of purity.

1.10. *Identity of isomers, impurities and additives (e.g. stabilizers), together with the structural formula and the content expressed as g/kg*

The maximum content in g/kg of inactive isomers as well as the ratio of the content of isomers/diastereo-isomers, where relevant, must be provided. In addition, the maximum content in g/kg of each further component other than additives, including by-products, and impurities, must be provided. In the case of additives the content in g/kg must be provided.

For each component, present in quantities of 1 g/kg or more, the following information, where relevant, must be provided:

— chemical name according to IUPAC and CA nomenclature,
— ISO common name or proposed common name if available,
— CAS number, EEC (EINECS or ELINCS) number, and CIPAC number if available,
— molecular and structural formula,
— molecular mass, and
— maximum content in g/kg.

Where the manufacturing process is such that impurities and by-products which are particularly undesirable because of their toxicological, ecotoxicological or environmental properties could be present in the active substance, the content of each such compound must be determined and reported. In such cases, the analytical methods used and the limits of determination, which must be sufficiently low, for each compound of concern, must be reported. Additionally the following information, where relevant, must be provided:

— chemical name according to IUPAC and CA nomenclature,
— ISO common name or proposed common name if available,
— CAS number, EEC (EINECS or ELINCS) number, and CIPAC number if available,
— molecular and structural formula,
— molecular mass, and
— maximum content in g/kg.

Where the information provided relates to a pilot plant production system, the information required must again be provided once industrial scale production methods and procedures have stabilized, if production changes result in a changed specification of purity.

Where the information provided does not fully identify a component viz. condensates, detailed information on the composition must be provided for each such component.

The trade name of components added to the active substance, prior to manufacture of formulated product, to preserve stability and facilitate ease of handling, where they are used, must also be provided. Additionally the following information, where relevant, must be provided for such additives:

— chemical name according to IUPAC and CA nomenclature,
— ISO common name or proposed common name if available,
— CAS number, EEC (EINECS or ELINCS) number, and CIPAC number if available,
— molecular and structural formula,
— molecular mass, and
— maximum content in g/kg.

For added components, other than active substance and other than impurities resulting from the manufacturing process, the function of the component (additive) must be given:

— antifoaming agent,
— antifreeze,
— binder,
— other (specify),

— buffer,

— dispersing agent,

— stabilizer.

1.11. *Analytical profile of batches*

Representative samples of the active substance must be analysed for content of pure active substance, inactive isomers, impurities and additives, as appropriate. The analytical results reported must include quantitative data, in terms of g/kg content, for all components present in quantities of more than 1 g/kg and typically should account for at least 98 % of the material analysed. The actual content of components which are particularly undesirable because of their toxicological, ecotoxicological or environmental properties, must be determined and reported. Data reported must include the results of the analysis of individual samples and a summary of that data, to show the minimum or maximum and typical content of each relevant component, as appropriate.

Where an active substance is produced in different plants this information must be provided for each of the plants separately.

In addition, where available and relevant, samples of the active substance produced in laboratory scale or pilot production systems, must be analyzed, if such material was used in generating toxicological or ecotoxicological data.

2. **Physical and chemical properties of the active substance**

(i) The information provided, must describe the physical and chemical properties of active substances and together with relevant information, must serve to characterize them. In particular, the information provided must permit:

— physical, chemical, and technical hazards associated with active substances, to be identified,

— classification of active substance as to harzard,

— appropriate restrictions and conditions to be associated with inclusions in Annex I to be selected, and

— appropriate risk and safety phrases to be specified.

The information and data referred to are required for all active substances, except where otherwise specified.

(ii) The information provided, taken together with that provided for relevant preparations, must permit the physical, chemical hazards associated with preparations, to be identified, permit preparations to be classified, and permit establishment that preparations can be used without unnecessary difficulty, and be such that exposure of man, animals, and the environment is minimized, taking account of manner of use.

(iii) The extent to wich active substances of which inclusion in Annex I is sought, comply with relevant FAO specifications, must be stated. Divergences from FAO specifications must be described in detail, and justified.

(iv) In certain specified instances, tests must be conducted using purified active substance of stated specification. In such cases the principles of the method(s) of purification must be reported. The purity of such test material, which must be as high as can be achieved using the best available technology, must be reported. A reasoned justification must be provided in cases where the degree of purity achieved is less than 980 g/kg.

Such justification must demonstrate that all technically feasible and reasonable possibilities for the production of the pure active substance have been exhausted.

2.1. *Melting point and boiling point*

2.1.1. The melting point or where appropriate the freezing or solidification point of purified active substance must be determined and reported according to EEC method A 1. Measurements should be taken up to 360 °C.

2.1.2. Where appropriate the boiling point of purified active substances must be determined and reported according to EEC method A 2. Measurements should be taken up to 360 °C.

2.1.3. Where melting point and/or boiling point cannot be determined because of decomposition or sublimation, the temperature at which decomposition or sublimation occurs, must be reported.

2.2. *Relative density*

In the case of active substances which are liquids or solids, the relative density of the purified active substance must be determined and reported according to EEC method A 3.

2.3. *Vapour pressure (in Pa), volatility (e.g. Henry's law constant)*

2.3.1. The vapour pressure of purified active substance must be reported according to EEC method A 4. Where vapour pressure is less than 10^{-5} Pa, the vapour pressure at 20 or 25 °C may be estimated by a vapour pressure curve.

2.3.2. In the case of active substances which are solids or liquids, volatility (Henry's law constant) of purified active substance must be determined or calculated from its water solubility and vapour pressure and be reported (in Pa × m^3 × mol^{-1}).

2.4. *Appearance (physical state, colour and odour; if known)*

2.4.1. A description of both the colour, if any, and the physical state of both the active substance as manufactured and purified active substance, must be provided.

2.4.2. A description of any odour associated with the active substance as manufactured and purfied active substance, noted when handling the materials in laboratories or production plants, must be reported.

2.5. *Spectra (UV/VIS, IR, NMR, MS), molecular extinction at relevant wavelengths*

2.5.1. The following specta including a table of signal characteristica needed for interpretation must be determined and reported: Ultraviolet/Visible (UV/VIS), infrared (R), nuclear magnetic resonance (NMR), and mass spectra (MS) of purified active substance and molecular extinction at relevant wavelengths, must be determined and reported.

The wavelengths at which UV/visible molecular extinction occurs are to be determined and reported and must include where appropriate a wavelength at the highest absorption value above 290 nm.

In the case of active substances which are resolved optical isomers their optical purity must be measured and reported.

2.5.2. The UV/visible absorption spectra, IR, NMR and MS spectra, where necessary for the identification of the impurities considered to be of toxicological, ecotoxicological or environmental significance must be determined and reported.

2.6. *Solubility in water including effect of pH (4 to 10) on solubility*

The water solubility of purified active substances under atmospheric pressure must be determined and reported according to EEC method A 6. These water solubility determinations must be made in the neutral range (i.e. in distilled water in equilibrium with atmospheric carbon dioxide). Where the active substance is capable of forming ions, determinations must also be made in the acidic range (pH 4 to 6) and in the alkaline range (pH 8 to 10), and be reported. Where the stability of the active substance in aqueous media is such that water solubility cannot be determined, a justification based on test data must be provided.

2.7. *Solubility in organic solvents*

The solubility of the active substances as manufactured in the following organic solvents at 15 to 25 °C must be determined and reported if less than 250 g/kg; the temperature applied must be specified:

— Aliphatic hydrocarbon: preferably n-heptane,

— Aromatic hydrocarbon: preferably xylene,

— Halogenated hydrocarbon: preferably 1,2-dichlorethane,

— Alcohol: preferably methanol or isopropyl alcohol,

— Ketone: preferably acetone,

— Ester: preferably ethyl acetate.

If for a particular active substance, one or more of these solvents is unsuitable (e.g. reacts with test material), alternative solvents can be used instead. In such cases, choices made must be justified in terms of their structure and polarity.

2.8. *Partition coefficient n-octanol/water including effect of pH (4 to 10)*

The n-octanol/water partition coefficient of purified active substance must be determined and reported according to EEC method A 8. The effect of pH (4 to 10) must be investigated when the substance is acidic or basic as defined by its pKa value (< 12 for acids, > 2 for bases).

2.9. *Stability in water, hydrolysis rate, photochemical degradation, quantum yield and identity of breakdown product(s), dissociation constant including effect of pH (4 to 9)*

2.9.1. The hydrolysis rate of purified active substances (usually radiolabelled active substance, > 95 % purity), for each of the pH values 4, 7 and 9, under sterile conditions, in the absence of light, must be determined and report according to EEC method C 7. For substances with a low rate of hydrolysis, the rate can be determined at 50 °C, or another appropriate temperature.

If degradation is observed at 50 °C, degradation rate at another temperature must be determined, and an Arrhenius plot must be constructed to permit an estimate to be made of hydrolysis at 20 °C. The identity of hydrolysis products formed and the rate constantly observed, must be reported. The estimated DT 50 value must also be reported.

2.9.2. For compounds with a molar (decadic) absorption coefficient (ε) > 10 ($l \times mol^{-1} \times cm^{-1}$) at a wavelength $\lambda \geq 290$ nm, direct phototransformation in purified (e.g. distilled) water at 20 to 25 °C, of purified active substance usually radio labelled using artificial light under sterile conditions, if necessary using a solubilizer, must be determined and reported. Sensitizers such as acetone must not be used as a cosolvent or solubilizer. The light source must simulate sunlight and be equipped with filters to exclude radiation at wavelengths $\lambda < 290$ nm. The identity of breakdown products formed which at any time during the study are present in quantities ≥ 10 % of the active substance added, a mass balance to account for at least 90 % of the applied radioactivity, as well as photochemical halflife must be reported.

2.9.3. Where necessary to investigate direct phototrans-formation, the *quantum yield of direct photodegradation in water* must be determined and reported, together with calculations to estimate theoretical lifetime of the active substance in the top layer of aqueous systems and the real lifetime of the substance.

The method is described in the FAO Revised Guidelines on Environmental Criteria for the Registration of Pesticides .

2.9.4. Where dissociation in water occurs, the dissociation constant(s) (pKa values) of the purified active substance must be determined and reported according to OECD Test Guideline 112. The identity of the dissociated species formed, based on theoretical considerations, must be reported. If the active, substance is a salt, the pKa value of the active principle must be given.

2.10. *Stability in air, photochemical degradation, identity of breakdown product(s)*

An estimation of the photochemical oxidative degradation (indirect hototransformation) of the active substance, must be submitted.

2.11. *Flammability including auto-flammability*

2.11.1. The flammability of active substances as manufactured, which are solids, gases, or are substances which evolve highly flammable gases, must be determined and reported according to EEC method A 10, A 11 or A 12 as as appropriate.

2.11.2. The auto-flamability of active substances as manufactured must be determined and reported according to EEC method A 15 or A 16 as appropriate, and/or, where necessary according to the UN-Bowes-Cameron-Cage-Test (UN-Recommendations on the Transport of Dangerous Goods, Chapter 14, No 14.3.4).

2.12. *Flash point*

The flash point of active substances as manufactured with a melting point below 40 °C, must be determined and reported according to EEC method A 9 ; only closed cup methods should be used.

2.13. *Explosive properties*

The explosive properties of active substances as manufactured, must be determined and reported according to EEC method A 14 where necessary.

2.14. *Surface tension*

The surface tension has to be determined and reported according to EEC method A 5.

2.15 *Oxidizing properties*

The oxidizing properties of active substances as manufactured, must be determined and reported according to EEC method A 17, except where examination of its sturctural formula, establishes beyond reasonable doubt that the active substance is incapable of reacting exothermically with a combustible material. In such cases, it is sufficient to provide that information as justification for not determining the oxidizing properties of the substance.

3. **Further information on the active substance**

(i) The information provided must describe the intended purposes for which preparations containing the active substance are used, or are to be used and the dose and manner of their use or proposed use.

(ii) The information provided must specify the normal methods and precautions to be followed, in the handling, storage and transport of the active substance.

(iii) The studies, data and information submitted, together with other relevant studies, data and information, must both specify and justify the methods and precautions to be followed in the event of fire. The possible products of combustion in the event of fire should be estimated, based on the chemical structure and the chemical and physical properties of the active substance.

(iv) The studies, data and information submitted, together with other relevant studies, data and information, must demonstrate the suitability of measures proposed for use in emergency situations.

(v) The informaton and data referred to are reqired for all active substances, except where otherwise specified.

3.1. *Function, e.g. fungicide, herbicide, insecticide, repellant, growth regulator*

The function must be specified from among the following:

— acaricide
— bactericide
— fungicide
— herbicide
— insecticide
— molluscicide
— nematicide
— plant growth regulator
— repellant
— rodenticide
— semio-chemicals
— talpicide
— viricide
— other (must be specified)

3.2. *Effects on harmful organisms, e.g. contact poison, inhalation poison, stomach poison, fungitoxic, etc. systematic or not in plants*

3.2.1. The nature of the effects on harmful organisms must be stated:

— contact action
— stomach action
— inhalation action
— fungitoxic action
— fungistatic action
— desiccant
— reproduction inhibitor
— other (must be specified)

3.2.2. It must be stated whether or not the active substance is translocated in plants and where relevant whether such translocation is apoplastic, symplastic or both.

3.3. *Field of use envisaged, e.g. field, protected crops, storage of plant products, home gardening*

The field(s) of use, existing and proposed, for preparations containing the active substance must be specified from among the following:

— Field use, such as agriculture, horticulture, forestry and viticulture
— Protected crops
— Amenity
— Weed control on non-cultivated areas
— Home gardening
— House plants
— Plant products storage practice
— Other (specify)

3.4. *Harmful organisms controlled and crops or products protected or treated*

3.4.1. Details of existing and the intended use in terms of crops, groups of crops, plants, or plant products treated and where relevant protected, must be provided.

3.4.2. Where relevant, details of harmful organisms against which protection is afforded, must be provided.

3.4.3 Where relevant, effects achieved e.g. sprout suppression, retardation of ripening, reduction in stem length, enhanced fertilization etc., must be reported.

3.5. *Mode of action*

3.5.1. To the extent that is has elucidated, a statement must be provided as to the mode of action of the active substance in terms, where relevant, of the biochemical and physiological mechanism(s) and biochemical pathway(s) involved. Where availble, the results of relevant experimental studies must be reported.

3.5.2. Where it is known that to exert its intended effect, the active substance must be converted to a metabolite or degradation product following application or use of preparations containing it, the following information, cross referenced to and drawing on information provided in the context of paragraphs 5.6, 5.11, 6.1, 6.2, 6.7, 7.1, 7.2 and 9, where relevant, must be provided for active metabolite or degradation product:

— chemical name according to IUPAC and CA nomenclature,
— ISO common name or porposed common name,
— CAS EEC-number EEC (EINECS or ELINCS) number, and CIPAC number if available,
— empirical and structural formula, and
— molecular mass.

3.5.3. Available information relating to the formation of active metabolites and degradation products, must be provided, to include:

— the processes, mechanisms and reactions involved,
— kinetic and other data concerning the rate of conversion and if known the rate limiting step,
— environmental and other factors effecting the rate and extent of conversion.

3.6. *Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies*

Where available information on possible occurrence of the development of resistance or cross-resistance must be provided.

3.7. *Recommended methods and precautions concerning handling, storage, transport or fire*

A safety data sheet pursuant to Article 27 of Council Directive 65/548/EEC [1] must be provided for all active substances.

[1] OJ No L 196, 16. 8. 1967, p. 1.

3.8. *Procedures for destruction or decontamination*

3.8.1. Controlled incineration

In many cases the preferred or sole means to safely dispose of active substances, contaminated materials, or contaminated packaging, is through controlled incineration in a licensed incinerator.

Where the content of halogens of the active substance is greater than 60 %, the pyrolytic behaviour of the active substance under controlled conditions (including where relevant supply of oxygen and defined residence time), at 800 °C and the content of polyhalogenated dibenzo-p-dioxins and dibenzo-furans in the products of pyrolysis must be reported. The application must provide detailed instructions for safe disposal.

3.8.2. Others

Other methods to dispose of the active substance, contaminated packaging and contaminated materials, where proposed, must be fully described. Data must be provided for such methods, to establish their effectiveness and safety.

3.9. *Emergency measures in case of an accident*

Procedures for the decontamination of water in case of an accident must be provided.

ANNEX II

1. **Identity of the plant protection product**

The information provided, taken together with that provided for the active substance(s), must be sufficient to precisely identify preparations and define them in terms of their specification and nature. The information and data referred to, unless otherwise specified, are required for all plant protection products.

1.1. *Applicant (name and address, etc.)*

The name and address of the applicant (permanent community address) must be provided as must the name, position, telephone and telefax number of the appropriate person to contact.

Where in addition, the applicant has an office, agent or representative in the Member State in which the authorization is being sought, the name and address of the local office agent or representative should be provided, as should the name, position, telephone and telefax number of the appropriate person to contact.

1.2. *Manufacturer of the preparation and the active substance(s) (names and addresses etc. including location of plants)*

The name and address of the manufacturer of the preparation and of each active substance in the preparation must be provided as must the name and address of each manufacturing plant in which the preparation and active substance are manufactured.

A contact point (preferable a central contact point, to include name, telephone and telefax numbers) must be provided for each.

If the active substance originates from a manufacturer from which data according to Annex II had not been submitted previously, a statement of purity and detailed information on the impurities in Annex II have to be provided.

1.3. *Trade name or proposed trade name, and manufacturer's development code number of the preparation if appropriate*

All former and current trade names and proposed trade names and development code numbers of the preparation as well as the current names and numbers must be provided. Where trade names and code numbers referred to, relate to similar but different preparations (possibly absolete), full details of the differences, must be provided. (The proposed trade name may not give rise to confusion with the trade name of already registered plant protection products.)

1.4. *Detailed quantitative and qualitative information on the composition of the preparation (active substance(s), and formulants)*

1.4.1. For preparations the following information must be reported:

— the content of both technical active substance(s) and pure active substance(s);

— the content of formulants.

The concentrations should be expressed in terms as provided for in Article 6 (2) of Directive 78/631/EEC.

1.4.2. For active substances their ISO common names or proposed ISO common names and their CIPAC numbers, and, where available, the EEC (EINECS or ELINCS) numbers must be provided. Where relevant it must be stated which salt, ester, anion or cation is present.

1.4.3. Formulants must where possible, be identified both by their chemical name as given in Annex I to Directive 67/548/EEC, or, if not included in this Directive, in accordance with both IUPAC and CA nomenclature. Their structure or structural formula must be provided. For each component of the formulants the relevant EEC (EINECS or ELINCS) number and CAS number where they exist, must be provided. Where the information provided does not fully identify a formulant, an appropriate specification must be provided. The trade name of formulants, where they exist, must also be provided.

1.4.4. For formulants the function must be given :
— adhesive (sticker),
— antifoaming agent,
— antifreeze,
— binder,
— buffer,
— carrier,
— deodorant,
— dispersing agent,
— dye,
— emetic,
— emulsifier,
— fertilizer,
— preservative,
— odourant,
— perfume,
— propellant,
— repellent,
— safener,
— solvent,
— stabilizer,
— synergist,
— thickener,
— wetting agent,
— miscellaneous (specify).

1.5. *Physical state and nature of the preparation (emulsifiable concentrate, wettable powder, solution etc).*

1.5.1. The type and code of preparation must be designated according to the 'Catalogue of pesticide formulation types and international coding system (GIFAP Technical Monograph No 2. 1989)'.

Where a particular preparation is not defined precisely in this publication a full description of the physical nature and state of the preparation must be provided, together with a proposal for a suitable description of the type of preparation and a proposal for its definition.

1.6. *Function (herbicide, insecticide, etc.)*

The function must be specified from among the following :
— acaricide,
— bactericide,
— fungicide,
— herbicide
— insecticide,
— molluscicide,
— nematicide,
— plant growth regulator,
— repellant,
— rodenticide,
— semio-chemicals,
— talpicide,
— viricide,
— other (must be specified).

2. **Physical, chemical and technical properties of the plant protection product**

The extent to which plant protection products for which authorization is sought, comply with relevant FAO specifications as agreed by the Group of Experts on Pesticide Specifications, of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements and Application Standards, must be stated. Divergences from FAO specifications must be described in detail, and justified.

2.1. *Appearance (colour and odour)*

A description of both the colour and odour, if any, and the physical state of the preparation, must be provided.

2.2. *Explosivity and oxidizing properties*

2.2.1. The explosive properties of preparations must be reported according to EEC method A 14. Where available thermodynamic information establishes beyond reasonable doubt that the preparation is incapable of exothermic reaction, it is sufficient to provide that information as a justification for not determining the explosive properties of the preparation.

2.2.2. Oxidizing properties of preparations which are solids must be determined and exported according to EEC method A 17. For other preparations the method used must be justified. The oxidizing properties do not have to be determined if it can be shown without reasonable doubt on the basis of thermodynamic information, that the preparation is incapable of reacting exothermically with combustible materials.

2.3. *Flash point and other indications of flammability or spontaneous ignition*

The flash point of liquids which contain flammable solvents, must be determined and reported according to EEC Method A 9. The flammability of solid preparations and gases must be determined and reported according to EEC methods A 10, A 11 and A 12 as appropriate. The autoflammability of preparations must be determined and reported in accordance with EEC methods A 15 or A 16 as appropriate, and or, where necessary, according to the UN-Bowes-Cameron-Cage-Test (UN-Recommendations on the Transport of Dangerous Goods, Chapter 14, No 14.3.4).

2.4. *Acidity/alkalinity and if necessary pH value*

2.4.1. In the case of preparations which are acidic (pH $<$ 4) or alkaline (pH $>$ 10) the acidity or alkalinity and the pH value must be determined and reported according to CIPAC Method MT 31 and MT 75 respectively.

2.4.2. Where relevant (if to be applied as aqueous dilution) the pH of a 1 % aqueous dilution, emulsion or dispersion of the preparation, must be determined and reported according to CIPAC Method MT 75.

2.5. *Viscosity and surface tension*

2.5.1. In the case of liquid preparations for Ultra Low Volume use (ULV) the kinematic viscosity must be determined and reported according to OECD Test Guideline 114.

2.5.2. For non newtonian liquids the viscosity must be determined and reported together with the test conditions.

2.5.3. In the case of liquid preparations the surface tension has to be determined and reported according to EEC method A 5.

2.6. *Relative density and bulk density*

2.6.1. The relative density of liquid preparations must be determined and reported according to EEC Method A 3.

2.6.2. The bulk (tap) density of preparations which are powders or granules, must be determined and reported according to CIPAC Methods MT 33, MT 159 or MT 169 as appropriate.

2.7. *Storage — stability and shelf-life : Effects of light, temperature and humidity on technical characteristics of the plant protection product*

2.7.1. The stability of the preparation after storage for 14 days at 54 °C must be determined and reported according to CIPAC Method MT 46.

Other times and/or temperatures may be needed (e.g. eight weeks at 40 °C or 12 weeks at 35 °C or 18 weeks at 30 °C) if the preparation is heat sensitive.

If the active substance content after the heat stability test has decreased by more than 5 % of the initially found content, the minimum content shall be declared and information on the degradation products shall be supplied.

2.7.2. Additionally in the case of liquid preparations, the effect of low temperatures on stability, must be determined and reported according to CIPAC Methods MT 39, MT 48, MT 51 or MT 54 as appropriate.

2.7.3. The shelf life of the preparation at ambient temperature must be reported. Where shelf life is less than two years, the shelf life in months, with appropriate temperature specifications, must be reported. Useful information is given in GIFAP Monograph No. 17.

2.8. *Technical characteristics of the plant protection product*

The technical characteristics of the preparation must be determined to permit a decision to be made as to its acceptability.

2.8.1. Wettability

The wettability of solid preparations which are diluted for use (e.g. wettable powders, water soluble powders, water soluble granules and water dispersible granules), must be determined and reported according to CIPAC Method MT 53.3.

2.8.2. Persistent foaming

The persistence of foaming of preparations to be diluted with water, must be determined and reported according to CIPAC Method MT 47.

2.8.3. Suspensibility and suspension stability

— The suspensibility of water dispersible products (e.g. wettable powders, water dispersible granules, suspension concentrates) must be determined and reported according to CIPAC Method MT 15, MT 161 or MT 168 as appropriate.

— The spontaneity of dispersion of water dispersible products (e.g. suspension concentrates and water dispersible granules) must be determined and reported according to CIPAC Methods MT 160 or MT 174 as appropriate.

2.8.4. Dilution stability

The dilution stability of water soluble products must be determined and reported according to CIPAC Method MT 41.

2.8.5. Dry sieve test and wet sieve test

In order to ensure that dustable powders have a suitable particle size distribution for ease of application, a dry sieve test must be conducted and reported according to CIPAC Method MT 59.1.

In the case of water dispersible products, a wet sieve test must be conducted and reported according to CIPAC Method MT 59.3 or MT 167 as appropriate.

2.8.6. Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)

2.8.6.1. The size distribution of particles in the case of powders, must be determined and reported according to OECD Method 110.

The nominal size range of granules for direct application must be determined and reported in accordance with CIPAC MT 58.3, for water dispersible granules in accordance with CIPAC MT 170.

2.8.6.2. The dust content of granular preparations, must be determined and reported according CIPAC Method MT 171. If relevant for operator exposure the particle size of dust must be determined and reported according to OECD Method 110.

2.8.6.3. The friability and attrition characteristics of granules, must be determined and reported once internationally agreed methods are available. Where already data are available they must be reported together with the method used.

2.8.7. Emulsifiability, Re-emulsifiability, emulsion stability

2.8.7.1. The emulsifiability, emulsion stability and re-emul-sifiability of preparations which form emulsions, must be determined and reported according to CIPAC Methods MT 36 or MT 173 as appropriate.

2.8.7.2. The stability of dilute emulsions and of preparations which are emulsions, must be determined and reported according to CIPAC Method MT 20 or MT 173.

2.8.8. Flowability, pourability (rinsability) and dustability

2.8.8.1. The flowability of granular preparations must be determined and reported according to CIPAC Mehtod MT 172.

2.8.8.2. The pourability (including rinsed residue) of suspensions (e.g. suspension concentrates, suspo-emulsions), must be determined and reported according to CIPAC Method MT 148.

2.8.8.3. The dustability of dustable powders following accelerated storage according 2.7.1 must be determined and reported according to CIPAC Method MT 34 or another suitable method.

2.9. *Physical and chemical compatibility with other products including plant protection products with which its use is to be authorized*

2.9.1. The physical compatibility of tank mixes must be reported based on in-house test methods. A practical test would be an acceptable alternative.

2.9.2. The chemical compatibility of tank mixes must be determined and reported except where examination of the individual properties of the preparations would establish beyond reasonable doubt that there is no possibility of reaction taking place. In such cases it is sufficient to provide that information as justification for not practically determining the chemical compatibility.

2.10. *Adherence and distribution to seeds*

In the case of preparations for seed treatment, both distribution and adhesion must be investigated and reported; in the case of distribution according to CIPAC Method MT 175.

2.11. *Summary and evaluation of data presented under points 2.1. to 2.10*

3. Data on application

3.1. *Field of use envisaged, e.g. field, protected crops, storage of plant products, home gardening*

The field(s) of use, existing and proposed, for preparations containing the active substance must be specified from among the following:

— field use, such as agriculture, horticulture, forestry and viticulture,
— protected crops,
— amenity,
— weed control on non-cultivated areas,
— home gardening,
— house plants,
— plant products storage practice,
— other (specify).

3.2. *Effects on harmful organisms, e.g. contact, inhalation or stomach poison, fungitoxic or fungistatic, etc., systemic or not in plants*

The nature of the effects on harmful organisms must be stated:

— contact action,
— stomach action,
— inhalation action,
— fungitoxic action,
— fungistatic action,
— desiccant,
— reproduction inhibitor,
— other (must be specified).

It must be stated whether or not the product is translocated in plants.

3.3. *Details of intended use e.g. types of harmful organisms controlled and/or plants or plant products to be protected*

Details of the intended use must be provided.

Where relevant, effects achieved e.g. sprout suppression, retardation of ripening, reduction in stem length, enhanced fertilization etc. must be reported.

3.4. *Application rate*

For each method of application and each use, the rate of application per unit (ha, m^2, m^3) treated, in terms of g or kg of both preparation and active substance, must be provided.

Application rates shall normally be expressed in g or kg/ha or in kg/m^3 and where appropriate in g or kg/tonne ; for protected crops and home gardening use rates shall be expressed in g or kg/100 m^2 or g or kg/m^3.

3.5. *Concentration of active substance in material used (e.g. in the diluted spray, baits or treated seed)*

The content of active substance shall be reported, as appropriate, in g/l, g/kg, mg/kg or in g/tonne.

3.6. *Method of application*

The method of application proposed must be described fully, indicating the type of equipment to be used, if any, as well as the type and volume of diluent to be used per unit of area or volume.

3.7. *Number and timing of applications and duration of protection*

The maximum number of applications to be used and their timing, must be reported. Where relevant the growth stages of the crop or plants to be protected and the development stages of the harmful organisms, must be indicated. Where possible the interval between applications, in days, must be stated.

The duration of protection afforded both by each application and by the maximum number of applications to be used, must be indicated.

3.8. *Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops*

Where relevant, minimum waiting periods between last application and sowing or planting of succeeding crops, which are necessary to avoid phytotoxic effects on succeeding crops, must be stated, and follow from the data provided under paragraph 6.6.

Limitations on choice of succeeding crops, if any, must be stated.

3.9. *Proposed instructions for use*

The proposed instructions for use of the preparation, to be printed on labels and leaflets, must be provided.

4. Further information on the plant protection product

4.1. *Packaging (type, materials, size etc.), compatibility of the preparation with proposed packaging materials*

4.1.1. Packaging to be used must be fully described and specified in terms of the materials used, manner of construction (e.g. extruded, welded etc.), size and capacity, size of opening, type of closure and seals. It must be designed in accordance with the criteria and guidelines specified in the FAO 'Guidelines for the Packaging of Pesticides'.

4.1.2. The suitability of the packaging, including closures, in terms of its strength, leakproofness and resistance to normal transport and handling, must be determined and reported according to ADR Methods 3552, 3553, 3560, 3554, 3555, 3556 3558, or appropriate ADR Methods for intermediate bulk containers, and, where for the preparation child-resistant closures are required, according to ISO standards 8317.

4.1.3. The resistance of the packaging material to its contents must be reported according to GIFAP Monograph No 17.

4.2. *Procedures for cleaning application equipment*

Cleaning procedures for both application equipment and protective clothing must be described in detail. The effectiveness of the cleaning procedure, must be fully investigated and reported.

4.3. *Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment*

The information provided must follow from and be supported by the data provided for the active substance(s) and that provided under sections 7 and 8.

4.3.1. Where relevant pre-harvest intervals, re-entry periods or withholding periods necessary to minimize the presence of residues in or on crops, plants and plant products, or in treated areas or spaces, with a view to protecting man or livestock, must be specified e.g.:

— pre-harvest interval (in days) for each relevant crop,

— re-entry period (in days) for livestock, to areas to be grazed,

— re-entry period (in hours or days) for man to crops, buildings or spaces treated,

— withholding period (in days) for animal feedingstuffs,

— waiting period (in days), between application and handling treated products, or

— waiting period (in days), between last application and sowing or planting succeeding crops.

4.3.2. Where necessary, in the light of the test results, information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used must be provided.

4.4. *Recommended methods and precautions concerning: handling, storage, transport or fire*

The recommended methods and precautions concerning handling procedures (detailed) for the storage, at both warehouse and user level of plant protection products, for their transport and in the event of fire must be provided. Where available information on combustion products must be provided. The risks likely to arise and the methods and procedures to minimize the hazards arising, must be specified. Procedures to preclude or minimize the generation of waste or leftovers must be provided.

Where relevant assessment has to be done according to ISO — TR 9122.

Where appropriate the nature and characteristics of protective clothing and equipment proposed must be provided. The data provided must be sufficient to evaluate the suitability and effectiveness under realistic conditions of use (e.g. field or glasshouse circumstances).

4.5. *Emergency measures in the case of an accident*

Whether arising during transport, storage or use, detailed procedures to be followed in the event of an emergency, must be provided; and include:

— containment of spillages,

— decontamination of areas, vehicles and buildings,

— disposal of damaged packaging, adsorbents and other materials,

— protection of emergency workers and bystanders,

— first aid measures.

4.6. *Procedures for destruction or decontamination of the plant protection product and its packaging*

Procedures for destruction and decontamination must be developed for both small quantities (user level) and large quantities (warehouse level). The procedures must be consistent with provisions in place relating to the disposal of waste and of toxic waste. The means of disposal proposed should be without unacceptable influence on the environment and be the most cost effective and practical means of disposal feasible.

4.6.1. Possibility of neutralization

Neutralization procedures (e.g by reaction with alkali to form less toxic compounds) for use in the event of accidental spillages, must where they are feasible, be described. The products produced after neutralization should be practically or theoretically evaluated and reported.

4.6.2. Controlled incineration

In many cases the preferred or sole means to safely dispose of active substances as well as plant protection products containing it, contaminated materials, or contaminated packaging, is through controlled incineration in a lincensed incinerator.

Where the content of halogens of the active substance(s) in the preparation is greater than 60 %, the pyrolytic behaviour of the active substance under controlled conditions (including where relevant supply of oxygen and defined residence time) at 800 °C and the content of polyhalogenated dibenzo-p-dioxins and dibenzo-furans in the products of pyrolysis must be reported. The applicant must provide detailed instructions for safe disposal.

4.6.3. Others

Other methods to dispose of plant protection products, packaging and contaminated materials, where proposed, must be fully described. Data must be provided for such methods, to establish their effectiveness and safety.