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.